

30 April 2012

COMMENT

AMERICAN ASSOCIATION FOR LABORATORY ACCREDITATION (A2LA)

ON OFFICE OF MANAGEMENT AND BUDGET (OMB)

REQUEST FOR INFORMATION (RFI)

ON FEDERAL PARTICIPATION IN THE DEVELOPMENT AND USE OF VOLUNTARY
CONSENSUS STANDARDS AND IN CONFORMITY ASSESSMENT ACTIVITIES

A2LA offers the following comments on OMB's Request for Information (RFI) on current issues focusing on Federal agencies' conformity assessment related activities and whether and how to supplement OMB Circular A-119: *Federal Participation in the Development and Use of Voluntary Consensus Standards and in Conformity Assessment Activities*.

A2LA is the largest, internationally-recognized laboratory accreditation body in the United States and one of the leading accreditation bodies in the world. A2LA is a non-profit organization headquartered in Frederick, Maryland. A2LA has three recommendations:

(1) Expand the Conformity Assessment Section of the OMB Circular A119

The OMB A119 needs to be expanded to include government reliance on private sector accreditation and conformity assessment infrastructure with preference for international systems and not duplicative national-only systems whenever possible.

While there are some regulatory enforcement activities requiring government-administered testing, inspection or certification, there is nothing 'inherently governmental' about testing, inspection or certification. Similarly, there is nothing 'inherently governmental' about accreditation or recognition of accreditation bodies. In fact, government laboratories have obtained accreditation by private sector accreditation bodies. A2LA has accredited laboratories in *all* fields of testing including government laboratories of the FDA, USDA, ICE, Coast Guard and DOD -- even emergency response, high-security, and bio-threat facilities. Several agencies are already using the recognition programs of accreditation bodies administered by the International Laboratory Accreditation Cooperation (ILAC) and the International Accreditation Forum (IAF).

(2) The Role of Government Agencies

No government agency should develop new accreditation or conformity assessment activity without evaluating what can be provided by the private sector. Any proposals for government-administered programs should be subject to the APA public comment process.

Federal agencies engaged in any conformity assessment activities already established should publish in the *Federal Register* a request for comment on whether the private sector can carry out such activities. If an agency chooses to continue its conformity assessment activity, its determination would need to be justified using principles similar to the preferences for using voluntary consensus standards instead of government standards.

All Federal, state and local government programs to inspect, assess and/or accredit laboratories should be phased out in favor of relying on internationally-recognized private sector accreditation bodies.

(3) NIST's Coordination Role

NIST's conformity assessment mission provided by the *National Technology Transfer and Advancement Act* (NTTAA) in 1996, is in 15 U.S.C. 272(b):

“(13) To coordinate Federal, State, and local technical standards activities and conformity assessment activities, with private sector technical standards activities and conformity assessment activities, with the goal of eliminating unnecessary duplication and complexity in the development and promulgation of conformity assessment requirements and measures.”

In 1995, a National Research Council report entitled: “*Standards, Conformity Assessment and Trade into the 21st Century*” provided two recommendations on conformity assessment which gave preference to private sector accreditation and conformity assessment activities:

- 1) Congress should provide NIST with a statutory mandate to implement a government-wide policy of phasing out federally operated conformity assessment activities . . . and
- 2) NIST should develop, within one year, a 10-year strategic plan to eliminate duplication in state and local criteria for accrediting testing laboratories and product certifiers. . . .”

While Congress never gave NIST this authority, it was clear from the Congressional Record that private sector accreditation and conformity assessment activities should be used instead of government programs just as voluntary consensus standards should replace government standards as the OMB Circular A119 policy urges.

Perhaps NIST avoids the purpose of coordination in its mandate from the NTTAA (i.e., “eliminating unnecessary duplication and complexity . . .”) due to the inherent conflict of

interest of operating both an accreditation body (i.e., NVLAP) as well as a recognition program for accreditation bodies (i.e., NVCASE). Both programs are duplications of what is now available in the private sector.

To effectively fulfill its mandate, NIST needs to focus on measuring and documenting the progress made to eliminate duplication and complexity in conformity assessment activities of the United States.