

Issue No : 01	Procedure for Conducting Renewal Assessment	
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1.0 PURPOSE

- 1.1 The purpose of the renewal audit is to confirm the continued conformity and effectiveness of the systems as a whole and its continuous relevance and applicability for the scope of the certification.
- 1.2 To define the procedure for planning, conducting and reporting of Renewal Audits carried out by FCI

2.0 SCOPE

- 2.1 This procedure applies to all Renewal Audits conducted by FCI at a client place on site visiting physical locations.

3.0 RESPONSIBILITIES

The Designated Person is responsible for overall implementation of this procedure.

4.0 PROCEDURE:

4.1 Renewal

- 4.1.1 FCI shall send the Renewal notice to the certified units at least four months prior to expiry of certificate validity period.
- 4.1.2 The client shall apply for renewal in the prescribed format along with fee, if any prescribed by FCI at least 3 months before expiry of the certification.
- 4.1.3 FCI 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.
- 4.1.4 The review shall be based on
- a) Surveillance and renewal evaluation reports,
 - b) Quantum of Ayush products conforming to criteria expressed as percentage of quantity manufactured
 - c) Handling and disposition of non conforming products
 - d) Test reports for samples drawn from the factory and the market,
 - e) Any suspension of certificate during the previous validity period;
 - f) corrective actions taken
 - g) complaints if any received,
 - h) Adverse information, if any.

Conditional grant of certificate is not allowed

- 4.1.5 Renewal of certificate shall be based on the satisfactory performance of the certified units.
- 4.1.6 FCI shall not renew certification with conditions for compliance to be verified subsequently. There shall be no conditional renewal of certification.
- 4.1.7 When performance of the certified units is not satisfactory, FCI shall withhold the renewal of the certificate to the client clearly stating the reasons and give time for effecting corrective actions. The verification and decision on renewal should be taken within 3 months of the expiry date.

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- 4.1.8 The corrective actions shall be verified generally on site unless FCI can verify the same off site prior to considering for renewal of certificate. The justification for off site review shall be recorded.
- 4.1.9 The renewal shall be effected from the date of the expiry of the previous certificate and the intervening period shall be treated as period of suspension and clearly stated on the Certificate. The client shall not claim certification or use the Certification Mark during this period.
- 4.1.10 In case the client does not complete satisfactorily actions within three months, the certificate shall stand expired from the date of expiry of previous validity.
- 4.1.11 When a certificate is not renewed, it shall expire at the end of validity period.
- 4.2 Designated Person will communicate to the client regarding the due dates of re-registration .
- 4.3 After verifying the information provided by the company, the Designated Person issues offer.
- 4.4 After receiving the duly signed contractual agreement, Designated Person initiates the process for scheduling the assessment.
- 4.5 Designated Person shall review the previous surveillance audit reports to consider the performance during the period of certification.
- 4.6 Designated Person will agree upon and schedule the audit with the Client. The goal is to schedule the assessment requested by the Client as per the target date and conduct the audit on the target date.
- 4.7 Designated Person will decide the composition of the audit team, ensuring that assessor qualifications match audit requirements . FCI may attach technical experts to support their audit team who are selected basing on FCI Procedure.

The calculation of mandays is as per AY/P-04.

In case the production facility is having inhouse lab for testing, then the assessment team is to be supported by a person having worked in a lab for a minimum period of 2 years working experience **in case any of the assessment team member do not have exposure to lab**. His mandays will not be counted for mandays calculation.

A brief description of each assessor's background and experience shall be provided upon request.

In case of any objection to the composition of audit team by the Client the Designated Person will consult the Certification Manager and the decision will be informed to the Client. In case the Client disagrees with the decision, then the process will go through appeal procedure.

- 4.8 The Designated Person shall file the confirmation in the Client history file.
- 4.9 Audit team members will assemble an audit packet with downloaded documents and documents sent by the Designated Person. Any missing information should be requested from the Designated Person.
- 4.10 Prior to the audit or prior to the opening meeting during the scheduled assessor preparation time, the Team Leader will conduct a team briefing, if applicable. The team briefing will cover the following items as a minimum:
- Introduce all audit team members.
 - Answer any questions the team members may have about conducting the audit.
 - Review the audit plan, scope and standard.
 - Review FCI definitions of minor and major nonconformances and potential registration recommendations.
 - Stress the importance of obtaining objective evidence

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4.11 Opening Meeting:

- 4.11.1** The Team Leader will be responsible for conducting the opening meeting and will:
- Review the items on Opening Meeting as per FSMS/G-02.
 - Have all present sign the opening/closing meeting attendance sheet
 - Giving the Client signed Confidentiality and Nondisclosure Statements
 - The Company Information Sheet should be reviewed, marked with any changes and signed by the Team Leader and Client before, during or immediately after the opening meeting. **If the Number of employees are different from the information given in the Client Information sheet then the lead assessor shall get in touch with the FCI office and confirm the number of man days required for the audit. In case of change in the number of man days required for the audit, the Team Leader shall resolve this issue by discussing with the Client and FCI office before proceeding further with the audit.**
- 4.11.2** Opening meeting should be brief in an attempt to hold to the established schedule.
- 4.11.3** Following the opening meeting the Team Leader may request, if applicable, a short plant tour to familiarize the audit team with the activities carried out within the Client's facility. The plant tour should be conducted per the audit schedule.
- 4.11.4** Team Leader may convene with any or all assessors at any time during the audit to review their findings and determine any changes in planned activities and the audit plan.
- 4.11.5** Individual assessors are responsible for documenting non-conformances and opportunities for improvement on the Non-conformance Report and submitting them to the Team Leader before the closing meeting.
- a. Assessors identifying a possible "major" nonconformance shall inform the Team Leader as soon as practical.
 - b. A nonconformance will only be sanctioned by the Team Leader if it is capable of being written in the words of the standard and/or documented system and is substantiated by objective evidence.
 - c. Assessors are encouraged to document opportunities for improvement to benefit the Client
- 4.11.6** Non-conformances are categorized into two levels of severity: , Major and minor..

4.12 Reporting of Renewal Audits:

- 4.12.1.1 Audit team report all the non conformances and hand over to the company to initiate necessary corrective actions for the closure of the NCs.
- 4.12.1.2 The Audit Team will document the audit results and communicate to the client non-conformity reports for comments.
- 4.12.1.3 After verification of the evidences submitted by the company for the non conformances and satisfactory closure of the NCs the report with recommendation is forwarded to FCI..
- 4.12.1.4 The reviewed report is submitted to Registration Committee for decision on re-registration.
- 4.13 The assessment team will then discuss the findings, agree on the severity of the non-conformances and agree upon one of the following recommendations;

A. Stage-1 Assessment in case of Ayush Premium Mark

- Preparedness for proceeding to Stage-II Assessment or at this point of time, the organization is not ready to go for Stage-II assessment.

Stage-1 in case of Ayush standard mark or Stage-II or follow up audit or Surveillance.

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B. Unable to recommend at this point of time because of open non-conformances if any and pending the testing of samples collected at NABL accredited lab as per parameters Annex-B or Annex-C as applicable. You are given 60 days time to respond with corrective actions, if required, these will be reviewed and verified at the site by one of the assessors.

In case of no NC's, wait till you hear from FCI about the results from Lab.

C. Recommendation not to maintain registration.(In case of surveillance)

- a. The audit process identifies more than one Major non-conformance or 10 minor non-conformances and additionally lack of non-conformance resolution within the specified time frame will also result not to maintain registration.

Follow up audit incase of Stage-I of Ayush Standard Mark or Stage-II or Surveillance or Re-registration.

The audit team indentified more than one Major NCR or 10 Minor non-conformance or non-conformances are such that the responses to be verified at the site, follow up audit recommended.

4.14 Ideally the decision will be unanimous but in the event of a dispute the decision of the TEAM LEADER is final.

4.15 Closing Meeting:

4.15.1 The Team Leader is responsible for conducting the closing meeting and will address the following points as a minimum;

- a. Thank the Client for their assistance and hospitality
- b. Review the items on Closing Meeting as per FSMS/G-03.
- c. Have all present sign the opening/closing meeting attendance sheet.

4.15.2 If the recommendation is "*Recommendation Not To Re-register*" the Team Leader must explain that the recommendation is subject to ratification by FCI and that it may be appealed by the Client.

4.15.3 The Team Leader is responsible for communicating this information clearly and concisely and ensuring that the closing meeting is not used to debate or negotiate the recommendation. The purpose of the closing meeting is to report the audit findings. Any challenge or dispute of the findings should be via the formal appeal process.

4.15.4 The Team Leader will leave a copy of the nonconformance reports with the Client at the conclusion of the audit and request the Client to respond to the Team Leader by the indicated date.

4.16 Follow up Audit

4.16.1 Follow-up audits should be recommended when Non-conformances are of such a nature that an on-site review of corrective action is required to substantiate the effective implementation. (Subsequent surveillance audits always verify effectiveness of corrective actions).

Follow-up audits shall be considered if greater than 1 major and/or 10 minor non-conformances or non-conformances are such that the responses to be verified at the site have been identified. The consideration may also take into account.

- a. The Client management's understanding of the non-conformances
- b. The overall Client initiative shown throughout the assessment.

The above consideration shall be addressed in the audit report.

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Note: At the follow-up audit the assessor will make a registration recommendation.

4.16.2 No more than 2 follow-up audits shall be conducted.

4.17 Decision of Re-registration

- 4.17.1 Applicant organizations found to be misusing the Ayush certification mark, while their application is processed for grant of certificate, shall not be processed any further and rejected after due notice of fifteen days and they shall be treated as fresh.
- 4.17.2 The audit documentation is reviewed by FCI Management/designated reviewer.
- 4.17.3 All corrective actions must be closed with root cause analysis and corrective actions verified as complete before consideration by the Registration Committee. The window for submission of satisfactory corrective actions by the client is 60 days from the date of audit and the process of certification to be completed within 90 days from the date of audit.
- 4.17.4 A Registration Committee will convene with at least two members to review the audit documentation per the requirements of FCI Policy Manual & Procedures.
- 4.17.5 The Registration Committee shall review the audit documentation and record its decision for re-registration on Recommendation Report. At a minimum they shall review;
 - a. The Company Information Sheet and contract review
 - b. The Assessment Report
 - c. Nonconformance reports and associated Client corrective action responses.
 - d. The Recommendation Report;
 - e. Complaints if any received from users of certification
 - f. The results of the review of the system over the period of certification.
 - g. Compliance with the requirements as mentioned in Para 4.1 of this procedure
- 4.17.6 The Director FCI shall make the registration continuation decision on the basis of the evaluation of audit findings and conclusions and any other relevant information provided by the registration committee.
- 4.17.7 The Designated Person shall notify the Client by letter of the decision with a validity period of three years and establish the tentative date for the next surveillance assessment.
- 4.17.8 Should the Client appeal the decision, the Registration Committee will examine this appeal and adjudicate based upon the objective evidence submitted by both parties. If a dispute still exists upon further review, the issue will be resolved as defined in procedure Appeals.

5.0 RECORDS & Forms

5.1 Conformance Audit History File section in Client History File

6.0 REVISIONS

Original Issue, Rev.00, Dt:1-Oct-2009

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