

[Received by email, 11/4/06:]

Subject: Commission Submission

Greetings:

The American Association for Laboratory Accreditation (A2LA) is a membership organization, tax exempt and non-profit under the laws of the United States offering accreditation services in the public interest similar to NATA.

However, the situation in the United States of America (USA) with regard to laboratory accreditation is very different than it is in Australia. Numerous narrow sector systems and several multi-discipline systems operate in the USA. There is much overlap. Laboratories find themselves needing several duplicative accreditations in order to offer services in a variety of markets because each system usually has a set of specifiers of its accreditation to the exclusion of others. Different standards are applied so the accreditations are not equivalent and most are not acceptable overseas because the standards used are not those that have been internationally accepted.

Needless to say, most observers believe the situation is a mess in need of a solution. Many want one nationally recognized body, such as that of Australia, but the existing multiple accreditation bodies in the USA cannot simply be legislated out of existence. More recently, for-profit accreditation bodies have entered the market offering allegedly cheaper, faster accreditation. One even offers an "international accreditation service" without an on-site assessment (just a document review). This has further exacerbated the USA situation by degrading the meaning and value of accreditation.

Coordination and mutual recognition or "an accreditation system of accreditation bodies" would seem to be the answer for the United States.

However, the most recent effort to "coordinate in order to eliminate duplication and complexity" initiated about 12 years ago to develop a national system for mutual recognition of laboratory accreditation bodies, the National Cooperation for Laboratory Accreditation (NACLA), a non-profit membership organization, has been an utter failure in its almost 10 years of existence. Many government agencies, including the lead agency for national standards and conformity assessment policy, the National Institute of Standards and Technology, and other stakeholders (i.e., accreditation bodies, laboratories, and industry specifiers) participated in its development. NACLA appeared to have good backing.

Nonetheless, of the over 150 accreditation bodies in the USA, less than ten applied for recognition and signatory status to the NACLA Mutual Recognition Arrangement (MRA) when it was announced in 1999. Of those, only three initially met the international requirements and signed the MRA in October 2000. Other newer bodies, which needed to be recognized to legitimize their operations in the marketplace, became frustrated by their lack of NACLA recognition. One threatened those individuals involved in the NACLA decision-making process with a lawsuit under USA anti-trust laws. Another threatened

NACLA itself. In the USA, civil cases may be brought by injured parties against individuals who, if found to have committed an "illegal anti-competitive act," can be held liable for "treble damages."

Decisions of recognition have been altered as a result of such lawsuit threats, thus undermining the technical credibility of the whole NACLA process. MRA commitments have not been upheld by NACLA MRA signatories nor enforced by NACLA. NACLA's MRA has no international recognition and as currently designed and administered never will. Further, the costs of maintaining the NACLA recognition scheme are inevitably passed onto the accredited laboratories. NACLA, once considered the solution to the complexity and redundancy of current accreditations, has only made matters worse in the USA.

Accreditation should not be treated in the same way as most commodities or services in the marketplace. Laboratories cannot expect to automatically become accredited. Unlike most services, it is not a right in response to payment of fees; it is an earned privilege and those which do not receive accreditation (based of course on sound technical grounds) should not have limitless opportunities to go 'shopping' to find the easiest route to accreditation.

Sincerely,

Peter S. Unger
A2LA President