


TECHEUROPA INSPECTION & CERTIFICATION PVT LTD				
	ISO 17021-1	WI - 09	WORK INSTRUCTION MANUAL CRITERIA FOR GRANTING CERTIFICATION	ISSUE NO. 01
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## Criteria and Procedure Guidelines for QMS Certification

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### 1. Purpose/Scope

- 1.1** TECHEUROPA INSPECTION AND CERTIFICATION PVT LTD – hereinafter referred to as ‘TIC’ – is a certification body for QMS ISO 9001, ISO 13485.
- 1.2** The provisions stipulated herein apply to QMS scheme operated by TIC and contain the requirements which clients have to meet in order to obtain or to maintain a certification.

### 2. Certification Process - Certification Agreement

On acceptance of the Quotation, this certification agreement is signed between TIC and the client for providing certification of the client’s management system by TIC as per applicable international standard.

#### Stage –1 Audit & Documentation Review

TIC shall conduct a stage –1 audit at client site to verify the adequacy of documentation with respect to the requirements as per applicable standard and also to understand and gather further information on the client activities and processes including applicable statutes, to plan for the stage –2 audit. The client shall satisfactorily resolve all the observations raised in document review along with other concerns / issues highlighted during the audit and the same confirmed to TIC before planning the stage –2 audit. TIC shall submit a formal report to the client.

#### Stage –2 Audit

TIC’s audit team shall visit the client’s premises, as per an agreed plan, to verify effectiveness of the client’s management system in meeting the requirements of the applicable ISO standard. TIC shall submit a formal report to the client.

#### Non-Conformity Report

If a nonconformance is detected during audit, a Nonconformity Report shall be issued to the client. For the non-conformities raised during the audit, client shall submit the correction and the corrective action (based on root cause) to TIC office within 20 working days from the last day of the audit. TIC shall verify the submitted correction and the corrective action and confirm the acceptance of the same to the client. Client shall take the correction and corrective action within the stipulated date and submit the documentary evidence to TIC to verify the effectiveness of action taken and accordingly to close the non-conformances.

In case of a major non-conformance, the effectiveness of action taken shall be verified at client site by a follow up visit or as communicated by the team leader on the closing day of the audit. This shall be completed within 90 days from the last day of the audit.

In case of certification audit (fresh client/certified clients) the TIC shall cancel/suspend the audit under the following conditions:

- (a) Client does not submit Corrective Action Plan for the Non Conformity raised within 20 working days as stipulated above.
- (b) In case of major Non Conformity the verification of effective of corrective action is not completed within 90 days as stipulated above.


#### Recommendation for Certification

TIC shall recommend certification of the client’s management system, based on the following:

- (a) TIC has reviewed the audit reports and has accepted the recommendations of the audit team.
- (b) The client has submitted the correction and corrective action for the non-conformities raised within the stipulated time and TIC has accepted the same.
- (c) In case of a major non-conformance, the effectiveness of correction and corrective action is verified by TIC's auditors as agreed and the non-conformity either closed or downgraded to minor.

If the client is not recommended for certification TIC shall accordingly inform the client.

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### Issue of certificate

TIC shall issue the certificate against the applicable standard to the client only after the closure of all the non-conformances as stated in this agreement.

The Certificate is the property of TIC, and shall be produced to TIC as and when requested. The certification will be valid for a period of three years from the date of approval of certification, subject to the satisfactory maintenance of the MS as confirmed through agreed surveillance audits.

### Surveillance Audit

Surveillance audits shall be conducted regularly at the client site at least once in a year to confirm that the Client's MS continues to conform to the requirements of the standard to which it is certified.

The first surveillance audit shall take place within twelve months from the last day of the stage-2 audit and failure to comply with this requirement will lead to suspension and subsequently withdrawal of certification.

For the non-conformity raised during the surveillance audit the conditions stipulated in this agreement shall be applicable.

In the case that a surveillance audit cannot be carried out because the client's operations are affected owing to factors outside its control, e.g.: employee union strike, natural calamity, etc. the case shall be presented to TIC for a decision. TIC shall submit a formal report to the client.

### Re-certification Audit

The purpose of recertification audit is to confirm the continued conformity and effectiveness of the client's management system as a whole and its continued relevance and applicability for the scope of certification.

The Re-Certification audit shall include site audit and shall consider the performance of MS over the period of certification and shall also include a review of previous surveillance audit reports. The recertification audit may have a stage -1 audit in situations where there have been significant changes to the management system, the client or changes to legislation.

TIC shall conduct the recertification audit at least 60 days in advance to the expiration of certification so that the client has time to implement corrective actions before the expiry of the certification.

For non-conformities raised during the audit has to be addressed as mentioned above. TIC shall submit a formal report to the client.

### Special Audit

TIC shall conduct special audits under the following conditions,

- Extension to the scope of certification already granted, on the request of client. This could be clubbed with routine surveillance audit.
- To investigate complaints received by TIC about the client.
- Follow up audit in case of suspension or major non-conformity raised in any audit.
- Changes to TIC's certification requirements.

For non-conformities raised during the audit has to be addressed as mentioned above. TIC shall submit a formal report to the client.

## 3. Notice of Changes

### Notice of changes by TIC


TIC shall inform the client in advance any changes to its requirements for certification and shall subsequently verify that each client complies with this requirement. It shall necessitate a special audit in certain cases.

### Notice of Changes by the client

Client shall inform TIC, without delay, of matters that may affect the capability of MS to continue to fulfil the requirements of the standard used for certification. These may include changes related to,

- The legal, commercial, organizational status or ownership,
- Organization and management (eg changes in top management or decision making authority)
- Contact address and sites
- Scope of operation under the certified management system
- Major changes to the management system and processes.

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#### 4. Maintaining Certifications

The Certification is maintained for a period of 3 years under these following conditions:

- The Surveillance Audits are conducted as planned and the client has demonstrated that it continues to satisfy the requirements of the management system standard as confirmed by TIC.
- All the non-conformance raised during previous surveillances are closed within the time frame agreed and correction and corrective actions for the non-conformities raised during the current audit are identified and accepted by TIC.
- The Internal audit and management reviews are conducted as scheduled and has no issues pending.
- The client shall maintain suitable records of customer complaints and keep the records of investigation and remedial actions taken with respect to such complaints for verification by auditors.
- All outstanding dues to TIC are paid.

#### Criteria for Granting Certification:

TIC may grant and issue the certificate to the client under the following criteria

- The client has a documented Management system that is laid in accordance to its scope of certification and that it conforms to the requirements of the applicable Management System Standard as mentioned above.
- The Client has completed at least one cycle of internal audit and management review of the management system established.
- Both internal audit and management review have been found effective as assessed by TIC auditors
- The client has paid all the dues including the certification fee.
- The client shall keep a record of all complaints and actions taken and the same shall be submitted to TIC auditors for verification when requested.
- The client has undergone the stage-1 and stage-2 audit satisfactory and the audit team has recommendation for certification.

#### Criteria for Refusing Certification

TIC will refuse client certification under following circumstances

- Customer does not have a documented management system that meets applicable standard or other normative documents.
- One internal Audit and management review cycle has not been completed and non-conformity's, if any have not been corrected.
- The applicant does not meet the criteria of certification and all major non-conformities, if any found during assessment have not been closed. For minor NC's corrective action has not been taken or planned has not been received.
- There are adverse reports/information/complaints with the TIC about the applicant regarding the quality and effectiveness of implementation of system as per TIC contract terms for registration.
- The applicant has not paid all the fees.

#### Criteria for Restoring Certification

After receiving successfully the compliance of reasons of suspension in writing by suspended companies, The suspense will be revoked. For this purpose an audit may be conducted (if necessary) to conform the elimination of the suspension reasons by TIC.

#### Criteria for Expanding Certification

In order to expand the scope of a certification covering additional sites, products, process or services, The certificate holder will be required to complete a new questionnaire ,The cost of expanding the scope of registration will be based on the nature and Programme of work.


#### 5. Suspending, Withdrawing or Reducing the scope of certification

##### (a) Suspension

TIC shall suspend certification in following cases:

- The client's certified management system has persistently or seriously failed to meet certification requirements, including requirements for the effectiveness of the management system.

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- The client does not allow surveillance and recertification audits to be conducted at the required frequencies.
- Wishful misuse of logo & reference to certification.
- Non-compliance to submission of Corrective action.

The suspension shall be for a period of maximum six months and the suspended status of the client shall be publicly made available in the register of certified clients being maintained by TIC at its registered office. During this period the client shall discontinue the use of logo or any reference of certification in advertising matter, as directed by TIC, at the time of giving notice of suspension.

#### **(b) Withdrawal**

TIC shall withdraw the certificate under the following circumstances:

- (a) Failure of the client to resolve the issues of suspension within six months shall result in withdrawal of certification
- (b) Other reason like major legal complaint, company involved in malpractices, TIC loses accreditation etc.
- (c) Client voluntarily requested for a withdrawal.

Upon withdrawal of certification the client ceases to enjoy the certification status and shall accordingly return the certificate as directed by TIC at the time of withdrawal notice.

#### **(c) Reduction in scope of certification**

TIC shall decide to reduce the client's scope of certification by excluding the parts not meeting the requirements, when the client has persistently and seriously failed to meet the certification requirements for those parts of the scope of certification. Such exclusions shall be consistent with the certification standard.

Upon request from any party, TIC shall provide information related to the validity of a given certificate.

TIC will inform client for refusing, expanding or reducing the scope of certification, renewing, suspending or restoring, or withdrawing of certification.

### **6. Publicly Accessible Information**

TIC shall make the following information publicly accessible through its web site [www.tech-europa.com](http://www.tech-europa.com).


- The activities of TIC
- The requirements for certification including information on the audit processes and certification process for granting, maintaining, extending, renewing, reducing suspending and withdrawing certification.
- Certification status of certified clients.
- Appeal and complaint process. All other information shall be treated as confidential.

### **7. Obligations of the applicant / certified organization**

The applicant / certified organization shall commit to fulfil continually the requirements of certification set by TIC for the scope for which certification has been granted including adapting changes in requirements for certification as and when communicated.

- (a) When requested the applicant / certified organization shall cooperate with TIC in the fulfilment of the requirements for certification. This shall apply to all locations included in the certification.
- (b) The applicant / certified organization shall provide access to information, documents and records as necessary for granting certification and maintaining certification.
- (c) Certified organization shall allow the personnel from the accreditation body access to their sites and shall provide access to information, documents and records when requested by TIC.
- (d) The certified client shall claim certification only with respect to the scope for which certification has been granted.
- (e) The certified organization shall not use its certification in such a manner as to bring TIC into disrepute.
- (f) The applicant / certified organization shall pay fees as determined by TIC.
- (g) The applicant / certified organization shall inform without delay any significant changes relevant to the certification in respect of its status or its operation related.
  - i) Its legal, commercial or ownership status
  - ii) The organization, top management & key personnel
  - iii) Resources and premises

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iv) Scope of certification

v) Other such matters that might affect the ability of the certified organization to fulfil requirements of certification.

#### Obligations of TIC

(a) TIC shall make publicly available information about the status of certification that it has granted to certified organization. The information shall be updated regularly. The information shall include the following:

- i) Name and location of the certified client
- ii) Dates of granting certification and expiry date as applicable
- iii) Scope of certification

TIC shall give due notice of any changes to its requirements for certification. It shall take into account the views expressed by interested parties before deciding on the precise form and the effective date of the changes. Following a decision on, and publication of, the changed requirements it shall verify that each certified client carries out necessary adjustments.

#### 8. General Terms and Conditions

**(a) Termination-** The client and TIC shall have the right to terminate this agreement at any time giving 30 days of written notice of such termination. The client shall, in case of termination, reimburse to TIC all the dues up to date of termination. TIC, if it so wishes, shall also charge a termination fee to be negotiated at the time of termination and this is in addition to the dues that are payable to TIC. In no case such termination fee shall not exceed 15% of the value of the agreement. All reimbursable are payable at the end of said 30 days period.

**(b) Confidentiality-** TIC shall not disclose any information about the client or individual to a third party without the written consent of the client or the individual concerned. If TIC is required by law to release confidential information to a third party, the client or the individual concerned shall, unless regulated by law, be notified in advance of the information provided.

**(c) Force majeure-** Delay in or failure of performance of either party hereto shall not constitute a default hereunder or give rise to any claim for damage if and to the extent such delay or failure is caused by an act of war, natural disaster, fire, explosion, labour dispute or any other event beyond the control of the party affected and which, by the exercise of reasonable diligence, said party is unable to prevent. The party affected shall notify the other party in writing of the causes and expected duration immediately after the occurrence of any such event.

**(d) Law & disputes-** The agreement for certification between TIC and client shall be governed by prevailing law in India. Any dispute arising in connection with the agreement, which cannot be settled by private negotiations between the parties, shall be referred to arbitration as per the Indian Arbitration Act, subject to Delhi jurisdiction. The decision of the arbitration shall be binding for the both parties.

**(e) Appeals:** Client shall appeal to TIC in respect of the following:


- Non acceptance of client's application for certification
- Granting, suspending, withdrawing or denying of certification.

TIC shall deal with the appeals according to its procedure and shall be responsible for all decisions at all levels of the appeal handling process. TIC shall acknowledge the receipt of the appeal and shall provide the client with progress reports and the outcome.

**(f) Complaints:** TIC shall investigate the complaint received about the client to decide what action need to be taken and the same shall be communicated to the client at an appropriate time. The identity of the complainant shall not be disclosed.

**(g) Fees:** The fees shall be detailed in the quotation submitted by TIC. Fees are charged on the basis of applicable rates at the time of submission of the quotation. TIC may revise the fee submitted in the quotation during the Certification period. Clients shall be notified of any change in the fee. If any special audit is performed on the, TIC shall charge an extra fee for such audits to cover the audit charges and other administrative costs and this shall be payable within 7 days from the date of invoice. Cancellation of Audit

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shall involve re-imbusement of expenses incurred by TIC, if any. TIC will not issue certificate without receiving complete amount.

**(h) Access to the client site:** The client, at the request of TIC, shall permit access to their sites and records for TIC's auditors and authorized personnel on behalf of the accreditation body to which TIC is accredited. The same shall be communicated to the client in advance.

**(i) Agreement Period:** This agreement comes to force on and remains in the force until the expiry of the certificate, unless withdrawn for justified reasons or withdrawn by either party upon due notice given to the other party.

**(j) Liability:** TIC's liability shall be limited to providing certification of the client's management system and shall not in any way be responsible for the liabilities arising out of the client's products or services.

#### 9. Use TIC name and the TIC logo

The client shall not be entitled to use the name of TIC or of any of the companies affiliated with TIC or their logo. The client may not create the impression that it is associated with TIC or with any company affiliated with TIC in a corporate relationship or similar relationship, or that it is able to act for or commit TIC or any company affiliated with TIC.

#### 10. Price list

The charges of the certification provided on request and are finalized based on the scope and sites of the customer.

Signed by Authorized Representatives of Client Organization, after having read, understood and agreed on the conditions of the above certification agreement.

For the client;(Company name)\_\_\_\_\_

Date\_\_\_\_\_

Name:\_\_\_\_\_

Signature: \_\_\_\_\_

Designation: \_\_\_\_\_

Company Seal

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