

MEMORANDUM BY FAX

TO: Office of Information and Regulatory Affairs
Office of Management and Budget

FROM: Milton Bush, Chief Executive Officer



DATE: April 30, 2012

Subject: ACIL Comment on Federal Participation in the Development
and Use of Voluntary Consensus Standards and in
Conformity Assessment Activities

Attached is ACIL's comment on the subject Request for Information (RFI).

Should you have any questions please feel free to contact me at 202-887-5872 or at mbush@acil.org.

attachment

COMMENT

AMERICAN COUNCIL OF INDEPENDENT LABORATORIES (ACIL)

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

APRIL 30, 2012 .

ACIL is pleased to submit comments on OMB's Request for Information (RFI) on current issues regarding Federal agencies' standards and 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).

ACIL was founded in 1937 as the national trade association representing independent scientific laboratory testing. An independent laboratory is not affiliated with any institution, company or trade group that might affect its ability to conduct investigations, render reports, or give professional counsel objectively and without bias. ACIL's 150 member companies operate approximately 1000 facilities across the U.S. and abroad. They range from the one-person specialty laboratories to multi-disciplined, international corporations employing thousands of engineers, analysts, risk management specialists, consultants, and support staff.

The majority of ACIL members are standards-users. As such, ACIL will confine its comments to the conformity assessment portions of the RFI.

On February 19, 1998, OMB revised Circular A-119 (hereinafter referred to as A-119) to make the terminology of the Circular consistent with the National Technology Transfer and Advancement Act of 1995 (NTTAA), to issue guidance to the agencies on making their reports to OMB, to direct the Secretary of Commerce to issue policy guidance for conformity assessment, and to make changes for clarity. The NTTAA directed NIST to *coordinate* (emphasis added) conformity assessment activities of Federal, state and local entities with private sector technical standards activities with the goal of eliminating any unnecessary duplication of conformity assessment activities. On August 10, 2000, the National Institute of Standards and Technology (NIST) issued policy guidance on Federal agency use of conformity assessment activities.

In ACIL's opinion, NIST has struggled to meet its mandate under the NTTAA because (1) it has wandered out of a *coordination* role and has strayed into a *policy* role and in some instances has dictated methods of conformity; and (2) there are inherent conflicts of interest in NIST's structure that compromise the NTTAA mandate.

ACIL believes that standards and conformity assessment are of equal importance for upholding regulators' missions and facilitating trade. ACIL believes that OMB, not NIST, should issue conformity assessment guidance in a manner parallel to that of the existing standards guidance, and that such guidance should be based upon the principles discussed immediately below. ACIL also believes that NIST's role must be redefined (also discussed below) to incorporate a rubric of transparency, measurability and competition.

ACIL's Conformity Assessment Principles

ACIL's Conformity Assessment Principles are (1) federal agency reliance on private sector conformity assessment programs, capacity and expertise whenever practicable, (2) a mechanism must be put in place to ensure cooperation and coordination among both federal and private sector conformity assessment executives, (3) accreditation of conformity assessment bodies based on principles of national treatment and reciprocity whenever practicable, and (4) flexibility in the acceptance of "higher confidence" models of conformity assessment to reduce duplicative testing and the burden on manufacturers.

These are by no means the only Conformity Assessment Principles that OMB should consider but they are the ones that are most pressing in the current economic climate.

Reliance on the Private Sector

In the fourteen years since A-119 was last updated, the private sector conformity assessment infrastructure has significantly expanded its scope, expertise and capabilities that support the regulatory needs of various agencies. ACIL members have invested and continue to invest massive amounts of money, time and human capital into developing, maintaining and operating conformity assessment programs that serve both marketplace and regulatory needs. In both relative and absolute terms these investments by ACIL member laboratories exceed those made by the federal government, and should thus be leveraged by the federal government.

Using Regulatory Impact Assessments (discussed below) government agencies should be mandated to take into account both direct labor costs and the significant overhead expenses associated with developing and maintaining their own conformity assessment programs and operating the various infrastructures necessary to provide confidence in their conformity assessment systems. ACIL is confident that when these government costs are properly taken into consideration, the private sector option will more effectively manage price, quality and speed to market.

Cooperation and Coordination Among Federal and Private Sector Conformity Assessment Executives

One of the reasons behind the promulgation of A-119 was to “encourage federal agencies to benefit from the expertise of the private sector”, and thus the Interagency Committee on Standards Policy (ICSP) was established. The ICSP is composed mainly of federal agency standards executives. Missing are private sector conformity assessment organizations. Also absent is an institutional mechanism to drive public-private consultations. Consequently, ACIL perceives the ICSP to provide little value beyond driving interagency consensus on related matters. As such, another mechanism needs to be considered.

ACIL also believes that NIST has regularly failed to invite the private sector to the table as regulators seek guidance on constructing conformity assessment frameworks. The lack of this bridging with the private sector reduces transparency into how the private sector can support regulatory goals and objectives. At the same time, it has often precluded competition that would further drive cost efficiencies in the system.

ACIL further believes that there should be greater reliance on a “public-private partnership” as envisioned in Executive Order 13563 (January 17, 2012), which emphasized “...that our regulatory system must protect public health, welfare, safety and our environment while promoting economic growth, innovation, competitiveness, and job creation, and which stresses the importance of public participation and of careful consideration of both benefits and costs.”

Accreditation of Conformity Assessment Bodies Based on Principles of National Treatment and Reciprocity

Accreditation requirements for any entity providing conformity assessment services should be a cornerstone of any conformity assessment system, regardless of whether the entity is public or private. The standards for accreditation should be equivalent to ensure that market deformities are not established in the United States. This concept must be applied universally: to private and public sector first-party, company-owned and

managed laboratories, private and public sector second-party laboratories, independent third-party laboratories, and, to certification bodies alike. Manufacturers operating in good faith by testing and certifying their products in accredited laboratories would have a level playing field and would allow them to compete effectively, improving public health, safety and the environment.

National treatment of conformity assessment bodies means that foreign countries accrediting domestic conformity assessment bodies to test and certify products sold in their countries should accredit foreign conformity assessment bodies under terms no less favorable and no more complex than granted to their own. National treatment is a highly efficient way for foreign regulators to both gain confidence in the capabilities of foreign conformity assessment bodies to approve products, and to streamline the product approval process. This results in the saving of significant amounts of time and resources in both the exporting and importing economies.

Under any system of market access, reciprocity in a global environment must become mandatory for the U.S inspection, testing and certification industry to remain competitive and to continue being a stable provider of skilled and high-paying jobs. The U.S. marketplace is the most open in the world. Historically, the U.S. conformity assessment industry has suffered severely because of some U.S. regulators reluctance to insist on reciprocity requirements in their conformity assessment systems.

OMB should require any U.S. regulator that currently operates or envisions operating a conformity assessment program that accredits foreign conformity assessment bodies, that the U.S. regulator require as a minimum condition of agreement, that both the foreign government offer reciprocal access to U.S. conformity assessment bodies under terms no less favorable and no more complex than granted to their own.

The two examples in the United States that embody this approach are the Occupational Safety and Health Administration's (OSHA) Nationally Recognized Testing Laboratory (NRTL) Program and the Federal Communications Commission (FCC) Telecommunications Certification Body (TCB) program. Both programs effectively deny access to foreign conformity assessment bodies unless and until the foreign government's accreditation infrastructure is open for foreign conformity assessment bodies. The U.S. conformity assessment system can no longer be a "bargaining chip" in trade negotiations because it is a key to market access globally.

It is important to note that the FCC TCB model was developed under another market access model – a mutual recognition agreement (MRA). The key to this model's success was and continues to be the FCC rigorous insistence on reciprocity. It has also

created greater competition among both test laboratories and TCBs, which lowers costs to manufacturers.

Flexibility In The Differing Models of Conformity Assessment

Where federal agencies select a model of conformity assessment that does not require independent third party conformity assessment, they should consider a mechanism that recognizes third party results when manufacturers choose to do so. Precluding such recognition drives down the level of safety to a minimum threshold and fails to reward manufacturers who choose to rely upon “higher confidence” models.

For example, if a federal agency required accredited testing but the industry is already using accredited product certification, then the agency should be allowed to accept product certification to fulfill its regulatory requirements. However, accredited testing would still remain the floor and still meet regulatory requirements.

In addition, where there are overlapping jurisdictions of products among multiple Federal agencies, OMB should set in motion a process that would develop a series of criteria that these Federal agencies can use to reduce redundancy and cost. This would be a project that would be performed under the new federal mechanism mentioned earlier in this comment.

Competition, Transparency, Measurability and NIST's Role

Competition

In the private sector conformity assessment infrastructure (inspection, testing, third party certification, quality systems registration, accreditation, and recognition), there is robust and highly effective competition. This is not the case with Federal and State regulatory agencies.

Government laboratories, particularly in the defense and homeland security sectors, routinely compete with private sector conformity assessment bodies in direct violation of A-76. Their activities are open and notorious. Government laboratories can be seen at trade shows passing out four-color brochures and marketing their services at taxpayer expense. The FAIR Act and circulars coming out of OMB have done nothing to stem this tide, and ACIL believes that will only worsen as the Federal budget continues to shrink. In addition, most government laboratories do not have to prove their competence through a recognized accreditation process as do private sector laboratories.

Except in a very few circumstances involving highly sensitive matters relating to national security, there is nothing “inherently governmental” about inspection, testing, third party certification, quality systems registration, accreditation or recognition. ACIL believes that OMB needs to make that determination, and it needs to advise Federal regulatory agencies that currently engage in conformity assessment activities to adopt the transparent process that is described below.

Transparency

While the Administrative Procedures Act (APA) provides levels of transparency in rulemaking, these are insufficient as they relate to government reliance on private sector conformity assessment, ACIL proposes the following changes:

First, any Federal agency considering engaging in any of the conformity assessment activities described above would be required to publish in the Federal Register a notice of intent to engage in such an activity. There would be an opportunity for public comment prior to a final agency decision.

Second, a part of that Federal Register notice should be a requirement to perform a Regulatory Impact Assessment (RIA) or similar assessment that takes into account all costs associated with developing and operating the envisioned conformity assessment program.

Third, should the agency choose NOT to use the private sector conformity assessment infrastructure that determination would need to be justified under a series of principles developed jointly among the federal agencies and representatives from private sector conformity assessment organizations. The principles should mirror agency determinations that are made on the standards side of A-119.

Finally, there should be a regulatory appeals process that is simple, straightforward and timely.

Measurability and NIST's Role

ACIL recommends that OMB ask NIST to develop a *measurement process* for reducing duplication and complexity in conformity assessment in the United States. While Congress gave NIST the goal of reducing and eliminating duplication in conformity assessment in the United States, they did not require a system or systems to measure whether such objectives are being achieved.

NIST's role as a coordinator should be three-fold. First, it should act as an "educator" for agencies developing conformity assessment programs and provide them with information on both public and private sector programs. Second, it should act as a "convener" among all public and private sector stakeholders when an agency is embarking on a new conformity assessment program or transitioning from a public program to a private sector one. Third, it should be an advisor on the "technical aspects" of conformity assessment.

As a non-regulatory agency, NIST should not engage in *specifying* the "method of conformity" to a particular regulatory agency or agencies, nor should it *specify* particular organizations to fill a particular need. Those decisions should be left to the regulator. In other words NIST should be "method-neutral" in its approach to coordinating conformity assessment in the United States.

Conclusion

ACIL believes that an OMB-issued set of high-level conformity assessment principles (paralleling the same concept behind the set of standards principles existing within the current OMB A-119) incorporating a rubric of transparency, measurability and competition are required. These OMB-issued high-level conformity assessment principles will, when coupled with a redefined NIST role in a supplement to A-119 will meet the letter and intent of the NTTAA, and will enhance the global competitiveness of United States industry.