SLMTA 2
Propelling Laboratories towards Accreditation
The SLMTA 2 Pilot has taken off and is climbing.

Roche Scientific Campus
South Africa
September 19-23, 2016
SLMTA 2 Pilot Workshop: 19-23 September 2016,
Johannesburg SOUTH AFRICA
5 day workshop that provided a practical application to ISO 15189.

<table>
<thead>
<tr>
<th>1. Unlocking ISO 15189</th>
<th>8. Introduction to Internal Auditing</th>
</tr>
</thead>
<tbody>
<tr>
<td>4. Selecting the Winning Problem</td>
<td>11. Audit Process - Conducting the Audit</td>
</tr>
<tr>
<td>6. RCA + PDCA = CA</td>
<td>13. Internal Audit Program</td>
</tr>
</tbody>
</table>
What did participants say?

This workshop helped me realize why NCEs reoccur in our system and provided tools on how to conduct effective root cause analysis and corrective action.

This training is another barrier breaker for pushing labs to five stars. It’s a must have for labs seeking improvement beyond 3 stars.

SLMTA 2 offers the best approach to help labs realize their full potential to accreditation.

Amazing workshop, a must attend to bridge the gaps between SLIPTA 2-3 and accreditation.

I believe this program was long overdue and even with my 20 years experience in QMS, I learned a whole lot of new concepts which I would recommend to all laboratorians.

[This workshop is] useful in overcoming the 4 game changers (MR, IA, CA, and continual improvement).

SLMTA 2 workshop is unimaginably a WOW eye-opener. The quality of training is above many I have been through.
The chief medical directors, chairman of the medical advisory committee, and directors of laboratory services from each facility comprising the new SLMTA cohort joined participants for a management review session using SLMTA 2 materials.

October 2016 – South Africa
NHLS facilitated Unlocking ISO 15189.

January 1, 2017
SLMTA 2 revision will be released.

September 2016 – SLMTA 2 Pilot
Know Your Processes
If you cannot describe what you are doing as a process, then you do not know what you are doing.

W. Edwards Deming

In order to audit a process, you must first understand what it is.

J.P. Russell
The quality management system shall provide for the integration of all processes required to fulfil its quality policy and objectives and meet the needs and requirements of the users.

The laboratory shall:

a) determine the processes needed for the quality management system and ensure their application throughout the laboratory;

b) determine the sequence and interaction of these processes;

c) determine criteria and methods needed to ensure that both the operation and control of these processes are effective;

d) ensure the availability of resources and information necessary to support the operation and monitoring of these processes;

e) monitor and evaluate these processes;

f) implement actions necessary to achieve planned results and continual improvement of these processes.
Unlocking ISO 15189 Plethora of Processes

Understand QMS as a whole and its interrelated processes

Target the Measurement, Analysis, and Improvement component of a QMS

Part I
Occurrence Management System

Part II
Internal Audit Program

Part III
Management Review System
Process-based Approach to a Continuously Improving a QMS
Measurement, Analysis, and Improvement
4.8 Resolution of Complaints
4.9 Identification and Control of Nonconformities
4.10 Corrective Action
4.11 Preventative Action
4.12 Continual Improvement
4.13 Evaluation and Audits
4.15 Management Review
5.6 Ensuring the Quality of Examination Results

addressed in QC/MV Workshop
SLMTA Roadmap

Month 0 | Month 1 | Month 4 | Month 7 | Month 12 | Month 18
--- | --- | --- | --- | --- | ---
Baseline audit | Workshop #1 | Improvement Projects (3 months) | Workshop #2 | Improvement Projects (3 months) | Workshop #3 | Improvement Projects (3 months) | Exit Audit

Pre-requisites to entry

SLMTA 2

Understanding ISO 15189 | Quality Management Systems | How To Be A Successful QA Manager | SOP Writing | Biosafety | Quality Control | QC/MV Workshop

Complementary Training or Mentoring
The SLMTA Approach To Process Mapping

I. Start with a commonly applied process
   A. Learning to read a complex process
      - Generic Analyzer Examination Process
   B. Learning to design a process from simple to complex
      - Document Control Process

II. Transfer skills to poorly understood processes
    (Mapping Nonconformities, CA/PA, Internal Audits, and Management Review)
Flowchart Considerations

Don’t worry too much about drawing the flowchart (process map) the right way. The right way is the way that helps those involved understand the process.
Measurement, Analysis, and Improvement Element of a QMS
4.9 Identification and Control of Nonconformities
**WHO** participates in this process?
- All staff (identification of NCE)
- Heads of Section
- Quality Manager
- Management Review Team

**What INFORMATION** is needed to perform the process? (procedures, methods, forms, information, etc.)
- NCE Individual Event Process
- NCE Log Maintenance Process
- NCE Identification and Control of Nonconformities Procedure
- NCE Report Form
- Analysis of trends

**With WHAT?** (tools, reagents, equipment, hardware, software, infrastructure, safety, etc.)
- NCE tracking software

**PROCESS:**
Identification and Control of Nonconformities

**PROCESS OWNER:**
Quality Manager

**OUTPUTS:**
- Identification, reporting and correction of problems throughout the laboratory.
- Detect trends of system level problems

**RECORDS:**
- NCE Reports
- NCE Log

**What METRICS are maintained to determine process effectiveness?**
- Number of Customer complaints
  - physicians
  - other health care staff
  - patients
- Numbers and types of nonconformances
- Number of investigations or proposed corrective actions returned for insufficiency
SLMTA 2
Propelling Laboratories Towards Accreditation
Use of SLMTA 2 Tools in Nigeria

Odafen Oke
SLMTA-Program POC
CDC/Nigeria
ASLM 2016
Cape Town
December 3 - 9, 2016
Performance of Labs on 12 Quality Essentials (Baseline and Follow-up Audits)
Our Interventions Using SLMTA-2

- Shared focus and outcome of SLMTA-2 workshop with the National Laboratory Technical Working Group – Oct 2016
  - Highlighting major areas of weaknesses as found in analysis of audit data

- Held Conference of SLMTAn in Nigeria – Nov 2016
  - Shared SLMTA-2 focus
  - Shared analysis of lab audit data
  - Re-trained SLMTANS on audit

- Held SLMTA step-down workshop; #1 for cohort 5, and #3 for Cohort 3 (Oct – Nov, 2016)

- What was new:
  - Workshops conducted with key management staff participating
  - Shared areas of poor performance by each cohort presented the role of management and the value of their involvement in performance improvement

- Outcomes
SLMTA-2: Next Steps for Nigeria

• Hold Special Sessions for Management staff in all future stepdown workshops
  • To intimate them of roles and responsibilities, and seek Commitment
  • Monitor Progress from Management Perspective

• Conduct SLMTA 2 workshop for in-country SLMTAns

• Conduct workshop for mentors/IP staff providing oversight to participating labs

• Monitor Outcome on Labs and Share Experience in ASLM 2018
Acknowledgement

• CDC – ILB
• PEPFAR - Nigeria
• Anna Murphy
• Katy Yao
• ASLM 2016
Questions ????
Comments !!!!!
Getting Practical about Root Cause Analysis
There will be problems.

The laboratory shall have a documented procedure to identify and manage nonconformities in any aspect of the quality management system, including pre-examination, examination or post-examination processes. ISO 15189 4.9
It’s not complicated, but it is a process

OMS SESSION 6: RCA + PDCA = CA
Measurement, Analysis, and Improvement Element of a QMS
Occurrence Management System (OMS)

- NCE Individual Event Process
- PNC Individual Event Process
- NCE Log Maintenance Process
- Corrective Action Process
  - RCA
  - PDCA
- Preventive Action Process
  - RCA
  - PDCA
- Management Review Process
Occurrence Management System (OMS)

Purpose: To identify and characterize problem-prone laboratory processes so improvement projects (IP) can be prioritized, designed, and implemented.

adapted from (CLSI QMS 11,2015, p. 2)
4.8 Resolution of Complaints

4.9 Identification & Control of Nonconformities

4.10 Corrective Action

5.6 Ensuring the Quality of Examination Results

4.11 Preventive Action

4.12 Continual Improvement

Nonconformities

Potential Nonconformities

Feedback

Suggestions

Trend analysis

Problems

Recalls

Variations

Measurement, Analysis

Improvement

4.14 Evaluation and Audit

- Internal Audit
- Quality Indicators
- External Audit

4.13 Trend Analysis

Nonconformities

Potential Nonconformities

Trend analysis
4.10 Corrective Action

NOTE: Action taken at the time of the nonconformity to mitigate its immediate effects is considered *immediate* action. Only action taken to *remove the root cause* of the problem that is causing the nonconformities is considered *corrective* action.

ISO 15189:2012
Not an actual cause, but a sign of an existing problem

Causes that directly lead to a problem (direct or proximate cause)

Do not directly cause the problem; explains *WHY* a lower level cause occurred at the system or process level (latent cause)

Sets in motion the entire cause-and-effect chain causing the problem; system or organizational cause
Fact or Fiction
Determine if the following statement is fact or fiction.
Every time something goes wrong, corrective action must be taken, regardless of cost.

Fiction: Corrective action does not have to be taken every time. Problems should be fixed when it makes good business sense.
Many people have been misled to believe that any occurrence of a nonconformance warrants the initiation of a corrective action request. They often reach this conclusion through error or intimidation. They would rather err on the side of caution than take a chance of getting caught during a surveillance audit for failing to perform the requisite corrective actions. Consequently, everything automatically triggers the issuance of a CAR [corrective action request].

Denise Robitaille
author of The Corrective Action Handbook and Root Cause Analysis: Basic Tools and Techniques
4.9. Identification & Control of Nonconformities

1 - process which manages all the inputs from different control points

4.10 Corrective Action

2 - process which guides the user or team to determine, implement, and monitor the appropriate action specific to the site.
Problems come in different sizes. In other words, they pose a different level of risk to the laboratory.
Problem

Risk assessment will guide the activities along different paths. If the risk is high, the process may differ from nonconforming events (NCEs) with lower risk.

Solution
Risk-based criteria that had been established by management will result in 2 paths.

1. Fixing the individual problem, keeping a record, and moving on.

2. Containing the problem and moving it to corrective action.
Resources are limited.

Having a need does not create a resource.

Laboratory management must prioritize problems so that the limited resources can be used wisely.
When determining the extent of the nonconformity, the course of action should be consistent with the risk it presents.
It’s far better to effectively solve a few problems than poorly solve many.

Craig Cochran,
author of *Problem Solving in Plain English*, *ISO 9001 in Plain English*, and *ISO 9001:2015 in Plain English*
Without defined criteria, you are stuck enacting corrective action in all cases, even when it’s not the best option.

When management does not define criteria, it can result in a proliferation of unwarranted corrective actions that are often of marginal value or even counterproductive to the organization.
1. Identification & Control of Nonconformities (4.9)

Corrective Action Process
- Formal root cause analysis (RCA)
- Process Improvement Project (IP) Initiative

Prioritized by management for Continual Improvement (CI)

2. Corrective Action (4.10)

Remedial Action

Short-term Containment / Correction

- Close individual NCE event
- Continued monitoring and containment through aggregate analysis of NCE log
Occurrence Management System (OMS)

- NCE Individual Event Process
- Corrective Action Process
- NCE Log Maintenance Process
- Preventive Action Process
- PNC Individual Event Process
- Management Review Process

RCA, PDCA
ISO 15189: 4.9 Identification and control of nonconformities

The laboratory shall have a documented procedure to identify and manage nonconformities in any aspect of the quality management system, including pre-examination, examination, or post examination processes.

........

When it is determined that nonconformities in pre-examination, examination and post-examination processes could recur or that there is doubt about the laboratory’s compliance with its own procedures, the laboratory shall take action to identify, document and eliminate the cause(s). Corrective action to be taken shall be determined and documented (see 4.10).
NCE Requirements

- Identify, report and record NCEs
- Investigate and take appropriate action on NCEs
- Classify, analyze, and present NCE data and information
- Identify underlying causes of process problems
- Report NCE information for management review.

ISO 15189: 4.9(h)
Each episode of nonconformity is documented and recorded,

with these records being reviewed at regular specified intervals to detect trends and initiate corrective action.

Requirements modified from CLSI:GP26-A4
ISO 15189: 4.10 Corrective action

The laboratory shall take corrective action to eliminate the cause(s) of nonconformities. Corrective actions shall be appropriate to the effects of the nonconformities encountered.

Who decides what is appropriate?
Corrective Action Process

- Identify the need for CA as an output from the NCE process
- Document and assign project leader
- Contain problem as needed
- Track progress
- Update progress to management
- Submit Close-out report
- Celebrate with staff

**RCA Process**
- Identify possible causes
- Collect and analyze data
- Determine actual causes(s) (problem statement)

**PDCA Process**
- Identify solutions
- Implement solutions
- Evaluate results (aim statement)
Root Cause Analysis (RCA)

- Method of problem solving that works to identify the root causes of problems.
- Powerful approach to solving problems
- A process to systematically detect and analyze the possible causes (the WHY) of a problem in order to determine corrective action(s) to be taken
How to solve a problem

Beneath every problem lies a cause for that problem

Step # 1  Identify the cause of the problem

RCA Process

Step # 2  Find ways to eliminate the cause and prevent it from recurring

PDCA Process
The purpose of RCA is intended to provide a framework for identifying issues buried beneath layers of documents, records, practices, excuses, and confusion to discover what really went wrong.

No more QUICK FIXES
1. Define the problem

Diagnostic Phase
(Find It)

Problem
Statement

Decision to do RCA has been met

Solution Phase
(Fix It)

RCA Process Map

image adapted from Okes, (2009), Fig. 1.2
RCA Step #1: Define the Problem

In order to define the problem, you must have some initial information.

2 parts to Step #1

A. Collect data to determine or confirm the facts.

B. Define the problem to solve.
A problem well stated is a problem half solved

Charles Kettering
In order to define the problem, you must have some initial information.

Effective RCA starts with a good NCE report.
Identification and Control of Nonconformities

CA: RCA Process

1. Define the problem

Problem Statement

INVESTIGATE

DEFINE

2 & 3

4 & 5

Root Cause

1. Define
2. Investigate
3. Define
4. Investigate
5. Define
| **WHAT exactly is the problem?** (Move one step beyond the symptoms) |
|WHERE does it occur?|
|WHEN does problem happen?|
|WHO experiences the problem?|
|HOW MUCH does it occur?|
|WHY DOES IT MATTER? (i.e., what requirements are violated by the problem?)|
Problem Statements

- Should contain specific facts (e.g. What, Who, When, Where, Why does it matter) obtained through investigation and research.
- Take nothing for granted; all facts are verified, if possible.
- Do not speculate on causes, but define the problem as factually as possible.
1. Define the problem

2. Understand the process &
3. Identify possible causes

Decision to do RCA has been met

RCA Process Map

Diagnostic Phase (Find It)

Problem Statement

Solution Phase (Fix It)

image adapted from Okes, (2009), Fig. 1.2
Understand the process first, then ask WHY.
1. Define the problem
2. Understand the process & identify possible causes
3. Identify possible solution(s)
4. Collect evidence to confirm or deny each cause &
5. Determine the root cause(s)
6. Identify possible solution(s)
7. Select solution(s) to be implemented
8. Implement Solution(s)
9. Evaluate effects

Decision to do RCA has been met

RCA Process Map

Diagnostic Phase (Find It)

Solution Phase (Fix It)

Preferred Solution(s)
Plan: Measure of Effectiveness

SECTION A - Identifying the Problem

I. State the apparent problem:

II. Collect Baseline Data:

   What data will be collected?

   Method: How will the data be collected?

   Who is responsible for collecting data?

   What are the tools/forms/checklists to be used?

   Over what period of time will the data be collected?

   When will the data be reviewed?

III. Analyze the baseline data:

   What is wrong?

SECTION B - Action Plan

I. Identified problem:

II. AIM Statement (overall goal of this project)

III. Actions to be implemented (following brainstorming of possible solutions)

<table>
<thead>
<tr>
<th>Action Item</th>
<th>Responsible Person</th>
<th>Timeline</th>
<th>Signature</th>
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</tbody>
</table>

IV. Select and Define ELEMENT TO BE MEASURED (to monitor effectiveness of implemented actions)

V. Results of element measured at baseline

VI. Acceptable results (target for this measure)

VII. Data Collection

   How will the data be collected?

   Who is responsible for collecting data?
1. Define the problem

2. Understand the process & 3 Identify possible causes

4. Collect evidence to confirm or deny each cause &
5. Determine the root cause(s)

6. Identify possible solution(s)

7. Select solution(s) to be implemented

8. Implement Solution(s)

9. Evaluate effects

10. Institutionalize the change

Decision to do RCA has been met

Diagnostic Phase (Find It)

Problem Statement

Root Cause Statement

RCA Process Map

Solution Phase (Fix It)
Laboratories should have a methodology that will allow their staff to do an investigation using a repeatable process to uncover cause every time. They can then go from problem to problem to problem. The data will change, the content will change, and the customer will change, but the process is so good that it will get them to the appropriate answer every time.
No studies have shown that NCE management is a more effective way to promote quality than up-front quality planning and design.

Quality planning and design keeps problems out of RCA.
How Much Does Failure Cost Us?
The Cost of Quality is NOT the cost of creating a quality product or service. Instead, the Cost of Quality is a FAILURE to create a quality product or service.

Every time work is redone (rework), the Cost of Quality increases.
Cost of Quality

- any cost that would not have been expended if quality was met the first time.
- also known as the Cost of Poor Quality (COPQ)

Cost when produced correctly; *done right the first time*

Actual cost incurred due to rework
Types of Quality Costs
Costs of Good Quality

I. Expenses for Maintaining Quality – line items in an operating budget

A. Prevention Costs – costs for laboratory activities designed to prevent poor quality in laboratory services

B. Appraisal Costs – costs for activities associated with measuring, evaluating, or auditing to assure conformance to quality standards.
Types of Quality Costs
Costs of Poor Quality (CoPQ)

II. Expenses for Rectifying Quality Problems – causes for running over (exceeding) the budget

A. Internal Failure Costs – costs for rework caught and corrected inside the laboratory (before it reaches the customer)

B. External Failure Costs – costs for rework not caught by the laboratory but was detected by the customers
How to Translate Failure into a Reasonable Estimate of Cost

Cost of Supplies (Materials)
1. Create a list of supplies used for only the failed process (Remember, SLMTA Module 3: Creating a List of Supplies for a Test?).
2. Determine the cost of the supplies using purchase order information.
3. Determine the quantity wasted due to the nonconformity.

Cost of Labor
1. Determine who, by job title, does what and for how long to address this failure.
2. Determine the hourly wage for that job title.
# Job Aid 3: COPQ

How to ESTIMATE the Cost of Poor Quality (COPQ)

<table>
<thead>
<tr>
<th>Material Item Description</th>
<th>Item Cost per 1 Item</th>
<th>Quantity Used</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Item 1</td>
<td>0.00</td>
<td></td>
<td>0.00</td>
</tr>
<tr>
<td>Item 2</td>
<td>0.00</td>
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<td>0.00</td>
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<td>Item 3</td>
<td>0.00</td>
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<tr>
<td>Item 4</td>
<td>0.00</td>
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<td>0.00</td>
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<tr>
<td>Item 5</td>
<td>0.00</td>
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<td>Item 10</td>
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</tbody>
</table>

Cost of Materials Subtotal: 0.00

<table>
<thead>
<tr>
<th>Labor Item Description</th>
<th>Hours per Task (in tenths of an hour)</th>
<th>Hourly Rate</th>
<th>Total</th>
</tr>
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<tbody>
<tr>
<td>Job Title 1</td>
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<td>Job Title 2</td>
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<tr>
<td>Job Title 4</td>
<td></td>
<td></td>
<td>0.00</td>
</tr>
<tr>
<td>Job Title 5</td>
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<td></td>
<td>0.00</td>
</tr>
</tbody>
</table>

Cost of Labor Subtotal: 0.00

Cost per Failure: 0.00

spreadsheet adapted from CLSI QM520-R, 2014, Appendix B1
Equipment Downtime incurs failure costs for:

• Alternate provision of laboratory services (i.e. sending samples to another laboratory)

• Verifying functionality after in-house service is restored

• Loss of revenues or customers during equipment downtime period
# ESTIMATED Cost of Poor Quality Worksheet

Failure: 60 electrolyte test requests from pediatrics were referred due to equipment downtime  
August 30 - Sept 10, 2016

<table>
<thead>
<tr>
<th>Material Item Description</th>
<th>Item Cost per 1</th>
<th>Quantity Used</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>gasoline for transport in liters</td>
<td>2.00</td>
<td>7.00</td>
<td>14.00</td>
</tr>
<tr>
<td>referral laboratory charge per request (used their reagents)</td>
<td>0.25</td>
<td>60.00</td>
<td>15.00</td>
</tr>
<tr>
<td>Item 3</td>
<td>0.00</td>
<td></td>
<td>0.00</td>
</tr>
<tr>
<td>Item 4</td>
<td>0.00</td>
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<td>0.00</td>
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Cost of Materials Subtotal: 29.00

<table>
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<tr>
<th>Labor Item Description</th>
<th>Hours per Task (in tenths of an hour)</th>
<th>Hourly Rate</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Transport Courier (3 trips/day * 12 days * 0.5 hours/trip)</td>
<td>18.00</td>
<td>3.00</td>
<td>54.00</td>
</tr>
<tr>
<td>Referral Testing Clerk (5 min to write transfer slip and aliquot 60 specimen)</td>
<td>5.00</td>
<td>6.00</td>
<td>30.00</td>
</tr>
<tr>
<td>General Laboratory Clerk (additional help with transfer log 15min/day * 12 days)</td>
<td>4.00</td>
<td>5.00</td>
<td>20.00</td>
</tr>
<tr>
<td>Job Title 4</td>
<td>0.00</td>
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</tr>
<tr>
<td>Job Title 5</td>
<td>0.00</td>
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</tr>
</tbody>
</table>

Hours of Labor: 27.00  
Cost of Labor Subtotal: 133.00

Cost per Failure: 162.00
Prevention is **ALWAYS** cheaper.

It is still easier, faster, and cheaper to prevent errors than to have to find them and fix them.
Questions ????
Comments !!!!!!