PRL Internal Audits			
Doc no	PRL-MGT-014	Revision 0.0	Effective Date:1 Sept 2020
Written By:Gugu Ditshego		Reviewed by: Gugu Ditshego	Approved by: Gugu Ditshego
Date:Aug 2020		Date:31Aug 2020	Date:31 Aug 2020
	18069 Ngungunyane Street Kwa Thema 1575 Tel: 011 737 1045/2518 Fax: 086 604 3815 Email: info@proteuslab.co.za		

1.0 Purpose

To give guidance on the management of audit programmes, the conduct of internal audits of quality management systems, as well as on the competence and evaluation of auditors.

2.0 Scope

This SOP covers the processes that are used to continuously monitor and evaluate the Laboratories Quality Management System (QMS) as compared to the Laboratory established Quality standards, Policies and Procedures as well as the requirements of the ISO 15189:2012. It also covers the responsibilities & requirements, planning, execution, reporting and maintaining records of internal audits.
This SOP is applicable to all laboratory personnel at Proteus Laboratories.

3.0 Terms, Definitions and Abbreviations

3.1 Terms and Definitions

● **Audit:** a systematic, independent and documented process for obtaining audit evidence and evaluating it objectively to determine the extent to which the audit criteria are fulfilled.

● **Audit criteria**: a set of policies, procedures or requirements e.g., ISO 15189:2012, National regulations, customer complaints amongst others.

● **Audit evidence:** records, statements of fact or other information, which are relevant to the audit criteria and verifiable

● **Auditee:** organization being audited

● **Auditor:** person with the competence to conduct an audit

● **Audit team:** one or more auditors conducting an audit, supported if needed by technical experts

3.2 Abbreviations

● GCLP Good Clinical Laboratory Practice

● ISO International Organization for Standardization

● PRL Proteus Laboratories

● QA Quality Assurance

● QMS Quality Management System

● NC Nonconformity

● IQC Internal Quality Control

● SOP Standard Operating Procedure

● N/A Not Applicable

● NC Non-Conformity

● MGT Management

4.0 Tasks, Responsibilities and Accountabilities		
Task	**Responsible**	**Accountable**
Planning Internal audit	Laboratory Management	Quality Manager
Conducting Internal audit	Trained internal auditor	Quality Manager
Reporting of Internal Audit result	Quality Manager	Quality Manager
Addressing Internal audit findings	Laboratory personnel	Quality Manager

Maintaining Internal audit records	Quality Manager	Quality Manager

5.0 Safety and Environment

Where applicable wear protective clothing during interviews or auditing

6.0 Quality Assurance and Quality control

N/A

7.0 Procedure

7.1 Audit Planning:

Laboratory management is responsible for the planning of the internal audit process and generation of the internal audit plan at the beginning of the calendar year.
Internal audit planning includes:

- **Establishing objectives and extent of the audit program**
- Establishing responsibilities and procedures and ensuring that resources are provided
- **Ensuring the implementation of the audit plan**
- Ensuring that appropriate audit program records are maintained
- **Monitoring, reviewing and improvement of the audit program**
- Instigating timely follow up to assess whether appropriate actions have been taken on the reported audit findings
- **Issuing of audit reports**

7.2 Audit Team and its selection

- The selection of auditors takes into consideration the competence and training which includes preferably trained in ISO 19011:2011 internal audit standard or *15189:2012 Medical Laboratory* standard.
- All internal auditors are preferably independent to the audited subject / section.

Where External auditors are also used, the selection criterion will be based on being a SANAS assessor.

7.3 Method for internal auditing

● An internal audit consists of assessing the quality documentation and a visit to the workstations which may involve interviewing, review of documents & records (horizontal audit), following a specimen through and observing the practical implementation of the documents (witnessing) and following sample through the entire quality management system (vertical)

● The methods are used in accordance with the audit criteria e.g. ISO *15189:2012* standard, established policies and regulations of Proteus Laboratories.

7.4 Criteria, types, frequency and scope of audits

7.4.1 Criteria

Audit criteria is based on one or a combination of the following:

● **ISO 15189:2012**

● **Statutory or regulatory requirements**

● **Organization process, policies, procedures etc.**

● **Customer requirements**

7.4.2 Types of Audit

● **Horizontal Audit:** is where one process is audited across many sections in the laboratory e.g., Document control, identification and control of NC's, IQC's etc.

● **Vertical Audit:** is where all processes across the laboratory are audited e.g., when you audit a test result reporting process and conduct a review of sample collection, processing, personnel training, record retention etc.

● **Witnessing:** Audit by observation e.g., Sample reception.

7.4.3 Audit tools

The tools to be used for internal audits include.

● SANAS management checklist F 88

- SANAS Vertical Checklist F 95
- SANAS witnessing checklist F15

7.4.4 Frequency

Audits are conducted annually for all sections of the QMS including pre-examination, examination, post examination and management.

7.4.5 Scope

The audit scope describes:

- when the audit is to be conducted
- who/what is to be audited.
- where the audit is to be done

7.5 Audit process

At Proteus Laboratories, the internal audit is done in three phases:

a) Quality Documentation

Before the audit team starts the interview(s), the quality documentation is checked. The Quality manager provides all the needed documentation, including previous audit reports, action plans, management reviews etc. but also SOPs and Quality Manual. By inspecting the documentation at hand, the audit team can identify subjects to focus on.

b) Interviews

Before starting the interview(s) the audit team gives the following information:

- an introduction of the audit team
- the purpose of the audit;
- the roles of different members in the team;
- the approximate duration of the interview;
- Confidentiality of the information received;
- explains that feedback will be given after the internal audit (same day)

c) Feedback

After conducting the internal audit, the audit team summarizes their findings for a brief feedback. The Internal Audit team prepares the Audit Report (Appendix 3 “Format audit report”) within two weeks after the internal audit has been performed.

7.6 Audit Report

7.6.1 Audit report content

The audit team leader reports the audit results in accordance with the audit programme procedures. The audit report provides a complete, accurate, concise and clear record of the audit, and should include or refer to the following:

a) the audit objectives;

b) the audit scope, particularly identification of the organizational and functional units or processes audited;

c) identification of the audit client;

d) identification of audit team and the auditee's participants in the audit;

e) the dates and locations where the audit activities were conducted;

f) the audit criteria;

g) the audit findings and related evidence;

h) the audit conclusions;

i) a statement on the degree to which the audit criteria have been fulfilled.

The audit report may also include or refer to the following, as appropriate:

The audit plan including time schedule;

● a summary of the audit process, including any obstacles encountered that may decrease the reliability of the audit conclusions;

● confirmation that the audit objectives have been achieved within the audit scope in accordance with the audit plan;

● **any areas within the audit scope not covered;**

● a summary covering the audit conclusions and the main audit findings that support them;

● any unresolved diverging opinions between the audit team and the auditee;

● opportunities for improvement, if specified in the audit plan;

● good practices identified;

● agreed follow-up action plans, if any;

● a statement of the confidential nature of the contents;

● any implications for the audit programme or subsequent audits;

● the distribution list for the audit report.

7.6.2 Audit report distribution

The internal auditor issues the audit report within an agreed period. If it is delayed, the reasons are communicated to the quality officer.
The audit report is dated, reviewed and Authorized, as appropriate, in accordance with audit plan. The audit report is then distributed to the recipients by the quality officer.

7.6.3 Completing the audit.

Documents pertaining to the audit are retained between the participating parties and in accordance with audit programme procedures and applicable requirements.
Any other information obtained during the audit, or the audit report, is not disclosed to any other third party without the explicit approval by laboratory.

7.6.4 Conducting audit follow-up

When the conclusions of the audit indicate the need for corrections, or for corrective, preventive or improvement actions. Such actions are usually decided and undertaken by the auditee within an agreed timeframe. As appropriate, the auditee keeps the Quality manager informed on the status of these actions. The completion and effectiveness of these actions is verified. This verification may be part of a subsequent audit.

7.6.5 Plan for corrective action following internal audit identified NC’s

● The Quality manager provides a filled in action plan of the corresponding findings with the NCs in the Action Plan (see Appendix 4).

● The Quality manager ensures that a prompt immediate action is taken where applicable, and a corrective action is taken following a root cause analysis.

● The corrective action must be implemented within one month.

7.7 Follow-up and closure of Non-Conformities

Follow up on the progress of the corrective actions is done at least monthly discussed in a lab meeting. After addressing the identified Non-Conformities, the nonconformity is dated and signed as closed by the quality manager.

7.8 Maintaining audit records.

The internal audit report, action plans generated from the audit are maintained by the quality officer.

7.9 Competency assessment

The evaluation of auditors and audit team leaders is done annually in accordance with audit programme procedures. This is done to ensure that the auditors remain objective, consistent, fair.
and reliable. The evaluation process also identifies training and other skill enhancement as needed.
The evaluation of auditors can occur at the following stages:

● the evaluation of the auditors as part of the audit team.

● the continual evaluation of auditor performance to identify needs for maintenance and improvement of knowledge and skills.

8.0 References/Related documents

● Quality Manual **(PRL- MAN -001)**

● ISO 15189:2012

● Document and Records Control (**PRL -MGT- 003)**

● Identification and control of non-conformities **(PRL- MGT- 009)**

9.0 Attachments/Annexes

● **Appendix 1: Internal Audit Year Plan**

- **Appendix 2: Audit Report**
- **Appendix 3: Action plan**
- **Appendix 4: Internal Audit Competency Assessment**
- Annex 1: SOP Attestation Form

Appendix 1: Internal Audit Year Plan

Month/year	Section	Auditor(s)	Type of audit	Date of report

Comments.....

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Compiled by……..…Sign……..….

Date……..……

Authorized by……... sign……..……

Date……

2: Audit Report

Internal Audit: (system or technical):	
Date of audit:	
Name of internal auditor(s):	
Date audit report	

1. Introduction

1.1 Compliance to the standard ISO 15189:2012

2. Findings.

The findings of the audit are listed below. Every finding is numbered uniquely: the degree to which a finding diverts from the ISO 15189:2012 standard or from agreed policies in quality documents. Only the audited items are mentioned in this report.

No.	Finding	ISO clause	Major or Minor

3. Date and signature of the management representative:

4. Date and Signature of the Lead Auditor:

Appendix 3: Action plans

NC No.	Non-conformance	ISO Clause	Major / Minor	Corrective action	Responsible Person	Timeline

Appendix 4: Internal Auditor Competency Assessment Form

Name of Auditor _____Observed by (Lead Auditor) _____

Date of assessment _____

Purpose of Assessment: (Tick that applies)

Initial for New staff ○

Annual ○ After Retraining ○

Competencies (based on ISO 15189:2012)		**Lead Auditors Comments**
Adequately prepares for audit by checking all. the necessary documentation?		
Possesses the audit checklists before the audit?		
Open minded and mature while conducting the audit?		
Was willing to consider alternative ideas or points of view?		

Possesses sound judgment & analytical skills?		
Ethical – fair, truthful, sincere, honest, and discreet?		
Observant – actively aware of physical environment and activities therein?		
Decisive – reaches timely conclusions based on logical reasoning and analysis?		
Self-reliant – acts and functions independently while interacting effectively with others?		
Tenacious – persistent, focused on achieving objectives?		
Obtains and assess objective evidence fairly?		
Remains true to the purpose of the assessment?		
Interacts with personnel in such a way that will best yield the assessment objective.		
Constantly evaluates the effect of assessment observations and		

personal interactions during an assessment?		
Commits full attention and support.		
Was willing to consider alternative ideas or points of view?		
Reacts effectively in stressful situations.		
Performs the assessment process without deviating due to distractions.		
Arrives at generally acceptable conclusions based on assessment observations.		
Understands the criteria in the relevant accreditation standard (i.e., ISO 15189, ISO 19011)?		
Understands SANAS policies applicable to the desired scope of accreditation?		
Accurately interprets and apply the criteria to the actual assessment situation?		
Demonstrates a track record of appropriate knowledge and skills		
Reacts effectively in stressful situations.		
Performs the assessment process without deviating due to distractions.		

Analysis of performance.

General Comment from Lead Auditor on performance for each test procedure.

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Action to be taken:

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Internal Auditor's Name: _____

Sign _____**Date**_____

Lead Auditor's Name: _____ **Signature/date**:

_____

Date of next assessment _____

Lead Auditor's comment:

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_____

_____

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_____

Lead Auditor: _____ **Signature/date:** _____

Date of next Review	Date of Review	Reviewed by	Description of Change	Version	Effective Date

Annex 1: SOP ATTESTATION FORM

Attestation Record (Internal Audit SOP – PRL-MGT-014

{Please ensure that you have read and understood before signing}

Names	**Signature**	**Date**