1 Scope

This document describes the procedure of mdc for the Audit and **certification of Management System Operated by a Multi-Site Organization.** When using this procedure, this document together with the procedure description "Certification of QM systems" becomes part of the general terms and conditions of mdc.

A contractual relationship between the applicant and mdc does exist.

In case sites are separate legal entities, contractual arrangements shall be in place between the applicant (headquarter) and the sites. These contractual arrangements shall be submitted to mdc for the application review.

New mdc customers (initial certification, takeovers) with non-independent sites (e.g. not listed in the applicant's commercial register shall submit alternative evidence of the site's official registration for the application review; e.g. a business registration (Germany) or, if not available, a tenancy agreement or similar.

The following requirements are derived from IAF MD 1:2023 - "Mandatory IAF document for auditing and certification of management systems in multi-site organizations"

Organizations with several locations to which this procedure can be applied are characterized by the fact that:

- a single management system is in place
- a central function is designated.
- identify its central function. The central function is part of the organization and shall not be subcontracted to an external organization
- the central function shall have organizational authority to define, establish and maintain the single management system
- the organization's only management system is subject to a central management review
- all sites are subject to the organization's internal audit program

2 Description of the process phases

2.1 Preparation phase

With the help of a questionnaire and, if necessary other customer documents and interviews, the certification body specifies the suitability of the applicant for the certification of QM systems for organizations with several locations.

Prior to the assessment phase by mdc, an internal audit which demonstrates extensive compliance with the certification standard and other relevant regulations, shall been carried out by the organization. The documentation of the internal audit with the corresponding analyses can be requested by mdc in advance of the declaration of suitability for the assessment procedure. The organization shall be able to collect and analyze data from all sites and initiate changes of these. Furthermore, a system for handling complaints shall be established, including the definition of corrective actions; the documentation on the above requirements may be included in the suitability survey by mdc.

The fulfilment of the above criteria shall be checked in advance, as any deficiencies in this respect could lead to the assessment being cancelled.

In case not all planned sites are ready to undergo certification at the same time, the client is obliged to name in advance the sites that are to be included in the assessment and the certificate.

2.2 Assessment Phase

2.2.1 Review of documentation

By reviewing the QM documentation and any other necessary documents, it is determined whether the criteria listed under point 1 apply and have been implemented in the documentation.

In particular, the planning, monitoring and management of the activities of the QM system by the designated headquarter and the QM representative, including his right of intervention, shall be mapped for all locations.

2.2.2 Audit

The certification audit starts at the headquarter which shall be audited every year. The other locations are selected using one of the IAF MD 1:2018 methods, depending on the organization's activities at respective sites and the results of the internal audits.

Method 1, the so-called "sampling procedure", can be used for locations that carry out very similar processes/activities. The selection of the sites to be audited can be made after the headquarter has been audited. At least 25% of the samples should be selected randomly. The selection of the remaining samples shall ensure that all processes included in the scope of certification are audited, taking into account the greatest differences between individual sites.

The samples are selected on the basis of the following criteria:

- the results of internal audits at the sites and management reviews or previous certification audits
- records of complaints and other relevant aspects of corrective and preventive actions,
- significant variations in the size of the sites
- any variations in shift models and working procedures,
- the complexity of the management system and the processes conducted at the different sites,
- any modifications since the last certification audit,
- the maturity of the management system and the knowledge of the organization,
- any existing differences in culture, language and legal regulations
- the geographical localization of the sites
- status of the locations (permanent, temporary or virtual locations)

In case important criteria that are a prerequisite for the random sample audit are not met, the audit may not be continued. Overall, the audit shall demonstrate that all applicable standard requirements in the QM system have been implemented comprehensively and are effective.

The QM system shall ensure that any non-conformities identified are investigated to determine whether other sites are also affected and shall include all affected sites in corrective actions. In case one site has a non-conformity, certification will be refused to the entire organization until satisfactory corrective actions have been implemented. A subsequent "exclusion" of affected sites from the scope of certification is not possible.

If necessary, the certification body can increase the frequency of samples until it is satisfied that control has been demonstrably re-established.

In addition, the size or frequency of sampling is adjusted in case relevant aspects become apparent, e.g. with regard to:

- size of sites and number of employees,
- complexity or risk level of the activities and the management system,
- variations in work practices (e.g. shift work),
- variations in executed processes/activities,

- records of complaints and other relevant aspects of corrective and preventive actions,
- multinational aspects,
- results of internal audits and management reviews

In case more than one auditor (audit team) is assigned, the certification body appoints a lead auditor who summarizes all findings and prepares a summary report and assesses whether the quality management system regulates and implements the activities at all locations.

In case the conditions for method 1 are not met, e.g. the processes/activities at the locations are too different, method 2 can be used in accordance with the requirements of IAF MD 1:2018; in this case the number of locations to be audited in each procedure is higher than for method 1.

In case the processes/activities in an organization are similar for not all but only some of the sites, a combination of method 1 and method 2 is possible and is presented as method 3.

For procedures in accordance with EN ISO 13485, sampling is not possible for sites involved in the planning, development and manufacture of medical devices in accordance with IAF MD9.

The on-site audit time for the respective method is calculated in accordance with the applicable IAF regulations (e.g. IAF MD 1, IAF MD 5, IAF MD 9) and further specifications by mdc.

2.3 Certification phase

A single certificate is with name and address of the applicant is issued. Sites involved in the certification process are listed in an annex to the certificate.

The certificate or the associated annex indicates the respective activities carried out by the individual sites. In case the scope of certification of individual sites is only issued for a part of the overall scope of the organization, this restriction is stated clearly on the certificate or the annex.

For each site an individual site certificate can be issued in case the scope or a part of it is identical. The validity of Site certificates is referenced in conjunction with the organization's certificate.

The certificate will be withdrawn entirely, in case the headquarter or on of the sites no longer fulfils the necessary criteria.

To ensure the constant actuality of the in the annex of the certificate listed sites, the client is obligated to inform the certification body about any site closures.

Failure of informing the certification body is interpreted as misuse of the certificate and will result in corresponding actions.

Additional locations can be added to a certificate in the course of surveillance or reassessment. The certification body shall be notified in a timely manner. A corresponding offer is to be prepared.

2.4 Surveillance phase

The procedure to determine the site audit as part of the surveillance audit is also defined by the method selected in each case.

The head quarter shall be audited in every procedure, regardless of the method selected.

The sites to be audited can be selected after the head quarter has been audited.

In case new locations are added, ensuring their suitability for inclusion in the process is required. If necessary, the corresponding sample size is required.

2.5 Recertification

The procedure is equal as for initial certification. According to IAF MD 1, generally, the effort required is less than for initial certification.