



Accreditation -- Facilitating Global Trade

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ILAC Chair**

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Accreditation in the TBT Agreement



“6.1.1 adequate and enduring technical competence of the relevant conformity assessment bodies in the exporting Member, so that confidence in the continued reliability of their conformity assessment results can exist; in this regard, verified compliance, for instance through *accreditation*, with relevant guides or recommendations issued by international standardizing bodies shall be taken into account as an indication of adequate technical competence;”

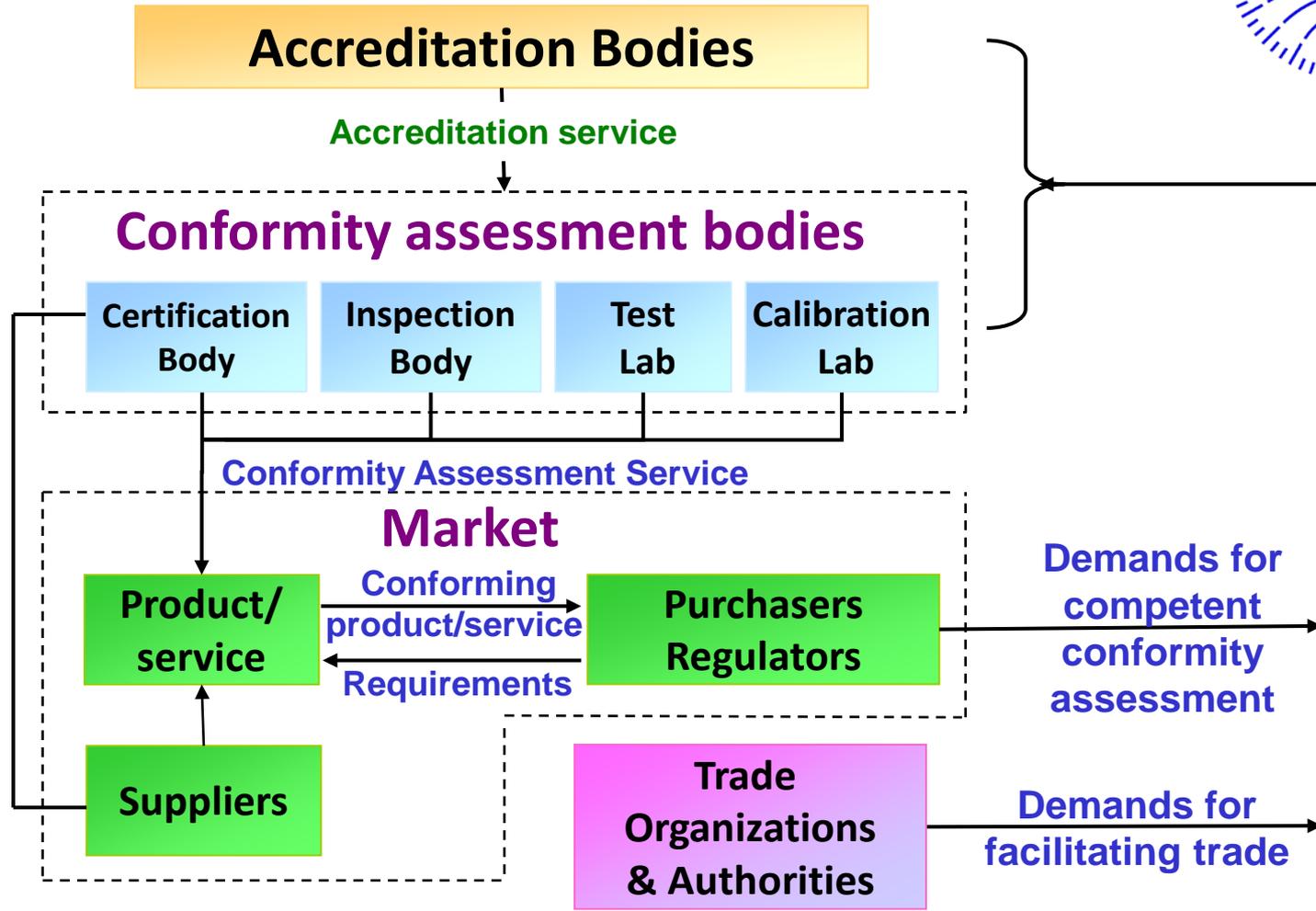
What is accreditation?



‘Independent evaluation of conformity assessment bodies against recognized standards to ensure their impartiality and competence to carry out specific activities, such as tests, calibrations, inspections and certifications.’



Accreditation to Support the Market



What is ILAC ?

International Laboratory Accreditation Cooperation



- **Established in 1977 to promote communication among laboratory accreditation bodies of the world.**
- **Formalized as a cooperation in 1996 with 44 bodies signing a Memorandum of Understanding (MOU).**
- **On 2 November 2000, a mutual recognition arrangement (MRA) was signed, among those members which had successfully completed a peer evaluation.**
- **MRA was extended in October 2012 to include inspection body accreditation**
- **81 Signatories (Full Members) to the Arrangement, representing 67 economies.**
- **ILAC was incorporated in the Netherlands on 20 January 2003.**
- **Approx. 45,000 laboratories & over 7,800 inspection bodies have been accredited by the 90 ILAC Full Members & Associates.**

ILAC's Global Role



Principal international forum for:

- **Recognition of competent test and calibration labs and inspection bodies world-wide through its Mutual Recognition Arrangement (MRA)**
- **Development and appropriate harmonization of laboratory and inspection body accreditation practice**
- **Promotion of laboratory and inspection accreditation as a trade facilitation tool**
- **Assisting with the development of laboratory and inspection accreditation systems**

ILAC Goals



- **Strengthen/deepen the existing ILAC MRA**
- **Promote the use of accredited labs and inspection bodies**
- **Appropriately link this activity to inter-governmental trade activity**
- **Continually promote the clear distinction between certification & accreditation to help reduce the confusion in the marketplace**

ILAC Goals (cont'd)

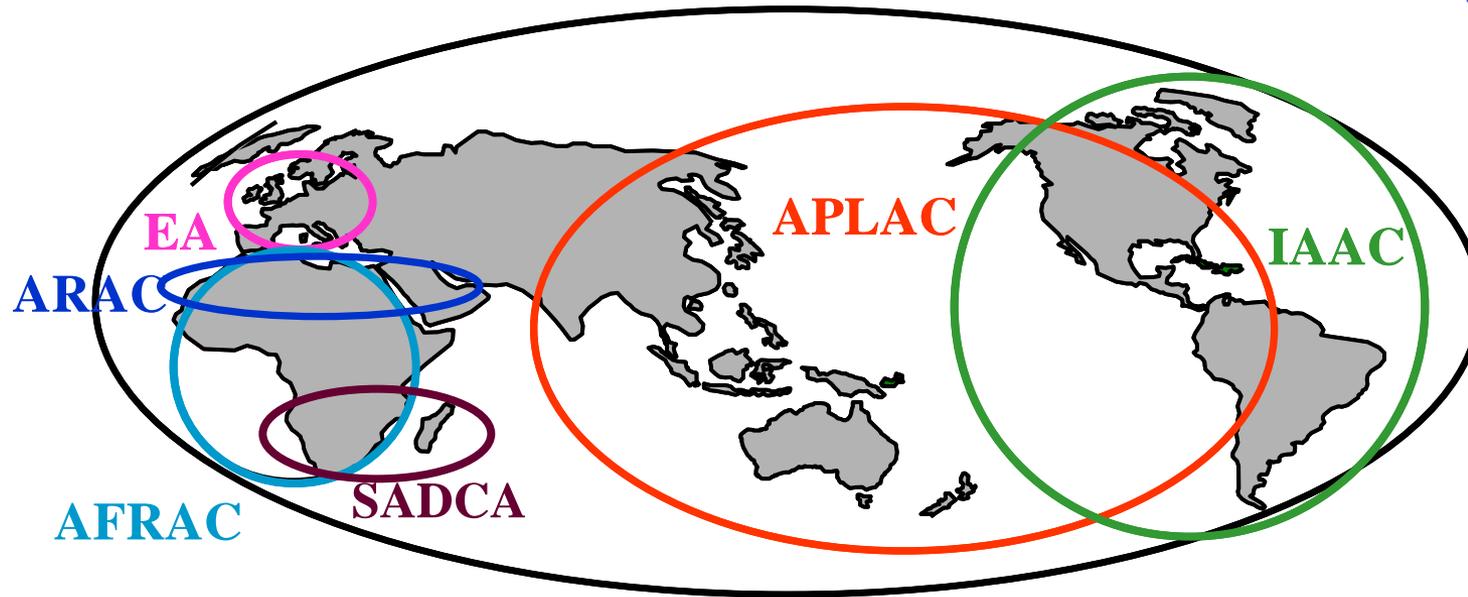


- **Provide assistance to developing countries by providing appropriate pre-MRA support to new accreditation systems**
- **Increase cooperation with all relevant stakeholders, i.e. labs, inspection bodies, regulators, industry groups, standard writing bodies and governments**

The International Picture



ILAC



- EA** European Cooperation for Accreditation
- APLAC** Asia Pacific Laboratory Accreditation Cooperation
- ILAC** International Laboratory Accreditation Cooperation
- IAAC** Inter-American Accreditation Cooperation
- SADCA** Southern African Development Community Accreditation
- AFRAC** African Regional Accreditation Cooperation
- ARAC** Arab Accreditation Cooperation
- Unaffiliated Bodies** Peer evaluated ABs who are not geographically located in one of the established regions

How is ILAC Structured?



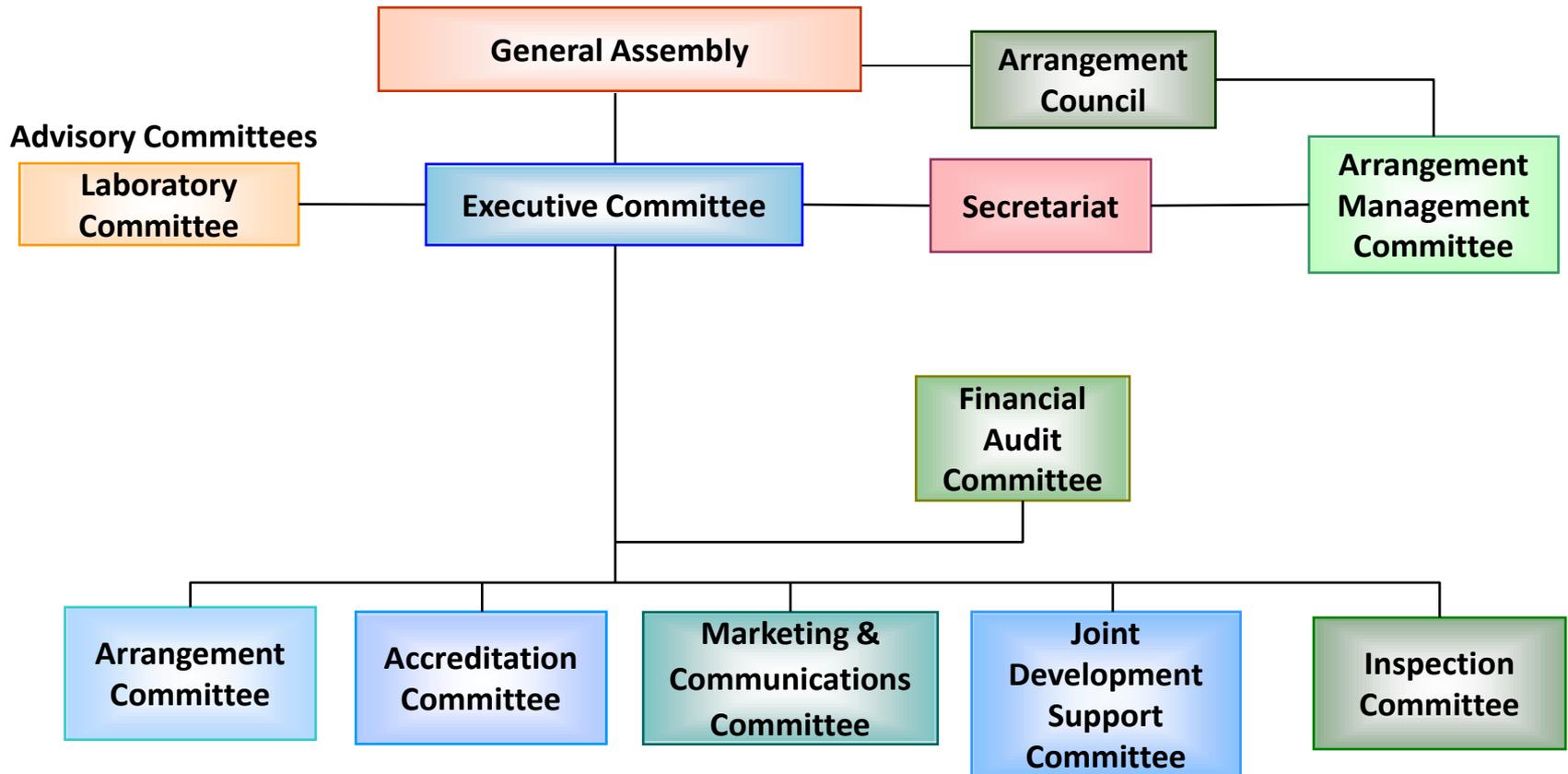
- **General Assembly: highest decision making body consisting of one representative from each membership category.**
- **General Assembly: meets once each year and these meetings are held in conjunction with the annual meetings of the International Accreditation Forum (IAF).**
- **All classes of membership and other interested parties (liaison organizations such as the BIPM, OIML, ISO/CASCO, IEC, IFCC, ITU, UNIDO, WTO, WADA) are invited to contribute to ILAC's work.**

How is ILAC Structured (cont'd)?



- **MEMBERSHIP CATEGORIES:**
 - Full Members (Signatories);
 - Associates;
 - Affiliates;
 - Stakeholders;
 - Regional Cooperation Bodies.
- **CURRENTLY:** (as of 24 June 2013)
 - 81 Full Members from 67 economies;
 - 19 Associates from 31 economies;
 - 18 Affiliates from 22 economies;
 - 24 Stakeholders;
 - 6 Regional Cooperation Bodies.
- Full Members & Associates have voting rights for all matters except admission of new Full Members, where voting is restricted to the Full Members only.

ILAC Organization Chart



MRAs Between Accreditation Bodies



The Fundamental Purpose -

A laboratory or inspection body accredited by one partner has equivalent competence to a laboratory or inspection body accredited by the other partner(s).

Status of ILAC MRA



- **The MRAs of the recognized regions underpin the ILAC Arrangement (MRA).**
- **Currently, the MRAs of 3 of the 6 Regional Cooperation Body members in ILAC are recognized by ILAC (EA, APLAC and IAAC).**
- **Recognition of a region is achieved after successful peer evaluation by ILAC.**
- **Each recognized region undergoes a re-evaluation by ILAC every 4 years.**
- **Signatories to the EA, APLAC and IAAC MRAs, who are also members of ILAC, are entitled to become signatories (Full Members) to the ILAC Arrangement.**

Status of ILAC MRA (cont'd)



- **Unaffiliated bodies are ABs who do not have a Regional Cooperation body in their region.**
- **ILAC relies on the evaluations undertaken by the recognized regions to grant and maintain ILAC signatory status for the ILAC members in their respective regions.**
- **ILAC itself undertakes the evaluations of the regions, the unaffiliated bodies (those ABs who do not have a region in their area) and those ABs who are part of a developing region, that has not yet obtained recognition (eg SADCA, AFRAC and ARAC).**
- **ILAC draws its peer evaluators from the regions and unaffiliated bodies.**

ILAC Arrangement



- **Accreditation body members deemed competent through a peer evaluation process:**
 - **ISO/IEC 17011**
 - **IAF-ILAC A series documents**
 - **ILAC P-series documents**
- **Signatories must recognize certificates and reports issued by organizations accredited by other Signatories**
- **Provides business with assurance that overseas bodies operate to the same standard**
- **Removes technical barriers to trade by reducing the need for redundant testing**

IAF/ILAC A2: Evaluation of an Accreditation Body



Two main sections; two main purposes:

–Criteria (Section 2): Requirements on an AB Signatory

–Procedures (Section 3): How to conduct an evaluation for IAF/ILAC

IAF/ILAC A2:

Evaluation of an Accreditation Body

Section 2.2 Supplementary Requirements



- **Demonstrated competence and experience**
- **Acceptable routes for measurement traceability**
- **Proficiency testing requirements**
- **Arrangement obligations**
- **Promotion of the Arrangements**
- **Contribute to peer evaluations**
- **Cross-frontier policy**

IAF/ILAC A2:

Evaluation of an Accreditation Body

Qualifications of Evaluators



– Team members:

- At least 3 years experience as staff member or assessor in a member accreditation body
- Evaluator training course completed
- English understood

– Team Leaders

- Senior AB staff
- Experience as a team member

IAF/ILAC A2: Evaluation of an Accreditation Body

Full Evaluation



- Four to six days duration**
- Three to seven team members**
- Several assessments witnessed**
- Summary report of findings at end of visit**

IAF/ILAC A2:

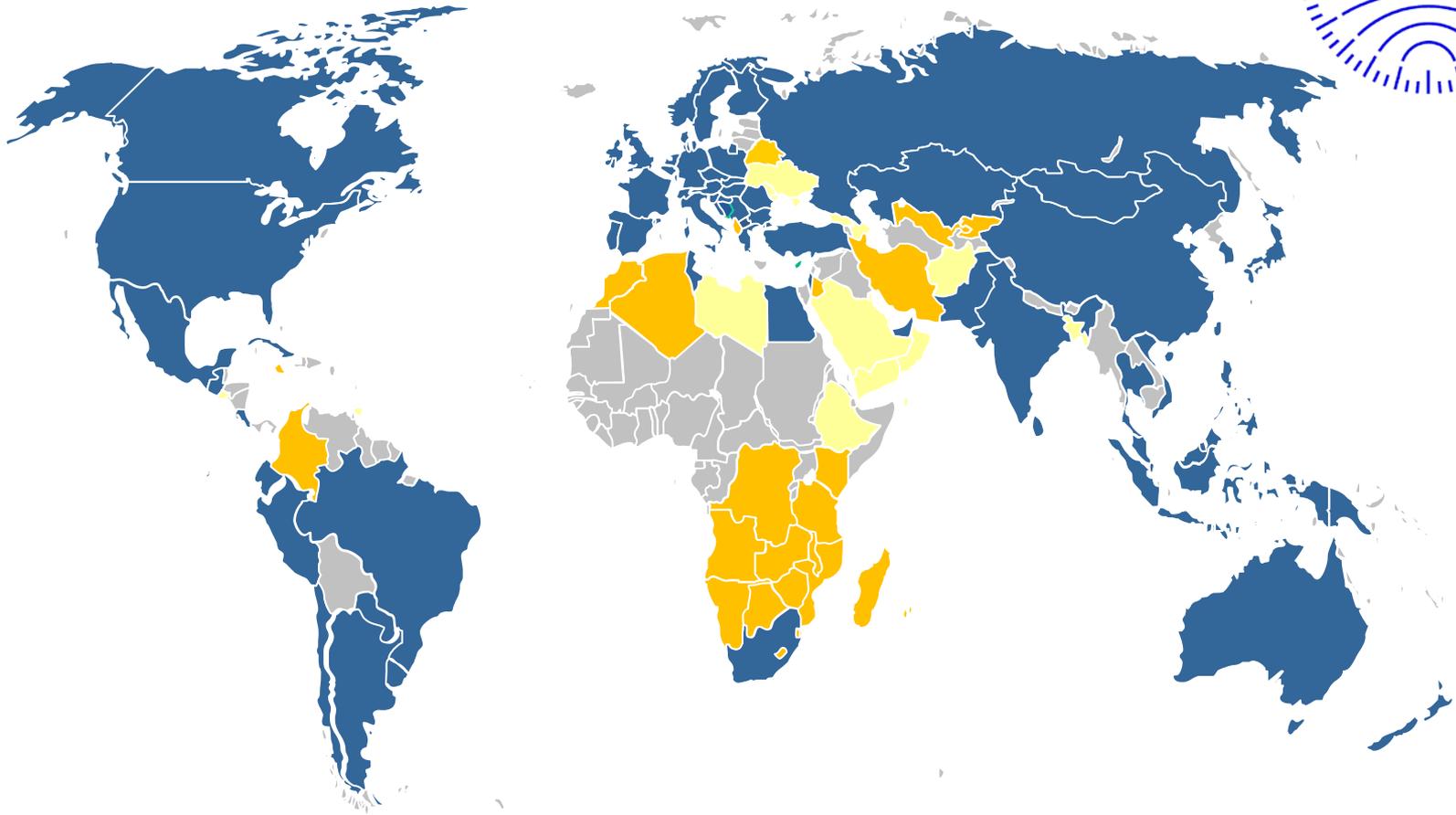
Evaluation of an Accreditation Body

Full Evaluation Report Process



- **Summary report with findings (non-conformities, concerns and comments):**
- **Draft full report**
- **Formal response by AB to findings**
- **Formal reaction of the evaluation team**
- **Often more than one iteration**
- **Follow-up visit possible**
- **Final report to the Arrangement group**
- **Decision by the Arrangement group**

Coverage of the ILAC MRA (June 2013)



- ILAC MRA Signatories
- ILAC Associate Members
- ILAC Affiliate Members



In Summary:



Primary Objective of the ILAC Arrangement

- **Eliminate testing and inspection as a Technical Barrier to Trade**
through
- **Recognition of Competence**
between
- **Accreditation Bodies**

ILAC-MRA Mark



ILAC-MRA Mark (cont'd)



- **52 ILAC Full Members have signed Licensing Agreements with ILAC, for the use of the Combined MRA Mark.**
- **The Combined MRA Mark is the ILAC-MRA Mark used in combination with the accreditation body's own mark.**
- **Once licensed, accreditation bodies can enter into a Sub-Licensing Agreement with their accredited laboratories for the use of the ILAC Laboratory Combined MRA Mark.**
- **The ILAC Laboratory Combined MRA Mark is the ILAC-MRA Mark used in combination with the mark which an accredited lab is entitled to use.**

International Partnerships



- **ILAC has signed a Memorandum of Understanding (MOU) with the following organizations:**
 - **CIPM - ILAC MoU**
 - **IAF - ISO - ILAC MoU**
 - **UNIDO - IAF - ILAC MoU**
 - **IAF - IEC - ILAC MoU**
 - **ILAC - IAF - OIML MoU**
 - **WADA - ILAC MoU**
 - **IFCC – ILAC MoU**
 - **ITU – IAF - ILAC**
 - **ICSCA - ILAC MoU**

International Partnerships (cont'd)



- **Joint BIPM/ILAC Statement on the roles of NMIs and NABs.**
- **Joint Declaration of the BIPM, OIML and ILAC promoting the existing three MRAs.**
- **Joint BIPM, OIML, ILAC and ISO Declaration on Metrological Traceability.**
- **Joint ISO-ILAC-IAF Communiqué on the alignment of ISO/IEC 17025:2005 with ISO/IEC 9001 (2008) updated January 2009.**
- **Joint ISO-ILAC-IAF Communiqué on the alignment of ISO15189:2007 with ISO/IEC 9001 (2008) released September 2009.**
- **Agreement for Closer Cooperation was signed between ILAC and IAF in September 2005 and was reaffirmed in October 2012.**

USA Specifiers of the ILAC MRA



- **Consumer Product Safety Commission**
- **Federal Highway Administration**
- **U.S. Coast Guard**
- **General Services Administration**
- **Department of Defense**
- **Nuclear Regulatory Commission**
- **Food and Drug Administration**
- **Environmental Protection Agency**

Consumer Product Safety Commission



- CPSC regulations issued to protect children under the Consumer Product Improvement Act of 2008
- Lists laboratories accredited by ILAC MRA signatory accreditation bodies
- Standard and test methods must appear on the scope
- Many children's products continue to be added within the scope of this requirement for accreditation

Consumer Product Safety Commission



Statement by Scott Hey, program manager of the CPSC Office of Hazard Identification and Reduction on the benefits of the ILAC MRA:

“The MRA has had a tremendous impact on our group. With all the products from manufacturers around the world – cribs and bunk beds from China and the United Kingdom, bike helmets and baby walkers from Taiwan and Italy – knowing that they have all been through an accepted standard of testing from an accredited lab gives us a greater level of confidence in those products. It provides a sense of consistency in quality.”

Federal Highway Administration



Testing of crash mitigation equipment and devices need to be tested in accordance with FHWA specifications by a laboratory accredited by an ILAC MRA signatory accreditation body

Rule in effect since 2010

Statement by Nicolas Armitovich, FHWA highway engineer:

“Even though being part of the MRA has had no impact on the work of the agency, the overall requirement for crash tests to be conducted by accredited laboratories has improved our confidence in the results received.”

U.S. Coast Guard



- Testing of equipment and devices used on Coast Guard vessels need to be tested in accordance with Coast Guard specifications by a laboratory accredited by an ILAC MRA signatory accreditation body
- Third-party certification of certain products also required

U.S. Coast Guard



Statement by Kurt Heinz, chief, life saving and fire safety, U.S. Coast Guard on the benefit of the **ILAC MRA:**

“Obviously, **avoiding duplicative tests saves a lot of time. A lot of the safety materials we use in ship construction, like the fire-resistant coatings we use on bulkheads and other areas, are manufactured in Europe and Asia, so being able to accept and depend on test results from labs in those countries makes sense. And, **less time spent doing routine approval work translates into more time spent on policy and standard development – which is a good thing.**”**

General Services Administration



- **Testing of star of life ambulances procured by the U.S. Government must be tested by an ILAC MRA signatory accreditation body**
- **The agency still does its own inspection but has confidence that the critical components of the ambulance have been tested by competent laboratories**

Department of Defense



- **DoD Environmental Laboratory Accreditation Program established its program using private sector laboratory accreditation bodies**
- **Accreditation bodies must be ILAC MRA signatories**
- **Cooperative agreement must be agreed**
- **DoD requires additional quality control requirements supplementing ISO/IEC 17025**

Nuclear Regulatory Commission



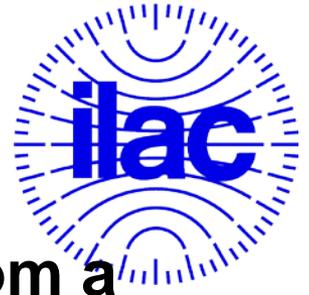
- NRC has been using NVLAP and A2LA accreditation for calibration laboratories
- NRC has expressed a desire to extend the accreditation recognition to ILAC MRA signatories in Europe and Far East
- Nuclear Energy Institute has been enlisted to evaluate the ILAC MRA peer evaluation process

Food and Drug Administration



- **Draft 2008 guidance** recommends test data for imported food should be from **an ISO/IEC 17025 accredited laboratory**
- Accreditation should be done by an **ILAC MRA signatory accreditation body**
- **Food Safety Modernization Act** calls for laboratory accreditation with FDA leaning toward using the **ILAC MRA to recognize accreditation bodies**
- FDA supports state public health laboratories to get **accredited by ILAC MRA signatories by August 2017**

Environmental Protection Agency



- **Water Sense Program** requires test results from a laboratory accredited by **an ILAC MRA signatory accreditation body**
- **Energy Star Program** requires test results from a laboratory accredited by **an ILAC MRA signatory accreditation body**
- Proposed rule to control **formaldehyde emissions from composite wood products** requires test results from a laboratory accredited by **an ILAC MRA signatory accreditation body**
- All programs require test methods to be shown on the **scope of accreditation**

Environmental Protection Agency



Statement by Eamon Monaghan, Program Integrity Lead,
ENERGYSTAR on the reason for using **the ILAC MRA**:

“We didn’t have to develop and implement our own set of rules. Any kind of **agency-specific rule creates costs or hassles for industry**, and that was something we really wanted to avoid. We currently certify products in **65 categories**, many of which are certified and tested overseas. Referencing the ILAC MRA took the EPA off the hook for developing a lot of criteria for labs or conducting our own lab oversight. And, by working with only **ILAC signatories**, we have **the confidence that the labs have been appropriately assessed**. We **now recognize 27 ILAC-signatory accreditation bodies** around the world.”

Benefits of the ILAC MRA



- **Eliminates the expense of government-administered accreditation and conformity assessment programs**
- **Increases the confidence in test results used to determine compliance with regulations**
- **Eliminates duplication in conformity assessment by reliance on recognized accreditation bodies**
- **Reduces costs of trade**
- **Encourages conformity assessment at the source of supply**
- **Upholds commitments of the WTO TBT Agreement**

For more information



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