Process for granting, maintaining renewing, suspending, withdrawing, reducing or expanding the scope of 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-MvPI mandates clients to maintain a documented management system in accordance with the relevant standards. Following each periodic ongoing surveillance, IPC-MvPI meticulously assesses the surveillance report and makes decisions regarding certification maintenance, scope expansion or reduction, renewal, and suspension. IPC-MvPI 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-MvPI that the client's compliance with certification requirements aligns with IPC-MvPI's Certification Procedures.

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4.5 Withdrawing Certification: Certification is withdrawn when the client fails to meet standard requirements and does not implement proposed corrective actions within the given timeframe.

4.6 Refusal of Certification: This occurs during application review if the client's activities are inconsistent with IPC-MvPI procedures or if the certification scope/scheme is unavailable under a particular accreditation. Detailed reasons for refusal are documented.

5.0 Process

5.1 Granting Certification

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

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. For example, activities such as design, R&D, testing, or any outsourced processes fall under this category.

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.

5.1.7 The applicant must provide a comprehensive list of medical devices intended to be covered under the scope of certification.

5.2 List of Documents

5.2.1 The applicant is required to furnish all essential documents, as per the applied criteria, to IPC-MvPI 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 Registration of Application

5.5.1 IPC-MvPI will respond to inquiries from prospective applicant organizations for certification, providing comprehensive information to facilitate the application registration process within seven working days of receiving the query.

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

5.5.3 Applicants must declare, in the form of an undertaking within the application, whether they have previously applied for or obtained certification under this scheme from any other certification body. If so, they must provide previous evaluation reports to IPC-MvPI, which may verify this information by contacting the earlier certification body.

5.5.4 Prospective 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 Certification is only granted based on the most current and relevant certification criteria and IPC-MvPI ensures this during the application review.

5.5.6 All certification applications undergo a review for adequacy. If deficiencies are observed, the applicant is informed within seven working days of receiving the application. A competent person conducts this review, and records of the review are maintained.

5.5.7 Only complete applications supported by all required documents will be accepted and registered in order of receipt, each assigned a unique identification number. Registration occurs within seven days of receiving the application or information in response to communicated deficiencies. In case an applicant discloses any legal proceedings, suspensions, etc., the applicant will not be entertained for a period of one year from the date of conviction, suspension, withdrawal, deregistration, etc.

5.5.8 If IPC-MvPI suspends or cancels the certification of a client at any level under the scheme, their application will not be accepted until the suspension is revoked by IPC-MvPI or for one year from the date of certification cancellation. This applies only to the client whose certification has been suspended or canceled and does not extend to other clients under the same legal entity.

5.5.9 The certifications (ISO 9001 and/ or ISO 13485) by CBs other than IAF MLA signatory accredited CBs shall not be accepted.

5.5.10 For clients certified by Certification Bodies accredited by NABCB, audits related to scheme criteria will be conducted.

5.5.11 If the certification for ISO 9001 and/or ISO 13485 is carried out by IAF MLA signatory accredited Certification Bodies other than NABCB, a full audit in accordance with scheme criteria requirements will be conducted.

5.5.12 If the ISO 9001 and/or ISO 13485 certification of the applicant is under suspension, their application for certification will not be entertained until the suspension of ISO 9001 and/or ISO 13485 certification is revoked. If a client's ISO 9001 and/or ISO 13485 certification is canceled by any certification body, the application for certification under the scheme may proceed as a new client.

5.5.13 The background and history of the applicants will be examined in relation to the scheme. Applications from clients who have previously misused certification, had their earlier certificates canceled for violations of terms and conditions or misuse, or have been implicated or convicted by a court in relation to their activities will not be entertained for a period of one year following their conviction, receipt of court strictures, or certificate cancellation by any certification body.

5.5.14 Applications from clients found to be misusing certification during the processing of their application will not be processed further and will be rejected after a notice period of 15 days. Fresh applications from such clients will be treated as new applications.

5.5.15 Requests for certification from previous applicants whose certificates have expired will be processed as if they were fresh applications, subject to the full certification procedure.

5.5.16 An application may be rejected or closed under the following conditions:

5.5.16.1 If the initial evaluation is not conducted within three months of application registration.

5.5.16.2 If the entire certification process is not completed within six months of application registration.

5.5.16.3 If the applicant shows no progress towards completing corrective actions within three months of the initial evaluation and six months of application registration.

5.5.16.4 In cases of misuse of certification under the scheme.

5.5.16.5 In the presence of evidence of any malpractice.

5.5.17 Application fees, if charged by IPC-MvPI, are non-refundable.

5.5.18 Initial Evaluation

5.5.18.1 Initial site evaluation - The site visit shall cover review of records (Stage 1) and onsite testing and laboratory testing (stage 2). If required, witnessing of testing shall be carried out, hence forth shall be called as on-site evaluation.

5.5.18.1.1 Initial evaluation shall be carried out by a competent evaluation team in two stages. Both the Stage 1 and Stage 2 evaluation shall be combined evaluation.

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

5.5.18.1.3 Timings and date of initial site evaluation shall be fixed in consultation with the applicant ensuring that all the activities related to the applicable certification criteria are carried out.

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

5.5.18.1.5 Stage 1 Evaluation - The Objectives of stage 1 evaluation shall be:

a. To review the documents and records submitted by the applicant for quality management system compliance to the applicable requirements as per ICMED certification criteria.

b. To review and revise, if required an evaluation plan for stage 2 evaluation.

i. Deficiencies (non-conformities) observed with respect to the certification criteria during the Stage 1 shall indicate non-compliance with respect to applicable requirements of the ICMED certification criteria. No further categorization of deficiencies/non-conformities is done.

ii. In case of any non-compliance with respect to a particular device is observed, the IPC-MvPI shall require from the applicant to submit a set of documents and records to indicate the compliance as per the applicable clause with fresh sample, as applicable for the relevant device.

iii. The evaluation team shall prepare a report that highlights the level of compliance for quality management system, as per the scope of certification, including the deficiencies. Whenever a deficiency is observed, a recommendation shall be made to withhold the certification until a reasonable time is given, allowing the applicant to submit compliant records, documents, and equipment, as may be the case.

5.5.18.1.6 Stage 2 Evaluation

a. The Stage 2 evaluation by IPC-MvPI shall take place only when all the applicable requirements of the ICMED 13485 certification criteria have been evaluated in stage 1 and compliance to requirements observed and no deficiencies (non-conformities) have been observed.

b. The objective of the stage 2 evaluation shall be:

The stage 2 evaluation shall cover on-site testing and laboratory testing for each of the medical device(s) applied for in the scope of application. Witnessing of testing shall be carried out as part of the stage 2 evaluation.

c. Deficiencies (non-conformities) observed with respect to the certification criteria during Stage 2 shall indicate non-compliance with the applicable requirements of the ICMED certification criteria. Whenever a deficiency is observed, a recommendation shall be made to withhold the certification until a reasonable time is provided, allowing the applicant to submit compliant records, documents, and equipment as may be necessary. Upon completion of the stipulated time, a recommendation shall be made for discontinuing the certification process and closing the certification.

d. If any non-compliance is observed regarding a particular device, IPC-MvPI shall make a recommendation to withhold the certification until a reasonable time is provided. This allows the applicant to submit compliant records, documents, and equipment as necessary. Upon completion of the stipulated time, a recommendation shall be made to discontinue the certification process and close the certification.

5.5.18.1.7 The evaluation report – The evaluation reports for stage 1 and stage 2 shall clearly provide evidence and conclusions about the fulfillment of the evaluation objectives as described above and shall contain sufficient detailed information regarding conformity with all the relevant certification requirements, including the certification criteria for each device singularly.

5.6 Maintaining Certification

IPC-MvPI 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 these standards.

5.7 Surveillance Activities

5.7.1 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 these activities.

5.7.2 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.

5.8 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 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.

5.9 Renewal

5.9.1 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.

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

5.9.3 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.

5.9.4 The onsite surveillance audit, conducted towards the end of the third year and prior to the certificate's expiration, serves as the recertification audit. Its objectives encompass a combination of stage 2 and surveillance audits, unless there have been changes in product and process requirements, necessitating an assessment of the organization's revised processes, controls, and systems.

5.9.5 IPC-MvPI reviews the certified unit's performance during the recertification audit, focusing on the following aspects:

- **a.** Surveillance and recertification audit reports from audits conducted during the certification cycle.
- **b.** Non-conformities raised and their satisfactory resolution, along with their effectiveness.
- **c.** Any certificate suspensions during the previous validity period.
- **d.** Corrective actions implemented.
- **e.** Any complaints received.
- **f.** Any adverse information from stakeholders and regulators, if applicable.

5.9.6 Competent personnel designated for the task conduct this review.

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

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

5.9.9 In cases where the certified unit's performance is unsatisfactory, IPC-MvPI withholds the certificate's renewal, clearly specifying the reasons, and provides time for corrective actions. The verification and decision on renewal are made within three months of the certification expiry date.

5.9.10 Corrective actions are generally verified on-site, unless IPC-MvPI can verify them off-site before considering certificate renewal. The rationale for off-site review is documented.

5.9.11 If the manufacturing unit fails to satisfactorily complete the required actions within three months, the certificate will expire from the previous validity's expiration date.

5.9.12. When a certificate is not renewed, it will expire at the end of its validity period.

5.10 Suspension

5.10.1 IPC-MvPI may suspend certification under the following circumstances:

5.10.1.1 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:

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

5.10.1.1.2 Repeated major NCs are identified in consecutive surveillance assessments.

5.10.1.1.3 There is non-payment of outstanding dues.

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

5.10.1.1.5 Willful misuse of the Scheme's logo is detected.

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

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

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

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

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

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

5.10.4 IPC-MvPI ensures that, during the suspension period, the certified organization refrains from making misleading claims.

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

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

5.11 Withdrawal

5.11.1 IPC-MvPI will initiate the withdrawal of a certificate under the following conditions:

5.11.1.1 When the certified organization violates the terms and conditions of certification and the provisions of the ICMED scheme.

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

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

5.11.2 IPC-MvPI 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.

5.12 Expanding or reducing the scope of certification

5.12.1 In response to an application to expand the scope of an already granted certification, IPC-MvPI will conduct a review of the application and determine any necessary audit activities to assess whether the extension can be approved. This review may coincide with a surveillance audit.

5.12.2 IPC-MvPI 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

Version	Description of Change	Release Date
00	New document for posting on IPC's website	11-OCT-2023