



PROCEDURE FOR MANAGEMENT SYSTEM CERTIFICATION

BHUTAN STANDARD BUREAU

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1 Application

The certification body shall require an authorized representative to view the following information:

- a) The desired scope of the certification;
- b) Details of the applicant organization as required by the specific certification scheme;
- c) Identification of outsourced processes used by the organization that will affect conformity to requirements;
- d) The standards or other requirements for which the applicant organization is seeking certification,
- e) Whether consultancy relating to the management system to be certified has been provided and, if so, by whom.

2 Application Review

The certification body shall conduct a review of the application and ensure that:

- a) The information about its management system is sufficient to develop an audit programme.
- b) Any known difference in understanding between the certification body and the applicant organization is resolved;
- c) The certification body has the competence and ability to perform the certification activity;
- d) The scope of certification sought, the site(s) of the applicant organization's operations and time required to complete audits.

Certification body declining an application for certification as a result of the review of application shall be documented and made clear to the client.

3 Audit Programme

The audit programme for the certification cycle shall cover the complete management system requirements.

The audit programme for the initial certification shall include a two-stage initial audit, Surveillance audits in the first and second years following the certification decision, and a recertification audit in the third year prior to expiration of certification.

Surveillance audits shall be conducted at least once a calendar year, except in recertification years. The date of the first surveillance audit following initial certification shall not be more than 12 months from the certification decision date.

4 Planning Audits

4.1 Determining audit objectives, scope and criteria

The audit objectives shall be determined by the certification body. The audit objectives shall include the following:

- a) Determination of the conformity of the client's management system,
- b) Determination of the ability of the management system to ensure the client meets applicable statutory, regulatory and contractual requirements;
- c) Determination of the effectiveness of the management system to ensure the client can reasonably expect to achieving its specified objectives;
- d) As applicable, identification of areas for potential improvement of the management system.

The audit scope shall describe the extent and boundaries of the audit, such as sites, organizational units, activities and processes to be audited.

The audit criteria shall be used as a reference against which conformity is determined, and shall include:

- a) The requirements of a defined normative document on management systems;
- b) The defined processes and documentation of the management system developed by the client.

4.2 Audit Team Selection

The certification body shall have a process for selecting and appointing the audit team, including the audit team leader and technical experts as necessary, taking into account the competence needed to achieve the objectives of the audit and requirements for impartiality.

The minimum competence required to be part of the certification process apart from individual knowledge and skill must have under gone training for;

- ISO 9001
Quality Management System
- ISO/IEC 17021
Conformity Assessment-Requirement for bodies providing audit and certification of management system

4.3 Observers, Technical Experts and Guides

The presence of observer, technical and guides during an audit activity shall be agreed to by the certification body and client prior to the conduct of the audit.

The audit team shall ensure that observer, technical and guides do not unduly influence or interfere in the audit process or outcome of the audit.

5 Audit plans

The certification body shall ensure that an audit plan is established prior to each audit identified in the audit programme to provide the basis for agreement regarding the conduct and scheduling of the audit activities.

5.1 Preparing the Audit Plan

The audit plan shall be appropriate to the objectives and the scope of the audit. The audit plan shall at least include the following:

- a) The audit objectives;
- b) The audit criteria;
- c) The audit scope;
- d) The dates and sites where the on-site audit activities will be conducted, including visits to temporary sites and remote auditing activities;
- e) The expected duration of on-site audit activities;
- f) The roles and responsibilities of the audit team members and accompanying person.
- g) An opening and a closing meeting

6 Stage 1 Audit

Planning shall ensure that the objectives of stage 1 can be met and the client shall be informed of any on site activities during stage 1.

Auditors to cover during stage 1 are:

- a) review the client's management system documented information;
- b) evaluate the client's site-specific conditions and to undertake discussions with the client's personnel to determine the preparedness for stage 2;
- c) review the client's status and understanding regarding requirements of the standard;
- d) obtain necessary information regarding the scope of the management system, including:
 - the client's site(s);
 - processes and equipment used;
 - applicable statutory and regulatory requirements;
- e) Review the allocation of resources for stage 2 and agree the details of stage 2 with the client;
- f) Provide a focus for planning stage 2 by gaining a sufficient understanding of the client's management system.
- g) Evaluate if the internal audits and management reviews are being planned and performed, and that the level of implementation of the management system substantiates that the client is ready for stage 2.

Documented conclusions with regard to fulfilment of the stage 1 objectives and the readiness for stage 2 shall be communicated to the client.

If any significant changes which would impact the management system occur, the certification body shall consider the need to repeat all or part of stage 1.

7 Stage 2 Audit

The purpose of stage 2 is to evaluate the implementation, including effectiveness of the client's management system.

The stage 2 auditing shall take place at the site(s) of the client and shall include the following:

- a) information and evidence about conformity to all requirements of the applicable management system standard and normative documents;
- b) performance monitoring, measuring, reporting and reviewing against key performance objectives and targets;
- c) the client's management system ability and its performance regarding meeting of applicable statutory, regulatory and contractual requirements;
- d) operational control of the client's processes;
- e) internal auditing and management review;
- f) Management responsibility for the client's policies.

7.1 Conducting Audits

The certification body shall have a process for conducting on-site audits. This process shall include an opening meeting at the start of the audit and a closing meeting at the conclusion of the audit.

7.1.1 Conducting the Opening Meeting

A formal opening meeting, shall be held with the client's management and those responsible for the functions or processes to be audited.

The purpose of the opening meeting, usually conducted by the audit team leader, is to provide a short explanation of how the audit activities will be undertaken.

7.1.2 Obtaining and verifying Information

During the audit, information relevant to the audit objectives, scope and criteria shall be obtained by appropriate sampling and verified to become audit evidence. Some methods to obtain information shall include:

- a) interviews;
- b) observation of processes and activities;
- c) Review of documentation and records.

7.1.3 Conducting the Closing Meeting

A formal closing meeting, where attendance shall be recorded, shall be held with the client's management and those responsible for the functions or processes audited.

The purpose of the closing meeting, usually conducted by the audit team leader, is to present the audit conclusions, including the recommendation regarding certification. Any nonconformities shall be presented in such a manner that they are understood, and the timeframe for responding shall be agreed.

8 Final Audit Report

The certification body shall provide a written report for each audit to the client. The audit team may identify opportunities for improvement but shall not recommend specific solutions. Ownership of the audit report shall be maintained by the certification body.

The audit team leader must make sure that the audit report is prepared and shall be responsible for the contents present in the report. The audit report shall provide an accurate, concise and clear record of the audit.

9 Technical Review

Certification body shall conduct technical review based on the report submitted by the Audit team before passing for the certification decision. Identification of any nonconformities during the review shall be communicated to the client and same auditors shall audit based on nonconformities and its necessities.

10 Certification Decision

10.1 General

The certification body shall ensure that the persons or committees that make the decisions for granting or refusing certification, expanding or reducing the scope of certification, suspending or restoring certification, withdrawing certification or renewing certification are different from those who carried out the audits.

The person(s) assigned by the certification body to make a certification decision shall be employed by, or shall be under legally enforceable arrangement with either the certification body or an entity under the organizational control of the certification body. In the case of BSB, the certification decision is made by the DG based on the recommendation of the technical review report prepared by the Head, CD. He/she shall be qualified to conduct the technical review.

The certification body shall record each certification decision including any additional information or clarification sought from the audit team or other sources.

10.2 Actions Prior to Making a Decision

The certification body shall have a process to conduct an effective review prior to making a decision for granting certification, expanding or reducing the scope of certification, renewing, suspending or restoring, or withdrawing of certification, including, that:

- a) The information provided by the audit team is sufficient with respect to the certification requirements and the scope for certification;
- b) For any major nonconformities, it has reviewed, accepted and verified the correction and corrective actions;
- c) For any minor nonconformities it has reviewed and accepted the client's plan for correction and corrective action.

10.3 Information for Granting Initial Certification

The information provided by the audit team to the certification body for the certification decision shall include:

- a) The audit report;

- b) Comments on the nonconformities and, where applicable, the correction and corrective actions taken by the client;
- c) Confirmation of the information provided to the certification body used in the application review;
- d) Confirmation that the audit objectives have been achieved;
- e) A recommendation whether or not to grant certification, together with any conditions or observations.

If the certification body is not able to verify the implementation of corrections and corrective actions of any major nonconformity within 6 months after the last day of stage 2, the certification body shall conduct another stage 2 prior to recommending certification.

11 Surveillance Activities

11.1 Surveillance Audit

Surveillance audits are on-site audits and shall include:

- a) Internal audits and management review;
- b) A review of actions taken on nonconformities identified during the previous audit;
- c) Complaints handling;
- d) Effectiveness of the management system with regard to achieving the certified client's objectives and the intended results of the respective management system (s);
- e) Progress of planned activities aimed at continual improvement;
- f) Continuing operational control;
- g) Review of any changes;
- h) Use of marks and/or any other reference to certification.

12 Recertification

12.1 Recertification Audit

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

The recertification audit shall include an on-site audit that addresses the following:

- a) The effectiveness of the management system in its entirety in the light of internal and external changes and its continued relevance and applicability to the scope of certification;
- b) Demonstrated commitment to maintain the effectiveness and improvement of the management system in order to enhance overall performance;
- c) The effectiveness of the management system with regard to achieving the certified client's objectives and the intended results of the respective management system (s).

For any major nonconformity, the certification body shall define time limits for correction and corrective actions. These actions shall be implemented and verified prior to the expiration of certification.

13 Special Audits

13.1 Expanding Scope

The certification body shall, in response to an application for expanding the scope of a certification already granted, undertake a review of the application and determine any audit activities necessary to decide whether or not the extension may be granted.

13.2 Short-notice Audits

It may be necessary for the certification body to conduct audits of certified clients at short notice or unannounced to investigate complaints, or in response to changes, or as follow up on suspended clients.

13.3 Suspending, Withdrawing or Reducing the Scope of Certification

The certification body shall suspend certification in cases when:

- a) The client's certified management system has seriously failed to meet certification requirements,
- b) The certified client does not allow surveillance/recertification audits to be conducted at the required frequencies;
- c) The certified client has voluntarily requested a suspension.

Under suspension, the client's management system certification is temporarily invalid.

The certification body shall restore the suspended certification if the issue that has resulted in the suspension has been resolved. Failure to resolve the issues that have resulted in the suspension in a time established by the certification body shall result in withdrawal or reduction of the scope of certification.

14 Appeals

The certification body shall review, evaluate and make decision on appeals.

The appeals-handling process shall include at least the following elements and methods:

- a) An outline of the process for receiving, validating and investigating the appeal,
- b) Actions need to be taken in response to it, taking into account the results of previous similar appeals;
- c) Tracking and recording appeals, including actions undertaken to resolve them;
- d) Ensuring that any appropriate correction and corrective action are taken.

The certification body shall give formal notice to the appellant of the end of the appeals handling process.

15 Complaints

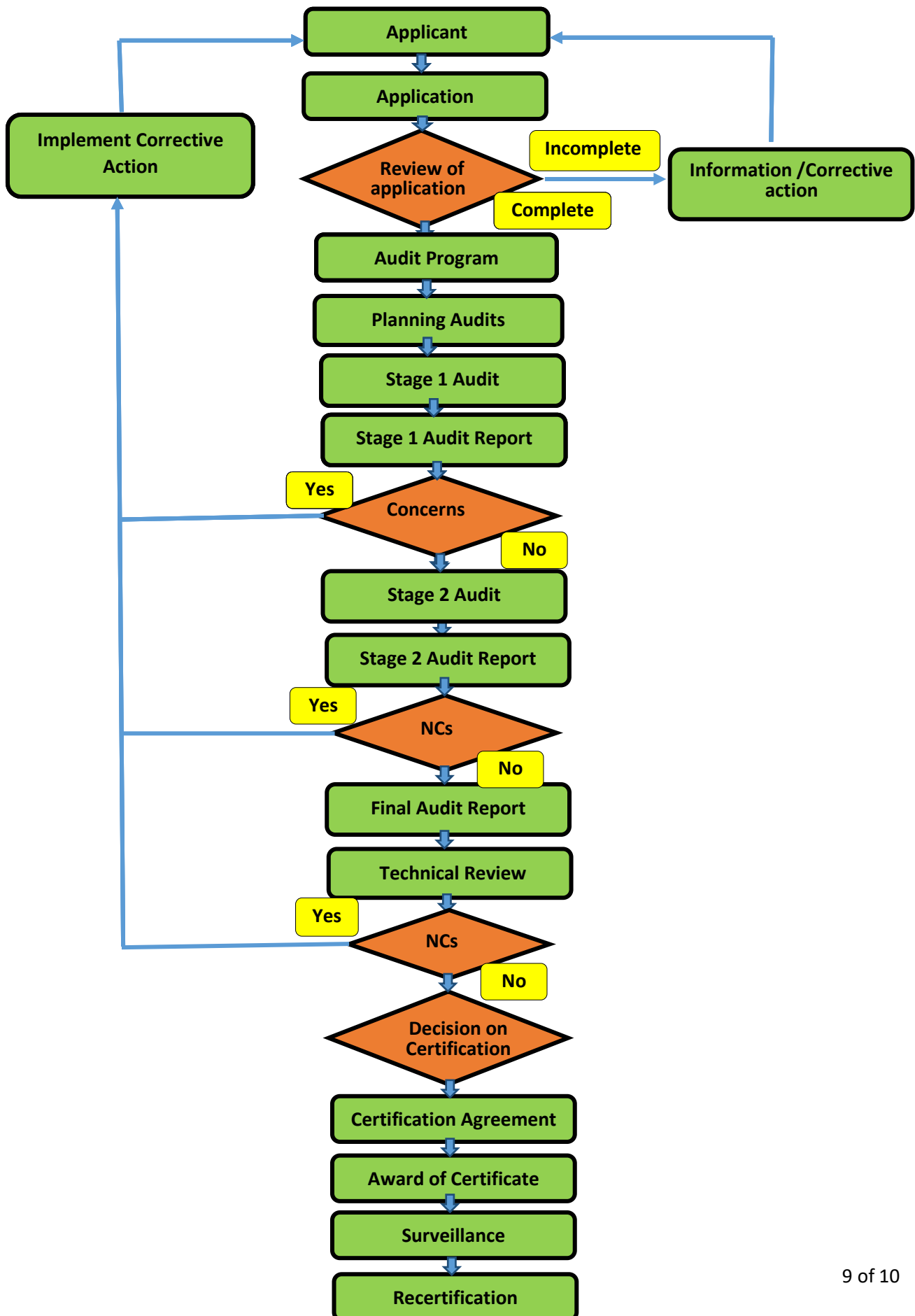
Upon receipt of a complaint, the certification body shall confirm whether the complaint relates to certification activities that it is responsible for and, if so, shall deal with it.

The complaints-handling process shall include at least the following elements and methods:

- a) An outline of the process for receiving, validating, investigating the complaint, and for deciding
- b) What actions need to be taken in response to it;
- c) Tracking and recording complaints, including actions undertaken in response to them;
- d) Ensuring that any appropriate correction and corrective action are taken.

The certification body shall give formal notice of the end of the complaints-handling process to the complainant.

16 Flow Chart



17 Reference

Conformity assessment-Requirements for bodies providing audit and certification of management system. (2015). In ISO/IEC 17021-1 (pp. 1-48). Geneva: Switzerland.

MSCS-P 9.4-01 Procedure for Conducting On-site Audits

MSCS-P 9.6-03 Procedure for Recertification (Renewal)

MSCS-P 9.2-01 Procedure for Planning Audits

MSCS-P 9.1-03 Procedure for Audit Programme

MSCS-P 9.6-05 Procedure for Suspension/Withdrawal/Reduced Scope of Certification

MSCS-P 9.7-01 Procedure for Appeals

MSCS-P 9.8-01 Procedure for Complaints Handling

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