



PROCEDURE FOR PRODUCT CERTIFICATION

BHUTAN STANDARDS BUREAU

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1 Application

The process of Product Certification starts with the receipt of application in the prescribed application form with information covering the aspects as shown below by the applicant organization, along with an application fee.

The applicant shall provide the following information:

- a) The product(s) to be certified,
- b) The standard(s) for which certification is sought,
- c) Name and the address of its physical location(s), significant aspects of its process and operations,
- d) The applicable legal obligations,
- e) Information relevant for the field of certification applied for, concerning the applicant, such as its activities, human and technical resources including laboratories and /or inspection facilities, functions and relationship in a larger corporation, if any;
- f) Information concerning all outsourced processes used by the applicant that will affect conformity to requirements,
- g) The BSB PCS can establish appropriate contractual controls over that legal entity(ies). If such contractual controls are needed, they can be established prior to providing formal certification documentation

The BSB PCS also uses a variety of media and mechanisms to collect this information at various times.

2 Application review

The BSB PCS assigns the responsibility to one of its officers to conduct a review of the information obtained with the application to ensure that:

- a) The information about the applicant and the product is sufficient for the conduct of the certification process,
- b) The differences, if any, in understanding between BSB PCS and the client is resolved including agreement regarding standard,
- c) The scope of certification sought is defined;
- d) The competent personnel to perform all evaluation activities are available,
- e) The competence and capability to undertake the certification activity such as review and decision-making process.

When new application is received, BSB PCS identifies product, processes and services, national standards and certification scheme if the BSB PCS has no prior experience. BSB PCS starts the process of developing national standards, by forwarding it to the Standardization Division, and certification scheme for such areas.

When BSB PCS lacks competence for the certification activities applied for, it declines to undertake certification in such areas.

2.1 Registration of application

When application review report confirms the application fulfilling the requirements of the certification scheme, it is registered and provided a unique application number.

The unique number will be alpha numeric such as PCS- A-00001, which will be the number for the first application.

An application register format given in PCS-P7.2-01-F03 is opened to record applications in a chronological order.

2.2 Closure of application

If application does not progress for grant of license within 6 months it should be considered for closure in accordance with BSB-PCS.

3 Preliminary Inspection

BSB PCS organizes a preliminary visit by appointing a Technical Auditor to gather information for evaluation of applicant's capability to implement the certification scheme.

The Technical Auditor submits a preliminary inspection report in the prescribed format recommending whether or not the applicant is ready for Factory audit.

Inspection report includes the following information;

- a) Competency in technical area
- b) Strength of employees
- c) Description of the production line
- d) Relevance to the scope for which certification is sought

4 Final Inspection

The BSB PCS based on the information provided in the application and the preliminary inspection report determines the man days required for the technical evaluation. A team is then constituted of technical auditors competent to carry out audit.

If any valid reasons for change in the team composition are received from the client it is examined on the basis of any conflict of interest.

The Technical Audit Team carries out full factory audit of the products against the requirements covered by the scope defined in its application including requirements specified in the certification scheme as follows:

- a) General information about company and its product
- b) Raw materials used for the production

- c) Manufacturing process
- d) Inspection on laboratory and testing personnel competency
- e) Manufacturing and testing equipment
- f) Nature of packing and marking of products
- g) Sampling at the factory
- h) Third party test reports
- i) In-house test records
- j) Calibration of equipment and certificates
- k) Other information such as storage facilities, marketing and hygienic conditions etc.
- l) Inspection/testing charges
- m) Recommendation and points for action

5 Sampling

The team shall take samples for independent testing in accordance with BSB-PCS guidelines for Drawl, Coding, Sealing and Dispatch of Samples.

A brief report of the evaluation especially indicating the nonconformities is provided to the client and seeking time taken for corrective action by the client.

Depending on the nature of nonconformities and if the client expresses interest in continuing the certification process, BSB PCS shall decide whether additional evaluation tasks needed to verify that nonconformities have been corrected at site.

6 Review and Recommendation

The BSB PCS shall assign at least one person to review all information and results related to the evaluation. The review shall be carried out by personnel who have not been involved in the evaluation activities.

The results of all evaluation activities as given below shall be documented prior to review. This documentation can provide the basis whether product requirements have been fulfilled:

- a) Preliminary inspection report
- b) Factory technical audit report
- c) Report of samples tested in an independent laboratory

The reviewing officer submits his/her review report including recommendations for consideration by the Certification Committee.

7 Certification Decision

Certification decision shall be the sole responsibility of the BSB PCS and the decision shall be taken by its internal person competent for the job. The BSB PCS shall be responsible for and shall retain authority for its decisions relating to certification.

The certification decision is carried out by the Certification Committee which has not been involved in the evaluation process. A member of the Certification Committee who has been involved in the evaluation process shall abstain from the meeting to avoid any conflict of interest.

The Director General BSB takes the certification decision on the recommendations of Certification Committee based on all information related to the evaluation, its review, and any other relevant information.

The Certification Committee consists of:

- a) Director General, BSB (Chairman)
- b) All Division Heads of BSB (Member)
- c) Representative from Department of Trade, Ministry of Economic Affairs (MoEA)
- d) Officer Designate (Member Secretary)

8 Award of Certificate

BSB PCS ensures completion of the following actions for grant of license:

- a) The factory is satisfactory;
- b) The corrective actions on nonconformities raised have been implemented and verified either by site visit or other appropriate forms of verification;
- c) Actions pointed out during factor audit have been addressed and verified by visits to the unit or through submission of necessary evidence by the firm;
- d) The test report(s) of the sample(s) drawn by the technical auditor during the factory audit and follow-up visits, if any is found to be satisfactory; If samples of more than one variety were drawn for testing, the grant of license shall be recommended restricting to the variety/group/sizes(s)/type(s) found satisfactory in testing,
- d) The testing charges as well as charges for all visits to the factory before the grant of license have been paid;
- e) The applicant has got all the testing facilities or has made arrangements for carrying out all the tests to the satisfaction of the BSB PCS;
- f) The applicant has declared the brand names/trade mark which would carry the Standard Mark and has declared their manufacturing machinery and testing equipment;
- g) The applicant has given an undertaking to intimate BSB PCS, whenever any machinery or equipment declared is taken out of the premises due to any reason;
- h) The applicant has accepted the Scheme of Inspection and testing (STI) and the rate of marking fee;

- i) Necessary approval has been obtained from statutory authorities under product specific guidelines, if required.

After the license is granted BSB, PCS will intimate the firm about the grant of license. The license document is sent to the licensee signed by Director General.

In the event BSB PCS declines to grant certification, it shall notify the client about decision made by CC indicating the reasons for not granting certificate.

9 Surveillance

Every licensee is visited at least once a year for surveillance and it is ensured that the same inspector does not visit the same factory successively. Frequency may be increased depending on the performance of the licensee and sensitivity of the product.

If sufficient information regarding product conformity is not available before recertification a surveillance visit shall be carried out after giving intimation to the licensee.

9.1 Preparation for Surveillance Visit

Before proceeding for visits the technical inspectors shall:

- a) Study the relevant Bhutan Standard and the requirements prescribed therein thoroughly,
- b) Acquaint himself completely with the laboratory procedures that have to be adopted to test the requirements given in the specification,
- c) Examine conditions, if any, imposed at the time of grant of license/recertification/inclusion and any other aspects requiring verification during the subsequent visit,
- d) Study at least the last two surveillance visits report as well as any contact reports of the visits and note down the actions which the licensee had been asked to take,
- e) Study the correspondence exchanged with the licensee after last visit and note down the points on which action by licensee is pending, such as, dispatch of samples drawn, payment of bills, etc.; and
- f) Check whether any sample had failed in independent tests and the correspondence and actions taken regarding the failure.

9.2 Technical Inspections at Site

During the visit to the factory the technical inspectors should:

- a) Inspect the factory thoroughly with respect to raw materials, storage and manufacturing process.
- b) Check availability of relevant standards, STI etc. and examine the various test procedures that are being followed to ensure that these procedures are according to those given in the specification.
- c) Check records of production, laboratory testing and calibration of equipment/instruments.

- d) Check if there is any change regarding the manufacturing machinery and test equipment declared earlier.
- e) Sign records indicating the date of visit and record observations about any improvements needed in maintaining the records.
- f) Draw samples of the material in adequate quantity with the Standard Mark and test it in the factory.
- g) Another sample with the Standard Mark preferably of different type/size/grade/lot/control unit should be drawn for independent testing.
- h) Take down names and addresses of the consumers to whom the material with the Standard Mark has been recently supplied to facilitate drawl of market sample.
- i) Ensure that the Standard Mark is removed from the batches or control unit which on testing by inspecting officer do not conform to the specification.
- j) Ensure that samples drawn during previous visits and left with the firm if any, have been dispatched to the desired laboratory.
- k) Discuss on details of improvements made in management/process/quality control with specific reference to the improvements required on the nonconformities observed during surveillance visits and testing of samples.

9.3 Submitting Reports

After completing the inspection, the technical inspectors should report to Head, Certification Division, and his conclusions regarding the operation of the license, particularly, if the operation is not satisfactory.

9.4 Sampling and Failure of Factory/Market Sample

In the event that factory samples drawn from the factory or market samples collected from authorized dealers fail in the laboratory tests then the matter shall be noted and a report submitted to the reviewing Personnel for recommendations to be put up to the DG.

A notice shall be sent to the factory regarding the failure of the samples and a decision communicated based on the severity of the case.

9.5 Supervisory Visits

The Head of the Certification Division may pay periodic surprise visits to the licensees for new products brought under certification and licensees whose performance is inconsistent to ensure that the procedures are strictly followed both by the licensees and the technical inspectors.

10 Renewal

A renewal notice as per prescribed proforma is issued to the licensee three months before the date of the current operative period.

The licensee should submit the renewal application at least one month in advance of the expiry of the license, in the prescribed form.

10.1 Review of Application for Recertification

All information regarding the surveillance visits carried out during the operative period and the factory and market samples drawn and tested during the period should be given.

The information about pending actions, and samples under test at the time of previous renewal shall also be included

10.2 Renewal and Deferment of Renewal

License is considered for renewal when the renewal application is received before the date of expiry, performance is satisfactory and dues stand cleared.

License shall not be considered for renewal when the application is not received even after one month of the validity date or when the application is received and overall assessment of performance is unsatisfactory and there exist no or little possibility of effecting an improvement.

After the renewal orders, necessary endorsements shall be prepared for signatures of the renewing authority on the original license document submitted by the licensee within one month.

Deferment of Renewal of License is deferred if:

- a) Renewal application is not received within the validity period or before the expiry date, renewal application is received in an incomplete form.
- b) The license is under suspension of marking at the end of validity period the renewal may be deferred for a period of six months.
- c) Renewal application has been received but overall performance needs improvement which may require not more than two months from the date of validity

10.3 Cancellation of Licence

Action is initiated for cancellation of licence when the normal operation of a licence is not feasible due to violation and also on account of following reasons;

- a) Nonconformity of serious nature affecting health and safety observed during inspection or independent testing.
- b) Any contravention of the licensing provisions or the STI are considered serious in nature
- c) The measures taken towards correcting the discrepancies are found inadequate or time taken is too long (six months or more).
- d) If the licensee does not wish to prolong the license and send a communication to that effect.
- e) If the standard is amended/revised and implemented and the licensee either will not or cannot ensure compliance to the new requirements.
- f) If a complaint against BSB certified product is found to be genuine, cancellation of the license may be considered depending upon the seriousness of the complaint.

The cancellation notice on the recommendations of the Head CD should be issued by DG. The cancellation notice shall give fourteen days' notice to the licensee.

10.4 Suspension of Licence

Suspension shall be based on unsatisfactory performance of the product and when it does not conform to specified BSB standards:

- a) Marked product for varieties not covered under the licence
- b) Violation of bond provisions
- c) Violation of license conditions
- d) Suspension based on unforeseen situations

A licence may be suspended by the Bureau on the request from the licensee, if the operation(s) in his premises can no longer be carried due to:

- a) Natural calamities such as flood, fire, earthquake etc.
- b) A lock out declared by the licensee's management,
- c) Closure of operations directed by a competent court or statutory authority

11 Appeal

The procedure is only enabled for the owner of the company (ies) whose product(s) are not certified by the Certification Committee. The appeal made shall be reviewed and decided regarding acceptance by the Appeals Committee.

12 Fee Structure

12.1 Application fee Structure for both National and International Manufacturers

Sl.no	Business Licence Category	Application fee (Nu)	
		New	Renewal
1	Small, Medium & Large	1000	750

12.2 Certification fee Structure for the National Manufacturers

Sl.no	Business Licence Category	Application Fee (Nu)		Validity(years)
		New	Renewal	
1	Small	10,000	7,500	2
2	Medium	15,000	10,000	2
3	Large	20,000	15,000	2

Note: Business licence category is based on the licence issued by the Department of Trade, MoEA, Bhutan

12.3 Certification fee Structure for the International Manufacturers

Sl.no	Business Licence Category	Application Fee (Nu)		Validity(years)
		New	Renewal	
3	Small, Medium & Large	20,000	15,000	2

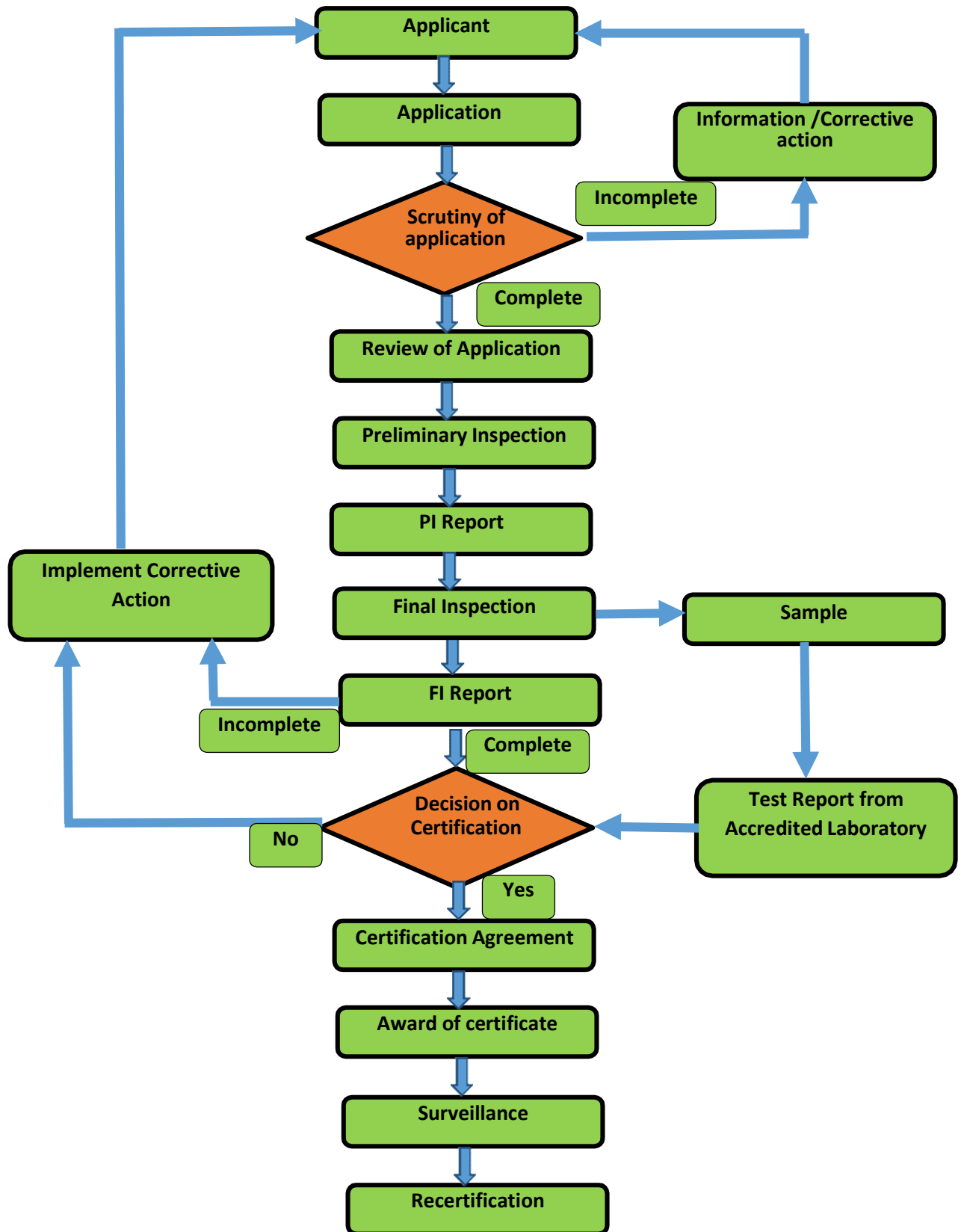
The fee is charged per product per brand. Management is responsible for the change in fee structure, with the approval of the BSB Board, and notifications shall be made available on BSB website (www.bsb.gov.bt) about the changes.

13 Complaints

Complaints may be from any source except the manufacturer of that particular product. Complaints shall be entertained only when submitted in writing. All complaints shall be referred to the Complaints Committee if found genuine during the review.

14 Flow Chart of the Certification Process

Operation of Product Certification Scheme



15 Reference

PCS P7.2-01 Procedure for receipt, review and registration of application

PCS P7.4-01 Procedure for Processing of application for Certification

PCS P7.6-01 Procedure for grant of certification

PCS P7.9-01 Procedure for Surveillance of Certified Companies

PCS P7.9-02 Procedure for Renewal

PCS P7.2-01-F02 Review of Application

PCS P7.4-01-F02 Preliminary Visit Report of Applicant Premises

PCS P7.9-01-F01 Periodic/surveillance inspection report