Management System Auditors Criteria

CRT 6. 22 Quality Management System for Medical Devices Auditor

AUTHORIZATION

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Authorized by	SAATCA Scheme Committee
Approved by	SAATCA Board  **Chairman: James Jordaan**
Contact Phone	(012) 349 2763
E-mail	admin@saatca.co.za

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1. INTRODUCTION

1.1. Purpose

This document describes the Quality Management System for Medical Devices (QMSMD) Scheme criteria for SAATCA auditor certification, based on ISO 13485:2016.

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 19011:2018.

1.2. Definitions and Abbreviations

For the purpose of these criteria, the terms and definitions in ISO 13485:2016, ISO 19011:2018, ISO/IEC 17000, ISO/IEC 17021-1:2015, ISO/IEC 17021-3:2017, ISO/IEC 17023:2013 and ISO/IEC 17024:2012 apply.

List of acronyms

QMS: Quality Management System

1.3. References

- ISO 19011: Guidelines for auditing management systems
- ISO/IEC 17024: Conformity Assessment – General Requirements for Bodies operating Certification of Persons
- ISO/IEC 17021-1 Conformity assessment — Requirements for bodies providing audit and certification of management systems
- ISO/IEC 17021-3 Conformity assessment - Requirements for bodies providing audit and certification of management systems - Part 3: Competence requirements for auditing and certification of quality management systems.
- ISO/IEC 17023 Conformity assessment – Guidelines for determining the duration of management systems certification audits.
- IAF Guidance on the Application of ISO/IEC 17024 Conformity assessment – General Requirements for Bodies operating Certification of Persons. (IAF GD 24)
- IAF MD 8 Mandatory Document For Duration of QMS for Medical Devices Audits:
- for Medical Devices for Medical Devices 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 Quality 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 17021-1

There are currently no equivalent standards for ISO/IEC 17021-1 as applicable to QMS auditor registration.

List of Equivalent Standards for ISO 9001

For initial certification the following are considered equivalent to ISO 13485 ~~9001~~:

- ISO TS 16949, Quality management systems — Particular requirements for the application of ISO 9001 for automotive production and relevant service part organizations
- ISO TS 29001, Petroleum, petrochemical and natural gas industries - Sector-specific quality management systems - Requirements for product and service supply organizations
- All requirements' standards listed in the ISO document ISO/TC 176 N881R3, List of ISO 9001 Sector Applications (available from SAATCA or ISO website)
- ISO/IEC 17025: General requirements for the competence of testing and calibration laboratories
- ISO 15189: Medical laboratories -- Particular requirements for quality and competence

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

- ISO 10006: Quality management systems -- Guidelines for quality management in projects
- SANS ARP 063 / IWA 4: Quality management systems - Guidelines for the application of ISO 9001 in local government.
- SANS ARP 082: /IWA 2: Quality Management Systems: Guidelines for the application of ISO 9001 in education
- ISO 10007: Quality 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 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 QMS for Medical Devices 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: **www.saatca.co.za**.

Requirements	Criteria			Submissions
Additional Sector/scope	Refer to SAATCA criteria for specific schemes E.g. 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: Minimum of 4 days, at least 3 separate of which one is a witnessed audit, and one with auditee feedback	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 Feedback
Witnessing	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: Minimum of 5 days, at least 3 separate audits of which one is a witnessed audit and one with auditee feedback	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 Witnessing lead Auditor Report
Training	Lead auditor training (ISO 19011 and ISO 17021-1 based) 5 days – once off Management system standard training. ISO 13485 standard [5days] – prior to lead auditor course Internal Auditor Training (ISO19011 based) 3 days once off Understanding & Implementation training 5 days			Certified copies of training certificates
Work experience	4 years work experience relevant to field (e.g. quality, environment, safety etc.) 2 years relevant to scheme MS standard (e.g. ISO 9001, 13485, 14001, 45001 , ISO 22000, etc). Can be concurrent with the 4 years work experience	5 years work experience relevant to field (e.g. quality, environment, safety etc.) 2 years relevant to scheme MS standard (e.g. ISO 9001, 13485,001, 45001, , ISO 22000, etc). Can be concurrent with the 4 years work experience		CV
Education	Degree/diploma Eg ISO/OHS standard	Degree/diploma equivalent - 4 years work experience relevant to degree/diploma/scheme field		Certified copies of certificates
	Matric or NQF equivalent			

2. INITIAL APPLICATION REQUIREMENTS

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

REQUIREMENT	ADMISSIBLE EVIDENCE
2.4. Work Experience	
2.4.1. General Work Experience **For the initial sector of application:** **Option 1: Where applicants have a degree/ diploma:** For the first sector applicants for all grades shall have completed a minimum of four years of work experience in a role that is Quality for Medical Devices related in a 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. **Option 2: Where applicants do not have a degree/ diploma:** Applicants for all grades shall have completed a minimum of **4** years of work experience as the education equivalent plus five years of work experience in a role that is Quality for Medical Devices related, in a 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 Quality for Medical Devices context or shall demonstrate a satisfactory level of work experience gained within an Quality for Medical Devices context	Verifiable evidence of work experience: Record of employment, eg CV verified by a line manager, through signature of SF51, attesting to technical, professional or managerial experience as well the applicant's involvement in the exercise of judgement, problem solving and communication with other managerial personnel, peers, customers, interested and affected parties and/or authorities. Copy of current and correct CV and Signed sponsor Code of Conduct SF51 (attestation).
Acceptable experience would be where the applicant has acquired 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 the management system applicable to the application. • Full time role relating to the performance of the management system applicable to the application and management of audits of all types (not necessarily management system audits). • Periods of training will <u>not</u> be considered as eligible toward meeting this criterion. **Note**: For auditors applying for a second (and third etc) scheme discipline, - the work experience related to the second (and third, etc) discipline may be concurrent with the work experience in the first scheme/discipline but must be scheme specific.	
2.4.2. Management System Work Experience The applicants shall have at least 2 years relevant Management System e.g. 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.	As for general work experience above
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 achieve the intended results of the audits undertaken.	Various evidence as itemized in the sections following.

REQUIREMENT	ADMISSIBLE EVIDENCE
The following knowledge and skills are generic to all auditors and grades: - Audit principles, procedures and methods - Management system and reference documents - Organizational context - Applicable legal and contractual requirements and other requirements that apply to the auditee. Refer to the next section for scheme specific detail. - Risk management principles, methods	
2.5.2. All auditor grades – scheme and sector specific knowledge and skills	
Quality for Medical Devices related legal and contractual requirements and other Quality for Medical Devices requirements applicable to the audit/auditee product and service Knowledge of Quality for Medical Devices-related law to enable the auditor to work within and be aware of the applicable legislation(s) that applies to the organisation being audited. **Note**: The competence required is not intended to be sufficient to enable the applicant to conduct legal compliance audits. Knowledge of and skills to judge whether an QMS for Medical Devices has been established, is being implemented, maintained and improved in line with the general principles and dictates of applicable law. This requirement entails. • Relevant knowledge of the applicable legal requirements for the location • Quality for Medical Devices aspects of the organization to identify errors or omissions and any deficiencies in the identification of, applicability of and access to legal requirements. • Skills to distil applicable local, regional and national laws as well as international treaties that apply to the auditee • Skills and knowledge in the areas of contracts and agreements that apply to the auditee • Skills to verify conformity to the applicable law	Knowledge of Quality for Medical Devices law is required. Knowledge may be demonstrated by means of either successful completion of course work, or by means of demonstrated case work or work experience. The extent of knowledge of Quality for Medical Devices law is limited to Quality for Medical Devices law that is applicable to the organisation for which certification is applied for. Applicants shall objectively demonstrate their ability to distil legal requirements that apply to specific Quality for Medical Devices aspects. SAATCA may also examine this knowledge by means of an examination, or interview or otherwise.
Quality for Medical Devices management methods, techniques, performance and technology The objective is to enable the auditor to comprehend the fundamental relationships between human activities and the environment and to examine Quality management system for Medical Devices and to generate appropriate audit findings and conclusions. Knowledge and skills in this area to cover as follows (also refer ISO 19011:2018, ISO 17021-1:2015, ISO/IEC 17021-3 and ISO/IEC 17023): Details from ISO 19011: 2011 • terminology relating to quality, management, • sector-specific terminology, • customer focus, customer-related processes, monitoring	Applicants shall objectively demonstrate their knowledge of the requirements. Knowledge may be acquired either by means of education, training, successful completion of course work, or by means of demonstrated case work or work experience. Applicants shall submit a compiled portfolio of evidence such as: • education • case work, • courses attended, • peer review reports • Witness reports (refer below – witnessing

REQUIREMENT	ADMISSIBLE EVIDENCE
and measuring of customer satisfaction, complaints handling, code of conduct, dispute resolution; • leadership – role of top management, managing for the sustained success of an organization – the quality management approach, realizing financial and economic benefits through management of quality, quality 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 quality management systems, quality management systems and other management system focuses, quality management system documentation), types and value, projects, quality plans, configuration management; • continual improvement, innovation and learning; • factual approach to decision making, risk assessment techniques (risk identification, analysis and evaluation), evaluation of quality 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, quality management system requirements and requirements for products, particular requirements for quality management in different sectors. • technical characteristics of processes and products, including services, and • sector-specific processes and practices.	SAATCA may also examine this competence by means of an examination, or interview or otherwise.
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, ISO 17021-1:2015, ISO/IEC 17021-3 and ISO/IEC 17023. • Ability to balance the strengths and weaknesses of the individual audit team members • Ability to develop a harmonious working relationship among the audit team members • Ability to manage the audit process, including	Completed Witnessing Lead Auditor's Report – Lead auditor (SF 45). Also refer below under – Witnessing. Applicant shall objectively demonstrate their knowledge of the requirements.

REQUIREMENT	ADMISSIBLE EVIDENCE
○ 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 ○ providing direction and guidance to auditors-in-training; ○ preventing and resolving conflicts, as necessary • represent the audit team in communications with the person managing the audit programme, audit client and auditee • 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 19011:2018, ISO 17021-1:2015, ISO/IEC 17021-3:2017 and ISO/IEC 17023:2013)	
Successfully completed a SAATCA certified lead auditor course based on ISO 19011, ISO 17021-1:2015, ISO/IEC 17021-3:2017 and ISO/IEC 17023:2013, of at least 5 days training, to auditing principles and practices as follows: ***Audit principles, procedures and techniques***: (ISO19011), 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) - 5 Day Lead Auditor Course based on ISO 19011:2018, ISO 17021-1:2015, ISO/IEC 17021-3:2017 and ISO/IEC 17023:2013. 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 QMS 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.	
2.6.2. Management System Training	
QMS and reference documents Attendance of training equivalent to at least 5 days contact duration on ISO 13485:2016 to ensure: • ISO 13485:2016: Knowledge Management system and reference documents; skills • ISO 13485:2016: Application that includes design, development, documentation, implementation, maintenance, and improvement of an QMS for Medical Devices	Certified copy of certificate of ISO 13485:2016 training. If the certificate is attained less than 5 days, the applicant must write SAATCA exam from the training course before apply to SAATCA.
2.6.3. Quality Specific Technical Training/Knowledge and Skills	
Refer to section above: Quality management methods,	

REQUIREMENT	ADMISSIBLE EVIDENCE
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, ISO 17021-1:2015, ISO/IEC 17021-3:2017: and ISO/IEC 17023:2013 and including all aspects of the scheme specific management system standard or an alternative equivalent 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). • Audits shall be at business units that have their own management structure and carry out the management functions associated with the organization's products, services, activities and facilities. • 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: 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; o 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 o audits where the ratio of applicant auditors to Lead Auditor/s is more than 4:1 o gap analysis; o close out or follow up visits; o audits of any site that are repeated more frequently than once every 12 months, o 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.	
2.7.1. Auditing Experience for Auditor Applicants are required to have participated in at least four complete, successful audits for a total of at least 20 days / 120 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. Details and description of each audit shall be entered onto the SAATCA audit log sheet. Details must include identification of the auditee; sufficient to allow verification of the audit by SAATCA. Relevant experience auditing of other schemes for which the applicant holds registration may be considered for up to 5 days	**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 and by the guiding lead auditor as confirmation of the correctness of the audits. **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).

REQUIREMENT	ADMISSIBLE EVIDENCE
(30 hours) of the auditing experience required. For each audit submitted for certification, the applicant shall either have been conversant with the language used or, alternatively, have effectively used a competent translator during the conduct of the audit. At least one witnessed audit (see below) of the applicant.	SAATCA may also verify the information provided by the applicant. Witnessed audit(s) - refer below **Audit Log sheets**: Refer SF 26
2.7.2. Auditing Experience Lead Auditor Grade In addition to satisfying all the auditing experience requirements for Auditor grade, applicants for Lead Auditor shall have participated as a leader of an audit team which included at least one other auditor, for a further minimum of 3 complete audits of QMS with a total not less than 15 days, of which at least 10 are on site and 5 off-site for planning and reporting. This audit experience additional to that required for Auditor grade must have been gained in the 3-year period prior to application. The above audits shall have been with an audit team size of at least two (including the applicant) on-site where the applicant acted as the team leader and shall have involved the applicant in making a judgement on whether the organisation: o is achieving the policy objectives as stated in the management system; o adheres to its own policies; o achieves Quality performance improvements; o adheres to its own arrangements; o conforms to the objectives and requirements of the QMS 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 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.**	**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 and by the guiding lead auditor as confirmation of the correctness of the audits. **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
2.7.3. Auditing Experience as related to Internal Auditor Grade Applicants for the Internal Auditor grade shall have participated in at least 3 complete internal audits for at least 5 days (30 hours) on site and must have competed all elements of the audit cycle, including: audit planning, documents review, auditing, interviewing, audit reporting. It must not have involved areas or activities of direct responsibility of the applicant. At least one witnessed audit (see below) of the applicant.	**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

REQUIREMENT	ADMISSIBLE EVIDENCE
2.8. Witnessing	Refer to ARP 2.4
2.8.1. 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 19011:2018, ISO 17021-1:2015, ISO/IEC 17021-3:2017 and ISO/IEC 17023:2013). Witnessing shall be carried out to verify all applicable auditing requirements as described in ISO 19011:2018, ISO 17021-1:2015, ISO/IEC 17021-3:2017 and ISO/IEC 17023:2013 during the course of one complete audit, or a number of partial audits, which in total includes all requirements of the management system standard. 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 19011:2018, ISO 17021-1:2015, ISO/IEC 17021-3:2017 and ISO/IEC 17023 . • Possession of the personal behaviours identified in ISO 19011:2018, ISO 17021-1:2015, ISO/IEC 17021-3:2017 and ISO/IEC 17023:2013 and any additional scheme specific behaviors. The Witnessing Lead Auditor shall complete a SAATCA Auditing Performance Report attesting to the satisfactory performance and behaviours of the applicant. Witnessing may involve more than one audit and more than one Witnessing Lead Auditor. Witnessing shall be carried out by a SAATCA QMS for Medical Devices 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.	Completed Witnessing Lead Auditor (s) report (s) for Auditors and Internal Auditors (SF 45) 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. 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.
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, ISO 17021-1:2015, ISO/IEC 17021-3:2017 and ISO/IEC 17023:2013. 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

REQUIREMENT	ADMISSIBLE EVIDENCE
	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. 4. If CM is suspicious of witnessing it will be forwarded to the Impartiality committee for review.

2.9. Training for Internal Auditor	
2.9.1. Internal Auditor Training (19011:2018)	
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***: (ISO 19011:2018), 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 QMS 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	
QMS for Medical Devices **and reference documents** Attendance of training equivalent to at least 5 days contact duration on ISO 13485:2016 to ensure: • ISO 13485:2016 Knowledge Management system and reference documents; skills • ISO 13485:2016 Application that includes design, development, documentation, implementation, maintenance and improvement of an QMS for Medical Devices • Risk based thinking and auditing	Certified copy of certificate of ISO 13485:2016 training. 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 19011:2018). 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. 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 19011:2018. • Possession of the personal behaviours identified in ISO 19011 and any additional scheme specific behaviors.	Completed Witnessing Lead Auditor (s) report (s) for Internal Auditors (SF 45) 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. 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**

The Witnessing Lead Auditor shall complete a SAATCA Auditing Performance Report attesting to the satisfactory performance and behaviours of the applicant. Witnessing may involve more than one audit and more than one Witnessing Lead Auditor. Witnessing shall be carried out by a SAATCA QMS for Medical Devices 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) the witnessing report. Responsibility for submission of a completed report and the signed Witnessing Lead Auditor(s)' Code of Conduct remains with the applicant.	**period of two years.** ***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*** 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.
2.9.5. 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 Audit Performance Report (witnessing SF45) and 3 audit feedback reports (SF72) from the audited organizations. b) Auditor: Minimum of 20 days audit logs (SF26), 4 separate audit logs (SF26) from different organizations, 1 Audit Performance Report (Witnessing - SF45) and 4 feedback reports (SF72) from the audited organizations c) Lead Auditor: Minimum of 15 days audit logs, (SF26), 4 separate audit logs (SF26) from different organizations, 1 Audit Performance Report *(Witnessing - SF45) and 4 feedback reports (SF72) from the audited organizations	**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 Audit Performance Report (SF45) Sign-off of fully completed audit log sheets as confirmation by the applicant of the authenticity of the logs. The guiding lead auditor must signed the last column of SF26 as confirmation of the correctness of the audits. Furthermore a guiding lead auditor cannot sign the witnessing report and witnessing code of conduct. ***NB: A guiding lead auditor is different from a witnessing lead auditor.*** **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 Witnessing Lead Auditor's report for Lead Auditors (SF45) 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.

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. (The details from this form are captured onto the SAATCA database).	Completed Application for Annual Re-registration (SF76) or information update form.
3.1.2. **Annual submission of Audit Log** (CPD logs and Auditee feedback may also be submitted annually but are mandatory for the 3 year certification). Refer below for details of audit and CPD requirements. ***Note:*** Audit Logs and CPD Logs (where CPD had taken place) shall be submitted annually with registration fees, and recorded by SAATCA certification as the annual surveillance. (These will be evaluated 3-yearly by the Evaluation Committee.)	**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**. (Refer SF 72). **CPD Log:** refer CPD Log (SF27) SAATCA may also verify the information provided by the applicant.
3.1.3. **An annual registration fee** (subscription) is payable to SAATCA. The SAATCA Board of Directors determines registration fees on an annual basis, and these are published on the SAATCA web site. Auditors who fail to meet the annual fee requirements may be subject to suspension or withdrawal of registration, as per ARP 2.7	Payment of fees as per the prevailing SAATCA fee structure - Personnel Registration Fees (SF 63)
3.2. 3 Yearly Application for Re-Certification	
All certified auditors shall be required to renew certification. The period between certifications (and between initial and renewals) would normally be 3 years and shall not exceed 3.5 years. Applicants for re-certification shall complete and submit the applicable application form and a signed Auditor's Code of Conduct.	Completed Application form for Re-certification (SF18) Completed signed Auditor's Code of Conduct (SF 29) Updated CV
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 the details of each audit undertaken. ***Note***: Audit Logs shall be evaluated 3-yearly by the Evaluation Committee.	**Audit Log sheets**: Completed in full and confirmed SAATCA audit log sheets (SF 26).
3.3.1. Re-Certification audit experience for Auditor and Lead Auditor grade At least two complete audits (minimum of 6 hours each) per year, with a minimum of 6 audit days in total over the re-certification cycle. These audits shall be conducted in accordance with ISO 19011:2018, ISO 17021-1:2015, ISO/IEC 17021-3:2017 and ISO/IEC 17023:2013, in the scheme relevant to certification.	**Audit Log sheets**: Completed and confirmed SAATCA audit log sheets (SF 26). .
3.3.2. Re-Certification audit experience for Lead Auditor grade At least one complete audit per year (of the 2 required above), acting on the capacity of Lead Auditor, including sole audits.	**Audit Log sheets**: Completed and confirmed SAATCA audit log sheets (SF 26).
3.3.3. Re-Certification audit experience for Internal Auditor	

REQUIREMENT	ADMISSIBLE EVIDENCE
grade 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, ISO 17021-1:2015, ISO/IEC 17021-3:2017 and ISO/IEC 17023:2013 , in the scheme relevant to certification.	**Audit Log sheets**: Completed and confirmed SAATCA audit log sheets (SF 26).
3.3.4. Provisional Auditors No specific minimum requirement, but logs of completed audits to be provided annually, with the aim of completing sufficient audits over three years to enable upgrade to auditor. This grade 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.	**If there have been audits completed:** **Audit Log sheets**: Completed and confirmed SAATCA audit log sheets (SF 26).
3.3.5. Auditee Feedback For at least one of the QMS audits, over the 3-year cycle, auditee feedback shall be obtained and for Lead Auditors, this feedback shall be where the re-certifying lead auditor applicant acts as the leader of an audit team or as sole auditor.	(SF72) Completed positive Auditee Feedback Report
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 least 45 hours of appropriate CPD during each 3-year period immediately prior to renewal of certification. At least 8 hours of CPD per three years shall be obtained from SAATCA Workshops. Evidence of that professional development, properly verified, shall be submitted as part of the application for renewal of certification. CPD may be undertaken in areas including: o The fields listed under Education; and/or o QMS auditing practices or techniques; and/or o QMS management system related and/or o Generic management tools or techniques, and/or o Quality 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.	**CPD Log:** CPD Log (SF27) completed in full and signed off with evidence of professional development, properly verified. For guidance on the allowable CPD claims, refer to the SAATCA CPD Guidelines - SF 58
3.5. Changes to these criteria and transition	
Clarifications - effective immediately on publication • Management system training – clarified the pre-requisite training on the applicable management system standard prior to the 5-day Lead Auditor Course. • Auditing experience for new applicants - the ratio of applicant auditors to Lead Auditors as 4:1 for qualifying audits. • Sponsorship – change from 2 sponsors to 1.	Training certificates Audit log (SF26) Application form (SF79 or SF68)

END OF CRITERIA

4. REVISION HISTORY

Doc Revision	Approved Date	Amendments	Doc change No.	Conformance
				Name
REV 1	-	Release	none	MO Khoza
REV 2	20 September 2022	Change 3 days understanding and implementation training to 5 days Witnessing Lead Auditor to be appointed by SAATCA not by Auditors Auditors to attend CPD workshop once in three years to maintain SAATCA registration. Add ISO/IEC 17021-1:2015	DC10309	W Maluleka