



*Who “Accredits” the
Accreditors?*

*Presented at the
Forum on Laboratory Accreditation*

Cambridge, MA

August 24, 2007

by

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TNI Mission

- ◆ The NELAC Institute (TNI) is a non-profit organization whose mission is to foster the generation of environmental *data of known and documented quality* through an *open, inclusive, and transparent process* that is *responsive to the needs of the community*.



A2LA Mission

- ◆ *Provide world-class accreditation and training services for testing and calibration laboratories, inspection bodies, proficiency testing providers, reference material producers and product certifiers. These and other future services are intended to create stakeholder confidence in the competence and integrity of all A2LA-accredited organizations and the data they produce.*



Topics of Talk

- ◆ What Accreditation is and isn't
- ◆ The ILAC “model” for mutual recognition
- ◆ The MRA Evaluation Process



What about me?

- ◆ **The evaluated (A2LA):** EA, APLAC, FQA, Environmental Lead (Pb) and NELAC for PTOB
- ◆ **The evaluator:** I am a recognized team leader for APLAC, EA, IAAC and ILAC
 - (Australia, New Zealand, Taiwan, Japan, India, Argentina, Canada, Greece, NVLAP etc.)



Conformity Assessment Terminology

- ◆ Accreditation
- ◆ Certification
- ◆ Registration

Certification

- ◆ Written assurance by a *third party* that a product, process, or service *conforms* to *specified requirements*.
 - Used internationally to include quality system (ISO 9000) and other management system (ISO 14000) certification/registration



Accreditation

- ◆ Formal recognition by **an authoritative body** that a laboratory's quality system conforms to the requirements of an appropriate standard and of a laboratory's technical competence to perform specific tests or calibrations
- ◆ ISO/IEC17025
- ◆ Scope of Accreditation

Accreditation vs. Certification

- ◆ Certification (Registration)
 - quality system requirements
 - ISO 9001
- ◆ Accreditation
 - 17025: quality system requirements +
 - *technical competency requirements*
 - testing and calibration procedures

The ISO 9000 Quality Systems Auditor Asks...

- ◆ Have you defined your policies and procedures?
- ◆ Are they documented in accordance with the standard?
- ◆ Are you following them?

The Laboratory Accreditation Assessor Asks...

- ◆ Have you defined and *validated* your procedures?
- ◆ Are they documented in accordance with the standard?
- ◆ Are you following them?
- ◆ Do your procedures ensure *accurate* and *reliable* results?

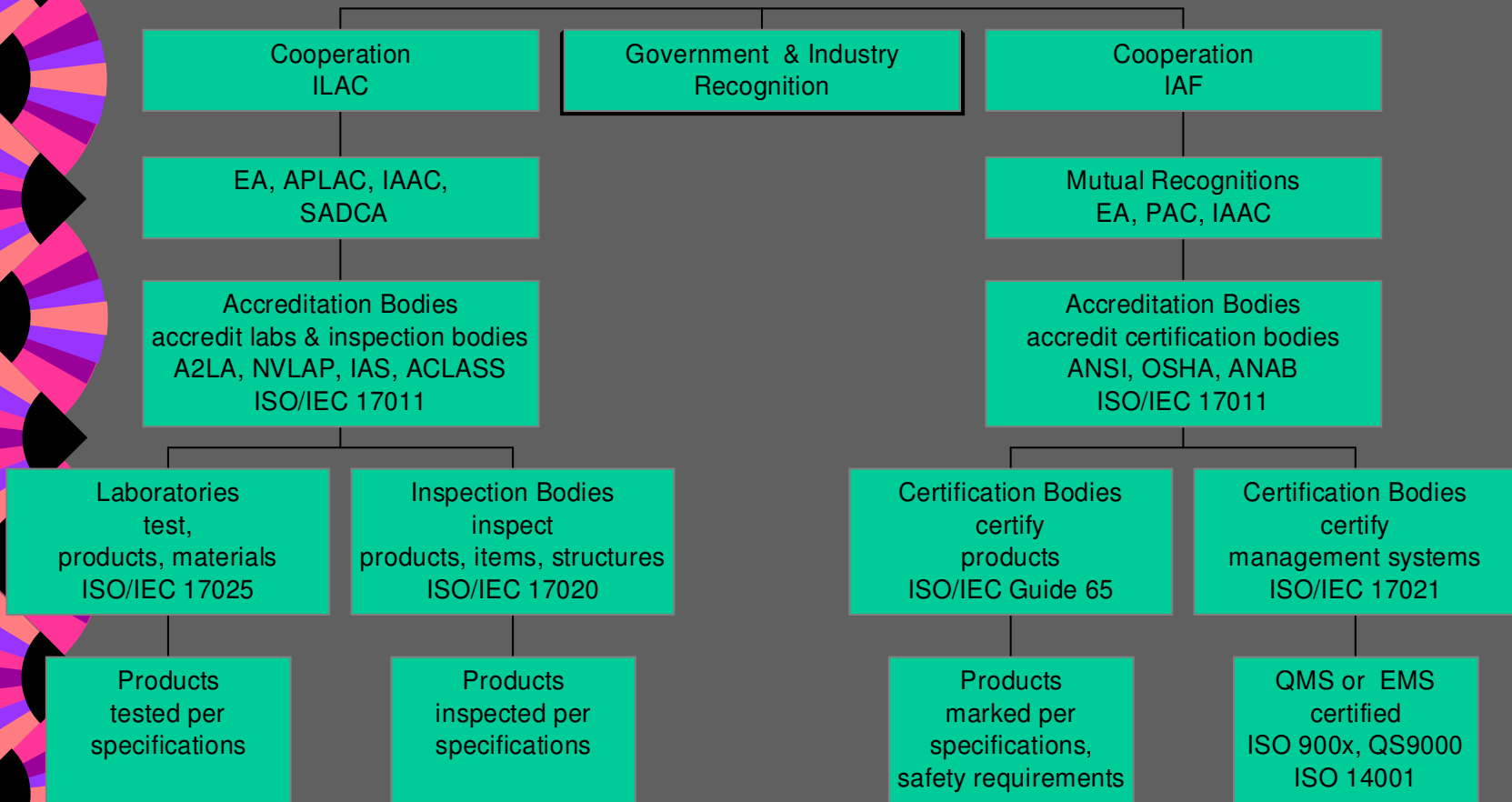
And...

- ◆ Do you understand the science behind the procedures?
- ◆ Can you foresee and cope with any technical problems that may arise?
- ◆ Do you have the correct equipment and adequate personnel?
- ◆ Have you calculated your uncertainties?

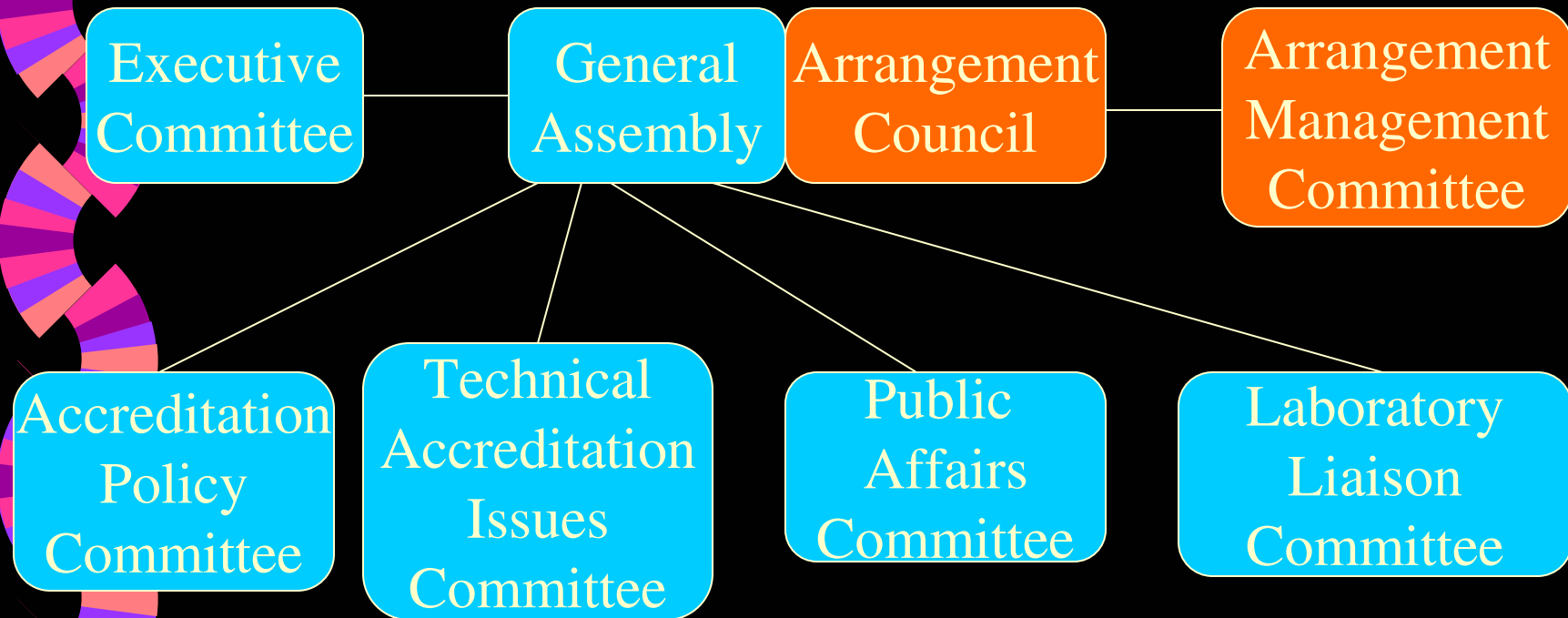
Key Distinction

- ◆ Accreditation = competence
- ◆ Certification = conformity

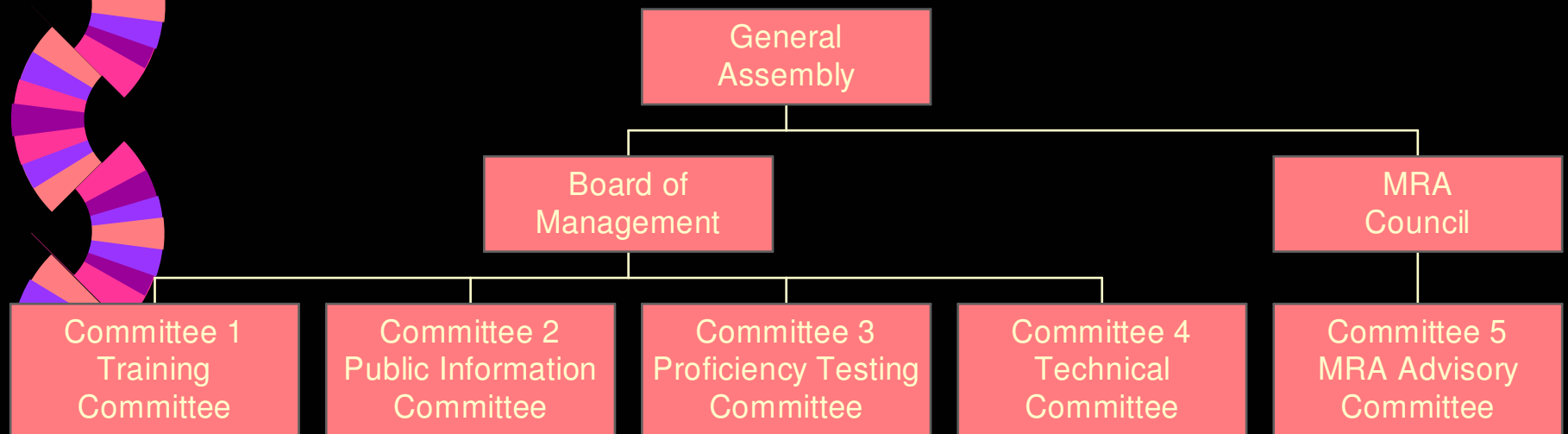
Conformity Assessment Accreditation Hierarchy



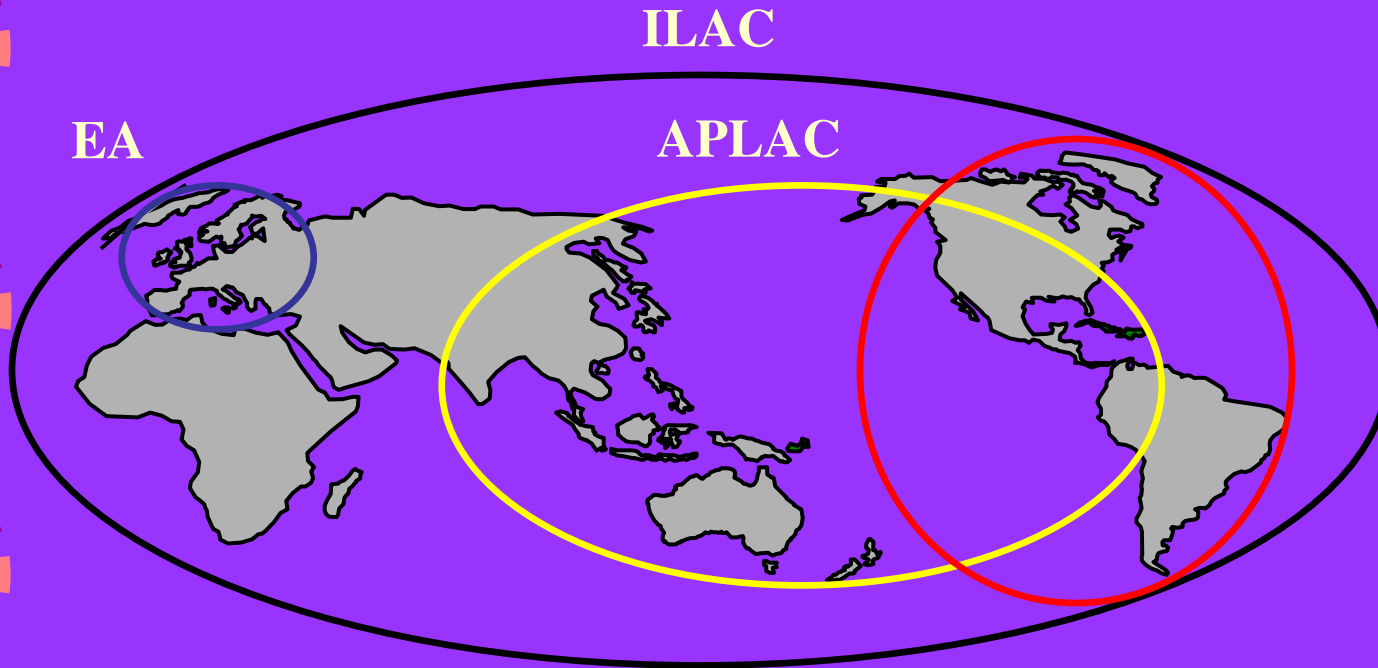
ILAC Organization



Typical Regional Cooperation Organization (e.g. EA, APLAC, IAAC)



Mutual Recognition Arrangements



- | | |
|-------|--|
| ILAC | International Laboratory Accreditation Cooperation |
| EA | European co-operation for Accreditation |
| APLAC | Asia Pacific Laboratory Accreditation Cooperation |
| IAAC | Inter-American Accreditation Cooperation |



The ILAC Arrangement

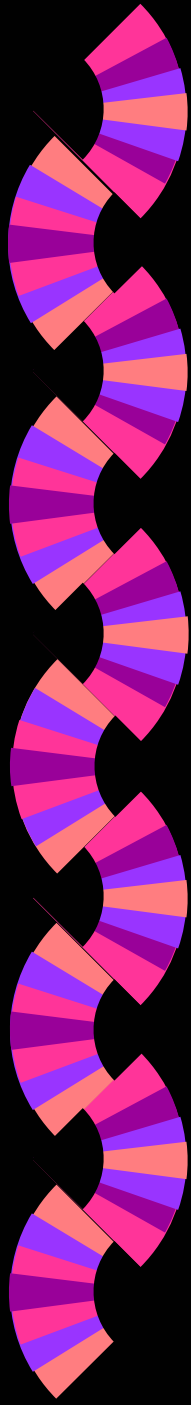
- ◆ ILAC has signed MOUs with:
 - ISO
 - WTO
 - APEC
 - WADA
 - Bluetooth SIG
 - CDMA Certification Forum (CCF)



The ILAC Arrangement

- ◆ Currently:
 - Regional Cooperation Bodies
 - 2 Not Recognized
 - Southern African Development Community in Accreditation (SADCA)
 - Central Asian Cooperation on Metrology Accreditation and Quality (CAC-MAS-Q)

The ILAC Arrangement

- 
- ◆ Currently:
 - 57 Full Members (Signatories to the MRA)
 - 17 Associates
 - 20 Affiliates
 - 1 National Coordination Body
 - 23 Stakeholder Bodies



New Conformity Assessment Activity included in MRA

- ◆ Reference Material Producer
 - Added to APLAC MRA March 2006
 - A2LA accepted September 2006
 - Signatories added to MRA once 4 ABs accepted by MRA Council – December 2007?
- ◆ Proficiency Testing Provider ?



Regional Cooperation Participation

- ◆ Join as a member
 - participate and learn
- ◆ Apply to be evaluated
 - ultimate goal to be an MRA signatory



MRA Peer Evaluation Process - Application

- ◆ Submit application to secretariat of the cooperation
- ◆ Series of documents must address:
 - the ISO/IEC 17011 requirements
 - measurement traceability policy
 - laboratories' participation in proficiency testing
 - pre-evaluation is possible



MRA Peer Evaluation Process - Evaluators

- ◆ Team leader recruited/assigned
 - generally senior accreditation body staff
 - trained through observing and then serving as evaluator
 - also trained at international seminars for evaluators or specifically, team leaders



MRA Peer Evaluation Process- Evaluators

- ◆ Team leader chooses team members
 - Technical backgrounds coincide with kinds of laboratories that the applicant accredits
 - usually four, sometimes six members
 - If calibration is included, one team member must have a strong metrology background
 - often a NMI staff person joins the team



MRA Peer Evaluation Process- the Evaluation

- ◆ Document review
- ◆ Evaluation of headquarters operations conformance to ISO/IEC 17011
- ◆ Witness assessments for laboratories' conformance to ISO/IEC 17025
 - effectiveness of the assessors is determined
 - technical expertise
 - assessment skills



MRA Peer Evaluation Process – The Evaluation

- ◆ International guidelines – such as IAF/ILAC A3 – Key Performance Indicators:
 - KPI 1: Access to Expertise
 - KPI 2: Accreditation criteria, scope of the AB and extension of the scope



MRA Peer Evaluation Process – The Evaluation

- ◆ KPI's (cont'd):
 - KPI 3: AB staff, assessors and experts
 - KPI 4: Assessor support system
 - KPI 5: The assessment and the assessment team
 - KPI 6: Impartiality of Assessors, Committees and Decision-Making Bodies
 - KPI 7: Monitoring Performance of Assessors and Experts



MRA Peer Evaluation Process – The Evaluation

- ◆ KPI's (cont'd):
 - KPI 8: Dealing with non-conformities and corrective actions of the accredited bodies, including decision making on accreditation
 - KPI 9: Internal audits and management reviews
 - KPI 10: Proficiency testing



MRA Peer Evaluation Process – The Evaluation

- ◆ KPI's (cont'd):
 - KPI 11: Calibration, traceability, and reference materials
 - KPI 12: Program of surveillance activities
 - KPI 13: Value-adding services



MRA Peer Evaluation Process - the Evaluation

- ◆ Determining arrangements for ensuring traceability to the appropriate primary standards
 - visiting the National Metrology Institute
 - evaluating the level of participation in international laboratory comparisons sponsored by other NMIs or BIPM



Proficiency Testing

- ◆ Minimum Requirements
 - One successful activity prior to accreditation
 - Cover the full scope of accreditation, by major sub disciplines, over the course of 4 year.



Proficiency Testing

- ◆ More rigorous frequency could be prescribed by regulatory or specifier criteria
- ◆ Accreditation Bodies may also run programs or use commercial sources but must demonstrate:
 - monitoring and corrective action process
 - revocation and re-instatement of accreditation process



Use of the Accreditation Symbol

- ◆ ABs must provide limits and guidelines on use of their logo by their accredited labs
 - AB must have process for requiring corrective action
- ◆ ILAC P8 is often invoked
 - Conveys rules on use of logo on test reports, calibration certificates and business literature.



MRA Peer Evaluation Process - Signatory Status

- ◆ Respond in writing to any concerns resulting from the evaluation
- ◆ Team leader coordinates the review of the corrective action
- ◆ Full evaluation information provided to the cooperation's acceptance panel
 - Decision made to include or continue as a signatory, possibly with conditions.



Impediments to Recognition

- Assessors' technical qualifications
- Laboratory Scope content
- Separation of activities
- Sufficient assessment length and depth
- Subcontractor qualifications and oversight



MRA Peer Evaluation Process - Continue Signatory Status

- ◆ Evaluation every four years
- ◆ Appeals mechanism for negative decisions
- ◆ Alert partners to changes
- ◆ Participate in international committee work
- ◆ Provide a liaison officer
- ◆ Participate in international laboratory comparisons (ILCs)
- ◆ Promote acceptance of test data across borders

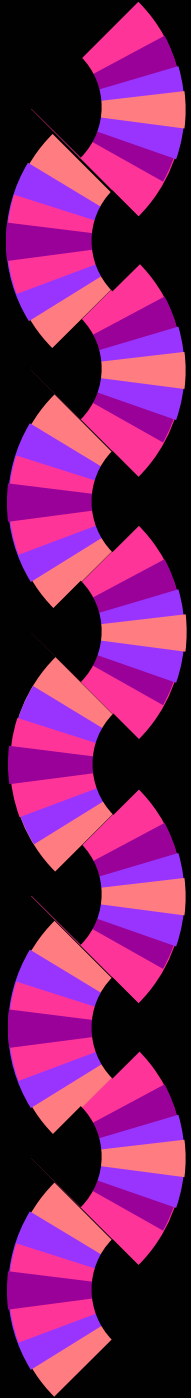
Conclusion

The International MRA Evaluation Process:

- Builds confidence between accrediting bodies
- Fosters uniformity in complying with ISO/IEC 17011 and ISO/IEC 17025
- Promotes acceptance of calibration and test results between MRA countries
- Reduces barriers to trade

Questions?

- ◆ www.A2LA.org
- ◆ www.ilac.org
- ◆ www.aplac.org
- ◆ www.european-accreditation.org
- ◆ www.iaac.org.mx/





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