

International Perspective: Non-Regulatory Quality Measures for Medical Laboratories

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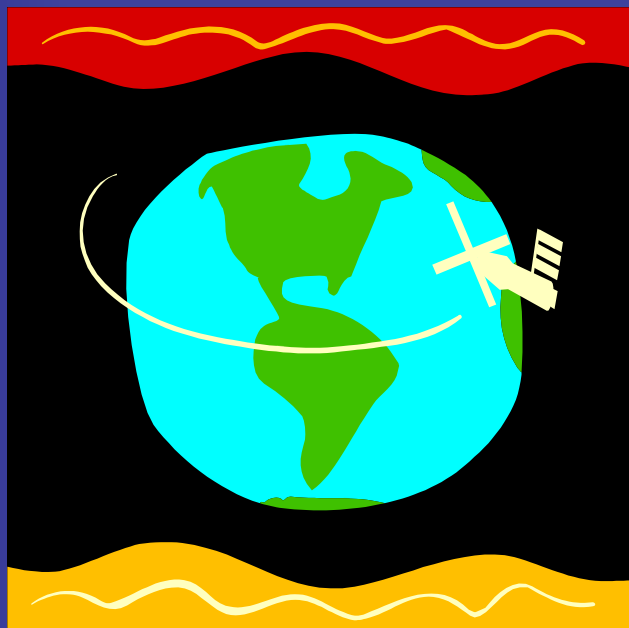
Presentation Plan

- International Options for Laboratory Recognition
 - History, Development and Relationships
- Benefits and Opportunities for Improvement with International Programs
- Summary and Conclusions

UBS Warburg Cup



- An annual fall international golf tournament played on Sea Island GA.
- Older Players
- US versus the *“Rest of the World”*



The two edge sword of
international standardization

Global Harmonization



The two edge sword of international standardization

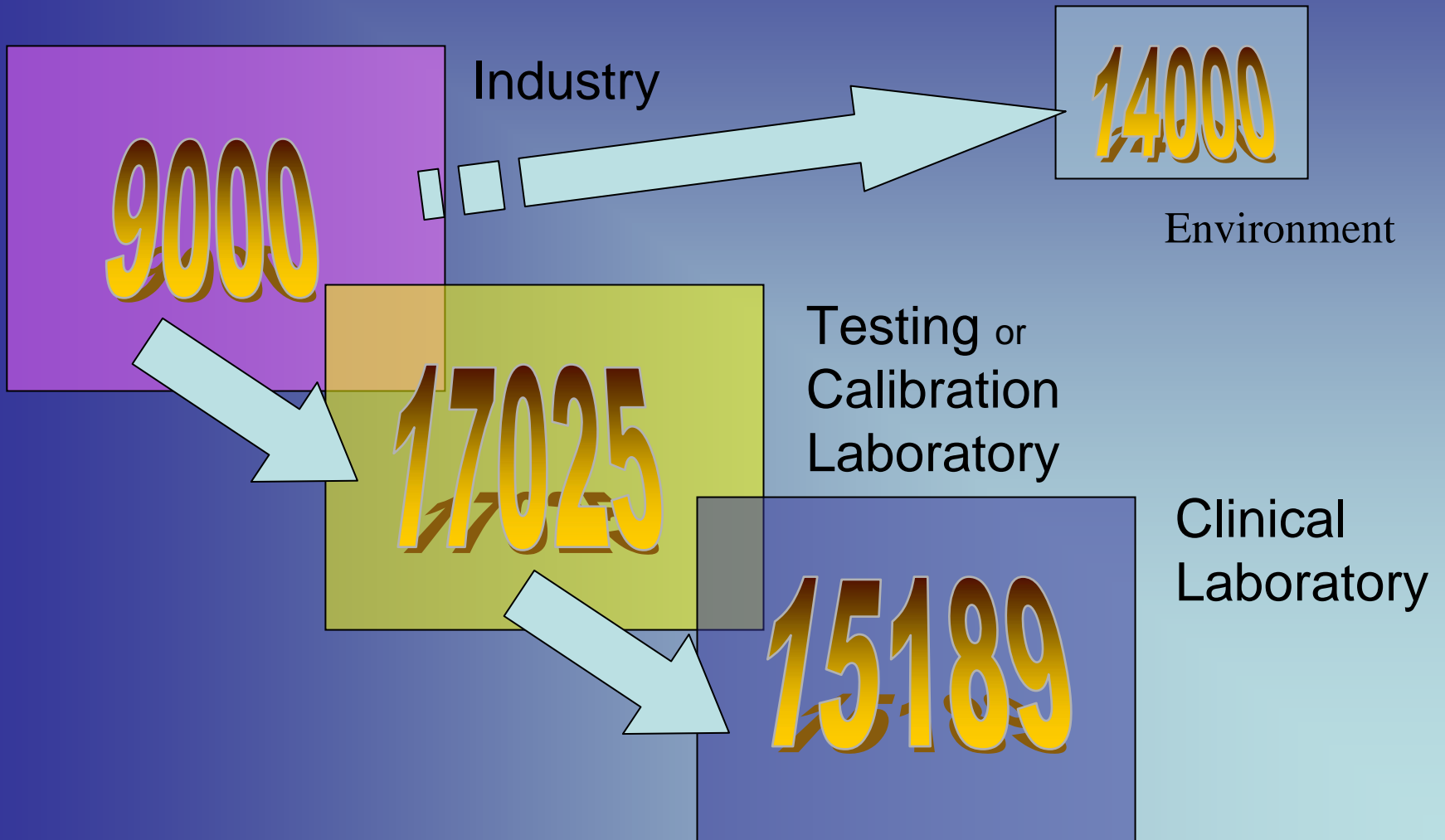
International Globalization



International
Organization for
Standardization



ISO Family of QM Standards



History of ISO Quality Management

- **1959** US Department of Defense established **MIL-Q-9858** quality management
- **1968** NATO adopted MIL-Q-9858A to produce Allied Quality Assurance Publication 1 (**AQAP-1**)
- **1970** UK Ministry of Defense adopted provisions of ADAP-1 as Management Program Defense Standard (**DEF/STAN 05-8**)
- **1979** British Standards Institute (BSI) developed Commercial Quality Standard **BS 5750**
- **1980** ISO TC 176 began work on **ISO 9000**
- **1987** SO issued ISO 9000b
- **1987** American Society for Quality Control adopted ISO 9000 standards as **ANSI/ASQC Q90** Standards
- **1994** SO issued ISO **9000:1994**
- **1994** US Department of Commerce (DOC) and DOD adopted ISO 9000 standards
- **2000** ISO issued **ISO 9000:2000**.

History of ISO/IEC 17025

International Laboratory Accreditation Cooperation

- **1978** International Laboratory Accreditation Conference created Guide 25: General Requirements for the competence of testing and calibration laboratories.
- **1990** Guide 25 revised 3 times
- **1996** Guide 25 adopted by ISO
- **1999** Guide 25 published as ISO/IEC 17025:1999
- **2002** Start the **bumpy** process of revision

Note the this document was not developed for use by medical laboratories, with the single exception of Australia



History of ISO 15189

- **1994** Inaugural meeting in Philadelphia hosted by NCCLS
- **2000** Consensus Document essentially completed and accepted within committee
- **2002** Requires a trial of formatting and reformatting
- **2003** Published in final form
- **2005** Begins revision cycle



International
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Standardization

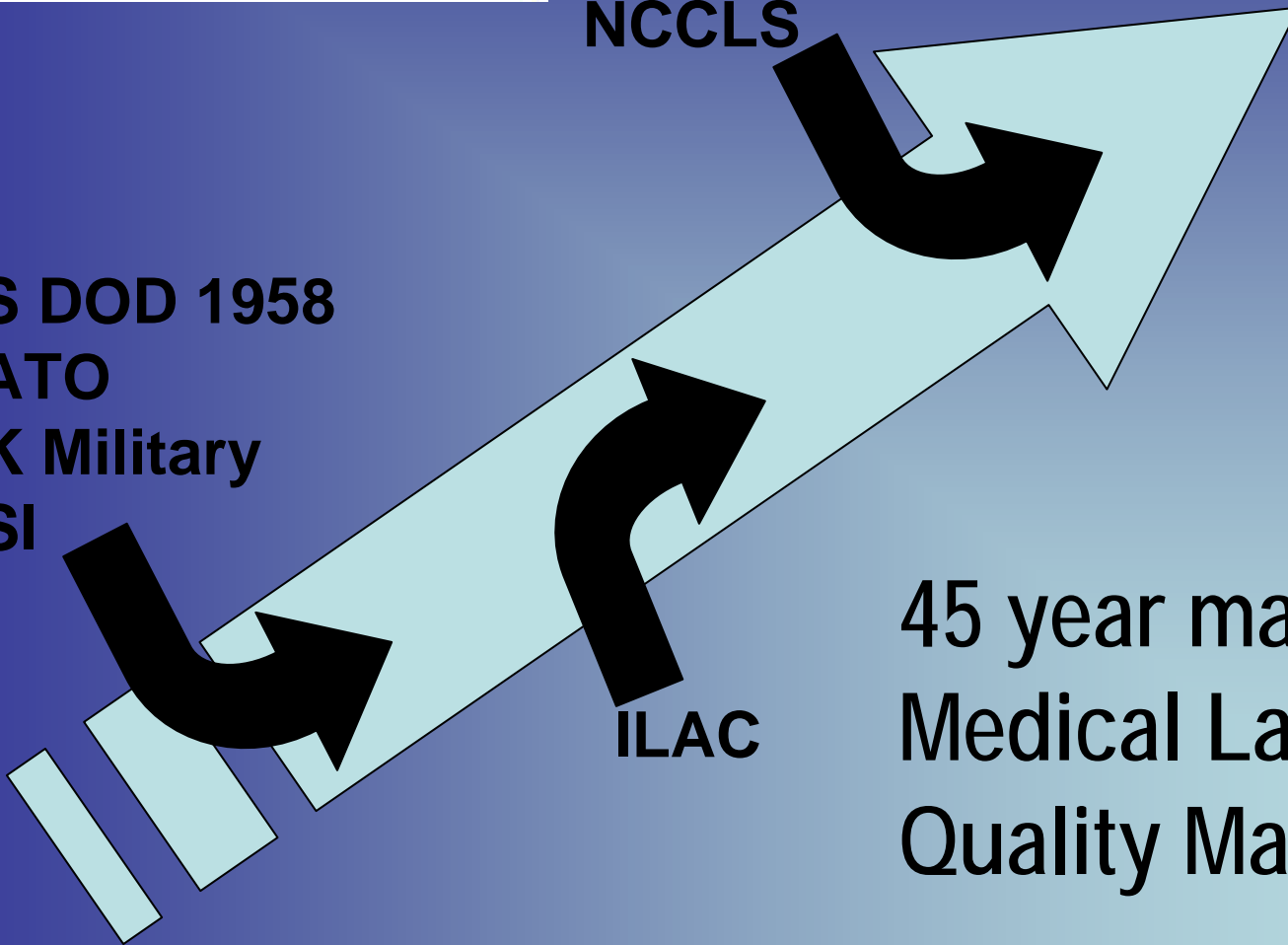
US DOD 1958
NATO
UK Military
BSI

NCCLS

2003

45 year march to
Medical Laboratory
Quality Management

ILAC



Benefits

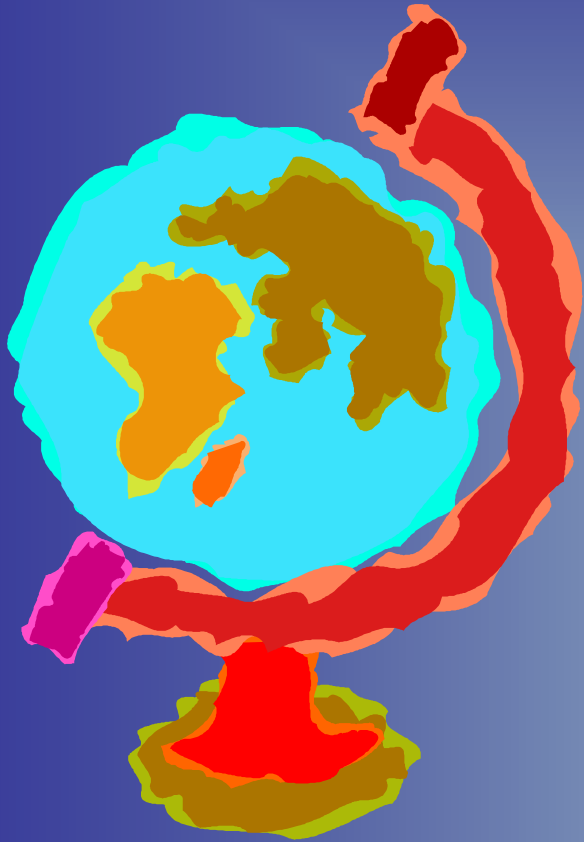


Document Effectiveness

- *Documents build upon each other*
- *Clear language*
- *High level documents*
- *Each document brings its own strength.*

ISO 9000	ISO 17025	15189
Continual Improvement	Technical Competence	Clinical Management
Satisfaction		Laboratory Cycle

Benefit 2:



Countries that have or are adopting ISO 15189 as their national document

Canada

European Union

Caribbean

Japan

Australia

UK

Benefit 3:

- **Mutual Recognition Arrangements (MRAs)**
- Countries work within MRA's.
- Laboratory accredited by an approved recognition body in one country is accepted as accredited in all countries.
- Under ILAC, 68 countries are linked through MRA's.

Note: Approved recognition bodies must comply with common guide (Guide 58) or standard (ISO 17011).

Benefit 4

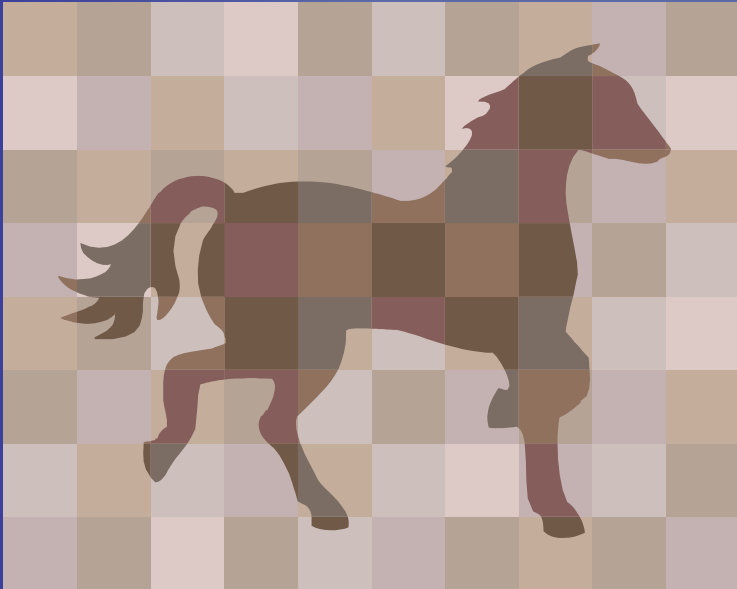
- ISO 15189 was written for adoption by laboratories, but can be used as the basis for recognition body checklists.

Flexible
Multipurpose

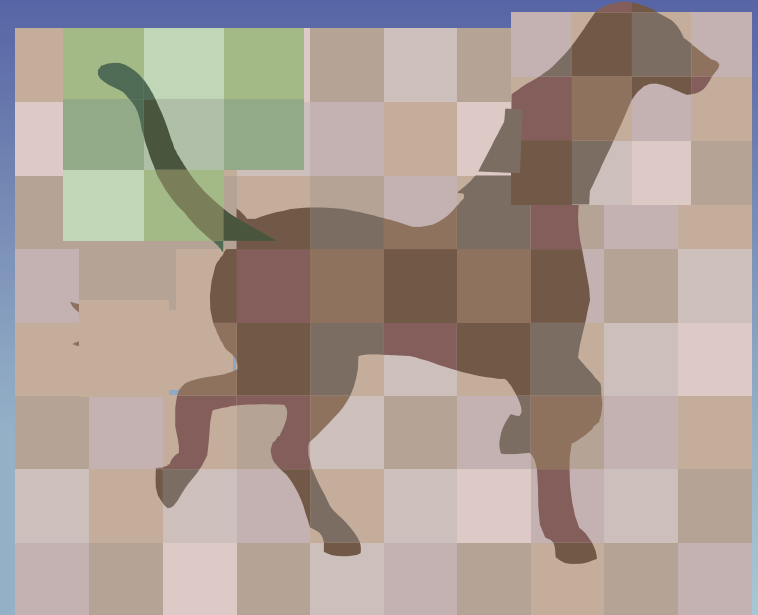


Opportunities for Improvement

OFI 1:



What you wanted

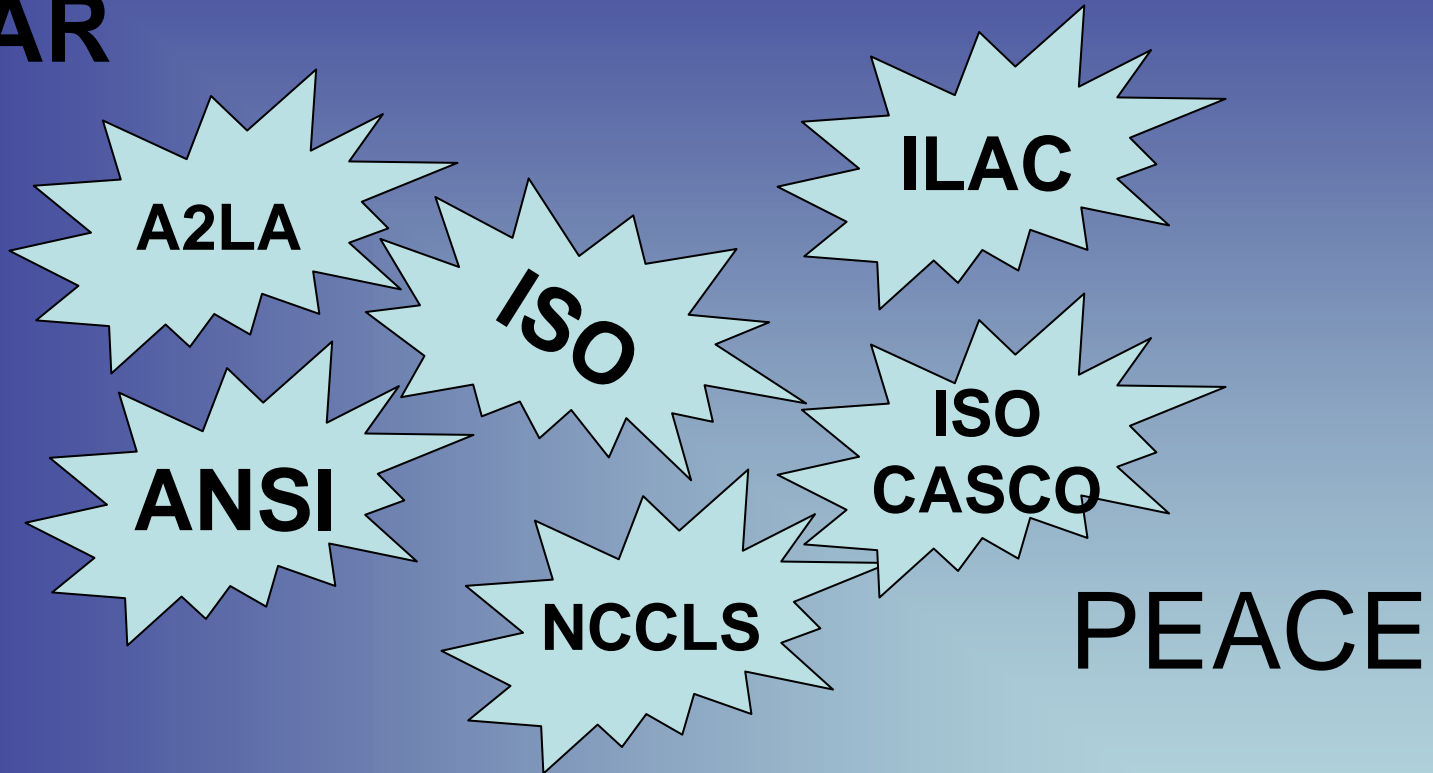


What you got

The curse of consensus documents

OFI 2:

WAR



Organizational Positioning

OFl 3:

Should

Shall

Accreditation

Recognition

Licensure

PT

EQA

Certification

Wordsmith:

*The craft of developing clear,
non-ambiguous efficient
and effective language structure*

OFl 3:

- **Laboratory Accreditation**
 - An authoritative body gives formal recognition that a body or person is competent to carry out specific tasks, by ensuring that the laboratory has the necessary means to perform the work properly
- **Certification**
 - A third party gives written assurance that a product, process or services conforms to specified requirements.
- **Registration**
 - An authoritative body indicates relevant characteristics of a product, process or service, or particulars of a body or person on an appropriately publically available list.

In Summary

- International efforts over a span of 45 years have resulted in a clinical laboratory standard based on foundation and consensus.

ISO 15189 is becoming THE national standard for clinical laboratories in many countries.



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