



1.0 OBJECTIVE

To ensure that the conditions for reducing, extending, suspending and withdrawing certification are clearly defined.

2.0 SCOPE

This procedure covers all certifications of management systems for the clients certified by TQ Cert and also for carrying out special audits when required.

3.0 RESPONSIBILITY

The responsibilities for implementation and compliance are as indicated in the procedure.

4.0 PROCEDURE

4.1. Criteria for extending the scope of certification

TQ Cert requires that a certified organization seeking extension to the existing scope, shall apply with the supporting documents. These are reviewed by Head-QA to assess whether the extension sought to current scope can be granted and it is within the capability of TQ Cert.

4.1.1 Procedures as applicable for contract review and for organizing audits covering the revised scope are followed for grant of extension.

4.1.2 Depending on the need, it may be combined with surveillance audits or an exclusive audit may be organized by Head-QA. The existing documented procedures are adhered to revise the certificate.

4.1.3 The conditions for extending or reducing the scope of certification are indicated in **ANNEXURE – I**.

4.2 Suspending, withdrawing or reducing scope of certification

The decision for suspension, withdrawal or reducing scope of certification is taken based on the criteria given in **ANNEXURE – I**. Any suspensions and withdrawals are denoted in the List of clients accordingly and the list shall be made publicly accessible.

4.2.1 Upon suspension the client's management system becomes temporarily invalid. Head-QA liaise with the client and invokes the enforceable arrangements made with the client and ensure that the client refrains from further promotion of certification.



4.2.2 The suspension status is made accessible to public and TQ Cert shall take any other measures considered appropriate.

4.2.3 Failure to resolve the issues that have resulted in suspension within 6 months shall result in withdrawal of certificate or reduction of the scope of certification.

4.2.4 Head-QA ensures, as a part of certification agreement that an enforceable arrangements are made with the clients, on the conditions of withdrawal. The agreement covers issuance of notice of withdrawal to the client, to discontinue its use of all advertising or any communication that contains reference to a certified status.

4.3 The directory of certified clients is updated incorporating current status and this is made publicly accessible. Upon receipt of request from any party, Head-QA ensures communication of current status correctly of the client's management system as being suspended, withdrawn or reduced.

4.4 **Short – notice audits.**

- Short notice audits may be required to be conducted to investigate complaints or in response to the changes or as a follow up of suspension of certification.
- In these cases Head-QA informs in advance to the certified clients providing the conditions for these short notice audits. Also additional care is taken in the assignment of the audit team because of the lack of opportunity for the client to object to audit team members.

4.5 **Modification of Scope for Ayush**

Extension of scope of certificate for inclusion of additional dosage forms and products therein under the same certificate shall be done after

- ascertaining that the certified organization has requisite resources required e.g. raw materials, process controls, manufacturing machinery, test facilities and technical skills .for dosage forms and products under extension of scope, through an on-site evaluation, and
- test reports for sample of products of the new dosage form are on independent testing found conforming to requirements of the Criteria

For extension of scope of certificate for inclusion of additional products within an existing dosage form of the Ayush Product under the same certificate, the certification body shall

- Draw samples of additional products as per sampling plan at Cl 4.2.9 for



Independent testing.

- Process for extension of scope for the additional products on the basis of test reports of additional products in the same dosage form, provided by the manufacturer, subject to conformity of samples on independent testing mentioned at a) above.

The extension of scope shall be clearly mentioned in the certificate document along with its date of inclusion for avoiding any misrepresentation or misinterpretation. Irrespective of the date of inclusion, the validity of the Certificate shall remain unchanged.

5.0

REFERENCES

Procedure for issuance of Registration - QMS-P15
Procedure for Complaints handling mechanism – QMS-P09
Procedure for Appeals and Disputes – QMS-P10
Ayush Scheme – Annexure II



ANNEXURE – I

Condition for Extending, Reducing, suspension and withdrawal of Certification

Sl. No	Activities	Requirements	NCR Status/Conditions
1	Refusing the Certification	<ul style="list-style-type: none">• Company is unable to demonstrate itself as a legal entity.• Applied scopes by the company are not evident• Company unable to demonstrate all the requirements of the standard.	<ul style="list-style-type: none">• Major NC's open
2	Extending scope of certification	<ul style="list-style-type: none">• The assessment of additional scope shall be covered during the surveillance audit, or special audits and a new certificate with the original validity period will be issued on fulfilling the requirements.	<ul style="list-style-type: none">• Major NCs-NIL• Minor NCs-Reported / closed
3	Reducing scope of certification	<ul style="list-style-type: none">• Request from the customer with reasons.• Review the implications of reduction of scope during surveillance TQ Cert may decide to carry out special audit when required.• Scope can be reduced to exclude the parts not meeting the requirements or when the client has seriously failed to meet the requirements for the parts covered in the scope. Any such reduction shall be in line with the requirements of the governing standard.	<ul style="list-style-type: none">• Based on Auditors report certificate will be revised and re- issued to customer with revised scope.



4	Suspending *	<ul style="list-style-type: none">• Clients certified management system has persistently or seriously failed to meet certification requirements including for the effectiveness of management system• The client does not allow surveillance or recertification audits to be conducted at the required frequency• The certified client has voluntarily requested for suspension...• If any NC is not closed or no response is received from the certified organization within a period of maximum 90 days.• Suspension period to be intimated to client with an advice to implement the system within the specified period.• Maximum suspension period would be 6 months, during which TQ Cert to verify by audit that the client is meeting the requirements of the standard in too.• Improper usage of logo• Failure to resolve the issues that have resulted in suspension within 6 months.• Fully not meeting the requirements of applicable standard.	<ul style="list-style-type: none">• Major NCs-Reported and when no actions are taken.• Minor NCs-Reported and not closed. <p>These may be verified during surveillance audits or in any special visits</p> <p>Major NCs- Reported Minor NCs - Reported</p>
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	Renewing of Certification	<ul style="list-style-type: none">Based on client application and satisfactory fulfillment of standard requirements.	<ul style="list-style-type: none">Nil Major NC's
4	Restoring Following Suspension	<ul style="list-style-type: none">When the client has closed all the Non Conformities to the satisfaction of the audit team.When the client is ready for onsite audit and successful completion of the audit.	<ul style="list-style-type: none">NCs Closed
5	Withdrawal *	<ul style="list-style-type: none">Failure to resolve the issues that have resulted in suspension within 6 months.Fully not meeting the requirements of applicable standard.Verifying and reporting by TQ Cert that the certified organization has not taken timely corrective action on all non-conformities during audit (major and minor) resulting non implementation of the systems.Request by the applicant / certified organization.	

- * Decision taken by Director shall be final
- * Confidentiality of the relevant information shall be maintained by TQ Cert.
- * Suspended status of certification shall be made publicly accessible.



Annexure II

Ayush Scheme

1. Suspension

1.1. TQ Cert shall issue instructions to the certified manufacturing units for suspension of certification within 15 days from the date of receipt of intimation regarding ;However no such notice is required in case of failures mentioned in a and c below.

- any sample fails to conform to the requirements relating to Contaminants
- 2 consecutive samples, from the factory or market, as determined by date of manufacture, fail to conform to the requirements of the product requirements other than contaminants;
- Unsatisfactory performance during two consecutive Surveillance evaluations on account of any of these aspects is observed;
 - Failure of sample on factory testing (in case of failure of contaminants 4.9.1 a) above applies)
 - Unsatisfactory hygienic conditions
 - Important testing equipment not calibrated
 - Testing equipment out of order and no alternate arrangements for testing
 - Non implementation of Internal Quality Assurance Protocol
 - Non availability of testing personnel and absence of alternate arrangements
 - Unsatisfactory hygienic conditions of serious nature during a surveillance evaluation.
- failure in scheduling surveillance audits as per stipulated time (once in six months)

Note : The test reports will be reviewed by the assessor/technical expert qualified under the scheme

AY F-16 completed forms for previous assessment will be used for tracking the History.

1.2. Change of Location

- The client shall inform TQ Cert of any changes in the location of manufacturing unit
- On receipt of such information, TQ Cert shall issue instructions to the client for suspension of certificate with immediate effect.



- The client shall be subject to an evaluation at the new site like an initial evaluation of an applicant. (refer to AY-P-01 and AY-P-02)
 - If the evaluation is satisfactory, New certificate will be issued in the name of new location with certificate issue number. and the manufacturing unit shall be permitted to affix the certification mark to the Ayush products produced therein.
 - TQ Cert shall endorse the change of premises on the certificate.
- 1.3. TQ Cert shall issue due notice of at least one week for suspension of certification to the manufacturing unit and also requesting the details of the stock held with the applicant as on the date of receipt of the notice. The client shall respond to the suspension notice within 7 days from the date of receipt along with the details of the stock of the products held. The response will be reviewed by TQ Cert office and inform the decision to the client within 10 days. In case of serious failures mentioned at 4.9.1 a) and c) of the criteria, the notice may not be required.
- 1.4. On receipt of suspension letter, the applicant shall suspend using Ayush certification mark on Ayush products being manufactured by them with immediate effect and the client shall inform TQ Cert about the compliance immediately. The Production and dispatches records will be verified during the follow up the visit to the factory for revoking suspension for compliance that AYUSH Certification mark is not used on the products manufactured from the date of suspension. The manufacturing unit shall be advised to undertake a root cause analysis and identify the necessary corrective actions for resolving the same.
- 1.5. While under suspension, TQ Cert shall ensure that dispatches of certified Ayush products to the market/customer are withheld until the product in stock has been reassessed for conformity to the criteria. The manufacturing organization shall reassess the quality of the products in stock and TQ Cert shall verify this reassessed stock for conformity to the certification criteria before allowing its dispatch. The reference to the quantity of stock as communicated by the client as on the date of receipt of suspension notice and the quantity as on the date of re-assessment to be verified to ensure that the product under suspension was not dispatched. The production and dispatch records will be verified during the follow up visit to the factory for revoking suspension for ensuring compliance.
- 1.6. TQ Cert shall revoke suspension only when ;
- Corrective actions have been taken and verified by the certification body.
 - Reports of Samples of Ayush products manufactured after corrective actions, both during factory and independent testing confirm compliance to Criteria requirements.



- The verification of corrective actions and reports of samples of Ayush products manufactures after corrective actions (factory and independent testing) will be verified by TQ Cert during the followup assessment as communicated to the applicant.

1.7. Suspension shall not exceed a period of six months. The manufacturing unit's inability to resolve issues relating to suspension within this period shall lead to cancellation of certification. The list of suspended companies is maintained in a directory indicating the name of the client, products certified, date of certification and its validity, date of suspension, reasons for suspension, period of suspension.

2. Cancellation

2.1. Certification body shall cancel the certificate when ;

- a. Certified unit contravenes the terms and conditions of certification and provisions of Ayush certification scheme like repeated failures of samples, suspension of certificate, inadequate corrective actions, lack of compliance to internal quality protocol, misuse of Ayush Certification Mark(s) etc
- b. Ayush products are failing and not conforming to the requirements of the Certification Criteria and the corrective actions taken are not ensuring compliance, or the proposed plan for corrective actions will take a considerable time beyond 6 months for implementation;

In case of any of the situations as mentioned above, TQ Cert will communicate the decision of cancelation to the client within Fifteen days from the date it is noticed by TQ Cert. In case of Two consecutive failure of test samples conducted externally will be considered as repeated failure of samples.

2.2. TQ Cert shall cancel the product certification certificate at the request of the certified unit, if the operation(s) in the certified units premises can no longer be carried due to reasons of natural calamities such as flood, fire, earthquake etc, lock out declared by the management, or closure of business operations etc.

On receipt of communication from the client, the designated person will review the reasons, record the same and forward the cancellation to the client.



2.3. Suspension of Registration is an interim measure that may lead to withdrawal of Registration. Suspension should not last longer than 180 days. Customer may request his registration be placed on Suspension. During Suspension the customer is allowed to retain the certificate but the registration is temporarily invalid and the customer shall refrain from promoting his registration, including use of marks or logos.

2.4. TQ Cert reserves the right to place a customer's registration on Suspension for the following conditions:

- Major nonconformance(s) indicating a failure of the client's product certification system.
- Client's failure to take corrective actions to identified nonconformance(s) within targeted date.
- The customer is unwilling or unable to make changes in response to registration system or TQ Cert procedure changes
- Improper use of the logo, symbol, registration, registration document or misrepresentation of registration
- Customer violates the spirit and intent of the registration in such a way as to do damage to the image of the registration process and its certified management system has persistently failed to meet certification requirements.
- Failure to meet their financial obligations to TQ Cert
- Any other violation of the requirements within the contractual agreement with TQ Cert.
- Customer may be placed on Suspension and subsequent cancellation for not undertaking surveillance audit according to the stipulated dates as defined in individual scheme procedure requirements (Refer to 4.1.6 of FSMS P-04). Customer has voluntarily requested a suspension.
- Any other reason that may be intimated from time to time.

2.5. TQ Cert shall notify the customer in writing of Suspension within 15 days. The Suspension letter requires satisfactory closure of all issues communicated by TQ Cert.

2.6. If the registered customer is unable to satisfy the requirement for reinstatement within 180 days or time given by TQ Cert whichever is less, the registration may be cancelled.

3. Change of Ownership



In the event of changes of ownership, the new management of the organization shall submit its acceptance to the agreement for certification with the TQ Cert, Internal Quality Assurance Protocol and payment of fees. Such changes shall not call for a visit to the production site and issue of revised Certificate.

4. Change of Name

In case of change of name the client shall inform the change in the name to TQ Cert with supported documentary evidence and if satisfied TQ Cert shall endorse the certificate in the new name

5. During the period of suspension, the client makes no misleading claims as to the status of certification and ceases to use the certification mark on the products from the date of notification.

6. General

- TQ Cert will provide notification to the registered customer of Suspension or cancellation or reinstatement immediately by telephone, fax, e-mail.
- TQ Cert reserves the right to publish notices of Suspension or cancellation or withdrawal.
- The registered customer shall be afforded the opportunity to appeal any Suspension or cancellation. The status of suspension and withdrawal shall be published in the TQ Cert website.