Progress and Process in International Laboratory Quality

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History of Quality

- Evidence of Quality Control, Measurement
  - Roman roads
  - Greek architecture
  - India architecture
• Evidence of inspection, quality assurance, standards, trueness.
  – 1000-1300
    • Germany
    • France
    • United Kingdom
Early China and Quality

Zhou Dynasty
1100 BC to 800 BC

Documentary evidence of
- Manufacturing standards,
- Quality control,
- Standard operating procedures,
- Quality assurance marking
Zhou Dynasty Folklore
commitment to standards and measures

Fuxi, the first ancestor of human beings was also the inventor of the rule and yardstick.
Coordinated activities to direct and control an organization with respect to quality.
History of Quality Management

1959
MIL-Q-9858

1968
NATO AQAP-1

1979
BSI 5750


2004

ISO 9000
1987, 2000

1967, 1988
Clinical Laboratory Improvement Amendments
International Organizations: Working together

ISO

ISO 9000

ISO 17025

ISO 15189

ILAC

1987

Guide 25

1999

CLSI

2003

International Laboratory Accreditation Cooperation

International Medical Laboratory Community
Quality Management and the Medical Laboratory
CLSI and Quality Management

Path of Workflow
Pre-Examination — Examination — Post-Examination

Quality System Essentials
- Organization
- Personnel
- Equipment
- Purchasing and Inventory
- Process Control
- Occurrence Management
- Assessment: Internal and External
- Information Management
- Process Improvement
- Documents and Records
- Facilities and Safety
- Customer Service

CLSI HS1 – A5 (2003)  
A quality management system model for health care

Application of a quality management system model for laboratory services
The Appeal of ISO

- Every country has an opportunity to participate.
- Every country has the opportunity to vote.
- Documents are sufficiently focused to ensure quality but are sufficiently open to allow local custom and interpretation.
The Appeal of ISO

• For some countries, it is easier for independent authorities to coalesce around an external document than to negotiate an internal agreement.
ISO 15189
Trail of International Acceptance

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<thead>
<tr>
<th>Australia</th>
<th>Canada*</th>
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<tr>
<td>New Zealand</td>
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<td>France</td>
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<td>China*</td>
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*work in progress
Promised benefits from ISO standards

1. Increased Efficiency
2. Increased Revenue
3. Employee Morale
4. International Recognition
5. Factual Approach to Decision Making
6. Supplier Relationships
7. Documentation
8. Consistency
9. Customer Satisfaction
10. Improvement Processes

www.iso.org
Demonstrated Benefits from ISO Certification

- 2-3 times more profitable than non-certified companies.
- Outperform on industry financial and sales measures.
- Higher market means with lower market variability as compared to non-certified companies.

Pinar and Ozgur
Qual Manage J.
2007
Evidence there is laboratory benefit to ISO 9001:2000

- **Clinical Microbiology Proficiency Testing**
    - Rework due to technical error and contamination reduced by 80%
    - All documented Opportunities for Improvement have documented follow-through
    - Consistent high annual ratings on composite client satisfaction scale.
  - Increased efficiency.
  - Increased visibility resulting in adjacency opportunities.
  - Accumulated debt (40% GAR) paid off with surplus in 2007 with no job losses.
Evidence there is benefit to ISO15189:2007

• Too early to say, but…
  – Most laboratories were already being accredited to other documents, especially ISO17025:1999.
  – Developing country programs are still early in their process.
  – Anecdotally, one province in Canada has had 4 years of experience and noting significant successes.

• Many laboratories that previously had not set up quality management systems are now engaged in quality and development.
In summary…

- The route to quality is not new in most sectors, but has been slow to come in the health care sector.
- The International standard for quality and competence for medical laboratories was only published in 2003, but has gained traction around the world.
- ISO standards for quality and competence have their core roots formulated around Mil-Q-9858.
In conclusion…
In conclusion…