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Accreditation: A Viable Tool for Import Safety

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The American Association for Laboratory Accreditation (A2LA) supports several of the suggested initiatives to prevent defective products from entering US markets.

In particular, A2LA believes the early and greater use of competent testing, inspection and product certification bodies to ensure product quality at supply sources is the most effective means of reducing the risk of importing defective products. More testing is needed in order to determine competence and to ensure product compliance with standards and regulations. In order to have confidence in testing, we need accreditation.

Accreditation is the tool for ensuring competence and providing confidence in the accuracy and reliability of testing, inspection and product certification results - accreditation that is internationally accepted and meets international standards.

The accreditation infrastructure is already well established both nationally and internationally through bodies such as A2LA (www.a2la.org) and the International Laboratory Accreditation Cooperation (ILAC)(www.ilac.org). ILAC member accreditation bodies have been internationally recognized as competent through rigorous peer evaluation to accredit testing and inspection organizations. ILAC-recognized accreditation bodies must meet the requirements of ANSI ISO/IEC 17011. In turn, under the ILAC Mutual Recognition Arrangement, competent laboratories and inspection bodies have been recognized globally to facilitate acceptance of testing and inspection results accompanying goods across national borders.

The laboratories and inspection bodies must be accredited to a specific scope of accreditation so it is very clear which tests and inspection processes they have been found competent to perform. As an example, a toy manufacturer might use the services of a testing laboratory that it thinks is competent to perform the full range of physical and chemical (e.g. paint analysis for lead) tests on a toy truck, when the laboratory is really only able to perform the physical tests in a competent manner. So while the toy truck may have been tested to be sure the wheels cannot be removed, testing for the lead (Pb) content of paint on the toy truck did not result in correct data.

The scope of accreditation transparently describes the limits of the laboratory's competence.

To improve product safety, both industry and government should rely on accreditation as one tool of product quality assurance. Since the infrastructure is already in place, there is no need for any government (or industry) expenditure to run new accreditation schemes.

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A2LA and other internationally recognized US accreditation bodies are available to assist government agencies and industry in providing suitably tailored accreditation to serve particular regulatory and industry needs. China has an ILAC-recognized accreditation body that can accredit laboratories, inspection bodies and product certifiers. It is suggested that the US government encourage the Chinese government to require accredited tests and inspections on their exported products coming to this country.

A2LA has already accredited almost 2,000 laboratories, many of which are in food safety, toy safety and related import testing. For example, A2LA has accredited seven Customs and Border Protection laboratories, several Food and Drug Administration laboratories and USDA laboratories as well as numerous private sector laboratories available to assist in testing or inspecting imported products. These available, competent testing/inspection resources simply need to be utilized more effectively particularly in the early stages of the supply chain. Once the product enters the marketplace and is found to be defective, it is really too late. Recalls are never 100% effective and are a tremendous waste to distributors and a nuisance, if not a threat, to consumers. The cost associated with accreditation of a laboratory or inspection body is far less than the costs and public scrutiny associated with the recalls this country has seen lately.

The Benefits of Accreditation

Testing and calibration laboratories and inspection bodies gain a great deal from a technically sound assessment and accreditation by an internationally recognized accreditation body. Here are some of those benefits:

- A "credential" that designates these organizations as qualified to provide services in the field or fields in which it is accredited.
- A regular, objective "check-up" that helps a organization's management to make continual improvements in its operation.
- In an increasing number of instances, an entrée to a given market that would otherwise be closed to these organizations.
- Increased productivity, resulting from a decrease in the number of clients who insist on having their own staff audit the organization. More of these clients now base their confidence on a third-party accreditation.
- International recognition of the accredited organization's competence if the accreditation body is a signatory to the mutual recognition arrangement of the International Laboratory Accreditation Cooperation (ILAC).
- Accreditation assessments help the staff to stay on the "cutting edge" of technology developments in its field.
- Significant discounts in liability insurance premiums are not uncommon, when the insurer appreciates the verification-of-competence that accreditation represents.
- Improved performance by organization staff. Undergoing regular assessments enhances staff discipline and its sense of professionalism. Employees are more likely to be committed to observing the firm's quality management system and standards of performance.
- For calibration laboratories, accreditation by an internationally recognized accreditation body validates their pivotal place in the chain of traceabilty to national and international measurement standards.
- For product certification, testing and calibration underpin the certification process, and accredited testing and calibration adds confidence and credibility to the certified product.

Users of laboratory and inspection services are a second category of beneficiaries of accreditation. Users have greater confidence in the accuracy of the test, calibration or inspection report they are purchasing because it has been generated by a competent facility. This is particularly true for an educated client, one who is conscious of the scope of the organization's accreditation. As examples, A2LA accreditation is used at the federal regulatory level by the Food and Drug Administration and the US Department of Agriculture and at the State government level by the Texas school lunch program to provide confidence in food testing; and at the municipal level, by the City of Houston Texas for confidence in construction materials testing.

Clients can make use of information sources like the ILAC (www.ilac.org) and its member regions linking the directories of ILAC Arrangement signatories to identify organizations qualified in their area of need.
Manufacturers also gain efficiency because of accreditation; instead of their own on-site assessments, they can defer to the assessments of competent accrediting authorities. Other manufacturers who have in-house testing or calibration facilities can reduce or eliminate these overhead costs and subcontract with assurance using outside accredited laboratories.

Users of inspection services can have greater confidence in the qualifications of inspectors from accredited inspection bodies and in the adequacy of the inspection applied to each task or product.

Specifiers, like Government regulators, have come to appreciate the importance of credible accreditation programs that are based on internationally recognized standards. With restricted budgets, many Government agencies can no longer do it all themselves; increasingly, they must rely on third-party organizations to support their regulatory efforts. When they do so, they need a fair and meaningful basis for identifying qualified providers. Accreditation provides that.

The specifier resources needed to support third party accreditation are generally minimal. Traditionally, accreditation bodies work with the regulators and specifiers to establish any specific technical laboratory or inspection body requirements to be applied to the ISO/IEC 17025 or ISO/IEC 17020 accreditation programs, respectively. The accreditation body is responsible for executing the assessment and accreditation process but the specifier can retain responsibility for the ultimate decision on the acceptance for their purposes of that organization's accreditation.

Accreditation also has a positive impact on the **general public**, by stimulating higher standards of quality within these laboratories and inspection bodies. This leads to more consistently reliable test and inspection data, thereby contributing to more effective health and safety regulation and to products of more consistent quality. Because the level of accreditation continues to improve, holding these organizations to even higher standards, these public benefits will continue to accrue resulting in greater consumer confidence.

Internationally recognized accreditation bodies around the globe are committed to this improved accreditation system and to maximizing the benefits of accreditation for all stakeholders.

The Standards for Competence

The general requirements for laboratory competence are described in the ISO/IEC 17025:2005 standard. This standard establishes a global baseline for accreditation of all types of laboratories. Since its origin from other documents beginning in the mid-70's, ISO/IEC 17025 emphasizes competence of laboratories to perform specified tests, not just mere compliance with requirements. The general standards for inspection body accreditation are ISO/IEC 17020 and ILAC/IAF A4 and like ISO/.IEC 17025, these are the standards used to determine the competency of inspection bodies.

Recognition of such competence generally requires that these organizations obtain accreditation. Accreditation involves on-site and performance assessments. Assessment of competence requires persons who not only understand the requirements of the standard, but know the specified tests or inspection methods with sufficient depth of understanding to make judgments of competence. The assessors must also understand the principles underlying the requirements of the international standards, which are not always obvious.

Blind adherence by these organizations to the requirements of the standard, while better than no system at all, is not an approach that instills confidence in its ability to produce valid test results. Nor is it the best approach to acquire recognition of such competence.

Principles. Several important principles are imbedded in the requirements of the standards. These are summarized as follows:

Capability
Responsibility
Scientific approach
Objectivity
Impartiality
Measurement traceability
Reproducibility
Transparency

Capability. An organization must have the resources in order to carry out the processes and produce reliable test or inspection results. These would include:

people with the required skills and knowledge,
- environment with the required facilities, equipment and instruments,
- procedures to ensure consistency of test or inspection processes, and
- quality control for the key steps in the processes.

Responsibility. An organization must have persons in its organization who have the authority to execute specific functions with its overall scope of test work -- and can demonstrate accountability for their results.

Scientific Approach. An organization should carry out its work based on accepted scientific principles, preferably following consensus-based methods or standards, and that deviations from accepted methods must be substantiated in a manner considered generally acceptable by experts in the field.

Objectivity. The results produced should be based upon measurable quantities. If results are subjective, they must be produced by people deemed qualified to make subjective judgments.

Impartiality. The pursuit of reliable results through the use of accepted scientific principles is the primary and overriding influence on the persons carrying out the testing or inspection. All other influences are secondary and not permitted to take precedence.

Measurement Traceability. For laboratory accreditation the results produced are based on a recognized system of measurement that derives from accepted known quantities (SI system of units of measurement) or other well-characterized references. The chain of comparison of measurement between these accepted, known quantities and the device providing the objective result is unbroken for the transfer of measurement characteristics, including uncertainty, for the whole of the measurement chain.

Reproducibility. The method used to produce results will produce results within an acceptable spread or range during future testing or inspections and within the constraints of using the same procedures, equipment and persons used for a prior execution of the process.

Transparency. The processes within an organization producing objective results must be open to external as well as internal scrutiny, so that factors which may adversely affect the organization's pursuit of objective results based upon scientific principles can be easily identified ad mitigated.

In Summary. These principles do not cover every requirement of the standard, but they are comprehensive enough to allow laboratories, inspection and product certification bodies and assessors to appreciate the reasons behind most of the individual requirements. They require assessors to exercise their professional judgment in evaluating whether an organization meets the requirements for recognition of its competence to perform specified tests or inspections.

Background on A2LA

The American Association for Laboratory Accreditation (A2LA) is a non-profit membership organization established in 1978, whose mission is to provide world-class accreditation and training services for testing and calibration laboratories, inspection bodies, proficiency testing providers, reference material producers and product certifiers.

A2LA is the leading US laboratory accreditation body with almost 2,000 laboratories accredited in accordance with the international standard ISO/IEC 17025:2005, about 50% of the total number of 17025 accreditations granted by all other US laboratory accreditation bodies. A2LA has a membership of 425 individuals and organizations representing a broad spectrum of interests.

Recognition of A2LA accreditation programs comes from organizations around the world with which A2LA has mutual recognition arrangements or other forms of recognition from domestic industry and government agencies.

Over 100 laboratories are accredited for tests related to food safety including government laboratories of the FDA, USDA, DOD, DOE, Customs, and the states of Michigan and Florida. The fact that these government laboratories seek accreditation voluntarily attests

to the benefits of accreditation. Five laboratories are accredited for tests related to toy safety including one in Shenzhen, China. A2LA has a large cadre of technical expert assessors who carry out the rigorous on-site assessments as a fundamental part of the accreditation process for these tests as well other tests in all fields of testing.

A2LA continues to provide leadership in the activities of ILAC and associated regional bodies. Peter Unger, A2LA President, was re-elected in October as ILAC Vice Chair for the 2007-2008 term. Mr. Unger continues to serve in a technical advisory role to the Executive Committee of the Inter-American Accreditation Cooperation (IAAC). Roxanne Robinson, A2LA Vice President, has been appointed as one of the Evaluation managers for the ILAC arrangement and is recognized as a lead evaluator for ILAC, the Asia Pacific Laboratory Accreditation Cooperation (APLAC) and IAAC. Ms. Robinson is a member of the APLAC Board of Management and also chairs or co-chairs a number of ILAC work groups.

ILAC is the premier international forum for the harmonization of laboratory accreditation procedures and policies as a means of reducing technical barriers to trade and the promotion of laboratory accreditation as a mechanism to enhance confidence in testing and calibration facilities, both domestically and internationally.

Other international cooperation arrangements involving A2LA include the MRA with the Asia Pacific Laboratory Accreditation Cooperation (APLAC), the bilateral agreement with the European Cooperation for Laboratory Accreditation (EA) MRA members and the multi-lateral agreement with the Inter-American Accreditation Cooperation (IAAC). A2LA attests to the competence of each accreditation system with which it has an MRA and has verified the fact that they follow the recognized norm for operating such systems, ISO/IEC 17011, and use ISO/IEC 17025 as the basis for the accreditation of laboratories.

Up-to-date information on cooperating laboratory accreditation systems can be obtained by visiting our website or contacting A2LA Headquarters.

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