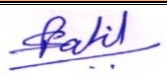
**DI Quality Certification Services Private Limited** *(hereinafter referred as DI QCS)*

**"Special Audits"**

*(Clause 9.6.4 of ISO/IEC 17021-1: 2015)*

| Process Description | Designation | Name | Signature |
|---|---|---|---|
| **Prepared by** | Executive Operations | Smita Patil |  |
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| **Issued & Controlled by** | Document Controller | Jaya Yadav |  |

## Revision History

| Sr. No. | REVISION NO. | CRN NO. | EFFECTIVE DATE | REASON FOR CHANGE | AUTHORIZED BY |
|---|---|---|---|---|---|
| **1** | 00 | Not Applicable | 15-02-2022 | Initial Release | Document Controller |
| **2** | 01 | CRN/22/02 | 17-08-2022 | -Section 2 ISO 9001 reference added<br>-Section 7 Audit report_ ISO 9001 added | Document Controller |
| **3** | 02 | CRN/24/02 | 27-06-2024 | -Section 6.4 included as per IAF MD 9 MD 9.6.4.2 requirement | Document Controller |
| **4** | 03 | CRN/24/04 | 26-08-2024 | The document is updated for revised Roles & Responsibility of Director, Technical & Operations head | Document Controller |
| **5** | 04 | CRN/24/05 | 05-09-2024 | DI QCS new logo updated | Document Controller |

## 1. Purpose

To document a procedure for conducting Special audits.

## 2. Scope

This procedure is applicable for ISO 9001 & ISO 13485 Management system certification schemes.

## 3. Responsibility

**3.1** Operations Head
**3.2** Programme Manager
**3.3** Auditors

## 4. Definitions/Abbreviations

**4.1** Audit duration:
Time needed to plan and accomplish a complete and effective audit of the client organization's management system.

**4.2** Duration of management system certification audits:
Part of audit duration spent conducting audit activities from the opening meeting to the closing meeting, inclusive.

**4.3** Audit day:
The duration of an audit day is normally 8 hours. As per DI QCS's norms, it does not include a lunch break and travel time.

**4.4** Client organization:
Entity or defined part of an entity operating a management system.

Refer 'D-MMS-G-0001 Definitions' for any further definitions.

## 5. References

**5.1** ISO/IEC 17021-1: 2015 Conformity assessment — Requirements for bodies providing audit and certification of management systems — Part 1: Requirements

## 6. Procedure

**6.1 Expanding Scope:**

**6.1.1** Certified client can apply for expanding the scope of certification already granted.

**6.1.2** DI QCS shall undertake application review to decide whether or not the expansion granted and if any audit activities are necessary.

**6.1.3** This type of audit can be conducted in conjunction with surveillance or recertification audit or a special audit for expanding scope can be conducted.

**6.1.4** In case client wants a separate scope extension audit, DI QCS receives the details of scope extension, provides and fulfils the commercial obligations and obtains a date confirmation. On receipt of date confirmation, technical area and man-days are ascertained as per Man day Calculation guideline (D-MMS-S-0010)

### 6.2 Short-notice audits:

**6.2.1** It may be necessary to conduct audits of certified clients at short notice to investigate complaints, or in response to changes, or as follow up on suspended clients.

In such cases:

a) DI QCS has described (MMS registration procedure) and makes known in advance to the certified clients the conditions under which such audits will be conducted;

b) Additional care shall be exercised in the assignment of the audit team because of the lack of opportunity for the client to object to audit team members. Experience auditors shall be appointed for such assignments.

### 6.3 Unannounced audits:

**6.3.1** An unannounced will be conducted at certified client's premises without prior information.

Examples in which an unannounced audit can be conducted:

a) DI QCS receives an intimation from accreditation body or regulatory body.

b) Occurrence of an incident where serious injury to user health or loss of life has happened due to use of product which is under scope of certified QMS.

### 6.4 Short notice or unannounced audits may be required when:

**6.4.1** external factors apply such as:

6.4.1.1 Devices in scope of certification indicate a possible significant deficiency in the quality management system. Available post-market surveillance data information reviewed by DI QCS on the subject devices indicate a possible significant deficiency in the quality management system

6.4.1.2 DI QCS is made aware of significant safety and performance related information

6.4.1.3 Significant changes occur which have been submitted as required by the regulations or become known to DI QCS, and which could affect the decision on the client's state of compliance with the regulatory requirements. The following are examples of such changes which could be significant and relevant when considering that a special audit is required, although none of these changes should automatically trigger a special audit:

**6.4.1.3.1 QMS – impact and changes:**

a. new ownership

b. extension to manufacturing and/or design control

c. new facility, site change : modification of the site operation involved in the manufacturing activity (e.g. relocation of the manufacturing operation to a new or centralizing the design and/or development functions for several manufacturing sites)

d. new processes, process changes: significant modifications to special processes (e.g. change in production from sterilization through a supplier to an on-site facilor a change in the method of sterilization)
e. QM management, personnel: modifications to the defined authority of the management representative that impact:

- quality management system effectiveness or regulatory compliance

- the capability and authority to assure that only safe and effective medical devices are released

**6.4.2 Product related changes:**

a. new products, categories
b. addition of a new device category to the manufacturing scope within the quality management system (e.g. addition of sterile single use dialysis sets to an existing scope limited to haemodialysis equipment, or the addition of magnetic resonance imaging to an existing scope limited to ultrasound equipment)

**6.4.3 QMS & Product related changes:**

a. changes in standards, regulations
b. post market surveillance, vigilance

An unannounced or short-notice audit may also be necessary if the DI QCS has justifiable concerns about implementation of corrective actions or compliance with standard and regulatory requirements.

## 6.5 Special Audits relating to Issuance of major nonconformity:

**6.5.1** Based on nature of non-conformity, the special assessment may be conducted as an onsite audit or with Programme Manager approval as an off-site evaluation.

**6.5.2** If the root cause of major non-conformity affects only QMS documentation, off-site assessment can be conducted with permission from Programme Manager.

**6.5.3** If the root cause of major non-conformity directly affects changes in product/process, the assessment shall be conducted as on-site audit.

**6.5.4** Quotation of special audit shall be prepared based on extent of audit. Upon client acceptance, the special assessment can be conducted. If the client refuses to accept the quotation, Programme Manager shall be notified and the registration suspensions process shall be initiated.

**6.5.5** Special assessment letter is sent to the client by the Programme Manager for informing them of the special assessment and the number of days required. Where the special assessment is to be done as an onsite audit, the Program Manager shall contact the client and arrange the onsite assessment with 90 days of the last day of the audit where the major nonconformity was issued.

**6.5.6** Offsite desktop assessments shall also be scheduled 90 days of the last day of the audit where the major nonconformity was issued.

### 6.6 Special Audits relating to complaints:

**6.6.1** Depending on the outcome of the review of the complaint the special audit may be conducted onsite or offsite.

**6.6.2** If the audit is to be conducted onsite it should be conducted as soon as possible.

**6.6.3** Where the audit is to be conducted less than 3 weeks from the notification to audit, the Program Manager shall try where possible to schedule auditors who have visited the client previously as there may be insufficient time for the auditee to object to the auditor, or request information on an auditor's background.

**6.6.4** If the client refuses to accept the increased cost, the Programme Manager shall be notified and the registration suspensions process shall be initiated.

**6.7** A special audit shall not count towards any continuous or recertification assessment and the regular audit schedule shall recommence after successful completion of the special audit.

**6.8 The audit shall be conducted as per 'D-MMS-S-0011 Preparing and Conducting Audits**

**6.9 Refer 'D-MMS-S-0010 Man-day calculation guideline' for man days required for special audits.**

## 7. Associated Procedures/Documents/Formats

**7.1** D-MMS-S-0010 Man-day calculation guideline

**7.2** D-MMS-S-0011 Preparing and Conducting Audits

**7.3** F-0011-01 Audit Plan

**7.4** F-0011-02 Attendance Sheet

**7.5** F-0011-03 Audit Report template_ ISO 13485

**7.6** F-0011-04 Non-conformity Report

**7.7** F-0011-05 Audit Report template_ ISO 9001