**1 PURPOSE**

**1.1** To put a system in place for creating and issuing of TQ Cert offer letters and contracts w.r.t. under AYUSH Certification Scheme

**2 SCOPE**

**2.1** Covers under AYUSH Certification registration schemes, initial, surveillance, renewal and change of location. TQ Cert shall confines its certification requirements to those matters specifically related to the scope of certification.

**3 RESPONSIBILITY**

**3.1** Designated Person (DP) shall be responsible to ensure the implementation of this procedure.

**4 PROCEDURE: REGISTRATION**

**4.1** On receipt of enquiry from applicant the DP or his deputy forwards the application form, basing on the requirements of the customer.

**4.2** On receipt of filled in form, the DP will review it to see that the information is complete. DP will first determine the relevant part of Scope; the client engages in and compares that to TQ Cert scope of accreditation. If the client activities do not fall within TQ Cert scope then the DP will notify the Director who will determine if TQ Cert wished to add the relevant scope to TQ Cert scope by submitting the scope extension documents to the accreditation board, if TQ Cert wishes to add new scope then it will approach Accreditation Body for scope extension and to create necessary resources meeting requirement of qualifications and selection of assessors and Technical experts as necessary for scope extension. In such a case the customer may be issued a quotation. Any differences will be resolved with the customer before proceeding to issue the offer letter. The contract review is done as per the format AY-F02. In case of not taking up the case the client will be informed accordingly stating with the reasons.

Request for grant of certificates from ex-applicant shall be processed like a fresh application.

**4.3** Fees to be charged to the organization for various activities of the Ayush Product Certification Scheme will be without any discrimination between units, geographical location, and size of the unit.

**4.4** TQ Cert shall respond all enquires received from prospective applicants for AYUSH product certification with complete information for facilitating a registration of applicant within seven days of the receipt of enquiry.

**4.5** The applicant who has earlier misused the Ayush certification mark or have been implicated by the court or cancelled because of violation shall not be registered with in three years of conviction or cancellation after a due notice of 15 days. If the manufacturing licence issued by Licensing authority has been suspended / cancelled for a product or the factory during the last one year, the application from the same manufacturing unit shall not be entertained.

TQ Cert shall reject or close all applications for certification under the following conditions;

a. If Initial Evaluation is not carried out within six months of registration of application
b. If more than 20% of samples fail on factory testing during the Initial Evaluation and during the follow up Evaluation carried out after organization has confirmed necessary corrective actions.
c. If testing facilities are not completed within three months of Initial Evaluation, or else arrangements for testing for specified requirements in NABL accredited laboratories have not been made;
d. If during the Initial Evaluation it is observed that significant number of batches of the specific product and dosage form have not conformed to the Master Formula submitted to the Licensing authority and or have been subjected to corrections and rework
e. Non acceptance of internal quality assurance protocol within a month of Initial Evaluation;
f. Lack of competent personnel for production and testing,
g. If organizations shows no progress towards completion of corrective actions within three months of Initial Evaluation and six months of Registration of application.
h. Misuse of AYUSH Certification Mark
i. Evidence of malpractice
j. Voluntary withdrawal of application.

**4.6** Calculation of audit man days required basing on the information provided in the company information sheet and additional clarifications obtained by the DP or deputy.

4.6.1 Required total man days is calculated as follows to cover Stage-1/Stage-2 or Initial/surveillances/ renewal and scope extension evaluations:

4.6.2 In determining the onsite assessment time consideration needs to be given to the aspects like complexity of operations, the no. of employees and the no. of products offered for certification.

- Basic onsite assessment time for Ayush standard mark = 1.5 man-day's
- Basic onsite assessment time for Ayush standard mark with own lab for testing samples = 2 mandays
- Basic onsite assessment time for Ayush Premium mark = 2.5 Mandays

4.6.3 Additionally consider the following requirements

- Assessment time for each additional dosage form = Add 0.5 manday
- Add 0.5 manday each for employee strength more than 20 full time equivalents and for any multiples of 20 thereafter.
- The minimum evaluation time as above does not include the time spent either on preparation for the evaluation or for preparing the evaluation report
- In case of complexity of operations, then additional 0.5 manday will be added to the regular mandays.
- Additional time for review of test Reports, (0.5 Man day), preparation of Assessment report (0.5 man day), preparation of internal quality assurance protocol (0.5 man day) to be considered.
- Additional time factor for verification of records for every 20 products over and above initial 20 products under each dosage form to be considered (0.5 man day), as the auditor need to verify the records of all the products and document as objective evidence during the assessment.
- TQ Cert shall not carry out any on site evaluation of duration lesser than as specified above, as testing for capability and verification of all production and testing records are an essential component of every on site evaluation. This includes all evaluations including

those for surveillance, extension of scope etc.

4.6.4 In case of Surveillance/Re-Registration Assessment the man days are to be calculated on the same bases as calculated for initial assessment.

4.6.5 The frequency of surveillance in the initial cycle is Six Months. The frequency may be considered once in a year, provided there have be no major non-conformities, failure of samples or complaints during the past Three years. However it shall river to normal frequency of Six months immediately in case of any change in this situation. The position to be reflected in the offer letter submitted to the client.

4.6.6 Scope Extension and Additional dosages or Additional products within the existing dosages:

Basic on site assessment for standard mark 1.5 man day and with own lab 2.0 man days and in case of premium mark 2.5 man days, plus each additional dosage or additional products within the dosage ( Add 0.5 Man day ) each addition of Twenty employees for the new dosage forms ( add 0.5 Man day ) , report writing ( 0.5 Man day ) and review of test reports ( 0.5 Man day )

**4.7** DP or his deputy will generate an offer letter and forwards to the customer. DP will also document the appropriate assessor man-day requirements for the conformance and surveillance assessments. All quotations are firm for 30 days from the date of issue. Director approval to be obtained if there is any deviations quoting the rates as per price list

**4.8** Effective number of employees includes non-permanent (Seasonal, temporary and subcontracted staff who will be present at the time of audit. Part time employees should be treated as full time equivalent employees.

**4.9** Discounts from the Actual Fees:

Any deviations or discounts in the audit fees shall be approved by the Director basing on the justification provided by DP.

**4.10** Changes to Quotation/Contracts

Any changes to the approved quotations/contracts and its terms will be documented in the client files. All changes in registration program requirements require that existing quotations/contracts will be revised to incorporate those changes.

**4.11** DP will forward welcome pack to the customer as per QMS/F-16,

- A copy of signed contract.
- TQ Cert contact information.
- Flow chart of activity for the assessment.
- Requirements of the standard
- Assessment expectations.
- Agreement for registration disclosure.

**4.12** Any changes to the approved offer and application for operational/surveillance assessments will be documented and mutually approved.

**4.13** Client must enter into the Agreement for Registration Disclosure typically quoted for a three years period.

**4.14** Surveillance assessment program – Refer to AY P-02

**4.15** Re-Registration. – Refer AY P-03

Quotations will be prepared accordance to this procedure and the process described in re-registration audit.

**4.16** Transfer of registration Refer QMS P-19

Quotation for transfer of registration from another register to TQ Cert will be prepared in accordance with this procedure and as per the process described in transfer of registration.

**4.17** Records & Forms

- Company Information Sheet.
- Contract review Checklist
- Assessor day deviation justification work sheet
- Letter of Offer for initial/re-registration/change of registrar
- Agreement for registration disclosure
- Welcome Pack
- Auditor time calculation Sheet

**5 REVISIONS**

**5.1** Original Issue. Rev.00, Dt: 01.12.2014