Document Title:		
Informative Guide		
Revision No: *11*	**Date:** *25-08-2020*	
Document No: ZQAPL/MSCD001/D-10	**Prepared By:** MR	**Approved By:** Director Operations

1. INTRODUCTION

The sections of this Code of Practice have been formulated to provide a comprehensive guidance to the applicant and / or certified client to know ZQAPL-MSCD001 policies and deal in accordance with the policies.

These policies are in accordance with our accreditation body/s requirements, published to date.

2. SCOPE

ZQAPL-MSCD001 provides independent certification service for organizations operating various Management Systems complying with the requirements of the International Standards, e.g.

- ISO 9001 Quality Management System
- ISO 13485 Medical Devices – Quality Management System
- ICMED 9000 - ISO 9001 requirements plus additional requirements specified under ICMED Scheme
- ICMED 13485 - ISO 13485 requirements plus additional requirements specified under ICMED Scheme

3. LEGAL STATUS

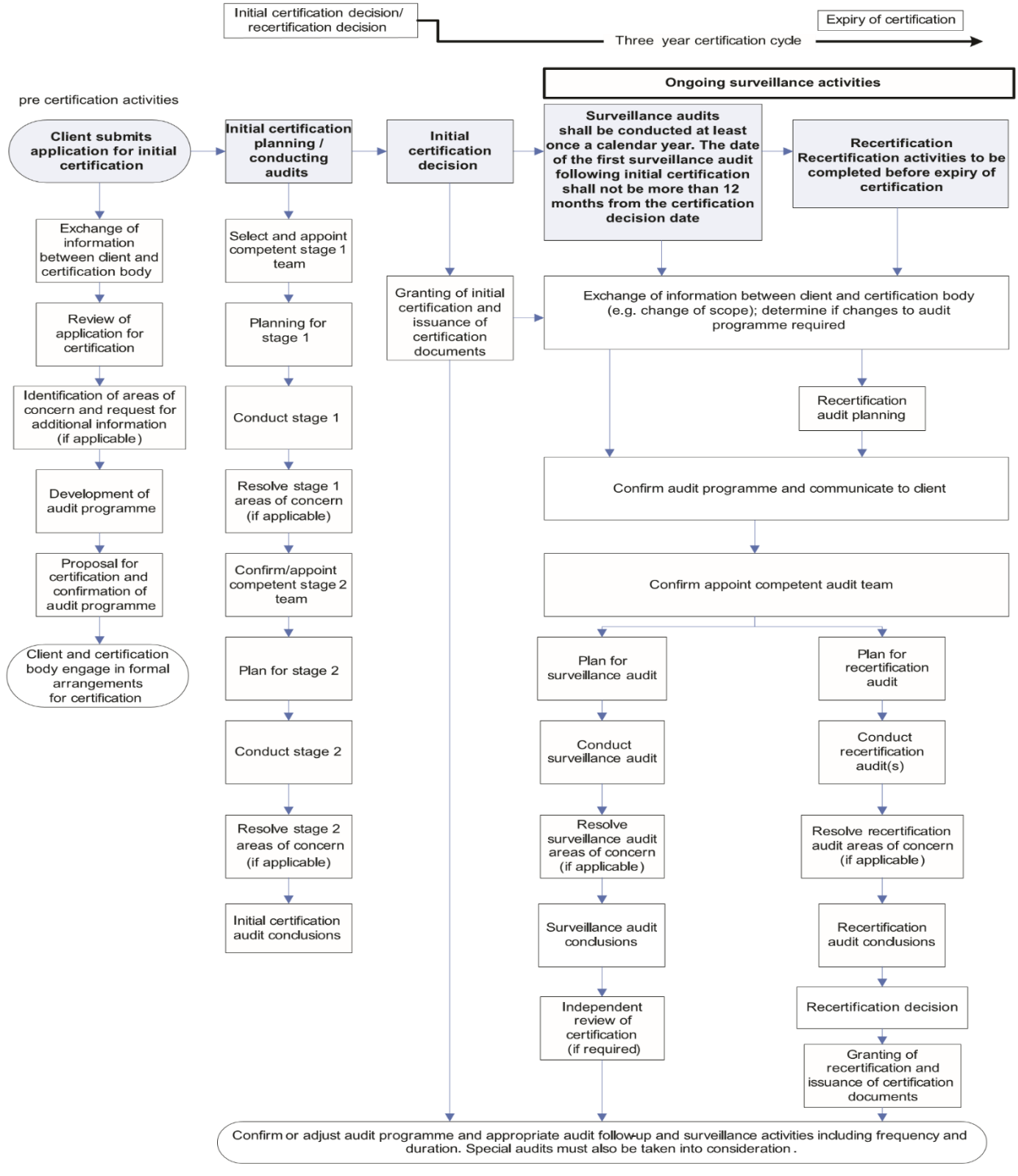
ZQAPL-MSCD001 is an internal business division of Zenith Quality Assessors Pvt. Ltd.
ZQAPL is legally responsible for all audit and certification services conducted by ZQAPL-MSCD001
ZQAPL is legally responsible by the main objects of the company to be pursued by the company on its incorporation and as described in "Memorandum of Association" dated 20th December 2005.
Zenith Quality Assessors Pvt. Ltd. which was incorporated on 14th October 2005 in Pune, Maharashtra, India under the Companies Act, 1956 (No. 1 of 1956).

- Certificate of Incorporation No. : CIN U 74 999 PN 2005 PTC 021411.
- PAN No. : AAACZ2426L
- Good and Service Tax No. : *27AAACZ2426L1Z4*

Additional specific requirements as per ICMED 9000 & ICMED 13485 are either highlighted in Blue or placed in Blue Text Box.

4. AUDIT & CERTIFICATION PROCESS

Following is the typical process flow for audit & certification processes (ISO 9001 / ISO 13485 / ICMED 9000 / ICMED 13485):



Additional specific requirements as per ICMED 9000 & ICMED 13485 are either highlighted in Blue or placed in Blue Text Box.

5. GENERAL CONDITIONS FOR CERTIFICATION

- The applicant shall make available to the Audit team all information required to establish the status of the management system.
- ZQAPL-MSCD001 approves the certification as per the applicant defined scope only if the applicant's documented management system conforms to applicable standard/s.
- The approval is also subject to, that there is no major discrepancy arising out of the audit and/or suitable corrective action has been applied and evidenced.
- Where the applicant cannot show that effective corrective action has occurred within the specified time limit, it may be necessary for ZQAPL-MSCD001 to conduct a further additional audit of the management system. The additional audit will be at extra cost to the applicant.
- In case of multi-site audits and subject to successful verification of compliance, a certificate clearly defining the activities and locations will be issued. The applicant shall not claim or otherwise imply that the certification applies to other locations or activities not covered by the issued certificate.
- Certification will be valid for a period of three years w.e.f the date of approval, on a condition that the Surveillance Audits are conducted as per the planned interval and reveal no deterioration in the management system. And the client does not breach the terms and conditions mentioned in the Certification Agreement.

6. APPLICATION

The applicant is required to submit a duly filled Application Form to ZQAPL-MSCD001.
ZQAPL-MSCD001 accepts the **Application Form** based on the positive application review output and ability to conduct audit and certification activity with compliance to review output.

The audit and certification service may be declined by ZQAPL-MSCD001 for one or more of the following reasons:

- Non-availability of accredited scope
- Non-availability of audit personnel with approval of specific technical area
- Non-availability of audit personnel to conduct audit in a specific geographical location
- Failure to establish legality of the business activity provided by the potential client
- Any other adverse market information which does not allow audit and certification activity to happen
- Any reason identified by ZQAPL-MSCD001 as an unavoidable threat to impartiality / bias

In addition, the client/ applicant needs to demonstrate the following for certification proceedings:

- Regulatory compliance applicable to the specific territory
- Minimum one round of Internal Audit and MRM conducted to ensure system effectiveness
- Complete cycle of product development (batch manufacturing for applied scope) with effective management system implementation

The applicant organization is formally informed with reasons through a mail about ZQAPL-MSCD001 decision to decline the application.

In case of acceptance of application, **Quotation** is submitted to the client. A **certification agreement** and **informative guide** are enclosed along with the **Quotation**.

When acceptance from client is received along with the application fee, a File Number will be allotted.

Our Client Manager / Administrative Executive will manage and liaise with applicant organization from the application stage to certification stage.

Our Client Manager / Administrative Executive will help applicant with any questions about our services and the progression of the Audit according to ZQAPL-MSCD001 procedures.

Note 1: In case client requests for a formal letter from ZQAPL stating that ZQAPL-MSCD001 has accepted the application for relevant QMS certification, then such letter may be provided. This letter must not be used in any way to imply that ZQAPL- MSCD001 assures/guarantees or has provided the certificate to such client.

(Ref. # 1.4.1_CPSC_ICMED) ZQAPL shall respond to all enquiries received from prospective applicant organisations for certification with complete information for facilitating registration of application, within 7 working days of receipt of the query.

(Ref. # 1.4.7_CPSC_ICMED) Only complete applications supported with all documents sought shall be accepted and registered in order of receipt with a unique identification number, acknowledged and records maintained. Registration shall be done within 7 days of receipt of application. In case the applicant discloses any proceedings leading to suspension, the applicant shall not be entertained for a period of one year from the date of conviction, suspension, withdrawal, deregistration etc..

(Ref. # 1.4.8_CPSC_ICMED) If the certification of any level under the Scheme has been suspended / cancelled by any approved Certification Body, the application from such a manufacturer shall not be accepted till suspension is revoked by the concerned Certification Body or for one year from the date cancellation of certification. This will be applicable only for the manufacturing facility whose certification has been suspended/cancelled. However, this will not be applicable to other manufacturing facilities under same legal entity.

(Ref. # 1.4.9_CPSC) The Certifications (ISO 9001 and/or ISO 13485) by Certification Bodies other than IAF MLA signatory accredited Certification Bodies shall not be accepted for ICMED Scheme Applicants. *Hence, the ICMED scheme audit will cover the audit to certify ISO 9001 and/or ISO 13485 accordingly and two separate certificates will be issued by Certification Body.*

(Ref. # 1.4.10_CPSC_ICMED) Where manufacturing facility is certified for ISO 9001 and/or ISO 13485 by Certification Bodies accredited by NABCB, audit related to scheme criteria shall be carried out, covering additional requirements of the scheme only for ICMED 9000 and/or ICMED 13485, i.e. '1' manday / site audit is required to cover only additional requirements of scheme ICMED (entire MD-QMS audit shall not be required)

(Ref. # 1.4.11_CPSC_ICMED) Where the certification (for ISO 9001 and/or ISO 13485) is carried out by IAF MLA signatory accredited Certification Bodies other than NABCB, then audit as per scheme criteria requirements shall be carried out covering additional requirements of the scheme only, i.e. '1' manday / site audit is required to cover only additional requirements of scheme ICMED (entire MD-QMS audit shall not be required)

(Ref. # 1.4.12_CPSC_ICMED) If ISO 9001 and/or ISO 13485 certification of the applicant is under suspension, application for certification shall not be entertained till the suspension of ISO 9001 and/or ISO 13485 certification is revoked. In case ISO 9001 and/or ISO 13485 certification of a manufacturing facility is cancelled by any Certification Body, the application certification under the Scheme may be carried out considering manufacturing facility as new client.

(Ref. # 1.4.13_CPSC_ICMED) The antecedents of the applicants shall be checked in relation to the Scheme. Applications from manufacturers who have earlier either misused the Certification, or whose earlier certificate was cancelled because of violation of terms & conditions / misuse of certification or have been implicated / convicted by the court in relation to their manufacturing activities, shall not be entertained for a period of one year of conviction / strictures by the court / cancellation of the certificate by any Certification Body.

(Ref. # 1.4.14_CPSC_ICMED) Applications from manufacturer found to be misusing the certification while their application is being processed for grant of certification, shall not be processed any further and rejected after a due notice of 15 days. Fresh applications from them shall be treated as stated above.

(Ref. # 1.4.15_CPSC) Requests for grant of certification from previous applicants as per 1.4.16 (a), (b) &(c) / expired certificates shall be processed like fresh applications and the entire procedure for grant of certification shall be adhered to subject to clauses 1.4.8 to 1.4.12 above.

(Ref. # 1.4.16_CPSC_ICMED) An application shall be rejected or closed under the following conditions;
a) If Initial Evaluation is not carried out within 3 months of registration of application
b) if the entire certification process is not completed within 6 months of registration of application.
c) If the applicant shows no progress towards completion of corrective actions within 3 months of Initial Evaluation and 6 months of Registration of application.
d) Misuse of certification under the Scheme
e) Evidence of any malpractice
f) Voluntary withdrawal of application.

(Ref. # 1.4.17_CPSC_ICMED) The Application Fee, if charged by ZQAPL, shall be non-refundable

7. STAGE 1 AUDIT

The purpose of the Stage 1 Audit is to verify information about the applicant company related to the size, complexity of operations and capabilities. The auditor will establish whether further development of the management system is necessary before the Stage 2 Audit takes place.
The stage 1 audit objectives are:

- to audit the client's management system documentation
- to evaluate the client's location and site specific conditions and to undertake discussions with the client's personnel to determine the preparedness for stage 2 audit
- to review the client's status and understanding regarding requirements of the standard, in particular with respect to the identification of key performance or significant aspects, processes, objectives and operation of the management system
- to collect necessary information regarding the scope of management system, processes and location/s of the client, and related statutory and regulatory aspects and compliance (e.g. quality, environmental, legal aspects of client's operation, associated risks etc)
- to review the allocation of resources for stage 2 audit and agree with the client on the details of the stage2 audit
- to provide a focus for planning the stage 2 audit by gaining a sufficient understanding of the client's management system and site operations in the context of possible significant aspects
- to evaluate if the internal audits and management review meetings are being planned and performed, and that the level of implementation of the management system substantiates that the client is ready for the stage 2 audit. Minimum one round of Internal Audit and Management Review Meeting conducted after regulatory compliances and complete cycle of product development (batch manufacturing for applied scope)
- Complete cycle of product development (batch manufacturing for applied scope) with effective management system implementation

8. STAGE 2 AUDIT

The stage 2 Audit is carried out to ascertain that whether the applicant company's Management System can be certified based on the objective evidences found
during audit.

The gap between Stage 1 Audit and Stage 2 audit should be minimum 7 days. The gap between Stage 1 and Stage 2 audit should not exceed 90 days. On Lapse of 90 days, Stage 1 audit is re-conducted.

The auditor will be looking for objective evidence (records, documents, etc) to verify that the activities of the organization are in accordance with the documentation and the requirements of the relevant management system standard.
All records resulting from the implementation and operation of the Management System must be made available to the Audit team for evaluation.

The stage 2 audit objectives will include but not limited to following:

- Information and evidence about conformity to all requirements of the applicable management system standard or other normative documents;
- Performance monitoring, measuring, reporting and reviewing against key performance objectives and targets (consistent with the expectations in the applicable management system standard or other normative document);
- The client's management system ability and its performance regarding meeting of applicable statutory, regulatory and contractual requirements;
- Operational control of the client's processes;
- Internal auditing and management review;
- Management responsibility for the client's policies.

Note 2 : Please refer Section 12 for information regarding Major/Minor non conformities and their Corrective Action Request.

9. INITIAL CERTIFICATION

After successful verification during initial certification audit (Stage 1 + Stage 2) of the system and no major deficiencies (or has subsequently rectified the deficiencies), then a recommendation will be made by audit team leader (lead auditor) to the ZQAPL-MSCD001 certification decision making authority. Upon approval and subsequent acceptance from ZQAPL-MSCD001 certification decision making authority, client is awarded a "Management System Certificate".

After Certification Decision, client will be provided with Management System Certificate, Certification Audit Programme, Initial Audit Reports, Certification & Accreditation Marks (as may apply).

The "Management System Certificate" will be valid, initially for a period of three years from the date of issue, and subjected to condition that the surveillance Audits have revealed no deterioration in the Management System.

Every three years of certification cycle, client will be subjected to Recertification Audit.

10. SURVEILLANCE ACTIVITIES

As a part of Surveillance activities, periodic surveillance audits will be carried out to ensure that the management system is not only being maintained, but is being reviewed and developed further to improve the efficiency and effectiveness of the business processes. 1st Surveillance audit shall be conducted within 12 months from date of

certification audit. The 2nd surveillance audit shall be conducted within 12 months from the date of 1st surveillance audit.

(Ref. #2.1_CPSC_ICMED)
Client shall ensure that surveillance audits are conducted at the planned / required frequencies. The first surveillance audit shall be conducted within 12 months from the date of certification decision. And the second surveillance audit (unannounced) shall be conducted within 9 to 12 months from the last day of the first surveillance audit.

Intimation for conducting planned surveillance audit shall be sent to client 2 months prior to surveillance audit due date. 2 reminders at progressive gap will be sent in case the date is not confirmed.

Failure to conduct audit within specified time will result in certificate suspension.

Note 3: Please refer Section 19 of this document for certificate suspension information.
The surveillance audit objectives will include, but not limited to following:

- Internal audits and management review;
- A review of actions taken on non-conformities identified during the previous audit;
- Complaints handling;
- Effectiveness of the management system with regard to achieving the certified client's objectives and the intended results of the respective management system (s);
- Progress of planned activities aimed at continual improvement;
- Continuing operational control;
- Review of any changes;
- Use of marks and/or any other reference to certification.

Other aspects of the Management System will be covered selectively, over the period of certification, depending on their importance of their scope of certification. This includes checking of certified client's website for the information provided by client in public domain related to audit & certification activities.

ZQAPL-MSCD001 shall be granted the right of access for surveillance purposes whenever deemed necessary and shall reserve the right to make short notice visits as required.

An audit report will be provided to client containing feedback regarding the results of the Audit.

Note 4: Please refer Section 12 for information regarding Major/Minor non conformities and their Corrective Action Request.

11. RECERTIFICATION

A recertification audit is planned and conducted to evaluate the continued fulfillment of all the requirements of the relevant management system standard. The purpose of the recertification audit is to confirm the continued conformity and effectiveness of the management system as a whole and its continued relevance and applicability for the scope of certification.

The recertification audit shall be conducted in the third year of certification cycle prior to expiration of certification
A reminder is sent to the client for recertification, 4 months prior to the expiry of certificate. 2 reminders at progressive gap will be sent in case the date is not confirmed.

The recertification audit objectives will include but not limited to following:

- The effectiveness of the management system in its entirety in the light of internal and external changes and its continued relevance and applicability to the scope of certification
- Demonstrated competence to maintain the effectiveness and improvement of the management system in order to enhance overall performance
- Whether the operation of certified management system contributes to the achievement of the organization's policy and objectives

Note-1 : ZQAPL shall not renew certification with conditions for compliance to be verified subsequently. There shall be no conditional renewal of certification

Note 5: Please refer Section 12 for information regarding Major/Minor non conformities and their Corrective Action Request.

12. NON-CONFORMITY & CORRECTIVE ACTION REQUEST

Non-conformity: Non-fulfillment of a standard's requirement

- **Major Non-conformity :** Non-conformity that affects the capability of the management system to achieve the intended results

Non-conformities could be classified as major in the following circumstances:

- if there is a significant doubt that effective process control is in place, or that products or services will meet specified requirements;
- a number of minor non-conformities associated with the same requirement or issue could demonstrate a systemic failure and thus constitute a major non-conformity.

- **Minor Non-conformity :**
  Non-conformity that does not affect the capability of the management system to achieve the intended results

In case of a Minor non-conformity during audit, the client needs to submit formal correction, identified *root* causes, corrective action/s plan within 7 days from the date of audit. Lead Auditor will check the effective implementation of correction and corrective action in the next subsequent audit, e.g. Surveillance Audit or Recertification Audit.

In case of Major nonconformity during audit, Lead Auditor shall recommend Follow up Audit. This audit shall be an additional full on-site audit (in case of lapses in core areas where the trail in other processes becomes necessary) or additional limited on-site / off-site audit (on-site incase of situation where the closure compliance need to be verified via onsite demonstration of compliance with participation of audittee and off-site audit in case where the closure compliance can be verified through documentary evidence remotely). The time frame for submission of correction, identified causes, corrective actions plan is within 7 days from the date of *audit*. The timeframe for implementing corrective action/s for Major non-conformity is maximum 90 days *(3 Months)*. The client shall inform and send the evidence of implemented corrective action/s. The Lead Auditor will decide the date for conducting follow-up audit as per the closure plan and confirmation from Client.

In case of delay in audit with respect to due date of audit program, the timeframe for implementing corrective action/s for non-conformity may be reduced than that of 90 days *(3 Months)* and will be informed by Lead Auditor.

(Ref. #4.3.2_CPSC_ICMED)
In case of Minor and Major non-conformities, the client organization shall carry out root cause analysis and inform the same along with correction and corrective actions, within a period of '1' month or '3' months respectively. All non-conformities are required to be closed before Initial Certification and Recertification through verification of

adequacy of the correction and corrective actions. All Major non-conformities, shall invariably require a follow-up audit. This audit shall be an additional full on-site audit (in case of lapses in core areas where the trail in other processes becomes necessary) or additional limited on-site / off-site audit (on-site incase of situation where the closure compliance need to be verified via onsite demonstration of compliance with participation of audittee and off-site audit in case where the closure compliance can be verified through documentary evidence remotely).

13. REFUSAL TO CERTIFICATION

The certification may be refused under following conditions:

- Non fulfilment of the requirements of the standard applied for.
- Failure to submit corrective actions for non-conformities (Major/ Minor) in stipulated time period
- Where the applicant cannot show that effective corrective action has occurred within the specified time limit, it may be necessary for ZQAPL-MSCD001 to conduct a further additional audit of the management system.
- Non-payment of financial dues after the conduct of audit activities.

(Ref. #1.4.16_CPSC_ICMED)
An application shall be rejected or closed under the following conditions;

a) If Initial Evaluation is not carried out within '3' months of registration of application
b) If the entire certification process is not completed within 6 months of registration of application.
c) If the applicant shows no progress towards completion of corrective actions within '3' months of Initial Evaluation and 6 months of Registration of application.
d) Misuse of certification under the Scheme
e) Evidence of any malpractice
f) Voluntary withdrawal of application.

14. INFORMATION EXCHANGE BETWEEN A CERTIFICATION BODY AND ITS CLIENTS

Notice of changes by ZQAPL:

The ZQAPL-MSCD001 will provide its certified clients due notice of any changes to its requirements for certification.

Notice of changes by a certified client:

The certification body shall have legally enforceable arrangements to ensure that the certified client informs the certification body, without delay, of matters that may affect the capability of the management system to continue to fulfil the requirements of the standard used for certification. These include, for example, changes relating to:

- the legal, commercial, organizational status or ownership;
- organization and management (e.g. key managerial, decision-making or technical staff);
- contact address and sites;
- scope of operations under the certified management system;
- major changes to the management system and processes;
- adverse event reporting and notification of corrective actions.

Based on information provided by client, ZQAPL-MSCD001 will take decision for conducting Special audit as described in section 15 of this document.

15. Special audits

a. Expanding scope

ZQAPL will, in response to an application for expanding the scope of a certification already granted, undertake a review of the application and determine any audit activities necessary to decide whether or not the extension may be granted. This may be conducted in conjunction with a surveillance audit.

Short-notice Audits and Unannounced Audits:

It may be necessary for ZQAPL-MSCD001 to conduct audits of certified clients at short notice or unannounced to investigate complaints, or in response to changes, or as follow up on suspended clients.

In such cases:

a) ZQAPL-MSCD001 describes and makes known in advance to the certified clients, the conditions under which such audits will be conducted.

b) ZQAPL-MSCD001 exercises additional care in the assignment of the audit team because of the lack of opportunity for the client to object to audit team members.

Short-notice:

Short Notice Audits can be conducted in following situations (but not limited to):

1. Customer of ZQAPL-MSCD001 certified client raises concerns/complaint to ZQAPL-MSCD001 about certified client.
2. During internal surveillance activity, ZQAPL-MSCD001 comes across following situations (but not limited to) ;
   - 2.1 Misrepresentation of scope or certificate issued by ZQAPL-MSCD001
   - 2.2 Available post-market surveillance data known to the ZQAPL-MSCD001 on the subject devices indicate a possible significant deficiency in the quality management system of certified client.
3. Significant changes occur which have been submitted as required by the regulations or become known to the ZQAPL-MSCD001 and which could affect the decision on the client's state of compliance with the regulatory requirements.

   The following are the cases of such changes which could be significant and relevant to the ZQAPL-MSCD001 when considering that a Short Notice audit is required.

   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 site 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 facility or a change in the method of sterilization)

   3.2 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)

Unannounced Audit

An unannounced audit is an audit which is conducted at certified client's premises without prior information. Such an audit can be initiated under following conditions (but not limited to):

- ZQAPL-MSCD001 accreditation body raises and reports serious concern about ZQAPL-MSCD001 certified client.
- The related regulatory authority responsible for relevant business sector raises & reports a serious concern about ZQAPL-MSCD001 certified client.
- In case of occurrence of serious injury or death of human or significant loss of property, which happen due to the product or service provided by certified client and covered in scope of Quality Management System

and indicating a possible significant deficiency in the quality management system of ZQAPL-MSCD001 certified customer etc.

The unannounced audit is a formal activity and report is provided to the certified client and relevant accreditation body or regulatory authority (as may apply).

An unannounced or short-notice audit may also be necessary if the ZQAPL-MSCD001 has justifiable concerns about implementation of corrective actions or compliance with standard and/or regulatory requirements.

16. SCOPE REDUCTION

ZQAPL-MSCD001 can reduce the scope of certification to exclude parts of the certified scope.

Certified scope reduction can be done in following scenarios (but not limited to):

1. The part of scope not meeting the requirements, when the certified client has persistently or seriously failed to meet the certification requirements for those parts of the scope of certification.
2. Deletion of a product category from the quality management system scope which client organization is no longer manufacturing.
3. Deletion of activity from scope (e.g. Organization previously certified with Manufacturing and Sales activity may reduce the 'Manufacturing' scope and opt only for 'Procurement and Sales' of product)

17. USE OF THE REFERENCE TO CERTIFICATION AND USE OF MARK

Use of Certification Mark:

a) The management system certification mark shall neither be used on product nor product packaging, nor in any other way that may be interpreted as denoting product conformity.
b) ZQAPL-MSCD001 does not permit its certification marks to be applied by certified clients to laboratory test reports, calibration or inspection reports or certificates.
c) The certification mark provided by ZQAPL-MSCD001 to the certified client can be used only on business advertising or promotional material. This certification mark shall be used in accordance with the guidelines and directives provided in 'D-12 Instructions for Use of Reference to Certification and Certification Marks"
d) The certification mark shall only be used whilst the quality system is maintained and the certification remains valid;

Reference to Certification:

a) Shall not be used on a product or affixed in any way on product packaging (i.e. primary packaging) that may be interpreted as denoting product certification or conformity. Primary Product packaging/label is considered as that removal of which will result in disintegration or damage of the product. The statement shall in no way imply that the product, process or service is certified by this means.
b) Can only be placed on product accompanying information or secondary / tertiary product packaging. Accompanying information is considered as separately available or easily detachable from product. Secondary/tertiary product packaging is considered as that which can be removed without the product disintegrating or being damaged.
The reference to certification statement shall be written as;
    - Identification (e.g. brand or name) of the certified client;
    - the type of management system (e.g. quality, environment) and the applicable standard;
    - The name of certification body issuing the certificate i.e. Zenith Quality Assessors Pvt. Ltd..

E.g. ABC Pvt. Ltd., An ISO 9001 Quality Management System certified by Zenith Quality Assessors Pvt. Ltd.

In addition to the points mentioned above, the certified client is obliged to ensure that the Reference to certification and use of mark;

- Does not provide any misleading statement regarding its certification
- Does not use or permit the use of a certification document or any part thereof in a misleading manner;
- Upon Suspension / Withdrawal of its certification, discontinues its use of all advertising matter that contains a reference to certification, as directed by the ZQAPL-MSCD001.
- Amends all advertising matter when the scope of certification has been reduced
- Does not allow reference to its management system certification to be used in such a way as to imply that the certification body certifies a product (including service) or process
- Does not imply that the certification applies to activities and sites that are outside the scope of certification
- Does not use its certification in such a manner that would bring the certification body and/or certification system into disrepute and lose public trust.

ZQAPL-MSCD001 is authorised to exercise proper control of ownership of certification references and use of certification marks and checks the usage during routine surveillance activities and during the conduct of on-site surveillance audits

ZQAPL-MSCD001 could include requests for correction and corrective action, suspension, withdrawal of certification, publication of the transgression and, if necessary, legal action if incorrect references to certification status or misleading use of certification documents, marks or audit reports are found during routine surveillance activities or during conduct of on-site Surveillance Audits / Recertification Audits.

18. MISUSE OF A CERTIFICATE

ZQAPL-MSCD001 takes reasonable precautions to control the use of its Certificates. Incorrect references to certification, or misleading use of Certificates found in advertisements, catalogues, etc., will be dealt with by suitable actions which could include suspension or withdrawal of Certificate, legal action and / or public notice.

19. SUSPENSION OF A CERTIFICATE

A Certificate may be suspended for a limited period (Not exceeding three months) in cases, such as the following;

a) If Corrective Action Requests have not been closed out within the designated time limit;
b) If a case of improper use of the Certificate or misleading prints or advertising, is not solved by suitable interactions or other appropriate remedial measures by the registrant;
c) Surveillance Audits are not conducted as planned.
d) Client fails to comply with due settlement of financial obligation of ZQAPL-MSCD001.
e) Client applies for voluntary suspension

f) A situation, where repeated major NCs are raised in consecutive surveillance assessments
g) A situation, where any major changes have taken place in the legal status, ownership, name etc without prior information to the ZQAPL
h) A situation, where any wilful false declaration in the application form or otherwise is detected
i) A situation, where excessive or serious complaints against the certified client management system are received and are found to be valid

Note : ZQAPL shall issue due notice of at least one week to the certified client for suspension of certification on above aspects.

The client shall not identify itself as certified, under a suspended certification status.

An official suspension of a Certificate will be confirmed in writing by ZQAPL-MSCD001 to the client. The conditions under which the suspension will be removed will also be included.

At the end of the suspension period, an investigation will be carried out to determine whether the conditions for reinstating the Certificate have been fulfilled. On fulfilment of these conditions, the suspension shall be lifted and the client shall be notified of the Certificate reinstatement. If the conditions are not fulfilled, the Certificate will be withdrawn.

All costs incurred by ZQAPL-MSCD001 in suspending and reinstating the certificate will be charged to the client.

20. WITHDRAWAL OF A CERTIFICATE

A Certificate may be withdrawn in the following cases:

a) If inadequate measures are taken by the company in the case of suspension;
b) If the company fails to comply with the due settlement of its financial obligation.
c) Client does not wish to continue / renew the certificate and provides a voluntary request for Certificate withdrawal.

If either of the above applies, ZQAPL-MSCD001 has the right to withdraw the Certificate and will inform the client accordingly. The client may give notice of appeal (refer section on Appeals).

No reimbursement of Audit fees will be given. Withdrawal of a Certificate may be published by ZQAPL-MSCD001.

21. FEES

Fees will be detailed in the quotation submitted to applicants. As costs are based on the rate applicable at the time of submitting a proposal. ZQAPL-MSCD001 reserves the right to increase charges during the certification period. Clients will be notified of any increase in fees.

Additional fees shall be charged for all additional work that is not included in the agreed proposal and for extra, unscheduled surveillance audits required due to non-compliances being identified in the Management System.

This will include, but is not restricted to, the costs resulting from:

a) Repeats of all, or any part, of the Audit program due to the initial certification requirements not being met;
b) Additional work due to suspension, withdrawal and / or reinstatement of a Certificate;
c) Additional audit / special audit due to any changes in the Management System.

Special Condition 1: In case the accreditation of ZQAPL is cancelled or ZQAPL decides to discontinue certification activity, then only certificate fee shall be refundable on the remaining period of certification validity i.e. on pro rata basis.

(Ref. #2.3.1_CPSC_ICMED)
ICMED 9000 / ICMED 13485 Audit mandays required shall be calculated in accordance with the following table :

	Audit Man-days *Bifurcation of Stage – I (20%) and Stage - II (80%)*	
Certification Activity	***ICMED 9000***	***ICMED 13485***
Certification Audit/ Surveillance/ Recertification	*As per IAF MD 5 Plus '1' man-day on Site*	*As per IAF MD 9 Plus '1' man-day on Site*
**Audit Man-day/s charges will be @ 15,000 INR (Rupees Fifteen Thousand only) per man-day*		

(Ref. #2.3.2_CPSC_ICMED)
Time duration shall be calculated for each manufacturing facility and each manufacturing facility shall be individually audited by ZQAPL

(Ref. #2.3.3_CPSC_ICMED)
The minimum audit time for each on site audit shall be at least one man-day (8 hrs. per day)

(Ref. #2.3.4_CPSC_ICMED)
Document Review, Audit Preparation and Report Preparation time shall be additional and shall be at least one man-day.

22. APPEALS

A ZQAPL-MSCD001 Applicant and/or Certified Client can appeal against any ZQAPL-MSCD001 in the following aspects

a. Audit or Certification Decision
b. Notification against suspension or withdrawal
c. Any other matters subject to procedures of ZQAPL-MSCD001.

A statement shall be in writing with identification of the sender for consideration as appeal.

The e-mail goes to ZQAPL-MSCD001 Director Operations who in turn deals with the appeal. The receipt of the appeal is acknowledged to the client in writing and appellant is regularly provided with progress reports and outcome.

It is ensured that the person/s engaged in the appeals-handling process are different from those who carried out the audits and made the certification decisions or been involved in the subject of appeal. And as such if Director Operations was involved as an auditor or certification decision maker in the case against which the appeal has been made, then the appeal is forwarded to CFSI Chairperson and appellant is informed about this.

Submission, investigation and decision on appeals do not result in any discriminatory actions against the appellant.

Effectiveness of these actions is reviewed by Director Operations or the CFSI Chairperson, as responsible to deal with specific appeal. The decisions taken by Director Operations or CFSI Chairperson is binding on ZQAPL-MSCD001 to take suitable actions.

ZQAPL-MSCD001 gives a formal notice to the appellant at the end of the appeals-handling process and the relevant records are maintained. The feedback is taken from the appellant / concerned client.

Once the appeal has been resolved by ZQAPL-MSCD001 Director Operations and/or ZQAPL-MSCD001 Committee for Safeguarding Impartiality Chairperson, CFSI, then no counter claim by either party in dispute can be made to amend or change the decision.

In instances where the appeal has been successful and the Certificate reinstated, then no claim can be made against ZQAPL-MSCD001 for reimbursement of costs or any losses incurred as a result of the initial withdrawal notification.

Contact e-mail id of ZQAPL-MSCD001 Director Operations – certification@zenith-worldwide.com
Contact e-mail id of ZQAPL-MSCD001 Chairperson for Committee for safeguarding impartiality - cfsi@zenith-worldwide.com

23. COMPLAINTS

A statement shall be in writing with identification of the sender for consideration as complaint.

The complaints can be made by the client expressing dissatisfaction over ZQAPL-MSCD001 decision related to certification i.e. granting, maintaining, renewing, extending, reducing, suspending and withdrawing of certification or any other unacceptable situation arising out of ZQAPL-MSCD001 activities with the client and a response is expected.

The e-mail goes to Director Operations who in turn deals with the complaint.

This process is subjected to requirements for confidentiality, as it relates to the complainant and to the subject of the complaint.

ZQAPL-MSCD001 gathers and verifies all necessary information to validate the complaint and acknowledge receipt of the complaint, and provides the complainant with progress reports and the outcome.

It is ensured that the person/s engaged in the complaint handling process are different from those who carried out the audits and made the certification decisions or been involved in the subject of complaint. If Director Operations was involved as an auditor or certification decision maker in the case against which the complaint has been made, then the complaint is forwarded to CFSI chairperson and complainant is informed about this.

Submission, investigation and decision on complaints do not result in any discriminatory actions against the Complainant.

Effectiveness of these actions is reviewed by Director Operations or the CFSI Chairperson, as responsible to deal with specific complaint. The decisions taken by Director Operations or CFSI Chairperson is binding on ZQAPL-MSCD001 to take suitable actions.

ZQAPL-MSCD001 gives a formal notice to the complainant at the end of the complaint handling process and the relevant records are maintained. And the feedback is taken from the complainant / concerned client.

In another case, a complaint can be made by an Interested Party against ZQAPL-MSCD001 certified client/s. An interested party is generally the one who has business interest with ZQAPL-MSCD001 certified client/s.

A statement shall be in writing with identification of the sender for consideration as complaint.

This process is subjected to requirements for confidentiality, as it relates to the complainant and to the subject of the complaint.

Upon receipt of a complaint from such an interested party, ZQAPL-MSCD001 confirms whether the complaint relates to certification activities that it is responsible for, and if so, takes necessary correction and corrective actions. If the complaint relates to a certified client, then examination of the complaint is done by a short notice audit at client's end and base on the audit outcome, necessary correction and corrective actions are taken.

Submission, investigation and decision on complaints do not result in any discriminatory actions against the complainant.

The complaint from an interested party is dealt by Director Operations. And in case, the interested party (complainant) does not accept the outcome reported by Director Operations then the interested party (complainant) has the right to raise the matter with CFSI chairperson.

ZQAPL-MSCD001 gives a formal notice to the complainant at the end of the complaint handling process and the relevant records are maintained. And the feedback is taken from the complainant / concerned client.

ZQAPL-MSCD001 determines together with the client and the complainant that to what an extent, the subject of the complaint and its resolution is to be made public.

Once the complaint has been resolved by ZQAPL-MSCD001 Director Operations and/or ZQAPL-MSCD001 Committee for Safeguarding Impartiality Chairperson CFSI, then no counter claim by either party in dispute can be made to amend or change the decision.

In instances where the complaint has been resolved in favour of the complainant, then no claim can be made against ZQAPL-MSCD001 for reimbursement of costs or any losses incurred as a result of the initial problems faced by the complainant.

Contact e-mail id of ZQAPL-MSCD001 Director Operations – certification@zenith-worldwide.com
Contact e-mail id of ZQAPL-MSCD001 Chairperson for Committee for safeguarding impartiality – cfsi@zenith-worldwide.com

24. CONFIDENTIALITY

a) ZQAPL-MSCD001 receives and gets access to client documents and records related to audit and certification during conduct of audit and certification activity.
ZQAPL-MSCD001 treats client information related to audit and certification as confidential with certain permissible exclusions. These exclusions are as follows:

- Information required by certified client's customer or potential customer
- Information required by State Government or Central Government as a part of investigation being carried out on the certified client
- Information required by Accreditation Body of ZQAPL-MSCD001 during planned audits being carried out by Accreditation Body on ZQAPL-MSCD001 and /or its certified client

i. In case the information is required by a certified client's customer or potential customer. Then ZQAPL-MSCD001 informs the certified client about such a request/enquiry. Upon mutual agreement between ZQAPL-MSCD001 and its certified client the related type and extent of information is provided to ZQAPL certified client's customer or potential customer in an official manner. This information is strictly related to audit and certification activity being carried out by ZQAPL on its certified client.

ii. In case the information required by State Government or Central Government as a part of investigation being carried out on the certified client, then ZQAPL-MSCD001 is obliged to provide the related audit and certification information to the State Government or Central Government in an official manner without informing to its certified client. This information is strictly related to audit and certification activity being carried out by ZQAPL-MSCD001 on its certified client.

iii. In case the information required by Accreditation Body of ZQAPL-MSCD001 about its certified client, this information is generally accessed during planned on-site audits being carried out by Accreditation Body on ZQAPL-MSCD001 or off site document review carried out by the Accreditation Body on ZQAPL-MSCD001. Then, ZQAPL is obliged to provide the related audit and certification information to its Accreditation Body in an official manner without informing to its certified client. This information is strictly related to audit and certification activity being carried out by ZQAPL-MSCD001 on its certified client.

ZQAPL places the information related to certified client in public domain (on its website www.zenith-worldwide.com) which includes; Client name, certification scheme, certificate number, validity of certificate, suspension or withdrawal information (if any) against the mentioned certificate. All other information except for this information which is made publically accessible for client shall be considered confidential and shall be treated in accordance with the terms detailed in this section above.

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