1. Scope

This document sets out the accreditation criteria for bodies seeking accreditation by NACI 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

- 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
- NACI-P10
- NACI-G05
- Legal requirement and regulatory of IMED

3. Specific Requirements for Accreditation Assessments

3.1 Office Client File Reviews

The following provisions shall be applied during file reviews:

i. 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.

ii. 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 NACI 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 NACI checklist and must include an accurate account of the activities witnessed. It may be necessary for the NACI 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 NACI assessor. At times surveillance audits as well as clients with multisite may be witnessed. It is the responsibility of the CB to ensure that NACI is given the necessary access to perform the witnessing. The following shall apply for witnessing activities. (Refer to NACI-W04)

3.2.1 At least two weeks before the witnessing activity, NACI shall be provided with the following documentation at the minimum:

3.2.1.1 A copy of the client's certificate if a surveillance, follow-up audit (however, named) or a recertification audit is scheduled for witnessing,

3.2.1.2 An audit plan, detailing the objectives of the conformity assessment activity,

3.2.1.3 Information on any special requirements such as safety, dress code, security clearance etc,

3.2.1.4 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 NACI may deem necessary for the preparation of the witness assessment,

3.2.1.5 An audit report after witnessing activities within two weeks after which NACI shall issue a witnessing report to the CB within two weeks.

3.2.2 The appointed NACI 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 NACI 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 NACI Assessor to review upon request.

3.2.3 If it happens that the NACI Assessor observes a non-conformance in the CB's client's operations which is not reported by the audit team, the NACI Assessor shall record this on the NACI-F150 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 NACI Assessor observes a practice that presents an immediate risk to health and safety for all involved. In such cases the NACI Assessor has a duty of care to report the issue without delay.

3.2.4 The CB is to ensure that NACI receives corrective actions for the nonconformances raised within stipulated timeframes.

3.2.5 After the initial assessment and the CB having been accredited, NACI disperses the witnessing activities throughout the 3-year cycle, with full coverage of all accredited schemes to be achieved in two successive accreditation cycles.

3.2.6 All annual witnessing's for maintenance of accreditation shall preferably be conducted before the office assessments.

4 Accreditation Scopes

The certification of Medical Devices 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.