

TR 91-02

CRITERIA FOR CERTIFICATION BODY ACCREDITATION IN THE SCOPE OF MEDICAL DEVICE QUALITY MANAGEMENT SYSTEMS (ISO 13485)

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1. Purpose and Scope

This document sets out the accreditation criteria for bodies seeking accreditation by the South African National Accreditation System (SANAS), to audit and certify organizations for Medical Devices Quality Management Systems in line with ISO 13485. Certification Bodies (CB's) seeking accreditation to Medical Devices Management System (MDQMS) certification services will be required to satisfy the requirements of ISO/IEC 17021-1, IAF MD9 and the requirements specified in this Technical Requirement document.

2. References and Definitions

The following references apply to this document. The current version of these documents can be downloaded from the SANAS website or that of the relevant organisation stated below:

SANAS A 01	References, Acronyms and Definitions
SANAS PM 01	SANAS Policy Manual
SANAS P 05	The Assessment of Certification Bodies
ISO/IEC 17021-1	Conformity assessment - Requirements for bodies providing Audit and certification of managements systems: Part 1- Requirements.
IAF MD 1	IAF Mandatory Document for the Audit and Certification of a Management System Operated by a Multi-Site Organization
IAF MD 2	IAF Mandatory Document for the Transfer of Accredited Certification of Management Systems
IAF MD 4	IAF Mandatory Document for the Use of Information and Communication Technology (ICT) for Auditing/Assessment Purposes
ISO 19011	Guidelines for auditing management systems
IAF MD 8	Application of ISO/IEC 17011 in the field of Medical Device Quality Management Systems (ISO 13485)
IAF MD 9	Application of ISO/IEC 17021-1 in the field of Medical Device Quality Management Systems (ISO 13485)
ISO 13485	Medical Devices – Quality Management Systems – Requirements for regulatory purposes
ISO 14971	Medical Devices – Application of risk management to medical devices
IAF MD 5	Determination of Audit time of quality, environmental, and occupational health and safety management systems
IAF MD 11	Application of ISO/IEC 17021 for audits of Integrated Management Systems Applicable legislation

Medicines and Related Substances Act (Act No 101 of 1965 as amended)
Hazardous Substances Act (Act No 15 of 1973).

3. Specific Requirements for Accreditation Assessments

3.1 Office Client File Reviews

The following provisions shall be applied during file reviews:

- 3.1.1 At least one complete client file or a complete certification record must be available for review during the initial assessment. The CB shall have established criteria to describe the technical competence applicable to each technical area as referenced in IAF MD9.
- 3.1.2 For surveillance assessment and re-assessments, at least one (1) client file per technical area must be available for review. The size of the assessment will depend on the scope of accreditation and the historical competence of the CB over a 3-year accreditation cycle.

3.2 Witness Assessment activities

The aim of the witnessing performed by SANAS is to verify that the CB has implemented the procedures on site (at the CB's client) and to verify that the CB covers all the necessary certification scheme requirements and that the auditors used by the CB are appropriately qualified, competent and able to verify the requirements of relevant regulations. The witnessing report shall be completed in full on the relevant SANAS checklist (e.g. F146) and must include an accurate account of the activities witnessed. It may be necessary for the SANAS assessor to witness more than one auditor during a witnessing assessment. When selecting witness activities for initial or re-assessments, it is preferable that witnessed audits planned by the CB cover the highest requirements as regards the competence of the selected client and are for initial or re-certification audits in order that the full process can be evaluated by the SANAS assessor. At times surveillance audits as well as clients with multisite may be witnessed. It is the responsibility of the CB to ensure that SANAS is given the necessary access to perform the witnessing. The following shall apply for witnessing activities.

- 3.2.1 At least two weeks before the witnessing activity, SANAS shall be provided with the following documentation at the minimum:
 - A copy of the client's certificate if a surveillance, follow-up audit (however, named) or a recertification audit is scheduled for witnessing,
 - An audit plan, detailing the objectives of the conformity assessment activity,
 - Information on any special requirements such as safety, dress code, security clearance etc,
 - A copy of the selected auditor's CV and a competency assessment report two weeks prior to the audit; and any other additional information that SANAS may deem necessary for the preparation of the witness assessment,
 - An audit report after witnessing activities within two weeks after which SANAS shall issue a witnessing report to the CB within two weeks.
- 3.2.2 The appointed SANAS Assessor shall clarify his/her role as an Observer to the CB Auditors and shall not involve themselves directly in the audit proceedings or inconvenience the CB's client in any way. However, the assessor must be allowed to ask questions for clarification purposes during the team's interim meetings to ensure a clear understanding of the audit process taking place and find out if there are any

adjustments to the audit plan. It is expected that the SANAS Assessor will be provided with access to the client's documentation that the CB reviews as part of its evaluation. Any documentation reviewed by the CB during the audit proceedings should be made available to the SANAS Assessor to review upon request.

- 3.2.3 If it happens that the SANAS Assessor observes a non-conformance in the CB's client's operations which is not reported by the audit team, the SANAS Assessor shall record this on the F03 and inform the team about such findings during the post witness feedback session rather than in front of the CB's client. The only exception is when the SANAS Assessor observes a practice that presents an immediate risk to health and safety for all involved. In such cases the SANAS Assessor has a duty of care to report the issue without delay.
- 3.2.4 All activities of the CB's audit should be witnessed, including the opening and closing meetings, unless directed otherwise by the SANAS Accreditation Manager. The SANAS Assessor shall hold a closing meeting with the representatives from the CB as soon as practicable after the CB's closing meeting with their client. The Assessor should provide clear findings to the CB in a form of a recommendation report, SANAS F226 "*Outcome of Certification Witnessing's*" and F03. It may be necessary to revise or refine the findings following further discussion with the certification body after the witnessing has finished. Where it is not possible to conduct this meeting at the end of the witnessing activity, it may be conducted after the witnessed assessment by additional meeting.
- 3.2.5 The CB is to ensure that SANAS receives corrective actions for the nonconformances raised within stipulated timeframes.
- 3.2.6 After the initial assessment and the CB having been accredited, SANAS disperses the witnessing activities throughout the 3-year cycle, with full coverage of all accredited schemes to be achieved in two successive accreditation cycles.
- 3.2.7 All annual witnessing's for maintenance of accreditation shall preferably be conducted before the office assessments. The AM can reduce the number of witnessing activities to a minimum of one per certification scheme based on the history of the CB, the number of certifications performed and the confidence because of consistent demonstrated competence.
- 3.2.8 The CB shall, upon request by SANAS, provide a schedule of audits planned to take place in a certain period to facilitate informed selection of audits for witnessing purposes.

3.3 Scope Extensions

The following assessment methods are used in case of an application for an additional scope extension:

- 3.3.1 Desk-review of documents and records (*Method 1*);
- 3.3.2 A visit to the office of the CB for file reviews and to verify documents and records and to interview relevant staff, especially in the case of multiple scopes applied for extensions (*Method 2*);

3.3.3 A witness assessment (*Method 3*).

As a minimum, the defined competence requirements in the technical area, records of the qualification process for auditors for that sector, and a complete client file in that sector will be verified in a scope extension assessment. Normally, methods 1 or 3 will be applied for 1 or 2 technical sectors falling within the main technical area that is already accredited. In case of multiple sectors, method 2 will be utilised. In case of multiple sectors in various technical areas, method 2 and 3 will be used in a complementary manner. In case of a new technical area altogether for which the CB is not accredited, a witness assessment shall be conducted.

4. Accreditation Scopes

The certification of Medical Devices and In Vitro Diagnostics will be based on ISO/IEC 13485. The accreditation scope shall be as contained in the IAF MD 8 Application of ISO/IEC 17021-1 in Medical Device Quality Management Systems (ISO 13485). Annex 1.

ADDENDUM 1: Amendment Record

Proposed By:	Section	Change
AM	All	Complete re-write of entire document