High Level Importance: ISO 17025 Microbiology compliance

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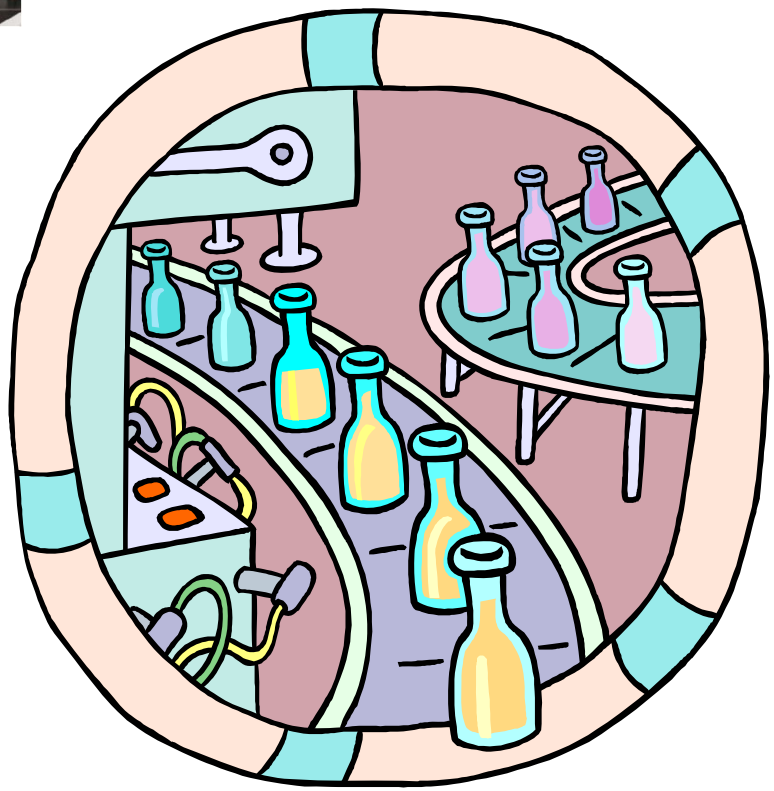
Topic Outline

- Lab Accreditation: ISO/IEC 17025
  - What is it?
  - Who Provides Accreditation?
  - How do you get it?
- ISO 17025 Microbiology compliance for Food Safety
  - Food Safety Challenges
  - ISO 17025 Microbiology compliance

Lab Accreditation



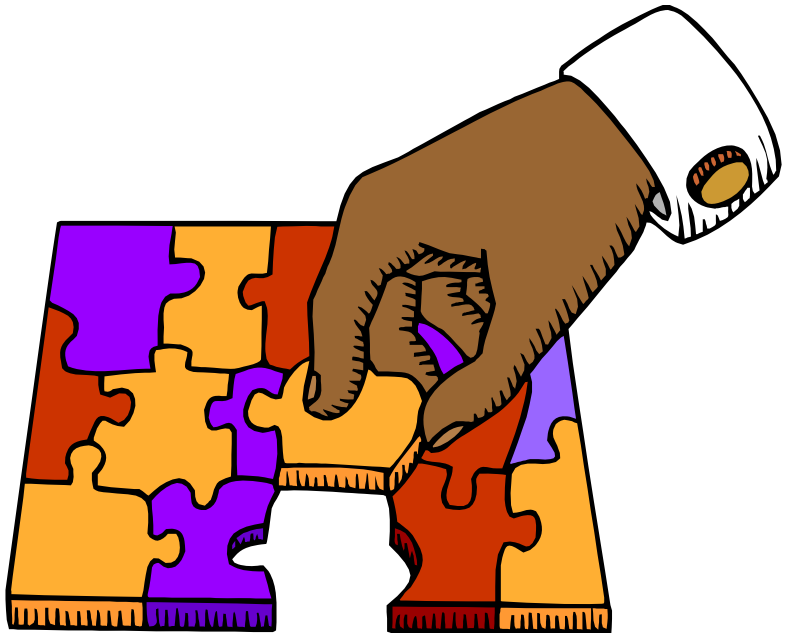
- As consumers, we want confidence in products
  - inspected
  - tested
- Verification that this has been done properly is the job of *recognized accreditation bodies*

What is it?

- Based on ISO *Guide* 25
- Since December 1999, a standard – ISO 17025
  - Defined, written procedures
  - Document you are following them

"SAY what you do, DO what you say"

What is it?

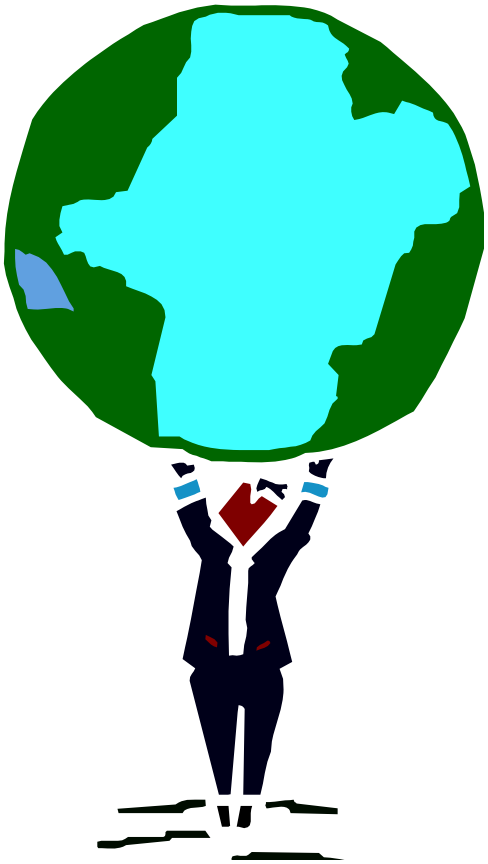


- Certification of lab:
  - Management systems
  - Personnel
  - Products
  - Testing & calibration
  - Inspection
  - Quality systems & procedures
  - Vendors
  - Complaint handling
  - Etc.

Accreditation: Benefits

- Provides confidence in the results
- Public and industry acceptance
- Meets purchaser or regulatory specifications
- National and International recognition
- Increase competitiveness and market share
- Assurance to customers of good laboratory practices
- Ensures better support in the event of legal challenge
- Save money by getting it right the first time

WHO Provides Accreditation?



- International Laboratory Accreditation Cooperation (ILAC)
- Formed in 1996 – 44 national bodies signed Memorandum of Understanding (MOU)
- International cooperation between accreditation schemes

ILAC

- Forum for development of lab *accreditation practices*
- Promotes lab accreditation as a *trade facilitation* tool
- Provides assistance to develop *accreditation systems*
- Recognizes *competent* global test facilities

WHO Provides Accreditation?

- Each country has own body
  - KOLAS
  - A2LA
  - COFRAC
  - EMA
- Multilateral Agreements are signed between regions
  - EA
  - APLAC

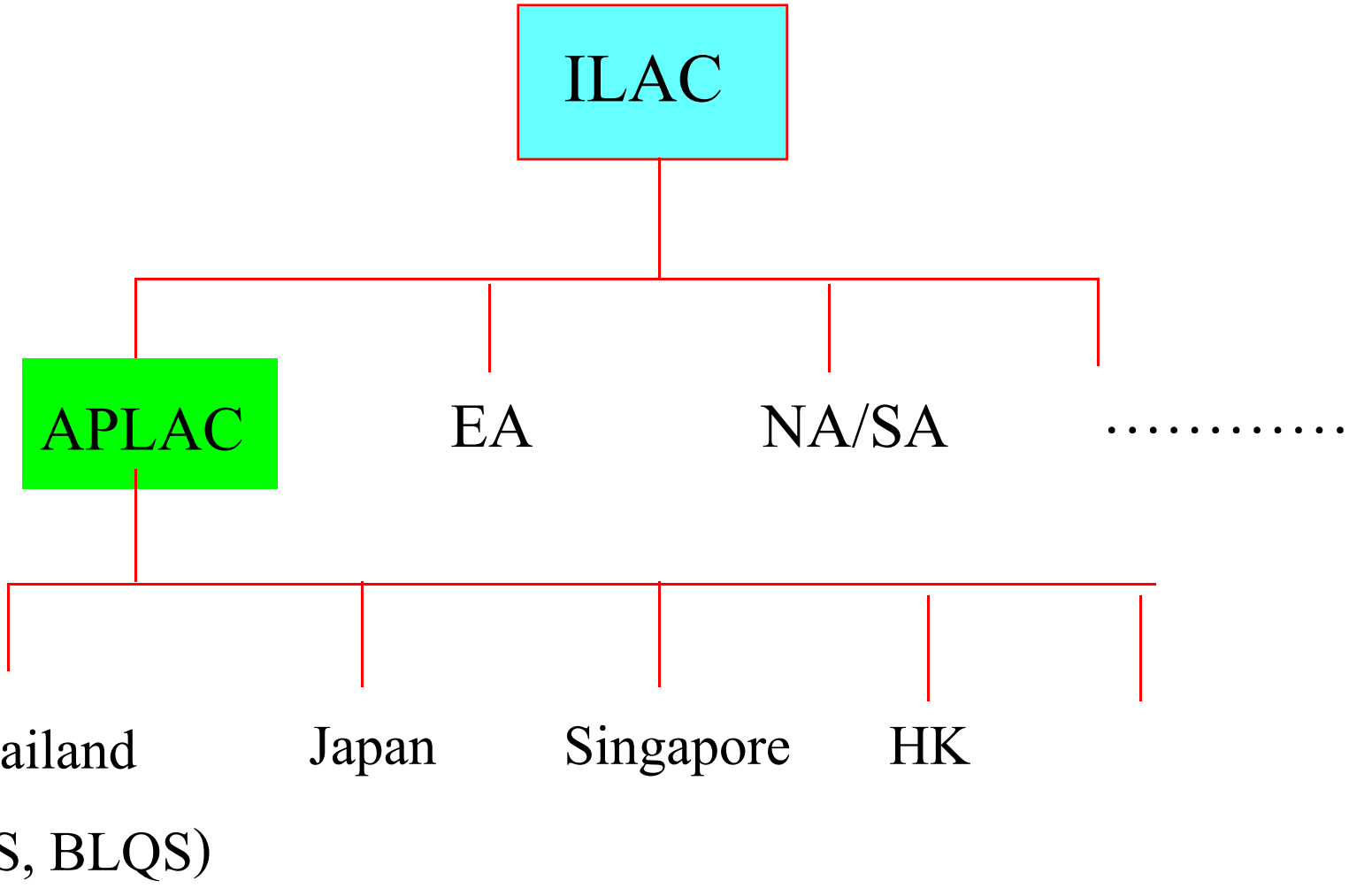
What Is a Multilateral Agreement?

- Agreement between cooperatives to recognize & promote equivalence of each other's:
  - Systems
  - Certificates
  - Reports

What Do These Agreements Mean?

- Agree on equivalency
- Assess each other
- Results from one lab can be accepted by another
- Can help intl trade - a supplier may need only 1 certificate to satisfy all governments
- Can be a competitive advantage

Accreditation Bodies



ILAC = International Laboratory Accreditation Coordination

APLAC = Asia Pacific Laboratory Accreditation Coordination

APLAC and ILAC

Mutual Recognition Arrangement

Accreditation bodies recognise the work of accredited laboratories as equivalent around the world

Regulator are also encouraged to accept local and foreign accredited results

Reduces Technical Barriers to Trade

APLAC member

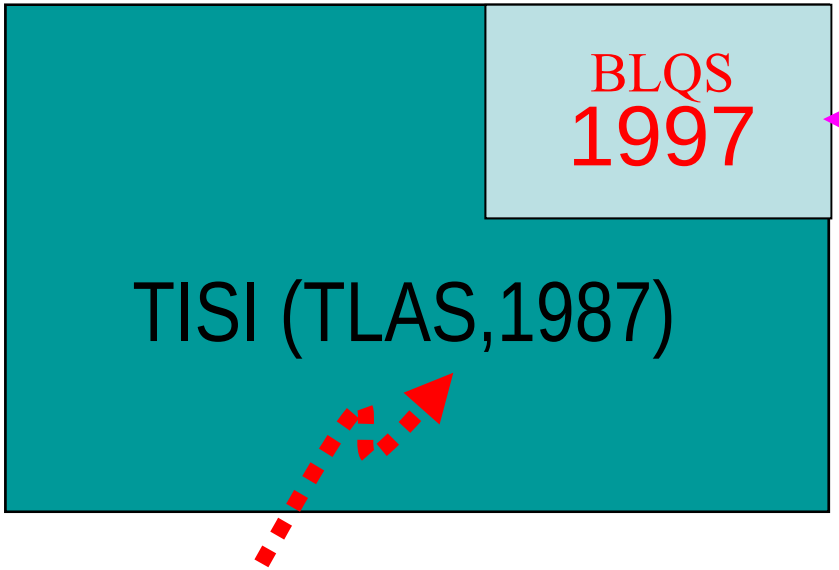
Mutual Recognition Arrangement (MRA- 001)

USA
CANADA
AUSTRALIA
NEW ZEALAND

SINGAPORE
INDONESIA
VIETNAM
THAILAND

JAPAN
CHINA
HONG KONG
REPUBLIC OF KOREA
CHINESE TAIPEI
INDIA

National Laboratory Accreditation Bodies



Health product testing labs.

Medical labs.

Engineering / others labs

Thai Industrial Standard Institute (TISI)

Thai Laboratory Accreditation Scheme (TLAS)

Bureau of Laboratory Quality Standards (BLQS), DMSc.

How Are Labs Accredited?

- After defining & documenting:
  - Quality management systems
  - Technical requirements for operation
- Initiating a 3rd party assessment of competence

ISO / IEC 17025 : 2005

Contents of ISO / IEC 17025 : 2005

1. Scope
2. Normative References
3. Terms and Definitions
4. Management Requirements
5. Technical Requirements

ISO / IEC 17025 : 2005

- Management Requirements (15)
- Technical Requirements (10)

ISO / IEC 17025 : 2005

4. MANAGEMENT REQUIREMENTS

- 4.1 Organization
- 4.2 Management System
- 4.3 Document control
- 4.4 Review of requests, tenders and contracts
- 4.5 Subcontracting of tests and calibrations
- 4.6 Purchasing services and supplies
- 4.7 Service to Customer
- 4.8 Complaints

ISO / IEC 17025 : 2005

4. MANAGEMENT REQUIREMENTS –contd.

4.9 Control of non-conforming testing/ calibration

4.10 Improvement

4.11 Corrective actions

4.12 Preventive actions

4.13 Control of records

4.14 Internal audits

4.15 Management reviews

Technical Requirements

ISO / IEC 17025 : 2005

5. TECHNICAL REQUIREMENTS

5.1 General

5.2 Personnel

5.3 Accommodation and environmental conditions

5.4 Test and calibration methods and method validation

5.5 Equipment

5.6 Measurement traceability

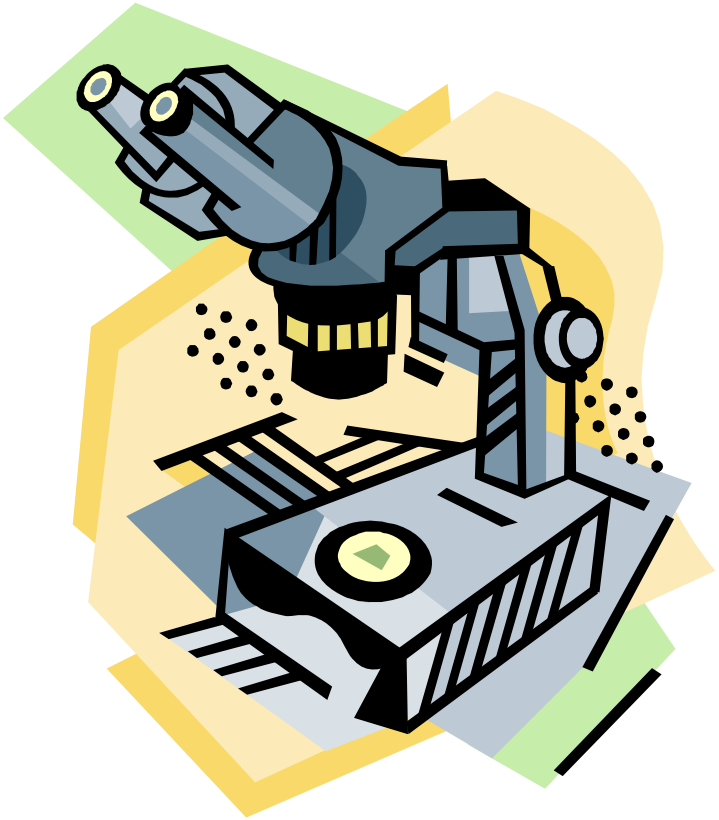
5.7 Sampling

5.8 Handling of test and calibration items

5.9 Assuring quality of test and calibration results

5.10 Reporting the results

Why do it?



Benefits for Labs

- *Improved* systems
- More *control* over testing protocols
- Better *training* & *discipline*
- *Fewer* repeat analysis
- Greater *confidence* in results

Why do it?

Benefits to Customers

- Greater *confidence* in reliability of test data
- Greater *acceptance* by government depts.
- Calibration standards & testing *traceable* to national standards
- Results accepted *nationally & abroad*

Food Safety: Why Should We Care?

Every year foodborne pathogens result in an estimated

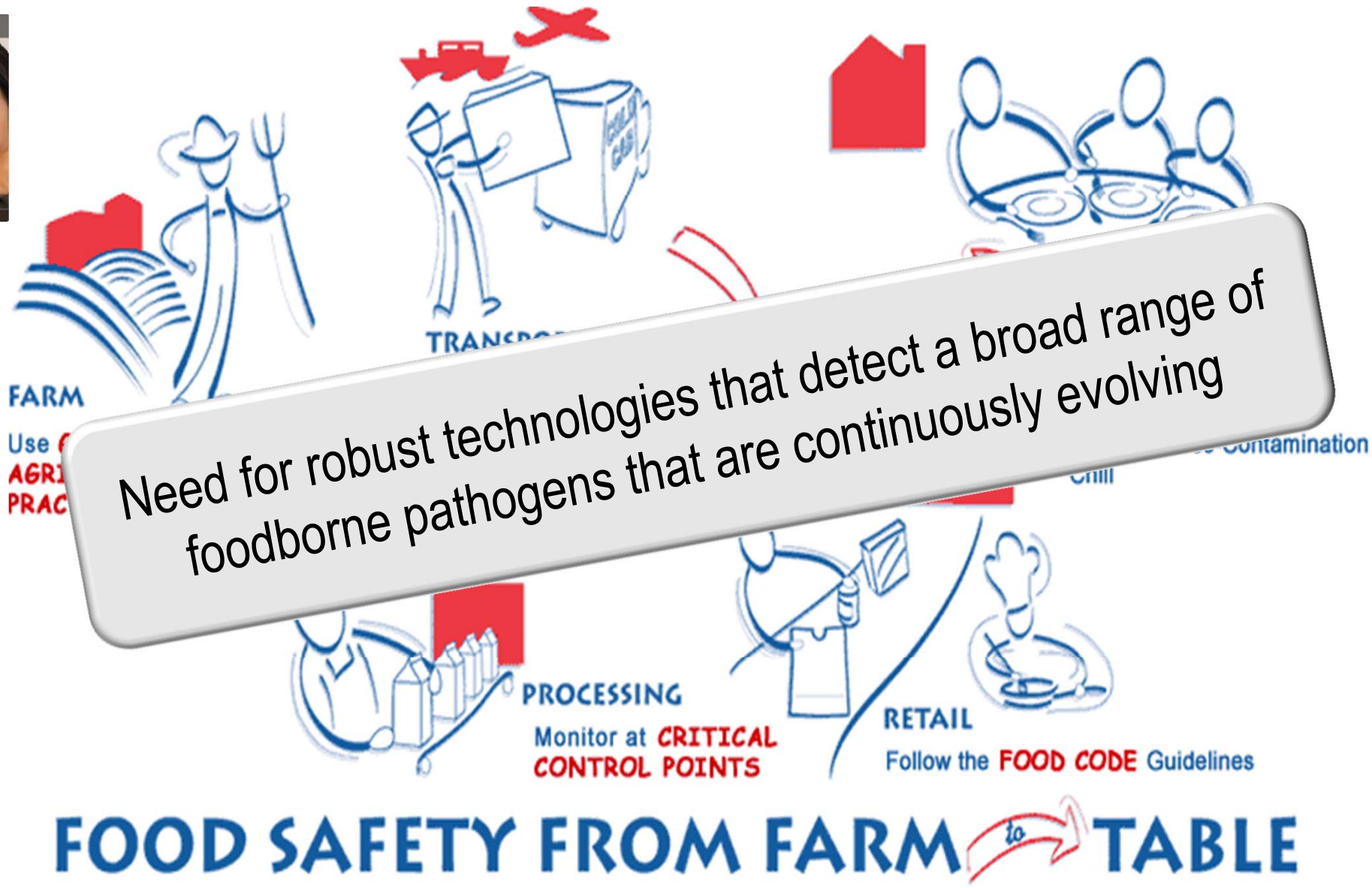
- 2 billions cases of foodborne illnesses
- 1.8 millions needless deaths each year
- Economic losses between $ 10-83 billion USD

WHO

Where do pathogens come from?

Sources of Contamination

- Raw materials (ingredients)
- Processing equipment
- Food Handlers
- Farmers and producers
- Packaging material
- Animals and insects
- Environment: Air, soil, water, waste, silage



Need for robust technologies that detect a broad range of foodborne pathogens that are continuously evolving

What Are The Challenges?

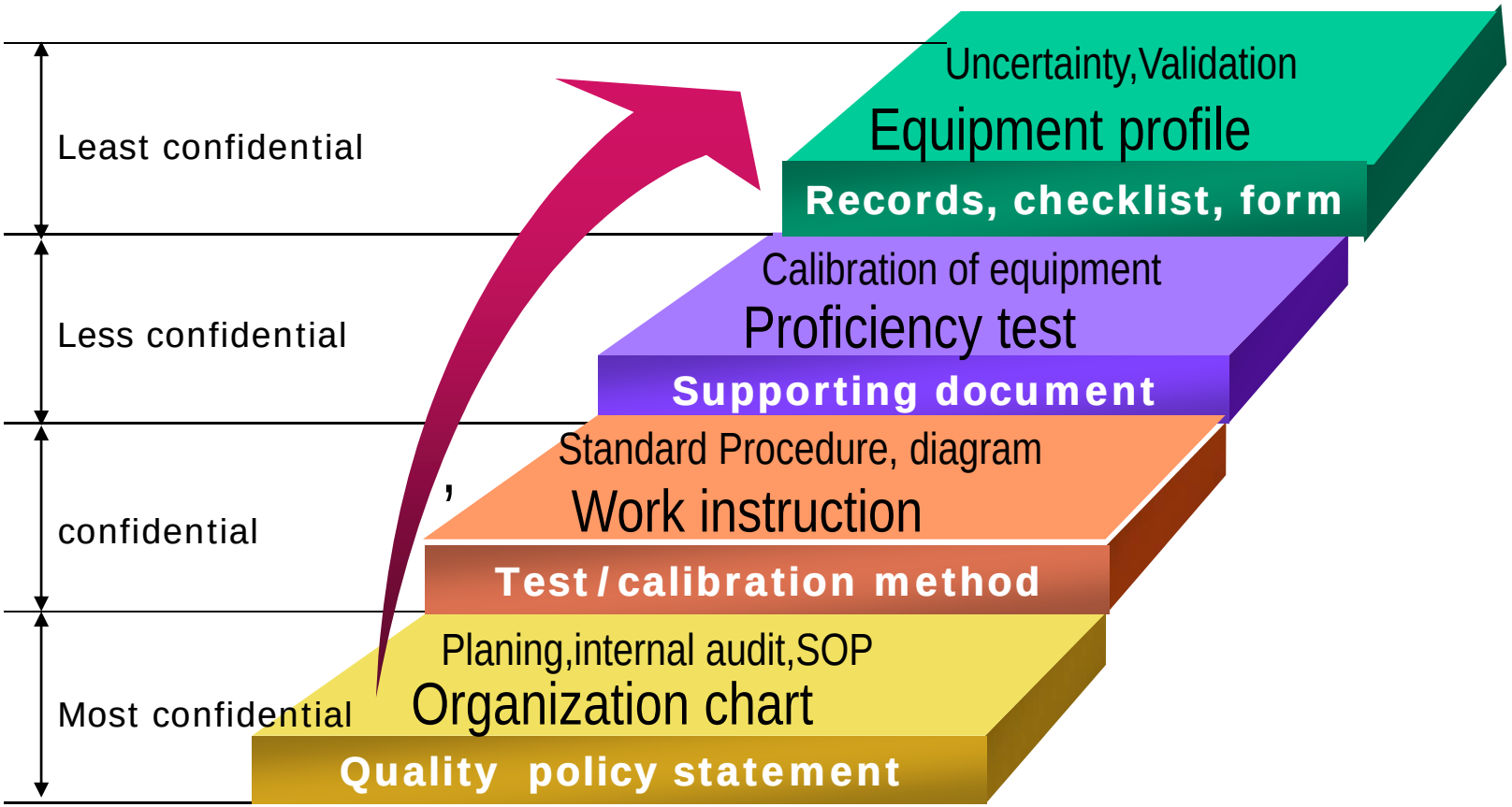
What are the issues impacting Food Safety?

- Globalization of the food supply
- Intensification of agriculture and animal husbandry
- New raw materials, new processes and new foods
- Changes in well known organisms & emerging microorganisms i.e. E.coli 0104 outbreak
- Climate changes
- Increased regulatory demands
- Consumer related issues (demographic change, awareness, behaviors, etc...)

What are benefits of ISO 17025 Microbiological Compliance?

- Establishes minimum competency standards
- Identifies laboratory's specific competencies
- Assures acceptance of data
- Assurance to meet quality requirements of consumers
- Reduced risk
- Ensure we provide products & services that support food safety world-wide

ISO 17025: Four levels of qualified documents



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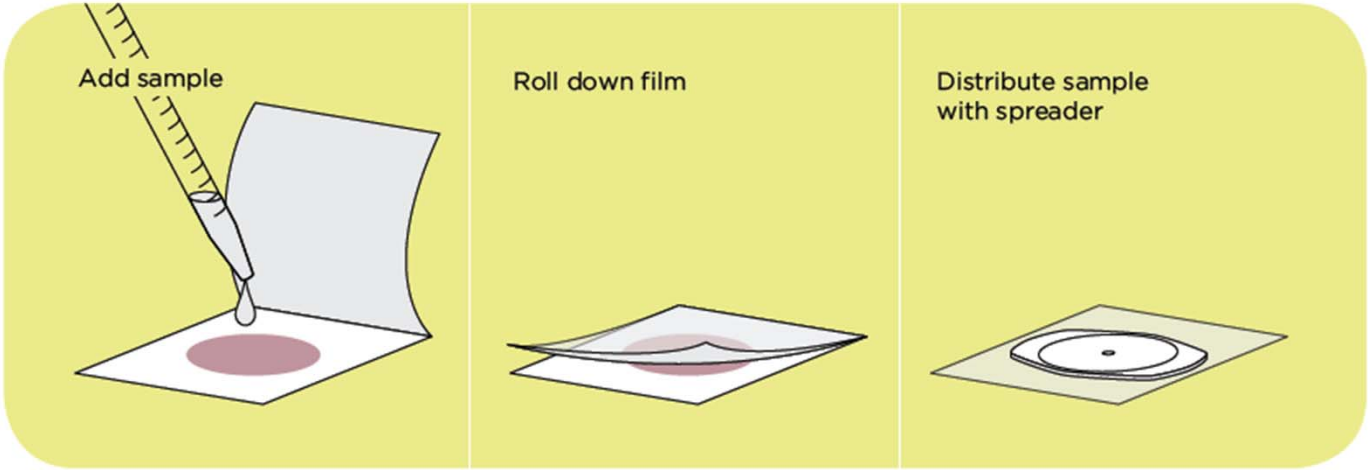
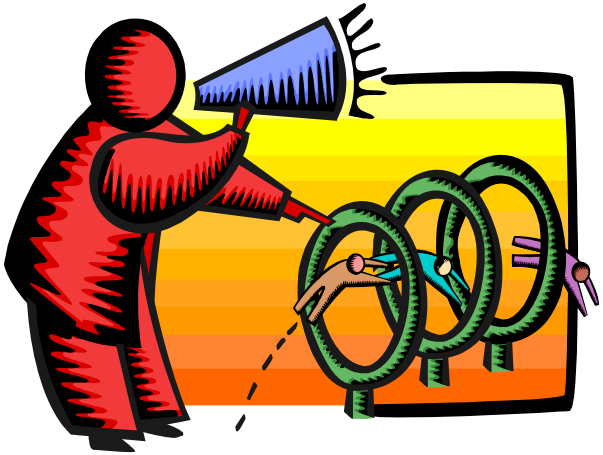
Microbiological Test Methods

- Legal methods approved for testing of product's quality
- International recognized standard methods
- Customer requirement methods
- For test methods that are in-house and adapted from standard method, there shall be validated and record of the data



Proficiency Testing (Pt)

- External control to measure a lab's:
  - Accuracy
  - Competency
- Verify lab & technicians are competent



Proficiency Tests - Microbiology

- Samples with known levels of target organisms
- Shipped periodically – at least 2x/yr
- Follow current methods
- Rotate technician participation
- Reported results compared to other labs

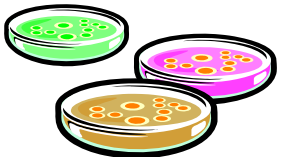
Define Measurement of Uncertainty

- Currently – some uncertainty!
  - Repeatability/ reproducibility

- The degree of rigor or/ and the need for reporting of uncertainty of measurement depends on:
  - the requirements of the client
  - the requirements of the test method
  - the existence of narrow limits on which decisions on conformance to specification are based

Microbiological testing

- Estimation of uncertainty of measurement is not possible in qualitative testing, laboratory shall at least attempt to identify all the components of uncertainty and make a reasonable estimation
- Previous validation data can be a support
- The standard strains or reference strains that using in testing shall be traceable to the national or international levels



Limitations of Accreditation

- Provides *assurance* – but not a guarantee
- Large volumes of food, small volumes tested – so can still miss:
  - Potential food spoilage
  - Potential food poisoning

Conclusion

- Lab Accreditation ISO 17025
  - Establishing quality management systems & technical requirements for operation
- ISO 17025 Microbiology Compliance
  - required for successful performance in food safety
  - critical importance in the risk assessment process

Thank you for your attention