

Management System Auditors Criteria

CRT 6.21 Laboratory Management System Auditors

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1. INTRODUCTION

1.1. Purpose

This document describes the Laboratory Management System (LMS) Scheme criteria for SAATCA auditor certification, based on ISO 17025.

These criteria are intended to be used by:

- 1. Potential applicants to determine their suitability / readiness for making application for initial certification and for maintenance thereof and for ensuring they submit all necessary evidence and
- 2. The SAATCA Evaluation Committee to evaluate such applications

General note: The term "scheme" is equivalent to "discipline" as referenced in ISO 19011.

1.2. Definitions and Abbreviations

For the purpose of these criteria, the terms and definitions in ISO 17025, ISO 19011:2018, ISO/IEC 17000, ISO/IEC 17021-1:2015 and ISO/IEC 17024:2012 apply.

List of acronyms

LMS: Laboratory Management System

1.3. References

- ISO 17025 Laboratory management system
- ISO 19011:2018 Guidelines for auditing management systems
- ISO/IEC 17024:2012 Conformity Assessment General Requirements for Bodies operating Certification of Persons
- ISO/IEC 17021-1:2015 Conformity assessment Requirements for bodies providing audit and certification of management systems
- IAF Guidance on the Application of ISO/IEC 17024:2018 Conformity assessment General Requirements for Bodies operating Certification of Persons. (IAF GD 24)
- IAF MD 5 Mandatory Document For Duration of LMS and EMS Audits:
- References related to Auditing Sampling (ISAE3000, GHTF/SG4/N30R20)
- SAATCA Procedures and Criteria:
 - QSP 1.4, Appeals, complaints and disputes
 - QSP 1.9 Transfer of Certification
 - ARP 2 7 Renewal Suspension and Withdrawal of Auditor Registration
 - ACR 5.1 Evaluation Committee
- SAATCA Forms/ documents various, referenced as SF
 - SF18 Application for Re-certification
 - SF26 SAATCA Audit log
 - SF27 SAATCA CPD log
 - SF29 Code of Conduct Auditor
 - SF45 Auditor performance report
 - SF51 Code of Conduct Sponsor
 - SF52 Code of Conduct Witnessing Lead Auditor
 - SF72 Auditee Feedback Report
 - SF79 Application form for certification
 - SF149 Application form for sectors

Note: Unless otherwise specified, the standards referenced in this document are deemed to be the current editions. Any standard or legislative references relate to the current published version. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.



1.4. Equivalent Standards

Whilst the SAATCA registration schemes are based on the primary international or national standard, where these exist, it recognises that there are other standards that may be equivalent for the purposes of SAATCA management system auditor registration.

Where there are such equivalent standards, the Laboratory Management System Scheme Committee develop and publish the list of equivalent standards which can be used as the basis of competence for each scheme. These equivalence lists are approved by the Technical Management Board as part of these criteria as follows:

List of Equivalent Standards for ISO/IEC 17021

There are currently no equivalent standards for ISO/IEC 17021 as applicable to LMS auditor registration.

List of Equivalent Standards for ISO 17025

For initial certification the following are considered equivalent to ISO 17025:

- ISO TS 16949, Laboratory management systems Particular requirements for the application of ISO 17025 for automotive production and relevant service part organizations
- ISO TS 29001, Petroleum, petrochemical and natural gas industries Sector-specific laboratory management systems - Requirements for product and service supply organizations
- All requirements standards listed in the ISO document ISO/TC 176 N881R3, List of ISO Sector Applications (available from SAATCA or ISO website)
- ISO/IEC 17025: General requirements for the competence of testing and calibration laboratories
- o ISO 15189: Medical laboratories -- Particular requirements for laboratory and competence

For maintenance of certification, the above standards as well as:

- ISO 10006: Laboratory management systems -- Guidelines for laboratory management in projects
- SANS ARP 063 / IWA 4: Laboratory management systems Guidelines for the application of ISO 17025 in local government.
- SANS ARP 082: /IWA 2: Laboratory Management Systems: Guidelines for the application of ISO 17025 in education
- ISO 10007: Laboratory management systems -- Guidelines for configuration management (includes specific requirements for configuration auditing).

If a standard has not been approved as equivalent, the onus is on the applicant to provide sufficient evidence to justify its acceptance by the Scheme Committee and approval by the Technical Management Board.

1.5. "Start Up" Concession for New Schemes

When this was a new SAATCA scheme being launched, where there were not yet any qualifying Lead Auditors for witnessing or evaluation purposes, the Scheme Committees had the option to grant applicable "Start Up" based registrations.

Note: the Start Up clause is the expression used when a scheme has to start / be initiated, to enable the scheme to get off the ground. It is based on accepting the existing competence and experience of practitioners already in the relevant field, who are not yet able to fulfil those requirements that rely on the existence of Lead Auditors in the new scheme, because there are no such Lead Auditors as yet.

Concessionary approval may be granted by SAATCA with the proviso that a suitable portfolio of evidence is maintained to demonstrate conformance with these Scheme Specific "Start Up" criteria.

"Start Up" auditors shall comply with all the criteria except where deviations have been noted.



1.6. SAATCA LMS Scheme Sectors

• Not yet applicable for this scheme

1.7. SAATCA Auditor Grades

1.7.1. Provisional Auditor (Also referred to as "in-training" in certain industry sectors)

This grade is the entry or training grade. It recognizes an applicant to have the appropriate personal behaviours, educational, professional and technical competence but does not yet meet the criteria for auditing experience and demonstration of audit competence of the other grades. This grade is qualifications based, without competence evaluation.

This is not SANAS accredited grade of management system auditor.

Provisional Auditors will be given non- accredited letters of acknowledgement, stating the applicant's applicable scheme of registration and registration number, but will not be formally issued with Certificates and registration cards.

This grade is a transition grade with the intention that, over time, Provisional Auditors progress to auditors once they meet the requirements.

No Provisional Auditor registered in terms of this grade may suggest or imply certification status as a management system auditor.

1.7.2. Auditor Grade

This grade recognizes the applicant as a competent Auditor, contributing as an effective member of an audit team. This grade applies typically to auditors who take part in audits as members of a team rather than audit team leaders.

Auditors shall be issued with Certificates and Auditor registration cards.

1.7.3. Lead Auditor Grade

The Lead Auditor grade is reserved for auditors who conform to the requirements of Auditor grade and who are competent and experienced at managing audits and leading audit teams. This grade applies typically to auditors who lead audits of more than one auditor.

Lead Auditors shall be issued with Certificates and Lead Auditor registration cards.

1.7.4. Internal Auditor Grade

This grade applies to applicants that conduct audits within and for or on behalf of organisations by whom they are employed, and may include supplier audits, provided they cover the full scope of the relevant management system.

It is not intended to imply that an Internal Auditor is less qualified than an Auditor, only that the application of the auditing practice is limited to one organisation. The same level of qualification and work experience is required as that of the Auditor grade.

Internal Auditor certification shall be granted in respect of the specific organisation for which internal audits are conducted.

Internal Auditors shall be issued with Certificates and Internal Auditor registration cards on which reference will be made to the organization where the internal audits are carried out and for which the Internal Auditor has been certified.

If a SAATCA certified Internal Auditor leaves the employment of the organisation for which internal auditor certification is held, his or her certification as a SAATCA certified internal auditor for that organisation is no longer valid. Should the auditor resume internal auditing at a different organisation, they would qualify to transfer their internal auditor certification, by making application relative to the new organisation. Alternatively, they could apply for full Auditor grade as they potentially satisfy the requirement for auditing multiple management systems.

Internal auditor is not recognised nor currently a SANAS accredited grade of management system auditors.



1.8. Advancement to Another Grade

Advancement to another certification grade can be attained at any time provided suitable competence and experience for that grade is gained.

Certificated auditors of any grade, who can demonstrate competence and are successfully evaluated against the applicable criteria required for another grade, shall qualify for advancement to such grade.

When applying for advancement from one grade to other applicants are required to complete the application form and submit the applicable evidence relevant to the new grade.

1.9. Suspension and Withdrawal of Certification - ARP 2.7

All suspensions and withdrawals of certification shall be managed in accordance with ARP 2.7

1.10. Complaints, Appeals and Disputes Process - QSP 1.4

All complaints, appeals and disputes shall be managed in accordance with QSP 1.4

1.11. Criteria for Auditor Transition in the Event of Substantial Changes to Criteria

In the event of any substantial changes to any of these auditor criteria eg a management system standard changing, etc the Scheme Committee shall develop and publish a process for transition and the transition period (if any). The transition requirements shall be clearly specified and approved by the Technical Management Board. These shall be published (for example as an annex to these criteria, a communique, etc and communicated to registered auditors and applicants.

Transition timelines for these criteria:

For transition details, refer to the Maintenance Section of the Criteria Table

1.12. Transfer of Certification - QSP 1.9

All transfers of auditor certification from other auditor certification bodies shall be processed in accordance with QSP 1.9

1.13. Use of the SAATCA Logo - SF 48

The use of the SAATCA logo shall be in accordance with: Regulations Governing the SAATCA Logo (SF48)

1.14. Notifiable Changes - SF 56

By signing the SAATCA Auditor's Code of Conduct, all auditors commit to notify SAATCA of any changes that can affect the auditor's state of conformance with SAATCA and compliance with regulatory or legal requirements. Refer to SF 56 regarding notifying SAATCA of any changes.

1.15. Publication of Details of SAATCA Registered Auditors

SAATCA shall publish details of registered auditors, (including grade and status, where applicable) on the website: <u>www.saatca.co.za</u>.



1.16 SUMMARY OF REQUIREMENTS FOR SAATCA AUDITOR REGISTRATION

Requirements	Criteria			Submissions	
Additional Sector/scope	Refer to SAATCA criteria for specific schemes Eg FS – 4 audits plus either training or work experience in the scope			CV, certificates audit log	
Auditing (additional scheme/s)	Auditor : Minimum of 15 days, at least 4 separate audits of which one is a witnessed audit, and one with auditee feedback	Internal Auditor: M least 3 separat one is a witnessed a with auditee	audit, and one	Lead auditor: None , unless otherwise specified by the specific scheme (automatically gain LA status if all other criteria are met)	Audit log (fully signed off) Witnessed Audit Report Auditee F eedback
Witnessing	Witnessing Lead Auc	Witnessing Lead Auditors shall be independent of the applicant they witness			Application form & Code of conduct
Sponsor	Sponsor has personal knowledge of the applicant and verified the CV			Performance Report & code of conduct	
Auditing (first scheme of certification)	Auditor: Minimum of 20 days, at least 4 separate audits of which one is a witnessed audit and one with auditee feedback	Internal Auditor: Minim least 3 separate aud witnessed audit a auditee fe	dits of which one is a and one with	Lead auditor: Minimum of 10 days on site with 5 days of off site lead audit activities, at least 3 audits (after auditor audits) of which one is a witnessed audit and one with auditee feedback	Audit log (fully signed off) Witnessed Audit Report Auditee Feedback
Attributes/ Personal behaviours	Desirable attributes/changing to personal behaviours (exhibited during the audit process and attested by Sponsor and Witnessing lead auditor)			Sponsor and W itnessing lead A uditor R eport	
	Lead auditor training (ISO 19011:2018 and ISO 17021-1:2015 based) 5 days – once off				Certified copies
Training	Management system standard training. ISO/OHS standard [5 days] – prior to lead auditor course				
	Internal Auditor Training (ISO19011 based) 3 days once off Understanding & Implementation training 5 days				certificates
Work experience	4 years work experience relevant to field (eg laboratory, environment, safety etc.) 2 years relevant to scheme MS standard (eg ISO 17025, 14001 OHS, ISO 22000, etc). Can be concurrent with the 4 years work experience		2 years relevant to scher OHS, ISO 22000, etc	rience relevant to field (eg laboratory, nvironment, safety etc.) me MS standard (eg ISO 17025, 14001). Can be concurrent with the 4 years work experience	cv
Education	Degree/diploma Eg	Degree/diploma Eg ISO/OHS standard Degree/diploma equivalent - 4 years wo to degree/diploma/scheme			Certified copies
	Matric or NQF equivalent				of certificates





1.16. Summary of Requirements for SAATCA Auditor Registration

2. INITIAL APPLICATION REQUIREMENTS

REQUIREMENT	ADMISSIBLE EVIDENCE
2.1. Application Documents and Codes of Conduct	
2.1.1. Application forms	Completed Application form and Checklist
Applicants shall complete and submit the SAATCA application	(Included in the Application form, SF79:),
documentation, according to the Application Checklist section of	including CV details and sponsorship from at
the application form, including: application form (SF79), with the	least one individual (who has a business
completed Sponsor's section and personal declaration (SF 29),	relationship) attesting to the applicant's
and ensure that a signed Sponsor's Code of Conduct (SF 51)	fulfilment of the requirements.
accompanies the application.	Certified copy of ID (Identity document).
As part of the application, applicants shall provide evidence of	Completed signed Auditor's Code of
work experience, audit experience, education and training.	Conduct (SF 29).
Sponsors : These may be either the applicants line manager or	Completed signed Sponsor's Code of
(in the case of self-employed applicants) or an individual with	Conduct (SF 51).
professional knowledge of the applicant and willing and able to	Certified true copies of relevant academic
attest to their personal behaviours (see below).	qualifications and/or professional
2.1.2. Code of Conduct	registration in the sector of the application
In the event of verified breach of the SAATCA applicants /	Self-employed applicants shall submit a
witnessing lead Code of Conduct, auditors will be precluded from	portfolio of evidence that demonstrates the
reapplying for 3 years.	attestations required.
2.2. Personal Behaviours	
Applicants shall be able to demonstrate the personal behaviours	Completed signed Sponsor Code of
necessary for the effective and efficient performance of an audit.	Conduct (SF 51).
Desirable personal behaviours for all auditors are:	Completed Sponsor's declaration on
Ethical, Open-minded, Diplomatic, Observant, Perceptive,	Application form for Certification.
Versatile, Tenacious, Decisive, Self-reliant, acting with	(Also refer below under Witnessing).
-	
fortitude, open to improvement, culturally sensitive,	
collaborative, Professional, Morally courage, Organized. 2.3. Education	
	Option 4. Cartified true conice of relevant
Applicants must have attained an educational standard that permits the necessary knowledge to perform effectively as an	Option 1: Certified true copies of relevant
auditor. This includes:	academic qualifications and/or professional
	registration in the sector of application
Option One: With a tertiary education:	
Matric or equivalent to NQF Level 4 (secondary education) and	Option 2: Certified true copies of Matric or
Tertiary education (e.g. degree or diploma).	equivalent to NQF Level 4 and copy of CV or
	equivalent evidence of the work experience.
Option Two: In the absence of degree or diploma (tertiary	
education):	Any break in work experience shall not be
Matric or equivalent to NQF Level 4 plus 4 years' work	longer than 10 years prior to application, and
experience in a relevant field.	supported by evidence of continuing
	professional development is provided.



REQUIREMENT	ADMISSIBLE EVIDENCE	
2.4. Work Experience		
2.4.1. General Work Experience	Verifiable evidence of work experience:	
For the initial sector of application:	Record of employment, eg CV verified by a line manager, through signature of SF51,	
Option 1: Where applicants have a degree/ diploma:	attesting to technical, professional or	
For the first sector applicants for all grades shall have completed	managerial experience as well the	
a minimum of four years of work experience in a role that is	applicant's involvement in the exercise of	
Laboratory related in a technical, professional or managerial	judgement, problem solving and	
position involving the exercise of judgement, problem solving and	communication with other managerial	
communication with other managerial personnel, peers,	personnel, peers, customers, interested and	
customers, interested and affected parties and/or authorities.	affected parties and/or authorities.	
Option 2: Where applicants do not have a degree/ diploma:		
Applicants for all grades shall have completed a minimum of 4	Copy of current and correct CV and Signed	
years of work experience as the education equivalent plus five	sponsor Code of Conduct SF51	
years of work experience in a role that is Laboratory related, in a	(attestation).	
technical, professional or managerial position involving the		
exercise of judgement, problem solving and communication with		
other managerial personnel, peers, customers, interested and		
affected parties and/or authorities.		
At least 3 years of this relevant experience shall be gained within		
an Laboratory context or shall demonstrate a satisfactory level of		
work experience gained within an Laboratory context		
Acceptable experience would be where the applicant has acquire	ed significant experience in at least one of the	
following:		
• Full time role as manager, supervisor, engineer or technician involved in the technical aspects of facility operation in compliance with applicable regulations.		
• Implementation and maintenance of a management system, or integrated management system applicable to the scope of application, involving management system conformity management.		
Monitoring compliance with applicable laws and regulation on	behalf of a regulating body.	
 Provision of appropriate consultancy services involving t application. 	he management system applicable to the	
 Full time role relating to the performance of the management 	ent system applicable to the application and	
management of audits of all types (not necessarily management		
 Periods of training will <u>not</u> be considered as eligible toward m 		
Note : For auditors applying for a second (and third etc) scheme of	0	
second (and third, etc) discipline may be concurrent with the worl		
must be scheme specific.		
2.4.2. Management System Work Experience		
The applicants shall have at least 2 years relevant Management	As for general work experience above	
System eg implementation, operation, consulting and/or auditing		
experience gained within the field for which certification is sought.		
This may be concurrent with the relevant general work		
experience.		
2.5. Knowledge and Skills		
2.5.1. All auditor grades – generic knowledge and skills		
All auditors shall possess the knowledge and skills necessary to	Various evidence as itemized in the sections	
achieve the intended results of the audits undertaken.	following.	
The following knowledge and skills are generic to all auditors and		
grades:		



-
e of Laboratory law is required.
e may be demonstrated by
either successful completion of
rk, or by means of demonstrated
or work experience.
t of knowledge of Laboratory law
o Laboratory law that is
to the organisation for which
n is applied for.
shall objectively demonstrate
to distil legal requirements that
pecific Laboratory aspects.
may also examine this knowledge
of an examination, or interview or
shall objectively demonstrate
ledge of the requirements.
e may be acquired either by
education, training, successful
n of course work, or by means of
ted case work or work
9.
shall submit a compiled portfolio
e such as:
lucation
se work,
ourses attended,
er review reports
itness reports (refer below –
tnessing
nay also examine this
nay also examine this ce by means of an examination,



REQUIREMENT	ADMISSIBLE EVIDENCE
laboratory management systems and excellence	
models;	
 involvement of people, human factors, competence, 	
training and awareness;	
 process approach, process analysis, capability and 	
control techniques, risk treatment methods;	
 system approach to management (rationale of 	
laboratory management systems, laboratory	
management systems and other management system	
focuses, laboratory management system	
documentation), types and value, projects, laboratory	
plans, configuration management;	
• continual improvement, innovation and learning;	
factual approach to decision making, risk assessment	
techniques (risk identification, analysis and evaluation),	
evaluation of laboratory management (audit, review and	
self-assessment), measurement and monitoring	
techniques, requirements for measurement processes	
and measuring equipment, root cause analysis,	
statistical techniques; — characteristics of processes	
and products, including services;	
 mutually beneficial supplier relationships, laboratory 	
management system requirements and requirements for	
products, particular requirements for laboratory	
management in different sectors.	
 technical characteristics of processes and products, 	
including services, and	
 sector-specific processes and practices. 	
2.5.3. Knowledge and skills of Lead Auditors for leading	
audits	
Lead Auditors shall have additional knowledge and skills in	
leadership to facilitate the efficient and effective leading of the	
audit, as per ISO 19011:2018 and ISO/IEC 17021-1:2015.	Completed Witnessing Lead Auditor's
 Ability to balance the strengths and weaknesses of the 	Report – Lead auditor (SF 45).
individual audit team members	Also refer below under – Witnessing.
• Ability to develop a harmonious working relationship among	Applicant shall objectively demonstrate their
the audit team members	knowledge of the requirements.
 Ability to manage the audit process, including 	
 planning the audit and making effective use of 	
resources during the audit	
 managing the uncertainty of achieving audit objectives 	
 protecting the health and safety of the audit team 	
members during the audit, including ensuring	
compliance of the auditors with the relevant health,	
safety and security requirements	
 organizing and directing the audit team members 	
 organizing and directing the addit team members providing direction and guidance to auditors-in-training; 	
 represent the audit team in communications with the person managing the audit programme, audit client and audited 	
managing the audit programme, audit client and auditee	



REQUIREMENT			
lead the audit team to reach the audit conclusions			
prepare and complete the audit report			
2.6. Training			
2.6.1. Auditor / Lead Auditor Training (ISO/IEC 17021-			
1:2018 & ISO 19011:2018)			
Successfully completed a SAATCA certified lead auditor course	Certified copy of SAATCA Qualification		
based on ISO 19011:2018and ISO/IEC 17021-1:2015, of at	Certificate (s) - 5 Day Lead Auditor Course		
least 5 days training, to auditing principles and practices as	based on ISO 19011:2018 and ISO 17021-		
follows:	1-2015.		
Audit principles, procedures and techniques:	SAATCA Confirmation that the course was		
(ISO19011:2018), to enable the Auditor to apply those	attended and successfully completed and		
appropriate to different scenarios to ensure that audits are	the learner must register with SAATCA.		
conducted in a consistent and systematic manner.	4		
Learner assessment score of at least 70%	OR, if more than 3 years prior -		
Approved training shall normally be gained in the 3 years immediately prior to the application for certification.	SAATCA Confirmation that the applicant has		
Note : The requirement for the 3-year period may be waived for	undertaken activities from the period		
applicants who can demonstrate that they have undertaken	between auditor training and making		
activities from the period between auditor training and making	application, for example through auditing of		
application through auditing of or implementation of applicable	or implementation of LMS and through		
management system (as per the application field) and through	continuing professional development.		
continuing professional development activities that would be			
consistent with the requirements for maintaining registration at			
the appropriate level.			
2.6.2. Management System Training			
reference documents	Certified copy of certificate of ISO 17025		
Attendance of training equivalent to 5 days contact duration on	training understanding and implementation.		
ISO/IEC 17025:2017 to ensure:			
ISO/IEC 17025:2017 : Knowledge Management system	If the certificate is attained less than 5 days		
and reference documents; skills	the applicant must write SAATCA exam		
 ISO/IEC 17025:2017: Application that includes design, 	from the training course before apply to		
development, documentation, implementation,	SAATCA		
maintenance and improvement of an LMS 2.6.3. Laboratory Specific Technical Training/Knowledge			
and Skills			
Refer to section above: Laboratory management methods,			
techniques, performance and technology			
2.7. Auditing Experience			
Complete/Qualifying Management System Audits			
• An audit covering the entire audit process as described in ISO 19011:2018 and ISO/IEC 17021-1:2015 and			
including all aspects of the scheme specific management system standard or an alternative equivalen			
standard acceptable to SAATCA.			
• Audit Day: A minimum of six hours of audit activity on site (typically part of an 8 hour audit day, as per IAF			
	audit day allocations).		
audit day allocations).			
audit day allocations).Audits shall be at business units that have their own manager	ment structure and carry out the management		

• For Auditor and Lead Auditor grades only independent audits satisfy the applicable scheme auditing experience requirements. The auditor and the auditor's organization shall have independent management and operating structure from the audited organization. Examples of acceptable relationships are:



REQUIREMENT

ADMISSIBLE EVIDENCE

- o a head office audit of a plant or division as applicable to internal audits;
- o one division or plant auditing another division or plant as applicable to internal audits;
- o a customer organization auditing a supplier;
- a third party certification audit and;
- o a consultant contracted to provide an independent conformance audit
- For Internal Auditor grade audits of the applicant's own organisation's management system or supplier audits covering the full management system of the same scheme for which certification is sought are acceptable.

• Unacceptable audits are:

- o audits of duration less than 6 hours on site
- \circ audits where the ratio of applicant auditors to Lead Auditor/s is more than 4:1
- o gap analysis;
- close out or follow up visits;
- o audits of any site that are repeated more frequently than once every 12 months,
- \circ $\;$ audits participated in as part of a training programme, and
- o audits performed before successful completion of the formal Auditor training requirement.
- Only audits carried out against a recognized international standard or an alternative recognized equivalent standard as defined in the specific scheme criteria will be accepted by SAATCA.
- Auditing on site includes the opening and closing meetings and the conformance auditing phase, but excludes planning, document review and preparation of the audit report even when these functions are performed at the premises of the auditee.
- The audits shall have been completed in the 3-year period prior to application.

• The addits shall have been completed in the 5-year period p	
2.7.1. Auditing Experience for Auditor	Audit Log sheets: Completed in full and
Applicants are required to have participated in at least four	confirmed SAATCA audit log sheets (SF 26).
complete, successful audits for a total of at least 20 days / 120	Sign-off of fully completed audit log sheets
hours on site, acquired under the direction and guidance of a	as confirmation by the applicant of the
Lead Auditor from the same scheme. The Lead Auditor shall sign	authenticity of the and by the guiding lead
the SAATCA log for each audit submitted to attest to such	auditor as confirmation of the correctness of
direction and guidance.	the audits and a copy of attendance register
	for the audit conducted.
Details and description of each audit shall be entered onto the	
SAATCA audit log sheet. Details must include identification of the	Auditee feedback: Completed, positive
auditee; sufficient to allow verification of the audit by SAATCA.	Auditee Feedback report per scheme of
Relevant experience auditing of other schemes for which the	registration regarding the performance of the
applicant holds registration may be considered for up to 5 days	applicant for at least one audit. (Refer SF
(30 hours) of the auditing experience required.	72).
For each audit submitted for certification, the applicant shall either	SAATCA may also verify the information
have been conversant with the language used or, alternatively,	provided by the applicant.
have effectively used a competent translator during the conduct	
of the audit.	Witnessed audit(s) - refer below
At least one witnessed audit (see below) of the applicant.	Audit Log sheets: Refer SF 26
2.7.2. Auditing Experience Lead Auditor Grade	
In addition to satisfying all the auditing experience requirements	Audit Log sheets: Completed in full and
for Auditor grade, applicants for Lead Auditor shall have	confirmed SAATCA audit log sheets (SF 26).
participated as a leader of an audit team which included at least	Sign-off of fully completed audit log sheets
one other auditor, for a further minimum of 3 complete audits of	as confirmation by the applicant of the
LMS with a total not less than 15 days, of which at least 10 are	authenticity of the and by the guiding lead
on site and 5 off-site for planning and reporting.	auditor as confirmation of the correctness of
This audit experience additional to that required for Auditor grade	the audits.
must have been gained in the 3-year period prior to application.	



REQUIREMENT	ADMISSIBLE EVIDENCE
The above audits shall have been with an audit team size of at	Auditee feedback: Completed, positive
least two (including the applicant) on-site where the applicant	Auditee Feedback report per scheme of
acted as the team leader and shall have involved the applicant in	registration regarding the performance of the
making a judgement on whether the organisation:	applicant for at least one audit. (Refer SF
o is achieving the policy objectives as stated in the	72).
management system;	
 adheres to its own policies; 	SAATCA may also verify the information
 achieves Laboratory performance improvements 	provided by the applicant.
 adheres to its own arrangements 	
 conforms to the objectives and requirements of the LMS 	
management system standard.	
The overall required auditing experience in reaching the Lead	
Auditor grade shall be gained at a minimum of 3 different	
operating facilities or business units.	
At least one witnessed audit (see below) of the applicant acting	Witnessed audit(s) - refer below
as Lead Auditor in the capacity of Team Leader.	
Note: Applicants qualified as Lead Auditor in any one	
scheme shall automatically qualify for Lead Auditor in all	
schemes where they meet the auditor's requirements.	
2.7.3. Auditing Experience as related to Internal Auditor	Audit Log sheets: Completed in full and
Grade	confirmed SAATCA audit log sheets (SF 26).
Applicants for the Internal Auditor grade shall have participated	Sign-off of fully completed audit log sheets
in at least 3 complete internal audits for at least 5 days (30 hours)	as confirmation by the applicant of the
on site and must have competed all elements of the audit cycle,	authenticity of the logs and a copy of
including: audit planning, documents review, auditing,	attendance register for the audit conducted.
interviewing, audit reporting. It must not have involved areas or	
activities of direct responsibility of the applicant.	Auditee feedback: Completed, positive
	Auditee Feedback report per scheme of
At least one witnessed audit (see below) of the applicant.	registration regarding the performance of the
	applicant for at least one audit. (Refer SF
	72).
	CANTON many place works, the information
	SAATCA may also verify the information
	provided by the applicant.
2.9 Witnessing	Witnessed audit(s) - refer below Refer to ARP 2.4
2.8. Witnessing2.8.1. Witnessing of Auditors and Internal Auditors	
The witnessed audit(s) shall cover the entire management	
system and all phases of the audit process. (As defined in ISO	Completed Witnessing Lead Auditor (s)
19011 and ISO/IEC 17021-1:2015).	report (s) for Auditors and Internal Auditors
Witnessing shall be carried out to verify all applicable auditing	(SF 45)
requirements as described in ISO 19011:2018 and ISO/IEC	
17021-1:2015 during the course of one complete audit, or a	Signed Witnessing Lead Auditor's Code of
number of partial audits, which in total includes all requirements	Conduct (SF 52) for each witnessing.
of the management system standard	
The duration of the witnessed audit and verification shall be	SAATCA may also examine this
sufficient to enable the witnessing auditor to determine:	competence by means of an examination, or
Competence in auditing against each relevant requirement	interview or otherwise.
of the applicable management system standard.	
or the applicable management system standard.	Witnessing Lead Auditors shall be
	independent of the applicant they witness, in



REQUIREMENT	ADMISSIBLE EVIDENCE
 Competence in performing the entire audit process, as applicable, according to ISO 19011:2018 and ISO/IEC 17021-1:2015. Possession of the personal behaviours identified in ISO 19011:2018 and ISO/IEC 17021-1:2015 and any additional scheme specific behaviours. The Witnessing Lead Auditor shall complete a SAATCA Auditing Performance Report attesting to the satisfactory performance and behaviours of the applicant. Witnessing Lead Auditor. Witnessing shall be carried out by a SAATCA LMS Lead Auditor. The Witnessing Lead Auditor(s) shall commit to the SAATCA Code of Conduct for witnessing and the applicant shall submit copy of signed Witnessing Lead Auditor Code of Conduct(s) their the witnessing report. Responsibility for submission of a completed report and the signed Witnessing Lead Auditor(s)' Code of Conduct remains with the applicant. 	 accordance with the Witnessing Lead Auditors Code of Conduct, SF52. The Witnessing Lead Auditor shall have had no involvement in the development of the candidate (e.g. education, training, development, mentoring) for a period of two years. 1. CM to follow up with client that witnessing did takes place. 2. CM to verify impartiality with auditee and auditor in training witnessed. 3. Attendance register must be signed at day of witnessing by the witness lead auditor. 4. If CM is suspicious of witnessing it will be forwarded to the Impartiality committee for review.
 2.8.2. Witnessing of Lead Auditors As above, except that the witnessing shall be carried out to verify all lead auditing requirements as described in ISO 19011:2018 and ISO/IEC 17021-1:2015. Note: For auditors that are registered as SAATCA Lead Auditors within schemes other than the one being applied for, the witnessing of Lead Auditor skills does not need to be repeated. Note: If a lead auditor applicant has been witnessed for auditor registration by a Witnessing Auditor in the scheme of application, then their Lead Auditor witnessing, in exceptional cases, may be considered from an acceptable Witnessing Auditor from another scheme. 	Completed Witnessing Lead Auditor's report for Lead Auditors (SF 45) A sign-off of the audit log sheet as confirmation by the applicant that he or she conforms to this requirement. SAATCA may also examine this competence by means of an examination, or interview or otherwise. Witnessing Lead Auditors shall be independent of the applicant they witness, in accordance with the Witnessing Lead Auditors Code of Conduct, SF52. The Witnessing Lead Auditor shall have had no involvement in the development of the candidate (e.g. education, training, development, mentoring) for a period of two years. The Witnessing Lead Auditor must be different from the Guiding/Mentoring Lead Auditor that sign SF26 1. CM to follow up with client that witnessing did takes place. 2. CM to verify impartiality with auditee and auditor in training witnessed. 3. Attendance register must be signed at day of witnessing by the witness lead auditor.



REQUIREMENT	ADMISSIBLE EVIDENCE
	4. If CM is suspicious of witnessing it will be forwarded to the Impartiality committee for review.
2.8.3. Upgrade to another grade/Auditing additional grade	
a) Internal auditor: Minimum of 4 days audit logs (SF26), 3 separate audit logs (SF26) from different organizations, 1 Auditor Performance Report (SF45) and 3 audit feedback reports (SF72) from the audited organizations and including attendance registers.	a) Audit Log sheets (SF 26): Completed in full and confirmed SAATCA audit log sheets and a copy of attendance register from the auditee to support the Auditor Performance Report (SF45)
 b) Auditor: Minimum of 20 days audit logs (SF26), 4 separate audit logs (SF26) from different organizations, 1 Auditor Performance Report (SF45) and 4 feedback reports (SF72) from the audited organizations and including attendance registers. c) Lead Auditor: Minimum of 15 days audit logs, (SF26), 4 separate audit logs (SF26) from different organizations, 1 Auditor Performance Report (SF45) and 4 feedback reports (SF72) from the audited organizations and including attendance registers. 	 The contents of the audit logs shall be legible without any alterations. Sign-off of fully completed audit log sheets as confirmation by the applicant of the authenticity of the logs. The guiding/mentor Lead Auditor must sign the last column of SF26 as confirmation of the correctness of the audits. Furthermore, a guiding/mentor Lead Auditor cannot sign the witnessing report and witnessing code of conduct. <i>NB: A guiding/mentor Lead Auditor is different from a witnessing lead auditor.</i> b) Auditee feedback (SF 72): Completed, positive Auditee Feedback report per scheme of registration regarding the performance of the applicant for at least four audits. c) Complete Performance Report (SF45) 1. CM to follow up with client that witnessing did take place. 2. CM to verify impartiality with auditee and auditor in training witnessed. 3. Attendance register must be signed on the day of witnessing by the witnessing it will be forwarded to the Impartiality committee for



2.0 Training for Informal Auditor	
2.9. Training for Internal Auditor	
 2.9.1. Internal Auditor Training (19011) Successfully completed a SAATCA certified internal auditor course based on ISO 19011:2018, of at least 3 days training, to auditing principles and practices as follows: Audit principles, procedures and techniques: (ISO19011:2018), to enable the Auditor to apply those appropriate to different scenarios to ensure that audits are conducted in a consistent and systematic manner. 	Certified copy of SAATCA Qualification Certificate (s) - 3 Day Internal Auditor Course based on ISO 19011:2018 SAATCA Confirmation that the course was attended and successfully completed in the 3 years immediately prior to the application for certification. OR, if more than 3 years prior - SAATCA Confirmation that the applicant has undertaken activities from the period between auditor training and making application, for example through auditing of or implementation of LMS and through
	continuing professional development.
Learner assessment score of at least 70%	
Approved training shall normally be gained in the 3 years immediately prior to the application for certification. Note : The requirement for the 3 year period may be waived for applicants who can demonstrate that they have undertaken activities from the period between auditor training and making application through auditing of or implementation of applicable management system (as per the application field) and through continuing professional development activities that would be consistent with the requirements for maintaining registration at the appropriate level.	
2.9.2. Management System Training: Understanding &	
Implementation	
Attendance of training equivalent to at least 5 days contact duration on ISO/IEC 17025:2017 to ensure:	Certified copy of certificate of ISO/IEC 17025:2017 training.
 ISO/IEC 17025:2017: Knowledge Management system and reference documents; skills ISO/IEC 17025:2017: Application that includes design, development, documentation, implementation, maintenance and improvement of an LMS 	If the certificate is attained less than 5 days the applicant must write SAATCA exam from the training course before apply to SAATCA.
2.9.3. Auditing Experience for Internal Auditor Applicants are required to have participated in at least three complete, successful audits for a total of at least 5 days / 30 hours on site, acquired under the direction and guidance of a Lead Auditor from the same scheme. The Lead Auditor shall sign the SAATCA log for each audit submitted to attest to such direction and guidance.	 Audit Log sheets: Completed in full and confirmed SAATCA audit log sheets (SF 26). Sign-off of fully completed audit log sheets as confirmation by the applicant of the authenticity of the logs. Auditee feedback: Completed, positive Auditee Feedback report per scheme of registration regarding the performance of the
	applicant for at least one audit. (Refer SF 72). SAATCA may also verify the information provided by the applicant.



	Witnessed audit(s) - refer below			
2.9.4. Witnessing of Internal Auditors The witnessed audit(s) shall cover the entire management system and all phases of the audit process. (As defined in ISO 19011).	Completed Witnessing Lead Auditor (s) report (s) for Internal Auditors (SF 45)			
Witnessing shall be carried out to verify all applicable auditing requirements as described in ISO 19011:2018 during the course of one complete audit, or a number of partial audits, which in total includes all requirements of the management system standard	Signed Witnessing Lead Auditor's Code of Conduct (SF 52) for each witnessing. SAATCA may also examine this competence by means of an examination, or interview or otherwise.			
 The duration of the witnessed audit and verification shall be sufficient to enable the witnessing auditor to determine: Competence in auditing against each relevant requirement of the applicable management system standard. Competence in performing the entire audit process, as applicable, according to ISO 19011. 	Witnessing Lead Auditors shall be independent of the applicant they witness, in accordance with the Witnessing Lead Auditors Code of Conduct, SF52.			
 Possession of the personal behaviours identified in ISO 19011 and any additional scheme specific behaviors. 	The Witnessing Lead Auditor shall have had no involvement in the development of the candidate (e.g. education, training development montoring) for a			
The Witnessing Lead Auditor shall complete a SAATCA Auditing Performance Report attesting to the satisfactory performance and behaviours of the applicant.	training, development, mentoring) for a period of two years.			
Witnessing may involve more than one audit and more than one Witnessing Lead Auditor. Witnessing shall be carried out by a SAATCA LMS Lead Auditor.	The Witnessing Lead Auditor performance report must be completed by a SAATCA registered Lead Auditor who is different person from the Guiding/Mentoring Lead Auditor that			
	signs SF26			
The Witnessing Lead Auditor(s) shall commit to the SAATCA Code of Conduct for witnessing and the applicant shall submit copy of signed Witnessing Lead Auditor Code of Conduct(s) their the witnessing report. Responsibility for submission of a completed report and the signed Witnessing Lead Auditor(s)' Code of Conduct remains with the applicant.	 CM to follow up with client that witnessing did takes place. CM to verify impartiality with auditee and auditor in training witnessed. Attendance register must be signed at day of witnessing by the witness lead auditor. If CM is suspicious of witnessing it will be forwarded to the Impartiality committee for review. 			



3. MAINTAINING CERTIFICATION

REQUIREMENT	ADMISSIBLE EVIDENCE		
3.1. Annual Surveillance, Card Re-issue and Fee for			
Maintenance			
3.1.1. An annual registration application form is required,			
when personal details changed and require update.	Completed Application for Annual Re-		
(The details from this form are captured onto the	registration (SF76) or information update		
SAATCA database).	form.		
3.1.2. Annual submission of Audit Log (CPD logs and	Audit Log sheets: Completed in full and		
Auditee feedback may also be submitted annually but	confirmed SAATCA audit log sheets (SF 26).		
are mandatory for the 3 year certification).	Sign-off of fully completed audit log sheets as		
	confirmation by the applicant of the		
Refer below for details of audit and CPD requirements.	authenticity of the logs.		
	Auditee feedback. (Refer SF 72).		
Note: Audit Logs and CPD Logs (where CPD had taken place)	CPD Log: refer CPD Log (SF27)		
shall be submitted annually with registration fees, and recorded	SAATCA may also verify the information		
by SAATCA certification as the annual surveillance. (These will	provided by the applicant.		
be evaluated 3-yearly by the Evaluation Committee.)			
3.1.3. An annual registration fee (subscription) is payable to			
SAATCA.	Payment of fees as per the prevailing		
The SAATCA Board of Directors determines registration fees on	SAATCA fee structure - Personnel		
an annual basis, and these are published on the SAATCA web	Registration Fees (SF 63)		
site. Auditors who fail to meet the annual fee requirements may			
be subject to suspension or withdrawal of registration, as per ARP			
2.7			
3.2. 3 Yearly Application for Re-Certification			
All certified auditors shall be required to renew certification. The	Completed Application form for Re-		
period between certifications (and between initial and renewals)	certification (SF18)		
would normally be 3 years and shall not exceed 3.5 years.	Completed signed Auditor's Code of Conduct		
Applicants for re-certification shall complete and submit the			
applicable application form and a signed Auditor's Code of	Updated CV		
Conduct.			
3.3. Maintenance of Auditing Ability			
Each applicant for re-certification shall maintain an audit log	- · ·		
(SAATCA prescribed format SF26) on which shall be recorded	confirmed SAATCA audit log sheets (SF 26).		
the details of each audit undertaken.			
Note: Audit Logs shall be evaluated 3-yearly by the Evaluation			
Committee.			
3.3.1. Re-Certification audit experience for Auditor and			
Lead Auditor grade	Audit Log sheets: Completed and confirmed		
At least two complete audits (minimum of 6 hours each) per year,	SAATCA audit log sheets (SF 26).		
with a minimum of 6 audit days in total over the re-certification			
cycle. These audits shall be conducted in accordance with ISO			
19011 and ISO/IEC 17021, in the scheme relevant to certification.			
3.3.2. Re-Certification audit experience for Lead Auditor			
grade	Audit Log sheets: Completed and confirmed		
At least one complete audit per year (of the 2 required above),	SAATCA audit log sheets (SF 26).		
acting on the capacity of Lead Auditor, including sole audits.			
3.3.3. Re-Certification audit experience for Internal Auditor			
grade	Audit Log sheets: Completed and confirmed		
	SAATCA audit log sheets (SF 26).		



REQUIREMENT	ADMISSIBLE EVIDENCE					
At least one complete audit (minimum of 6 hours each) per year,						
with a minimum of three audits over the re-certification cycle.						
These audits shall be conducted in accordance with ISO						
19011:2018 and or ISO/IEC 17021-1:2015, in the scheme						
relevant to certification.						
3.3.4. Provisional Auditors						
No specific minimum requirement, but logs of completed audits	If there have been audits completed:					
to be provided annually, with the aim of completing sufficient	Audit Log sheets: Completed and confirmed					
audits over three years to enable upgrade to auditor. This grade	SAATCA audit log sheets (SF 26).					
may be maintained up to 3 years on satisfactory demonstration						
of compliance with the other requirements specified for Internal						
Auditors. After 3 years, the status of Provisional Auditor will be						
reviewed.						
3.3.5. Auditee Feedback						
For at least one of the LMS audits, over the 3-year cycle, auditee	(SF72) Completed positive Auditee Feedback					
feedback shall be obtained and for Lead Auditors, this feedback	Report					
shall be where the re-certifying lead auditor applicant acts as the						
leader of an audit team or as sole auditor.						
3.4. Continual Professional Development (CPD)	Refer to SF 58: Guidelines for CPD					
CPD Requirements						
It is mandatory that each SAATCA certified auditor undertake at	CPD Log:					
least 45 hours of appropriate CPD during each 3-year period	CPD Log (SF27) completed in full and signed					
immediately prior to renewal of certification. At least 8 hours of	off with evidence of professional development,					
CPD per three years shall be obtained from SAATCA Workshops.	properly verified.					
Evidence of that professional development, properly verified,	For guidance on the allowable CPD claims,					
shall be submitted as part of the application for renewal of	refer to the SAATCA CPD Guidelines - SF 58					
certification.						
CPD may be undertaken in areas including:						
• The fields listed under Education; and/or						
 LMS auditing practices or techniques; and/or 						
 LMS management system related and/or 						
 Generic management tools or techniques, and/or 						
 Laboratory risk assessment 						
At least 8 hours of CPD per three-year cycle shall be related to						
updating legal knowledge.						
CPD Logs may be submitted annually with registration fees.						
Note: In the selection of appropriate professional development,						
auditors shall consider their personal strengths and weaknesses						
and identify areas for personal improvement.						
Eand identity areas for personal improvement.	-					

END OF CRITERIA

REVISION HISTORY

			Doc change No.	Conformance
Doc Revision	Approved Date	Amendments		Name
REV 1	20 September 2022	Release	none	W Maluleka