Integrated Quality Certification Private Limited

Conditions for Certification (CFC)

Integrated Quality Certification Pvt Ltd (IQC) is an accredited Certification Body for providing management system certification services.

Certification services are provided based on the principles of Impartiality, Competence, Responsibility, Openness, confidentiality and responsive to complaints.

All Management System Certification services are delivered within a frame of conditions applicable from initial review of inquiry to issue of certificate of compliance and post certification activities as applicable.

Compliance to conditions of certification shall be mandatory upon the client's signing of certification agreement.

IQC reserves the right to make any changes in conditions of certification. However, such changes shall be communicated to client listed in certification directory.

1.0. Definitions

1.1. IQC: Integrated Quality Certification Pvt. Ltd. (IQC) is an independent third party certification body providing Management System certification services.

1.2. Client: An applicant organization applying to IQC by providing client information for certification and subsequent signing of certification agreement for Management System Certification services.

1.3. Certificate of compliance: Document issued to client after the satisfactory assessment of client's Management System meeting the requirement of the contractual standard. The certificate of compliance demonstrates the effective implementation of the Management System and confidence in the product and services provided as defined in the scope of certification. Clients have got the right to use the certification and accreditation body logo as per the instructions provided along with certificate of compliance. Certificate of compliance is identified by certificate number specific to each client and is not transferable. Certificate of compliance is valid for minimum one year and maximum three years from the date of certification as specified in the Certificate. In case, where certificate of compliance is issued with 1 year validity for un-accredited schemes, certificate of compliance shall be re-issued for another ONE year after successful completion of audit on or before 12th month following initial certification audit.

Certificate of compliance issued to a client is a demonstration of their capability to develop and effectively implement a management system meeting the contractual requirements for a specific scope of product category. Certificate of compliance is not a product certification.

2.0. Confidentiality and Impartiality (ISO/IEC 17021-1 Cl. # 4.2, 4.6, 5.2 & 8.4)

All personnel associated with service delivery process of IQC including members of various committees, associates / sub-contractors and external organizations including accreditation body shall keep all

information pertaining to business / process / activities obtained during the service delivery process as confidential; Communication of confidential information to any other person or organization including accreditation body shall be with specific approval of client and as per any local regulation, if applicable. If the local laws as legal requirements permit disclosing of confidential information, IQC may communicate such information for a specific purpose with prior permission from the client.

IQC maintains impartiality in all phases of certification service delivery process. Impartiality of services is ensured through a committee to safeguard impartiality.

3.0. Certification Agreement (ISO/IEC 17021-1, Cl. # 5.1.2)

IQC shall provide certification services to clients who have signed certification agreement and agreed to abide by Conditions for Certification provided in this document. Certification agreement is a legally enforceable agreement binding on both IQC and the client. Certification agreement shall be signed by client after review of proposal for certification and understanding the conditions for certification. The certification agreement is valid for an initial period of three years (3 years) subject to satisfactory completion of periodic surveillance and renewed subsequently for every three years (3 years) upon signing recertification contract/Agreement.

In case of non-compliance to any of the requirement(s) of certification agreement, IQC reserve the right to initiate actions for withdrawal, suspension, publication of transgression or other appropriate actions including legal action. However, IQC shall provide notification with adequate justification for initiating any such action(s).

4.0. Certification requirements: (ISO/IEC 17021-1, Cl. # 8.5.1)

Client organization shall:

4.1 Identify a responsible function and assign responsibility and authority for:

4.1.1. Effective implementation of management systems and

4.1.2. Communications and coordination with IQC.

4.2. Maintain a documented Management System in accordance with applicable contractual standard and demonstrate effective implementation for a minimum period of three months prior to initial certification assessment.

4.3. Comply with all applicable legal requirements as any breach or contravention will be recognised as nonconformity during assessment and may have an impact on certification recommendation.

4.4. Conduct a minimum of one cycle of internal audit and one management review covering the specific management system developed and implemented for certification prior to initial certification assessment.

4.5. IQC nominated audit team members shall be provided access to all processes, production areas, personnel, applicable documents, records, organization structure, policy and procedures.

IQC audit team may also comprise technical experts, auditors in training, audit observers, accreditation body representatives and other relevant authorities as applicable. IQC shall communicate to client on participation

of IQC audit observers and accreditation body observers in the audit team. IQC audit observers and technical experts shall accompany any one of IQC audit team members but shall not be auditing independently. Accreditation body audit observers shall observe the auditing process of IQC but shall not be auditing the client management system independently.

4.6. Accreditation Body will accompany IQC audit team during any planned management system audits to carryout witnessing of IQC audit process as per the accreditation requirements. Client shall co operate and provide access to accreditation body auditors for witnessing.

4.7. Provide facilities needed by the audit team.

4.8. Arrange guides to audit team with responsibilities to take the auditors to different functions, introduce the auditors to the auditee and resolve any communication issues during the audit. Guides will not participate in the audit.

4.9. Ensure that consultants involved in the development of their management system do not participate in the audit.

4.10. Unannounced Visits by Accreditation Body:

Client shall cooperate with the applicable Accreditation body during any unannounced visits by accreditation body assessors and they must be permitted access to the facility, management system documentation and all associated records. Client must have a readily available copy of the last audit report issued by IQC and have demonstrable evidence of the certification process (e.g., Management Review, internal audits, audit report, closure of findings, corrective action etc.) Accreditation Body will only accept certified client's audit report provided directly by IQC.

5.0. Responsibilities and rights (ISO/IEC 17021-1, Cl. # 4.4 & 5.1.3)

5.1. Client:

5.1.1. Review and understand the purpose of conditions for certification.

5.1.2. Maintain records of certification documents issued by IQC at all times and accessible to responsible functions and interested parties as and when requested including accreditation body.

5.1.3. Respond to IQC requests and correspondences within a reasonable time frame as requested.

5.1.4. Cooperate with IQC for conducting Initial Certification assessment, surveillance audits and recertification audits at agreed frequencies without undue delay.

5.1.5. Provide corrective actions for the identified non-conformances identified during Initial Certification assessment, surveillance audits and recertification audits within 30 days of last day of the audit

5.1.6.

Coordinate for conducting 1st surveillance audit following initial certification within or not more than 12 months from the certification decision date. Surveillance audits shall be conducted at least once a calendar year as per agreed terms and conditions. (9.1.3.3) and / or otherwise, as per the audit programme specified in the contract document.

5.1.7. Coordinate for recertification audit at least one month prior to expiry of the certificate of compliance and propose corrective action(s) for any non-conformance prior to the expiry of the certificate of compliance

5.1.8. Develop and effectively implement a documented system for adequacy to the contractual standard at all times.

5.1.9. Appoint a responsible function and assign responsibility and authority for effective implementation and monitor the management systems through internal audits and management review at planned frequencies.

5.1.10. Provide factual information on the organization structure, manpower, statutory and legal requirements and customer complaints.

5.1.11. Do not promote the certification status during suspension period of management system certification

5.1.12. In case of withdrawal of certificate due to any reason, client shall return back the original certificate to IQC and discontinue use of logo on all advertising material.

5.1.13. Communicate with IQC as and when required during the certification validity period for following information:

a) Any major organizational changes

b) Addition of new products and change in business processes with impact on the scope of certification

c) Changes relating to legal, commercial, ownership,

d) Major changes to organization structure and management personnel

e) Change in contact address and communication details

f) Addition or deletion in the number of branches, location and contacts which has impact on the scope of certification sites and size of the organisation

g) confidentiality of specific information, if required

h) Any ongoing legal issues pertaining to product, environmental or safety issues and their status including any impact on business activities.

i) Any disturbances with in the country with impact on audit schedule

j) Any other Auditing language other than English which needs to be followed

k) Serious incident and breach of regulation necessitating the involvement of the competent regulatory authority.

5.1.14. Provide necessary working place, communication facilities and guides during assessments.

5.1.15. Provide access to all records of customer complaints and corrective action taken as per the requirement of implemented management System.

5.1.16. Comply with requirements of certification agreement including referred documents. Cooperate with IQC in case of any legal actions initiated arising out of non-compliance with certification agreement.

5.1.17. Inform IQC audit team on safety, emergency and security requirements to be observed within the plant areas.

5.1.18. Ensure that management legally responsible for occupational health and safety, personnel responsible for monitoring employees' health and the employees'/workers representative(s) with responsibility for occupational health and safety attend the closing meeting and if not available, appropriate justification may be provided to the audit team

- **Types of Assessment**

a) Initial Certification: Verify compliance to defined criteria (ISO/IEC 17021-1, Cl. # 9.3)

b) Surveillance Audit: Verify continued compliance to defined criteria (ISO/IEC 17021-1, Cl. # 9.6.2)

c) Recertification Assessment: Verify continued compliance to defined criteria and issue new certificate of compliance (ISO/IEC 17021-1, Cl. # 9.6.3)

d) Special audits (ISO/IEC 17021-1, Cl. # 9.6.4)

- ✓ Scope expansion or scope reduction audit: Verify the revised scope of certification to defined criteria
- ✓ Short notice audit: Verify any reported complaint or special audit to verify corrective actions and in-case of MD-QMS to ensure the following as below,
  - post market surveillance or vigilance data known to the CAB or significant safety related information known to the CAB or significant changes in regulations which have been known to the CAB and affect clients state of compliance to regulatory requirements
  - New owner ship
  - Extension of manufacturing and /or design control
  - New facility, site change
  - New processes, process changes or new products or categories
  - Change in quality management personnel change (capability and authority to release safe and effective medical devices)

e) Integrated Management System Audit: Audit of multiple management systems in a single audit based on following configuration.

✓ Document developed covering all management systems as one Integrated Management System document
✓ Level of integration achieved based on:
a) Documentation (Document control and Record Control):
b) Policy and Objectives:
c) Support Processes:
d) Operation of processes:
e) Monitoring and Measurement:
f) Correction, Corrective & Preventive Actions:
g) Internal Audits:
h) Management Reviews:
i) Continual Improvement:
j) Ability of client management to respond to audit questions:
k) Others, if any.

5.1.19. **Single site assessment**: Audit of single site without any branches

5.1.20. Multi-site certification (ISO/IEC 17021-1, Cl. # 9.1.5)

5.1.20.1. All sites shall have a legal or contractual link with the identified central office of the organisation

5.1.20.2. All sites shall be implementing a common management system, which is laid down, established and subject to continuous surveillance and internal audit by the identified central office.

5.1.20.3. Audit process will not be completed or delayed if any of the provisions for multi-site certifications are not met.

5.1.20.4. In case of non-conformities are identified at central authority or any of audited sites during certification process or during internal audit, requirement of client organization to review the non-conformities for their impact on overall system deficiencies as applicable to other sites.

a) If the non-conformities identified are analysed as detailed above, corrective action should be performed and verified at identified central authority and individual affected sites. If the analysis not done to evaluate the impact on overall system deficiencies as applicable to other sites, justification for limiting the follow-up corrective action shall be informed to IQC.

b) IQC reserve the right to increase the sample size to establish confidence in the certification.

c) Exclusion of any site during the audit or after the audit to overcome any findings of audit is not acceptable. Any required exclusion can be agreed prior to the audit.

5.1.20.5. Understand that IQC will not issue certificate of compliance in case of non-conformance issued at any site unless resolved as detailed in 5.1.19.4

5.1.20.6. Understand that sites with non-conformances will not be allowed to be withdrawn from the scope of certification after completion of initial assessment.

5.1.20.7. Cooperate with IQC to conduct assessment of additional sites irrespective of the proposal for certification to gain confidence in the implementation across all the sites, in case of non-conformances issued at any of the sites and subsequent corrective action as detailed in 5.1.11.2.

5.1.20.8. Cooperate with IQC to increase the frequency of samples or increase sample size to re-establish satisfactory controls by IQC and at additional cost

5.1.20.9. Inform IQC of closure of any branches covered by scope of certification. Failure of client to communicate such information to IQC shall be considered as misuse of certification

5.1.20.10. Management process like Internal Audit, Management Review and data analysis shall cover all the sites which are identified for multi site Certification.

5.1.21. Provide information on health, safety and environmental requirements to be followed by audit team during the assessment.

5.1.22. Inform IQC audit team on confidential nature of any document.

5.1.23. Provide information on the applicable statutory and regulatory requirements for the scope of certification.

5.1.24. Comply with certification requirements as communicated by IQC including changes, statutory and regulatory requirements at all times.

5.1.25. Cooperate for short notice audits for:

a. Investigation of any complaint received from the interested parties,

b. Response to any changes

c. Follow up on suspended certificate of compliance

Agree for any additional visit at cost, which may be necessitated, from such short notice audits for investigation, which is outside the scope of proposal for certification.

5.1.26. Agree for follow-up audit, if recommended by Lead Auditor during any of the assessment and / or requirement of the IQC Certification Decision Committee.

5.1.27. Ensure proper use of certificate of compliance, quality mark, and accreditation mark when making reference in communication media as per the IQC instructions.

5.1.28. Inform IQC for any change of audit team members/technical experts in advance with cause like conflict of interest.

5.1.29. Coordinate for planning and conducting surveillance audit and recertification audits at agreed frequency as per the certification agreement to ensure continued validity of the certificate of compliance.

5.1.30. Provide corrective action(s) for the non-compliances recorded during any assessments

5.1.31. Ensure use certificate of compliance in a planned and controlled manner which will not bring IQC and Accreditation body to disrepute and loose trust of interested parties.

5.1.32. Change relevant documents within an agreed timeframe, in case of changes to conditions for certification, as and when communicated by IQC.

5.1.33. Understand the certification process as detailed in 6.0 of conditions for certification

5.1.34. Maintain confidentiality of proceedings of the assessments

5.2. Integrated Quality Certification (5.1.3)

5.2.1. Provide impartial certification services to clients with in the configuration of the accredited scope

5.2.2. Maintain confidentiality of the information obtained during the certification service delivery

5.2.3. Communicate requirement for certification to the client

5.2.4. Description of initial certification including the application, certificate maintenance and process for granting, refusing, maintaining, extending, reducing, suspending, withdrawing and renewal of certification.

5.2.5. Communicate the professional service charges for certification services for 3 years period

5.2.6. Certification of multi site clients shall be done as per the requirements of IAF Mandatory Document IAF MD1.

5.2.7. Information on procedure for handling complaints and appeals

5.2.8. Communicate changes to certification criteria to clients for implementation with in an agreed time frame considering the views of interested parties

5.2.9. Provide adequate notice for surveillance and recertification audits

5.2.10. Provide all opportunities to client to explain their stand point for any identified non-compliance

5.2.11. Responsible and retain authority for decisions relating to certification, including granting, , refusing, maintaining, renewing, extending scope, reducing scope, suspending, restoring and withdrawing of certification.

5.2.12. Responsive to complaints from interested parties

5.2.13. Ensure availability of publicly accessible information pertaining to certification process, list of certified clients and their status of certification.

5.2.14. Multi-site clients (ISO/IEC 17021-1, Cl. # 9.1.5)

5.2.14.1. Communicate the criteria for multi site application and Decision on eligibility of a client with multiple sites for sample audit as per IAF and accreditation body guidelines.

5.2.14.2. Select appropriate sample size to gain confidence on the implementation of centrally controlled management systems in all branches prior to decision on certification.

5.2.14.3. Provide an opportunity to client to withdraw branches which are not ready for certification from scope of certification prior to initial assessment.

5.2.14.4. Increase the frequency of samples or increase sample size to re-establish satisfactory controls across the sites

6.0. Certification process

6.1. Application (ISO/IEC 17021-1, Cl. # 9.1.1)

Information about the applicant organisation is gathered through client information for certification (CIC). Details such as type of organization, scope of certification, manpower, statutory & regulatory requirements, applicability and or non applicability of any process, outsourced process, processes & product information and infrastructure details are critical inputs for certification process.

6.2. Application Review (ISO/IEC 17021-1, Cl. # 9.1.2)

The submitted CIC is reviewed to ensure the adequacy of the information for submitting the proposal and subsequent provision of certification services. The ability and competence to perform the certification is decided by IQC considering its accreditation scope. IQC shall submit the proposal for certification services for initial assessment and surveillance audits for the 3 years period along with certification agreement and conditions for certification.

6.3. Proposal & Agreement

Commercial proposal is submitted to client providing information on number of audit Mandays required for each stage of audit process and professional fees associated. Upon acceptance of terms and condition stated in the proposal and client acceptance to condition for certification, a certification agreement is signed between IQC & Client. Agreement is signed in two originals. One is retained with client and other with IQC.

subject to approval by client, IQC may offer services for an unaccredited certificate. IQC may plan to transfer such certificate to accredited certificate subject to approval by accreditation body with in a time frame.

6.4. Initial Certification Audit (ISO/IEC 17021-1, Cl. # 9.3.1)

Initial Certification Audit is conducted to evaluate the implemented management system and decide on the maturity of the system and issue certificate of compliance. Initial assessment is conducted in two stages (stage 1 and stage 2) as per the requirement of ISO 17021 Audit team leader and audit team of IQC are responsible to for the audit and control of the audit execution as per audit plan.

a. **Stage I Audit**: Conducted to assess the management system planning, validate the information provided in the client information for certification, required logistics and planning for Stage II assessment. It is recommended that part of stage 1 or complete stage 1 audit is carried out at the client's premises. Internal audit and management review shall have been completed prior to conducting Stage I Audit. Only observations are recorded during stage I audit in case of any non-compliance to audit criteria which shall be closed with corrective action prior to Stage II audit. Stage II audit shall be planned after confirmation of completed corrective action for any observations, if any.

b. **Stage II Audit**: Verify compliance of the management systems to the planned arrangements and decide on the recommendation for certification based on assessment output.

6.4.1. Upon signing of the certification agreement, client shall coordinate the date for stage I audit. IQC shall inform client of the stage I audit schedule. Stage 1 is conducted to evaluate site specific conditions, focus on Management System planning and planning for stage II audit, document review to evaluate the adequacy of the document to the applicable standard, allocation of resources for stage II audit, understand the scope/clause applicability and or non applicability/ applicable statutory requirements/product standards/processes/evaluate client's understanding of the applicable standard/aspect-impact study for EMS and /hazard-risk analysis for OHSMS, statement of applicability, risk analysis and management in case of ISMS & ItSMS, product line, work-environment, infrastructure and applicable statutory / regulatory requirement in case of MD-QMS and client business sector, hierarchy within the organization and business model adopted along with specific ABMS related elements such as anti-bribery commitment, controls, bribery risk assessment due-diligence etc.

Assessment report shall be provided to client along with audit observations, if any. Client is responsible to plan for adequate corrective actions, as applicable and as per the recommendation provided, for audit observations along with revision to system documents, if required. Client shall communicate the corrective actions to IQC prior to stage II assessment, as recommended. Non-fulfillment of stage 1 objective may lead to recommending for follow up of stage 1 audit. Output of stage I assessment and nature of observations may have impact on the stage II assessment schedule. Inadequate and ineffective corrective actions for stage I assessment may lead to major non-conformances in stage II assessment.

6.4.2. Stage II audit (ISO/IEC 17021-1, Cl. # 9.3.1.3)

Stage II audit is conducted to evaluate effective implementation of the Management System.

6.4.2.1. Inform audit team nomination and audit programme in advance.

6.4.2.2. Conduct opening meeting to explain audit methodology

6.4.2.3. Verify effective implementation of the management System for adequacy to the scope of certification by examining personnel, policies, procedure and records on sample basis against the contractual standard.

6.4.2.4. Stage II audit is conducted by using auditor notes/checklist. Check list is an internal document of IQC and is used to assist auditors during the audit.

6.4.2.5. Record Non conformance and classify as Major or Minor

6.4.2.6. Conduct closing meeting to explain audit findings, recommendations and revision to scope of certifications if required.

6.4.2.7. Provide copy of assessment report along with non-conformance report if any and recommendations including schedule for surveillance / recertification audit.

6.4.2.8. Review the adequacy of surveillance frequency and/or man days based on the audit findings.

6.4.2.9. Review corrective actions provided by client for all the non-conformance reports by follow up audit or documentation verification.

6.4.2.10. Audit team may terminate the audit prematurely if there is no evidence of implementation of planned management system and / or compliance to applicable legal requirements.

6.4.2.11. In case of AQMS audits, IQC shall inform to the other party that the report is available in OASIS database.

6.5. Assessment Report Review and Issue of Certificate of Compliance (ISO/IEC 17021-1, Cl. # 9.4.8)

6.5.1. Assessment Review of audit reports by IQC certification decision committee. Impartiality shall be maintained during such reviews.

6.5.2. Resolutions of clarifications in the audit reports if any prior to approval of recommendations.

6.5.3. Issue certificate of compliance after approval by certification decision committee, which is valid for a period of 1 year minimum or 3 years maximum from the date of certification decision subject to successful completion of surveillance audit on or before 12th and 24th month following initial certification. In case, where certificate of compliance is issued with 1 year validity for un-accredited schemes, certificate of compliance shall be re-issued for another ONE year after successful completion of audit on or before 12th month following initial certification audit. IQC maintains list of certified clients in web site https://www.iqcglobal.com and also accreditation body web site, if applicable**.** Clients shall verify the IQC web site for the reference of their organization in the web site and contact IQC Corporate office for any clarification.

6.5.4. Certificate of compliance is considered invalid under following conditions.

a. Client organization is not listed in IQC web site and / or in Accreditation Body web site, if applicable

b. Certificate of compliance is not having certificate number

Client shall verify the validity of the issued certificate with IQC Corporate office at the address and or contact details given below,

Integrated Quality Certification Pvt. Ltd
Platinum City, G/13/03, site # 02, Next to CMTI, HMT Main Road, Yeshwanthpur Post.
Bangalore – 560 022, India
Tel: + 91(80) 41172752, 41277353, 41280347
E-mail: iqccorporate@iqcglobal.com | Web: www.iqcglobal.com

Client shall not accept Certificate of compliance from any other sources except from IQC Corporate office unless otherwise informed of alternative arrangement for delivery of certificate of compliance.

6.5.5. Issue instructions on the use of quality marks and accreditation mark

6.6. Surveillance Audit (ISO/IEC 17021-1, Cl. # 9.6.2)

6.6.1. Conduct surveillance audit at agreed frequency to verify continued implementation of Management System as per the proposal. First surveillance audit shall be conducted within 12 months from the Certification decision of initial certification cycle.

6.6.2. Except for first surveillance of initial certification, all subsequent surveillance audits including surveillance audits after recertification shall be completed within 06 months from due date. However, Failure to take up the audit within suspension period will lead to withdrawal of certificate**.**

6.6.3. Verify the effectiveness of continuous implementation of Management System and planned processes during each surveillance audit ensuring to cover all processes at least once during each certification cycle.

6.6.4. Conduct follow-up audit, if required.

6.6.5. Verify use of Quality mark and accreditation mark as per IQC instructions.

6.6.6. Provide recommendations on continuation of certification as per audit report provided at the conclusion of each surveillance audit.

6.7. Re-certification (ISO/IEC 17021-1, Cl. # 9.6.3.2)

6.7.1. Conduct re-certification audit prior to certification period for continuation of certificate of compliance and subsequently followed up by Surveillance audits as per the accepted proposal. Re-certification audit shall be completed, preferably prioior to one month of expiry of the present COC including provision of adequate time to close any NCRs.

6.8.Special Audits (Scope Extension / Scope Reduction) (ISO/IEC 17021-1, Cl. # 9.6.4)

6.8.1 .Scope Extension (ISO/IEC 17021-1, Cl. # 9.6.4.1)

Scope extension audits shall be conducted upon request from client organization under following conditions.

6.8.1.1. Inclusion of process (es) in the system which was earlier excluded. Example: Design and Development

6.8.1.2. Inclusion of additional product(s)

Request for scope extension shall be reviewed and conducted as detailed in clause 6.1 to 6.5 except that requirement for conducting stage 1 audit may be waived with justification. Scope extension audit may be conducted as a separate assessment or combined with surveillance or recertification audit.

6.8.2. Scope Reduction (ISO/IEC 17021-1, Cl. # 9.6.4)

Scope of certification may be considered for scope reduction under following conditions

6.8.2.1. Client discontinuation of product from manufacturing as and when requested by client

6.8.2.2. Restriction on sale of certain product(s) by regulatory authorities

6.8.2.3. Inadequate corrective action for complaints by regulatory authorities

6.9 Short Notice Audit (ISO/IEC 17021-1, Cl. # 9.6.4.2)

Condition arising out of a complaint from interested parties including regulatory authorities under which audit has to be planned preliminarily for the purpose of investigation and review planned corrective action, and in case of MD-QMS for the following reasons as below,

- post market surveillance or vigilance data known to the CAB
- significant safety related information known to the CAB or significant changes in regulations which have been known to the CAB and affect clients state of compliance to regulatory requirements but not limited to the above and include the following,
- New owner ship
- Extension of manufacturing and /or design control
- New facility, site change
- New processes, process changes or new products or categories
- Change in quality management personnel change (capability and authority to release safe and effective medical devices)

Upon receipt of complaint, IQC shall communicate with the client immediately on the requirement for an immediate audit and coordinate for an audit schedule.

Audit shall be planned preferably after completion of initial investigation by IQC client. Time frame for planning the audit shall be appropriate to the nature of complaint. If the complaint has an impact on the interested parties health and safety, audit shall be planned within a maximum of 7 working days.

In case of AQMS, if IQC determines that a short notice audit is necessary, this audit is completed within 90 calendar days from receipt of the complaint

6.10 Transfer of certificate (ISO/IEC 17021-1, Cl. # 9.5.3.3 and JAS-ANZ Procedure 02 Part 1, Issue 3**)**

Recognition of an existing and valid management system certification, granted by one accredited certification body (Issuing certification body), by another accredited certification body (accepting certification body) for the purpose of issuing its own certificate. Following documents shall be submitted by client for review.

a. Copy of certificate of compliance from the previous certification body. Review the certificate of compliance for the scope, EA / NACE / ANZSIC classification and the capability of IQC to provide accredited certificate.

b. Copy of assessment report of previous certification body. Review for any adverse remarks in the report.

c. Copy of NCRs of previous certification body. Verify if the NCRs are major or minor and open or closed. Review the criticality of the report.

d. Compliance status to applicable legal requirements (EMS, OHSAS/OHSMS, ISMS & ItSMS, MD-QMS and ABMS)

e. List of aspects and impacts identified (EMS)

f. List of Hazards identified (OHSAS/OHSMS)

g. Copy of last internal audit report and management review. Review for meeting the requirement of the contractual standard.

6.11 Criteria for Suspension and withdrawal of Certificate (ISO/IEC 17021-1, Cl. # 9.6.5)

6.11.1.1.1.1 Certificate may be withdrawn under following conditions.

6.11.1.2 At the request of the client

6.11.1.3 Client fails to offer surveillance audit as per the agreed frequency. Certificate may be kept under suspension for a maximum period of six months from the due date of surveillance audit.

6.11.1.4 Recertification audits are not offered by the client prior to the expiry of the validity period of the certificate.

6.11.1.5 Client does not comply with any part of the conditions of certification (Eg: misuse of logo)

6.11.1.6 Based on the outcome of special audit arising due to information on incidents or accidents or serious breach of regulatory requirements where competent regulatory authority is involved

IQC adopts a policy of providing continuous services based on regular surveillance to client without any lapse on the procedural requirements to maintain the certification. IQC forwards the surveillance audit notifications to client organization as a reminder of the forthcoming /delayed surveillance audit to ensure that validity of the certificate of compliance is maintained. IQC provides an opportunity to client to initiate action but without any responsibility for coordinating the surveillance audit.

Following is the plan of action of IQC to enable client to coordinate for the surveillance audit within the agreed time frame.

a) Surveillance Notification letter 1 is forwarded to client two months ahead of the due date of surveillance audit.

b) Surveillance Notification letter 2 is forwarded to client one month ahead of the due date of surveillance audit.

c) Surveillance Notification letter 3 is forwarded to client on the due date of surveillance audit, informing the client of keeping the Certificate of Compliance under suspension for a period of 6 months from the due date and provide an opportunity to the client to coordinate for the surveillance audit.

6.8.1. Except for first surveillance of initial certification, all subsequent surveillance audits including surveillance audits after recertification shall be completed within 06 months from due date. However, Failure to take up the audit within suspension period will lead to withdrawal of certificate**.**

d) Withdrawal notification is forwarded to client after 06 months after the due date of surveillance audit informing the client regarding the withdrawal of certificate of compliance with immediate effect

e) If the client wishes to re apply for certification after withdrawal same will be considered as a new contract.

Certificate of Compliance shall be withdrawn or scope of certification of client's management system shall be reduced (for client failed to meet the requirements for those part of the scope), when the client does not comply with any part of the conditions of Certification. When the certificate of compliance is suspended/ withdrawn, certified organization directory including information on IQC web site is updated accordingly.

Client shall return the certificate of compliance to IQC corporate office immediately and discontinue use of reference to certificate of compliance.

6.12 Inactive certification

Certified management system may be kept as inactive when:

6.12.1 Client makes a request in view of current market situation. The current certification shall be allowed to continue for a period up to next surveillance due.

6.12.2 Request for further extension may be reviewed and granted by certification Decision committee. Such extension shall not be more than two surveillance duration from the certification time. A fresh audit shall be conducted before revoking the inactive certificate.

6.12.3 IQC shall withdraw the certificate of compliance after the above period, with advance notice to client and requesting to return the original certificate.

6.13 Use of quality mark and accreditation mark (ISO/IEC 17021-1, Cl. # 8.3)

6.13.1. Accreditation mark shall be used only in conjunction with IQC Quality Mark.

6.13.2FSMS Certified clients shall not use the Quality and Accreditation mark on the product nor the product packaging. Also, shall not use any statement on product packaging that the client is FSMS certified. This includes all product packaging, both primary packaging (which contains the product) and any outer or secondary packaging. (ISO 220003-1:2022 8.3, 8.4)

6.13.3 Client is not permitted to make any misleading statement regarding its certification

6.13.4 Client is not permitted to use certification document or any part thereof in a misleading manner

6.13.5. The size of the accreditation shall be the same as the quality mark.

6.13.6. The Quality mark and accreditation mark may only be used on correspondence, advertising, invoice, stock form and promotional material for the products or services described in the scope of certification. Accreditation mark shall not be used on business cards and on a product or product packaging.

6.13.7. On size A4 stationery the Quality mark and accreditation mark shall be 15 x12 mm.

6.13.8 Proportional increase/reductions may be allowed on stationary of larger/smaller size than A4 and shall be legible to have Management System standard and certificate number without any distortion or overlapping.

6.13.9. The conditions as indicated shall also apply to packaging material and promotional products. The party reporting the violations to the attention of IQC is informed of appropriate action being taken but is not provided with the details as it may be violating right to confidentiality. Further, client shall not allow reference to its management system certification to be used in such a way as to imply that IQC certifies a product (including service) or process.

6.13.10 . Any deviation or specific use of mark for special purposes like small advertisements, on client vehicles shall not be allowed.

6.13.11 The mark shall not be displayed on vehicles except in publicity material like part of a large advertisement.

6.13.12 The Accreditation mark shall only be printed in the colour combination or in the grey-black combination as specified in the instructions attached to certificate of compliance.

6.13.13 The mark shall not be used on any inspection reports, calibration certificates, laboratory test certificates etc as such reports are deemed to be products for such organisations.

6.13.14 . Accreditation mark of NABCB shall not be used on business cards. However, in case of JAS ANZ, Accreditation mark may be used.

6.13.15 . The certified organization shall abide by the IQC rules of certification to discontinue any use of Quality mark and Accreditation mark that is unacceptable to IQC.

6.13.16 The certified organization shall not use certification marks in such a manner that would bring IQC into any dispute and lose public trust.

6.13.17 . IQC shall initiate corrective action with the certified organization to avoid misuse of the Quality mark and Accreditation mark brought to the notice of IQC by any interested parties and/or general public subject to thorough investigation.

6.13.18 Client shall not use the certification marks to the activities and sites which are outside the scope of Certification

6.13.19 Upon withdrawal of certification by IQC or upon request by client to withdraw certification or due to cancellation of certification contract with IQC, the certified organization shall immediately discontinue use of all marks and to destroy all stocks of material on which they appear.

6.13.20 Client shall amend all advertising matter when the scope of certification has been reduced

6.13.21 Usage of marks shall be verified during each surveillance, recertification audits and findings reported in assessment report. Misuse of quality marks, if any, shall be recorded as non-conformance and corrective action taken verified prior to continuation of certification or reissue of certificate. Misuse may also be reported by any interested party and IQC shall take action against misuse.

7 Complaints, Disputes and Appeals (ISO/IEC 17021-1, Cl. # 9.7 & 9.8)

7.1 IQC has established an impartial appeals committee constituted by Director to investigate complaints, appeals and disputes related to the certification services.

7.2 Analyse and take corrective actions and inform client on the action taken.

7.3 Provide an opportunity to the client to appeal against actions taken by IQC appeals committee.

7.4 Appeals committee shall prepare a report after investigation including providing an opportunity to the client to represent their evidence.

7.5 Decision of the Director who is responsible for the approval of report is binding on both the parties

8 Certification Service Professional Charges

8.1 IQC shall submit the invoices for the professional services as indicated in proposal for certification, for the client approval and payment within 15 days.

8.2 Certificate of compliance shall be forwarded after receipt of the professional service charges as per proposal.

9 Liability of IQC

Certification services are provided by IQC as per the agreed proposal for certification. Liability of IQC shall be limited to the commercial terms referred in the proposal under any circumstances. Client agrees to indemnify, hold harmless and defend IQC from any and all liability of any and all kinds and types, including without limitation, claims, demands, or causes of action, including attorney fees, made or brought by any entity, person, firm or corporation arising out of or incidental to the certification services to be provided in connection with this agreement by reason of injury of any entity, person or damage of any property regardless of whether such injury or loss, cost, damage or expenses is occasioned in whole or partly by any negligent or omission on the part of IQC, its subcontractors or employees and regardless of where any such loss or any action may occur.

Client agree to indemnify and hold IQC harmless from and against any fines, taxes, levies imposed which may be asserted or imposed upon IQC by any country. Client shall also indemnify and hold and save IQC against all expenses and out-of-pocket expenses incurred by IQC in connection with or related to the assertion by any such country or jurisdiction of liability of IQC to pay any such fine, tax, and levy imposed.

This Agreement shall be governed by and construed and enforced in accordance with the laws of India and subject to jurisdiction of courts at Bangalore.

10. Validity and authenticity of the certificate of compliance (ISO/IEC 17021-1, Cl. # 8.1 & 8.5.1)

IQC updates the webpage www.iqcglobal.com of all certified clients and also JAS-ANZ Web page https://www.jas-anz.org of JAS-ANZ accredited clients subject to receipt of payment. Client shall ensure validity and authenticity of the issued certificate of compliance by verifying the IQC Webpage https://www.iqcglobal.com (all clients) and **www.jas-anz.org** (JAS-ANZ accredited clients).

Client is requested to report any discrepancy in issued certificate of compliance to IQC Corporate Office.

11. Logo of INTEGRATED QUALITY CERTIFICATION PVT. LTD, is a protected trade mark registered in India. This trade mark shall be used only by Integrated Quality Certification Pvt. Ltd, India. Any use of this trade mark by any other entity shall be liable for appropriate legal action.

12. OASIS Database (for AQMS Certification)

12.1 AQMS Certified Organisations shall allow IQC to provide Tier 1 and Tier 2 data to the OASIS database.

12.2 Organisation shall provide access to the data in OASIS database to the customers/authorities unless justification is provided.

12.3 If organisation loses the AQMS standard certificate they shall provide immediate justification to the customers.

12.4 Organisation shall identify an OASIS administrator and be responsible for notifying the certification body significant changes in the organization.

12.5 Failure to comply with the above shall be the cause for the withdrawal from the ICOP scheme and OASIS database both.