GLI Stepwise Process Towards TB Lab Accreditation

Overview of International Standards and Quality Management System for Laboratory Accreditation

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06 July 2011
Dispelling Misconceptions

- Only high quality labs are accredited
- Accreditation is a final destination
  - Is only one point on a quality journey
  - Very easy to backslide
- You discuss *accreditation* without discussing *standards*
Dispelling Misconceptions

- There is one single “best” standard that can be used anywhere in the world.

- An overarching *Quality Management System (QMS)* can only be applied to complex laboratory environments.
  - Scalability
Dispelling Misconceptions

**International Organisation for Standardization (ISO)**

- ISO accredits Medical Laboratories

- A laboratory can implement ISO 15189 “as is”.
  - ISO documents, by definition, are very broad and overarching
Getting our Terms Correct

REGULATIONS

- Typically are country specific directives and laws.
- Delineate the minimal requirements by the country.
- They typically take the form of lab licensure
STANDARDS

A published set of requirements of activities and/or processes that must be conducted. They define \textbf{WHAT} must be done.
Standards

May be written by anyone....

“Recognized” ones are set by *accredited* Standards Development Organizations (SDO’s).

- Nationally based:
  - Ex: AFNOR, ANSI, DIN, NATA, SANAS, etc.

- Internationally based:
  - EX: ASTM, ISO....CLSI, etc
Standards

Typically → Developing countries rely on someone else’s standards
GUIDELINES

Tell us **HOW** to apply standards and use guidelines. (ex: WHO, GLI, CDC, CLSI, etc.)

- Often leads to the development of location specific policies, processes and procedures
ACCREDITATION

External validation of actual performance by a recognized authority. (ex: CAP, SANAS, NATA, etc...)
Accreditation

Not all Accreditation Bodies carry international recognition

Ex: In sub-Saharan Africa there are 10 accreditation bodies but only 3 are ILAC recognized (SANAS, TUNAC (Tunisia), EGAC (Egypt))
Accreditation

- Required in most developed countries’ medical laboratories

- Not in resource countries

  Ex; In sub-Saharan Africa there are only 30 fully accredited medical labs (excluding South Africa)
Accreditation

For the GLI process towards accreditation....

2 Major Assumptions:

1. Base the accreditation preparedness process on international standard **ISO 15189**

2. Organize the process by using the **CLSI Quality Management System**
An Overview
Overview

- A non-governmental organization based here in Geneva
- Worldwide federation of national standards bodies
- Largest international standards organization
- Develops voluntary consensus standards
- One nation = One Vote model
- The work of ISO gets done through Technical Committees
Mission

ISO develops International Standards to:

- Facilitate international exchange of goods and services
- Promote smooth and equitable economic growth, protect health, safety and the environment
Derivation of ISO 15189

ISO TC 176
ISO CASCO
ISO TC 212

Industry
Reference Laboratory
Clinical Laboratory

Medical Devices
Environment

9000
17025
13485
14000
15189
ISO CASCO Reference Laboratory
ISO/TC 212

- established in 1995
- 19 published documents to-date
- meets annually
  - working group meetings throughout the year and in conjunction with the plenary
ISO: Quality in the Medical Laboratory

ISO 15189:2003 – Medical laboratories – Particular requirements for quality and competence

- Has rapidly become the major global standard for medical laboratory applications
- Used as the standard by many accreditation bodies
<table>
<thead>
<tr>
<th>4 Management requirements (15)</th>
<th>5 Technical requirements (8)</th>
</tr>
</thead>
<tbody>
<tr>
<td>4.1 Organisation and management</td>
<td>5.1 Personnel</td>
</tr>
<tr>
<td>4.2 Quality management system</td>
<td>5.2 Accommodation and environmental conditions</td>
</tr>
<tr>
<td>4.3 Document control</td>
<td>5.3 Laboratory equipment</td>
</tr>
<tr>
<td>4.4 Review of contracts</td>
<td>5.4 Pre-examination procedures</td>
</tr>
<tr>
<td>4.5 Examination by referral laboratories</td>
<td>5.5 Examination procedures</td>
</tr>
<tr>
<td>4.6 External services and supplies</td>
<td>5.6 Assuring the quality of examination procedures</td>
</tr>
<tr>
<td>4.7 Advisory services</td>
<td>5.7 Post-examination process</td>
</tr>
<tr>
<td>4.8 Resolution of complaints</td>
<td>5.8 Reporting results</td>
</tr>
<tr>
<td>4.9 Identification and control of nonconformities</td>
<td></td>
</tr>
<tr>
<td>4.10 Corrective action</td>
<td></td>
</tr>
<tr>
<td>4.11 Preventive action</td>
<td></td>
</tr>
<tr>
<td>4.12 Continual improvement</td>
<td></td>
</tr>
<tr>
<td>4.13 Quality and technical records</td>
<td></td>
</tr>
<tr>
<td>4.14 Internal audits</td>
<td></td>
</tr>
<tr>
<td>4.15 Management review</td>
<td></td>
</tr>
</tbody>
</table>

ISO 15189:2003/07
Implementing ISO Requirements

- ISO Standards outline broad requirements for the medical laboratory
- Necessitate a Quality Management System approach and guidance documents / tools for implementation of ISO 15189
CLSI

- A non-profit NGO comprised of >2,000 member organizations

- Produce about 200 voluntary consensus standards and guidelines in medical laboratory areas. 75 active projects at any given time.

- Membership from 50+ countries
CLSI

- WHO Collaborating Center for the development of medical laboratory standards

- Is the ISO (through ANSI) appointed Secretariat to ISO TC212 → which authors ISO 15189
Nature of Medical Laboratory

Path of Workflow Concept….

Causes of error in medical laboratory

- Pre-analytic  46-68%
- Analytic  7-13%
- Post-analytic  19-47%
Quality System Essentials (QSEs)

12 fundamental components for building a quality management system
CLSI Quality System Essentials (QSEs)

- Documents and Records
- Organization
- Personnel
- Equipment
- Purchasing and Inventory
- Process Control
- Information Management
- Occurrence Management
- Assessments: Internal and External
- Process Improvement
- Customer Satisfaction
- Facilities and Safety
Path of Workflow & QSE’s

From CLSI document HS1 - A Quality Management System Model for Health Care
QSEs and Patient Safety

From CLSI document HS1 - A Quality Management System Model for Health Care
The GLI Model is based on ISO 15189 Laboratory Standard and the CLSI Quality Management System.
Is the GLI TB Stepwise Process the best model?

If the senior decision makers commitment exists:

• Almost any soundly organized accreditation preparedness program will work.

• If not.....the most elegantly constructed of systems will fail.