

## Process on Suspension and Withdrawal or Cancellation of Certificates, reducing or expanding the scope of Certification

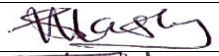

### A. Grounds for Suspension and Withdrawal or Cancellation of Certificates

The following reasons are considered grounds for suspension or cancellation:

- i) Major non-conformance(s) or effective corrective action not implemented within a specified time period.
- ii) Improper use of the certificate, symbol or logo not remedied to the satisfaction of IBRATSA.
- iii) Client ceases to supply product or service of the certified quality system for an extended period of time.
- iv) Client's certified management system has persistently failed to meet any of the requirements for certification including requirements for the effectiveness of the management system.
- v) Client fails to meet financial obligations to IBRATSA.
- vi) Client makes a formal request to suspend certification.
- vii) Infringement by the client of any contractual conditions between the client and IBRATSA.
- viii) Client is unable or unwilling to ensure conformance to revisions of standards.
- ix) Existence of a serious complaint, or a large number of second- or third-party complaints, which indicate that the quality management system is not being maintained.
- x) Client does not allow routine surveillance or recertification audits to be conducted at the required frequency.
- xi) The routine surveillance is carried out more than 12 months from the last audit. In case the audit is not done within 12 months, the certificate is suspended, and a letter is sent to the client requesting him to agree for the audit. In case of a delay up to 3 months (15 months from the last audit), the audit time shall be extended by 50% of the routine surveillance time (at least 1 day). Successful completion of the audit within 15 months shall not impact the certification. In case the audit is not done within 15 months, the certificate is cancelled, and the client shall be considered as a fresh case for certification.

### B. Suspension of Certificates

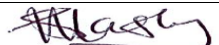

- i) If Grounds for action brought to the attention of the Quality Assurance Manager are determined to be grounds on which a certificate can be suspended, the Quality Assurance Manager shall follow the steps indicated below:
- ii) The Quality Assurance Manager sends a letter to the client outlining the reasons why the

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- cancellation, suspension or withdrawal is being considered and shall give the client 14 days within which to respond to the allegations on which the action is being considered.
- iii) The client's response to Quality Assurance Manager's letter will be reviewed, and the proceedings may be put on hold while clarification is sought.
  - iv) If the Quality Assurance Manager determines that the action or position contained in the client reply is satisfactory, he issues a letter stating this, and mails it to the client via registered mail and this shall be the end of the matter.
  - v) If the client's response is deemed to be inadequate and further action is considered as necessary, then the Quality Assurance Manager shall proceed with the process.
  - vi) If further actions are required, due dates must be set, and Quality Assurance Manager reviews the actions at those times to ensure that they are effectively completed in order to prevent suspension.
  - vii) Where mutually agreed-upon corrective action is to be implemented, a time period for implementation will be specified and a review of the corrective action undertaken at the appointed time. This may be the subject of a special surveillance visit or of review of submitted objective evidence, at the discretion of IBRATSA. Should the corrective action not be considered adequate or not be completed by the appointed time, certification will be automatically suspended.
  - viii) In the case of serious circumstances, IBRATSA may invoke suspension during the period pending the implementation of corrective action.
  - ix) Where suspension has been invoked, unless otherwise specified, the client must advise IBRATSA every 14 days of the current situation of corrective action. Failure to meet this requirement will result in withdrawal or reduction of the scope of certification.
  - x) Where suspension has been invoked due to failure to conduct surveillance audit, the client shall give justification for failure and offer suitable dates. An additional day shall be added to routine surveillance days. The date shall not be later than 15 months from last audit. Failure to offer for audit within 15 months shall result in cancellation of certification.
  - xi) Under suspension, the client's management system certification is temporarily invalid.
  - xii) When corrective action to resolve the problem(s) taken by the client has been verified, certification will be resumed. The period of certification will not be revised to cover the period of suspension.

### C. Withdrawal or Cancellation of Certificates

- i) Cancellation of certification will be invoked where, following suspension of certification, the client fails to respond to IBRATSA communications within the 14-day grace period or fails to implement corrective action within the appointed time period.

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- ii) In extreme circumstances IBRATSA may invoke the cancellation of certification with immediate effect without recourse to initial certification suspension.
- iii) If the decision is made to cancel certification, the Managing Director is responsible for cancelling the client from the Register of Approved Firms, advising the client by email, mail / courier, and publicizing the cancellation, if necessary.

#### **D. Reduction in scope of Certificates issued**

- i) IBRATSA shall wherever applicable reduce the scope of certification if during the time of routine surveillance audits / Re approval or Renewal audits it finds that the certified client has continually / seriously failed to meet the certification requirements for those parts of the scope of certification.
- ii) Any such reduction will be in line with the requirements of ISO Standard.
- iii) The reduction in scope will be approved by the Managing Director.

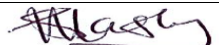

#### **E. Consequences of Suspension, Withdrawal or Cancellation of Client**

##### **Certification**

- i) Cancellation of certification will require the client to assume the status of non-approval and return all certification documentation to IBRATSA.
- ii) Use of certification documents, symbols, or logos by the client following certification cancellation may result in legal action being taken against the client.
- iii) Re-approval after certification cancellation will be on the same basis, and follow the same process, as that of initial application for a new client. This will require a full assessment, with optional document review at the discretion of IBRATSA.
- iv) The de-certification will be published as a separate list and will be available at IBRATSA offices, website and is available upon request.
- v) The client has the right to appeal any decisions of IBRATSA and a copy of the appeals procedures will be made available upon request.
- vi) The Quality Assurance Manager shall remove the client's details from the Register of Approved Clients where the certificate has been cancelled.
- vii) During suspension, suspension remark shall be placed in the registered of approved firms.
- viii) The client files for all cancelled cases shall be archived for a period of 36 months and then destroyed following the "Procedure on Records Management".

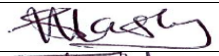

#### **F. Expanding Scope of Certification**

- i) The expansion of Scope of Certification may refer to a situation in which an organization seek to expand its activities under the same existing quality

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management system (for example a client certified as a distributor of medical devices, may seek to expand into manufacturing of the medical devices) or seeks to implement a new management system.

- ii) If a client wishes to expand the scope of an existing certification, they complete a contract review form and submit all supporting documentation to IBRATSA.
- iii) IBRATSA reviews the submitted documents and if the requested expansion of scope falls within IBRATSA's certification scheme, a quotation is provided which once accepted, a new contract is signed.
- iv) IBRATSA will determine whether a full (off and on-site audits) or partial Stage 1 is required. This is informed by the client's type of expansion. If the expansion involves a new established location, with new equipment and new personnel, then an on-site visit may be warranted even in Stage 1 of the audit.
- v) Under no circumstances must the above visit be carried out at the same time as Surveillance audits unless extra time or an extra auditor has been allocated. The Stage 1 is completed before the Stage 2 on-site audit.
- vi) Expansion of scope audits for the above reasons are carried out in the same manner as the initial audit.
- vii) A Stage 2 Audit Report form is completed in the normal way and submitted to the Certification Committee for approval. If successful, a new certificate is issued by IBRATSA.

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## 6. History of Document Changes

Rev No./ Issue No.	Date	Description of Changes	State (Approved / Not Approved)	Change Initiator (Initials)	New Rev No./ Issue No.
0/1	20/07/22	Initial issue	Approved	FM	0/1
0/1	10/06/2024	New Rev/Issue as part of the Re-coding and re-structuring of QMS documents. Revision of relevant in-text.	Approved	FM	1/1

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