CRITICAL ROLE OF EFFECTIVE AUDITS IN FACILITATING ACCREDITATION READINESS

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STRENGTHENING LABORATORY MANAGEMENT TOWARD ACCREDITATION

The revolution in LQMS implementation
SLMTA

- **5138** laboratory personnel trained
- **1333** laboratories enrolled
- **52** countries
WHO-AFRO Stepwise Laboratory (Quality) Improvement Process Towards Accreditation (SLIPTA)
ULTIMATE OUTCOME: ACCREDITATION

ISO 15189
CAP ACCREDITED
COLLEGE of AMERICAN PATHOLOGISTS

ISO 17025
Accredited

92 SLMTA Laboratories
Accredited to Date

ISO 15189 ACCREDITATION
MEDICAL LABORATORY

Sanas
South African National Accreditation System
WHAT DOES IT TAKE TO GET A LABORATORY ACCREDITATION READY?

- Resources
- Training/capacity building on standards, LQMS
- Expert support & mentoring
- Commitment from management & staff
- **Strong audit program**
AUDIT PROGRAMS

- Internal
- External
External Audits

- Adherence to requirements (compliance to standards)
- Actual and potential areas of error and/or weakness to address
- LQMS competency
- Verification of implementation
EXTERNAL AUDITS : VERIFICATION

- Quality Assurance Manual
- In-House Media QC log
- Policies
- Procedure

[Verification symbol]
EXTERNAL AUDITS: VERIFICATION

ESTABLISHMENT & COMPLIANCE

- Have you implemented system as documented?
- Are you maintaining system?
- Are you complying with system?
WHAT DO EXTERNAL AUDITS REPRESENT FOR LABS

0 Star 1 Star 2 Star 3 Star 4 Star 5 Star

Score on external validation:

55-64% 65-74% 85-94% >95%

Laboratory Validation

VERIFIED
WHAT DO EXTERNAL AUDITS REPRESENT FOR LABS

We’ve got it!

We know what we are doing!

We CAN get Accredited!
KEY COMPONENTS TO ENSURE AUDITS DELIVER

- Audit Process
- Tools
- Auditors
SLIPTA AUDITS

- Ultimate validation for many SLMTA Labs
- Benchmark for labs assessing accreditation readiness
- Deciding factor for moving forward to seek accreditation.
SLIPTA AUDIT OBJECTIVES

- Evaluate and recognize the progress of QMS implementation & **recommend for ISO accreditation**

**TARGET: 250 accredited Labs by 2020**

- Provide feedback and guidance to address the requirements of QMS based on ISO 15189:2012 Standards

- Mentor SLIPTA Auditor trainees for certification purpose
ARE SLIPTA AUDITS DELIVERING?

Surveyed 8 Laboratories who have gone through SLMTA program, SLIPTA process and have either:

- Attained international accreditation
- Undergone assessment pre-check
- Have had more than one SLIPTA Audit
How important were SLIPTA Audits in your preparation towards accreditation?

- Very Important: 7
- Important: 1
- Not Important: 0
How important were SLIPTA Audits in your preparation towards accreditation?

- Ensuring system is ISO compliant
- Independent assessment of Labs LQMS implementation process
- Check on knowledge and capacity of lab management and staff: *do we know what we are doing?*
- Guidance on LQMS implementation process: *are we doing it right?*
Were outcomes of SLIPTA Audits **THE** deciding factor in decision to seek accreditation?

- Yes: 6
- No: 2
Were outcomes of SLIPTA Audits THE deciding factor in decision to seek accreditation?

- Deciding factor for upper management support.
- Gave management and staff of Lab approval and confidence to move forward with process

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<tr>
<th>Yes</th>
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Were outcomes of SLIPTA Audits THE deciding factor in decision to seek accreditation?

- Already committed to accreditation
- Proceeded despite outcomes from SLIPTA Audit

(6 Yes, 2 No)
Had SLIPTA Audits been effective at assessing readiness for accreditation?

Yes: 4
No: 4
Had SLIPTA Audits been effective at assessing readiness for accreditation?

- Had accurately determined accreditation preparedness
- Addressing findings from SLIPTA assessment alone was enough to have system accreditation ready.
Had SLIPTA Audits been effective at assessing readiness for accreditation?

- Under-estimated accreditation readiness
- Over-estimated accreditation readiness
- Did not address some crucial elements for accreditation
FEEDBACK FROM LABS: SLIPTA PROCESS

- More time (days) to conduct Audits
- Audit team contain technical expertise for each discipline.
- Guidance/technical support for labs moving forward with accreditation process
FEEDBACK FROM LABS: CHECKLIST

- Checklist very documentation biased.
- Checklist does not adequately address discipline specific requirements
FEEDBACK FROM LABS: SLIPTA AUDITORS

- Standardized audit practice.
- Standardized interpretation of standard
- Auditors experienced in LQMS
- Ethics and professionalism
- SLIPTA Audits are vital bridge between LQMS implementation and accreditation.

- Provide **VALIDATION** and **CONFIDENCE** to decide to move forward with accreditation process.
• Need to review and where necessary address issues highlighted to ensure improved more effective audits that deliver on mandate.
• Increase in length of time audits are conducted.
  (More time for verification, guidance & other support)

• Addition of appendix to checklist that addresses discipline specific requirements

• Technical advice & guidance to labs moving forward to seek accreditation.
- Standardization of SLIPTA audit practice (e.g. guideline document for auditors)
- Auditor selection and certification criteria more stringently applied
- CPD & Competency program for auditors
GUIDANCE IS ALREADY AVAILABLE

SLMTA SYMPOSIUM 2016
Bridging the SLIPTA stars and ISO Accreditation

Published responses from discussion
https://www.slmta.org/resources
How do you ensure competency of your auditors? What measurements are collected and analyzed?

1. Systematic evaluation after each mission
   - Review of assessment reports (50 points)
   - Consideration of complaints or observations related to the assessor’s behavior and deemed to be well cohesive (20 points)
   - Professional and ethical awareness (30 points)

https://www.slmta.org/uploads/category_file/30/1.5
EXAMPLE: CRESAC AUDITOR COMPETENCY PROGRAM

2. Evaluation every 3 years
   - Participation in capacity building workshops for assessors organized by CRESAC once a year (40 points)
   - Systematic assessment at each engagement (60 points)

3. Results
   - Maintenance 70%;
   - Warning (between 60 and 70%);
   - Removal from the list <60%

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WHAT WE WANT TO ACHIEVE

Improved SLIPTA Audits

MORE ACCREDITED LABS

QUALITY LABORATORY & HEALTHCARE SERVICES FOR ALL

Target: 250 Accredited Labs by 2020
THANK YOU