Process for granting and maintaining certification.

1.0 Purpose

To describe process for granting, maintaining, renewing, suspending, withdrawing, reducing or expanding the scope of certification.

2.0 Scope

This document provides detailed instructions and requirements for the processes associated with granting, maintaining, expanding, reducing the scope of certification, renewing, suspending, restoring, or withdrawing certification.

3.0 Instruction and policy

IPC-MDD mandates clients to maintain a documented management system in accordance with the relevant standards. Following each periodic ongoing surveillance, IPC-MDD meticulously assesses the surveillance report and makes decisions regarding certification maintenance, scope expansion or reduction, renewal, and suspension. IPC-MDD bears the responsibility and authority for determining certification status, including maintenance, extension, reduction, suspension, and withdrawal.

4.0 Definition

4.1 **Granting Certification:** This signifies confirmation by IPC-MDD that the client complies with the certification criteria.

4.2 **Maintaining Certification:** This demonstrates the client's continued fulfillment of management system standard requirements, substantiated by documentary evidence collected during audits.

4.3 **Suspending Certification:** Temporary suspension occurs due to non-compliance, restorable only upon successful implementation of corrective action.

4.4 **Reducing the Scope of Certification:** This action is taken when the client's management system lacks the capability for the specified scope of certification.

4.5 **Withdrawing Certification:** Certification is withdrawn when the client fails to meet standard requirements and does not implement proposed corrective actions within the given timeframe.

5.0 Process

5.1 Granting Certification

5.1.1 The client is required to submit an application in the format prescribed by IPC-MDD.

5.1.2 The applicant must clearly specify the type of certification being sought.

5.1.3 Detailed information about each manufacturing facility to be certified must be provided by the applicant.

5.1.4 If any activities covered under the certification criteria are conducted at premises other than the main site, the applicant must clearly indicate this. This information aids in planning and ensuring that all relevant criteria are audited comprehensively.

5.1.5 The applicant is required to specify and list all the activities to be audited and certified. Additionally, it should be stated whether these activities are conducted at a single location or multiple sites. In the case of multiple sites, any overlapping activities must be explicitly mentioned.

5.1.6 Regardless of the number of facilities belonging to a client seeking certification, each facility must undergo an audit to assess compliance with applicable criteria.

5.2 List of Required Documents

The applicant is required to furnish all essential documents, as specified in Application Form, to IPC-MDD for a thorough document review.

5.3 Any information deemed crucial for assessing auditor competence and estimating the required auditor man-days should also be provided.

5.4 Additionally, any pertinent information concerning regulatory bodies, suspension, cancellation, or withdrawal of relevant approvals or certifications under any regulations or other relevant circumstances must be disclosed.

5.5 Application Review and Registration

5.5.1 The IPC-MDD shall conduct a review of the application and supplementary information for certification to ensure that;

a) the information about the applicant organization and its management system is sufficient to develop an audit programme;

b) any known difference in understanding between the certification body and the applicant organization is resolved;

c) the IPC-MDD has the competence and ability to perform the certification activity;

d) the scope of certification sought, the site(s) of the applicant organization's operations, time required to complete audits and any other points influencing the certification activity are taken into account (language, safety conditions, threats to impartiality, etc.,)

e) If the applicant organization uses outsourced processes, the IPC-MDD shall determine and document whether specific competence in the audit team is necessary to evaluate the control of the outsourced

process.

5.5.2 Applicants for certification must use the prescribed IPC-MDD application form and furnish all information as outlined in previous clauses. Any additional information that IPC-MDD deems relevant to the certification process should also be included.

5.5.3 Applicants must declare, in the form of an undertaking, whether they have previously applied for or obtained certification from any other certification body. If so, they must provide previous evaluation reports to IPC-MDD, which may be verified by contacting the earlier certification body.

5.5.4 Applicants must declare any ongoing judicial proceedings related to their operations, regulatory body actions, or any suspension, cancellation, or withdrawal of certifications or approvals under any regulations. This declaration is an integral part of the undertaking mentioned in 5.5.3.

5.5.5 All certification applications undergo a review for adequacy. Following the review of the application, the IPC-MDD shall either accept or decline an application for certification. When IPC-MDD declines an application for certification as a result of the review of application, the reasons for declining an application shall be documented and made clear to the client.

5.5.6 Only complete applications supported by all required documents shall be accepted and registered in order of receipt, each assigned a unique identification number.

5.6 Initial Certification

5.6.1 Initial Certification Audit

5.6.1.1 Initial evaluation shall be carried out by a competent evaluation team in two stages stage -1 and stage-2.

5.6.1.2 The information gathered during stage 1 audit shall be used for making adjustment in audit time and/or audit team competence for stage 2 audit, as necessary.

5.6.1.3 The evaluation plan covering the relevant evaluation objectives shall be prepared and communicated to the applicant well in advance.

5.6.1.4 Stage 1 Audit

i) The Objectives of stage 1 shall be:

a. Review the client's management system documentation.
b. Evaluate the client's location and specific conditions and to undertake discussions with the client's personnel to determine the preparedness for the stage 2 audit;
c. 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;

d. Obtain necessary information regarding the scope of the management system, client's site(s), processes, equipment used, levels of controls established and applicable statutory and regulatory aspects;
e. Review the allocation of resources for stage 2 audit and agree with the client on the details of the stage 2 audit;
f. 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 management system standard;
g. Evaluate if the internal audits and management reviews 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;

ii) Documented conclusions with regard to fulfilment of the stage-1 objectives and the readiness for stage-2 shall be communicated to the client, including identification of any areas of concern that could be classified as a nonconformity during stage-2.

5.6.1.5 Stage 2 Audit

5.6.1.5.1 The purpose of stage 2 is to evaluate the implementation, including effectiveness of the client's management system. The stage 2 shall take place at the site(s) of the client. It shall include the auditing of at least the following:

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

5.6.1.6 Initial certification audit conclusions

5.6.1.6.1 The audit team shall analyze all information and audit evidence gathered during stage1 and stage 2 to review the audit findings and agree on audit conclusion.

5.6.1.6.2 Preparing Audit Conclusion: Under the responsibility of the ATL and prior to the closing meeting, the audit team shall:

a. Review the audit findings, and any other appropriate information obtained during the audit, against the audit objectives and audit criteria and classify the non-conformities;
b. Agree with the audit conclusions, considering the uncertainty inherent in the audit process;
c. Agree any necessary follow–up actions;
d. Confirm the appropriateness of the audit program or identify any modification required for future audits (e.g., scope of certification, audit time or dates, surveillance frequency, audit team competence).

5.6.1.7 Audit Report

5.6.1.7.1 The audit team leader shall ensure that the audit report is prepared and shall be responsible for its content. The audit report shall provide an accurate, concise and clear record of the audit to enable an informed certification decision to be made

5.6.1.7.2 IPC-MDD shall provide the audit report to the client. The ownership of the audit report shall be maintained by IPC-MDD.

5.6.1.8 Cause analysis of nonconformities

Any non-conformity observed during audit, with respect to the certification criteria shall be informed in writing to the applicant for taking necessary action. IPC-MDD shall require the client to analyze the cause and describe the specific correction and corrective actions taken, or planned to be taken, to eliminate detected nonconformities.

5.6.1.9 Effectiveness of corrections and corrective actions

IPC-MDD shall review the corrections, identified causes and corrective actions submitted by the client to determine if these are acceptable. IPC-MDD shall verify the effectiveness of any correction and corrective actions taken. The evidence obtained to support the resolution of nonconformities shall be recorded. The client shall be informed of the result of the review and verification.

5.7 Maintaining Certification

IPC-MDD ensures the continuous certification of clients by verifying their ongoing compliance with the requirements of the management system standard. Certification is maintained as long as the client

demonstrates consistent adherence to applicable management system standard.

5.8 Surveillance Activities

5.8.1 Surveillance activities encompass the continuous monitoring of the areas and functions within the scope of certification. Any modifications or developments related to the certified client and their management system are duly considered during surveillance activities.

5.8.2 Surveillance activities involve on-site audits of the certified client's management system to ensure ongoing compliance with the specified requirements outlined in the standard for which certification has been granted.

5.9 Surveillance Audit

Surveillance audits, which are conducted on-site and tailored to the relevant management system standard, encompass the following key components:

a. **Internal audits and Management Review:** Assessment of the client's internal audit processes and management review.
b. **Review of Previous Non-Conformities:** Evaluation of actions taken in response to non-conformities identified during the previous audit.
c. **Complaints Handling:** Examination of the client's procedures and effectiveness in handling complaints.
d. **Effectiveness of the Management System:** A review of how well the management system aligns with the certified client's objectives and its ability to achieve the intended results.
e. **Progress toward Continual Improvement:** An assessment of the progress made in planned activities aimed at achieving continual improvement.
f. **Continual Operational Control:** Verification of ongoing operational control measures.
g. **Review of Any Changes:** Evaluation of any changes made since the previous audit.
h. **Use of Marks and Certification References:** Review of the client's use of marks and other references related to certification.

5.10 Recertification

5.10.1 To initiate the renewal of certification, a recertification audit is meticulously planned and executed to assess the continued fulfillment of all the requirements of the relevant management system standard. This process is scheduled well in advance, ensuring that the certification is renewed promptly before it expires.

5.10.2 Certification renewal is conducted at the conclusion of the three-year validity period. IPC-MDD is responsible for sending a renewal notice to certified units at least four months prior to the certificate's expiration.

5.10.3 Certified organizations are required to apply for renewal using the prescribed format and submit the necessary fees at least three months before the certification's expiry. Recertification audit activities may need to have a stage 1 in situations where there have been significant changes to the management system, the organization, or the context in which the management system is operating (e.g., changes to legislation).

5.10.4 IPC-MDD shall review the performance of the certified unit who has sought renewal of the certificate, with respect to compliance to certification criteria during the entire certification cycle, prior to a decision on the renewal of the certificate.

5.10.5 The recertification audit shall include an onsite audit that addresses the following:

a) 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;

b) demonstrated commitment to maintain the effectiveness and improvement of the management system in order to enhance overall performance.

c) the effectiveness of the management system with regard to achieving the certified client's objectives and the intended results of the respective management system (s).

5.10.6 Competent personnel designated for the task conduct this review.

5.10.7 The decision regarding the renewal of the certificate is made by authorized competent personnel, based on the certified organization's satisfactory performance.

5.10.8 Certification renewal is not granted with conditions that require subsequent verification for compliance. There is no conditional renewal of certification.

5.10.9 If IPC-MDD has not completed the recertification audit or IPC-MDD is unable to verify the implementation of corrections and corrective actions for any major nonconformity prior to the expiry date of the certification, then recertification shall not be recommended and the validity of the certification shall not be extended. The client shall be informed and the consequences shall be explained.

5.10.10 Following expiration of certification, IPC-MDD can restore certification within 6 months provided that the outstanding recertification activities are completed, otherwise at least a stage 2 shall be conducted. The effective date on the certificate shall be on or after the recertification decision and the expiry date shall be based on prior certification cycle.

5.11 Suspension

5.11.1 IPC-MDD may suspend certification under the following circumstances:

5.11.1.1 When the client's certified management system persistently or significantly fails to meet certification requirements, including requirements for the effectiveness of the management system. This includes situations where:

5.11.1.1.1 Major non-conformities (NCs) are not closed within the prescribed timelines.

5.11.1.1.2 Repeated major NCs are identified in consecutive surveillance assessments.

5.11.1.1.3 There is non-payment of outstanding dues.

5.11.1.1.4 Major changes have occurred in the legal status, ownership, name, etc., without prior notification to IPC-MDD.

5.11.1.1.5 Willful misuse of the certification mark is detected.

5.11.1.1.6 Willful false declarations in the application form or otherwise are identified.

5.11.1.1.7 Excessive or serious complaints against the certified organization's management system are received and found to be valid.

5.11.1.2 When the certified client does not allow surveillance or recertification audits to be conducted at the required frequencies.

5.11.1.3 When the certified client voluntarily requests suspension. Such a request must be submitted in writing to IPC-MDD, along with the reasons. While IPC-MDD may decide to accept the request, the client may not unilaterally revoke the suspension.

5.11.2 IPC-MDD will issue a notice of at least one week before suspending certification to the certified organization.

5.11.3 During the suspension period, the client's management system certification becomes temporarily invalid.

5.11.4 IPC-MDD shall ensure that, during the suspension period, the certified organization refrains from making misleading claims.

5.11.5 IPC-MDD will reinstate the suspended certification if the issues that led to the suspension are resolved, and corrective actions are verified by IPC-MDD.

Failure to resolve these issues within the time frame established by IPC-MDD will result in the withdrawal or reduction of the scope of certification.

5.11.6 IPC-MDD shall reduce the scope of certification to exclude the parts not meeting the requirement, when the certified client has persistently or seriously failed to meet the

certification requirements for those parts of the scope of certification. Any such reduction shall be in line with the requirements of the standard used for certification.

5.12 Withdrawal

5.12.1 IPC-MDD will initiate the withdrawal of a certificate under the following conditions:

5.12.1.1 When the certified organization violates the terms and conditions of certification and the provisions of the ISO 13485 requirements.

5.12.1.2 When the certified organization fails to adhere to the certification criteria and the corrective actions taken do not ensure compliance.

5.12.1.3 When the proposed plan for corrective actions will take a substantial amount of time, extending beyond 6 months, for full implementation.

5.12.2 IPC-MDD may withdraw the certificate at the request of the certified organization if the certified operations within the organization can no longer be carried out due to natural calamities, such as flood, fire, earthquake, or due to a lockout declared by the management or closure of business operations, and other similar reasons.

5.13 Expanding or reducing the scope of certification

5.13.1 In response to an application to expand the scope of an already granted certification, IPC-MDD shall conduct a review of the application and determine any necessary audit activities to assess whether or not the extension may be granted. This may be conducted in conjunction with a surveillance audit.

5.13.2 IPC-MDD may reduce the scope of certification to exclude the parts that do not meet the requirements when the certified client persistently or significantly fails to meet the certification requirements for those specific parts of the scope. Any such reduction aligns with the requirements of the standard used for certification.

REVISION LOG

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