

	BUREAU OF INDIAN STANDARDS			GUIDELINES
TITLE: GUIDELINES FOR APPLICANTS				
DOC: MSC-G11-01		ISSUE: 05	DATE: May 2016	PAGE: 1 OF 8
PREPARED BY: HEAD (MSCD)			APPROVED BY: DDG	

GUIDELINES FOR APPLICANTS

INTRODUCTION

Bureau of Indian Standards (BIS), the National Standards Body of India, has been guiding the Indian industry for more than five decades by formulation of national standards and operation of product certification scheme. The certification activities are carried through five Regional Offices and also utilizing the auditors from Branch Offices spread throughout the country along with external approved auditors and experts. In the wake of international trends and competitiveness taking new dimensions, the Bureau of Indian Standards is operating Management Systems Certification Scheme according to the published standards by BIS.

These guidelines contain useful information related to processing of an application, procedure for grant of licence, subsequent surveillance; obligations and responsibilities of the organizations interested in obtaining and operating licence according to relevant standards against which certification is operated. These guidelines contain the information extracted from the applicable regulations. For complete details, reference may be made to Bureau of Indian Standards (Certification) Regulations.

BIS, being a certifying body does not provide any form of consultancy services for implementation of the requirements of Management Systems Certification Scheme.

HOW TO OBTAIN LICENCE

Application and its Processing

Organizations interested in obtaining licence for any management systems should ensure that they have the ability to provide products / services that consistently meet customer requirements and regulatory requirements applicable with the requirements of the standard. They should apply on the prescribed forms at the concerned Regional Office of BIS along with prescribed application fee, as applicable which may be ascertained from BIS office. The application fee is non- refundable. Each application shall be accompanied by a with a copy of Quality Manual and other information as required.

The applicant shall have completed minimum **one Internal Audit** and **one Management Review**.

The application & the questionnaire are to be signed by the proprietor, partner or the Managing Director of the organization or any other person authorized to sign any declaration on behalf of the organization.

If necessary, BIS shall provide to the applicant further information about the scheme and also ask for further information from the applicant, as necessary.

BIS reserves the right to reject an application which is incomplete and does not fulfill one or more of following requirements:

- i) Application fee not accompanying the application;
- ii) Application form is incomplete;
- iii) Annexes to the application are not clear or incomplete

However, ample opportunity and information will be provided to applicant to fulfill the requirements. In addition, BIS may call for any supplementary information or documentary evidence from any applicant in support of or to substantiate any statement made in the application, within such time as may be directed by BIS.

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The reason for rejection of the application shall be communicated to the organization by BIS.

BIS shall acknowledge the receipt of the application and issue receipt of application fee. Every application shall be given a serial number to be known as 'Application Number'. In all future correspondence, reference shall be made to the 'Application Number'.

AUDITS FOR GRANTING CERTIFICATION

The audits for granting certification for the Management System would be conducted by BIS in two stages, namely Stage 1 & Stage 2. The Stage 1 comprises of the Adequacy Audit and the Preliminary Visit. The Stage 2 audit comprises of an Initial (Certification) Audit.

STAGE 1 AUDIT

In stage –I Audit, the Quality Manual will be examined by the BIS for verifying the conformance to the relevant standard. Any significant omissions or deviations from the prescribed requirements intimated by BIS will have to be corrected by the applicant and intimated to BIS.

BIS official(s) will make a visit to the premises of the applicant to acquaint with the size, nature of the operations, location & site-specific conditions, status and level of implementation of management system including evaluation of internal audit and management review undertaken by the organization. During the visit, the organization's readiness for the Stage 2 audit would also be ascertained and an assessment made for the resources (man-days, expertise) required for that audit. The number of audit man-days would depend on the size, nature and sites of operations of the organization being assessed. Any significant omissions or deviations from the prescribed requirements intimated by BIS shall have to be corrected by the organization and intimated to BIS to process the application further. A formal report will be submitted to the applicant by the audit team leader.

Stage 2 audit

Assessment Fee

Assessment fee shall be payable in advance, estimate of which will be intimated by BIS, depending upon the man-days (for auditors & expert) expected to be spent on the audit and the anticipated expenses for travel and/or stay, etc for the audit team, as applicable.

Initial (Certification) Audit

An Audit Team from BIS shall carry out Initial (Certification) Audit to evaluate the implementation, including effectiveness, of the organization's management system complying with the requirements of relevant standard, processes, procedures and activities enumerated in the documented Management System as established.

The Initial (Certification) Audit shall comprise the following:

- Opening Meeting** - This meeting shall be conducted by the leader of the BIS audit team in which the organization's top management, the management representative and Heads of all departments being audited are expected to be present. The purpose of an opening meeting is to confirm the audit plan; provide a short summary of how the audit activities will be undertaken; confirm communication channels; and to provide an opportunity for the auditee to seek clarification on any related issue.
- Conduct of Audit** – The audit shall be carried by team members as per the audit plan. Each auditor may be accompanied by a guide who is conversant with the activities of the department(s)/function(s) the auditor is

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auditing. Observations recorded by the auditors shall be signed by the guide as a token of acceptance, if desired by the auditor.

Handling Non-conformities - The non-conformities observed, if any during the audit shall be handed over to the auditee and shall be signed by the Management Representative or authorized signatory as a token of acceptance. The applicant shall carry out root cause analysis for the nonconformity and take correction and corrective actions in a fixed time frame. BIS will verify the actions taken by the applicant subsequently through the documents submitted and if necessary through a follow-up audit.

c) Closing Meeting

All the members present in the opening meeting should preferably be present in the closing meeting, when the audit team will present its findings to the applicant.

Audit team leader will present the audit findings and recommendations of the audit team regarding the grant of license during the closing meeting. A formal report will be submitted to the applicant by the audit team leader.

BIS will seek feedback on the conduct of the audit from the applicant.

RESPONSIBILITIES OF APPLICANT DURING THE AUDIT

The organization is expected to provide following assistance to the audit team during the audit:

- a) Arrangements of stay, local guidance and travel arrangements, secretarial assistance, photocopies, etc.
- b) The Top Management and the Management Representative of the organization should be present during the opening and closing meetings. As far as possible, all responsible personnel of the organization whose departments/functions are being audited should be present in these meetings.
- c) In the interest of the applicant, all efforts should be made that time of the audit team is not wasted on account of non-availability of relevant personnel, documents, records, shut down of unit(s) being audited, etc.
- d) Make provisions, where applicable, to accommodate the presence of observers (e.g. trainee auditors or accreditation auditors).
- e) Make arrangements for the conduct of the audits, including provision for examining documentation and the access to all processes and areas, records and personnel for the purposes of audit and also arrange for a place/room where members of the audit team can meet to discuss, exchange notes & findings during the day and at the end of the day.

GRANT OF LICENCE

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BIS shall make decision regarding granting certification based on the evaluation of the audit findings and conclusions and any other relevant information (e.g., public information, comments on the audit report from the organization). Before grant of licence, corrections and corrective actions taken by the organization on pending non-conformities, if any from the audit will have to be verified.

BIS may consider granting certification based on organization's planned corrections and corrective actions for certain non-conformities provided such planned correction and corrective actions are reviewed and accepted by BIS depending upon the nature of non-conformities.

When the competent authority of BIS is satisfied with

- a) the actions of the organization on any pending nonconformities
- b) the recommendations of the assessment team for grant of licence

It shall grant the licence to the organization.

The licence shall be granted for a period of **three** years.

Prior to the grant of licence, the applicant shall give the following undertaking:

"We shall make no claim direct or implied that the licence granted to us relates to products or processes other than those set out in the said licence and the Schedule thereof."

OPERATION OF LICENCE

Grant of licence would be followed by surveillance audits conducted at least once a year. These surveillance audits would be carried out by auditor(s) nominated by BIS to verify the effective implementation and maintenance of the Management system established by the organization. The date of the first surveillance audit following initial certification shall not be more than 12 months from the last day of the Stage 2 audit. If the organization does not allow surveillance audit to be conducted at the required frequency, the licence is liable to be suspended. The third surveillance audit may be combined with or replaced by renewal (re-certification) audit. Wherever there are contractual obligations regarding more number of surveillance audits, the same has to be followed.

During the operation of licence, when a licensee fails to observe the conditions of the Management Systems Certification Scheme or where there have been significant changes in the organization, licence of the organization is liable to be suspended and may call for special verification visits for which organization is liable to pay the applicable charges.

A renewal notice will be issued to the organization by the concerned regional/branch office of BIS reasonably in advance before the expiry of the current operative period. For considering renewal of Management system certification licence, BIS will carry out Stage 2 audit in the manner same as for Initial (certification) audit. The licensee shall arrange for the renewal audit well before the expiry of the validity period.

OBLIGATIONS OF LICENSEE

A licensee on grant of certification for Management system will:

- a) at all times comply with the requirements of the licence as set out therein and comply with BIS (Certification) Amendment Regulations or any amendments thereto.
- b) only claim that he is holding a licence in respect of the products, processes or systems in accordance with the licence requirements.

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- c) to use the licence in any manner to which the BIS may object and shall not make any statement concerning the authority of the licensee's use of the licence which, in the opinion of the BIS, may be misleading.
- d) submit to the BIS for approval the form in which it proposes to use the licence or proposes to make references to the licence.
- e) upon expiry of its period of validity, suspension or termination of the licence, however determined, discontinue its use forthwith and withdraw all promotional and advertising matter which contains any reference thereto.
- f) not make any change in the Management System which forms the basis for the grant or renewal of the licence and which prevents its compliance with the Scheme without prior approval of the BIS.
- g) submit to BIS any amendments to the approved documented system.
- h) document all changes made to the Management System and make records of such changes available to Bureau's designated officers on request. A change in key personnel in relation to management of the licenced systems and technological functions or senior management shall be notified to the BIS by the licensee.
- i) permit access to a team appointed by BIS for purposes of audits. The licensee shall give full details of all actions taken in response to field problems arising from allegations of defects in products, processes or systems covered in the licence and allow BIS officers access to all relevant records and documents for the purpose of verifying such details.
- j) be required to produce evidence of continuing operations for the products, processes or systems covered by the licence. Organization shall notify to BIS in writing of discontinuance in such operations exceeding three months. Discontinuance of a licence in excess of six months or more may lead to cancellation of the licence. In such cases, a fresh application shall be submitted to the Bureau and assessment visit will be necessary prior to grant of a new licence.
- k) pay all financial dues to BIS, in the manner specified by it, even for the period of discontinuance or suspension of licence.
- l) operate and maintain procedures for handling and recording of complaints and shall report any complaints against the Management system being operated to BIS and shall also cooperate and assist BIS on the investigation and resolution of such complaints.
- m) operate within the provisions of the BIS Act 1986; BIS Rules, 1987; BIS (Certification) Amendment Regulations, and Certification Scheme Procedure for grant of licence.

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PRIVILEGES OF LICENSEE

The privileges enjoyed by BIS licensees include:

- a) Original Management System Certification licence which can be demonstrated by the licensees to anyone concerned. If need be, it can be photocopied & displayed at various locations.
- b) Use of Standard Mark for Management Systems wherever specified on letterheads in advertisements, brochures, complementaries and for other promotional purposes. However this mark shall not be directly applied on the product or its packaging so as to avoid the impression that product itself is certified by BIS.
- c) Each licence shall be listed in the register of licensees maintained by BIS.

APPEALS

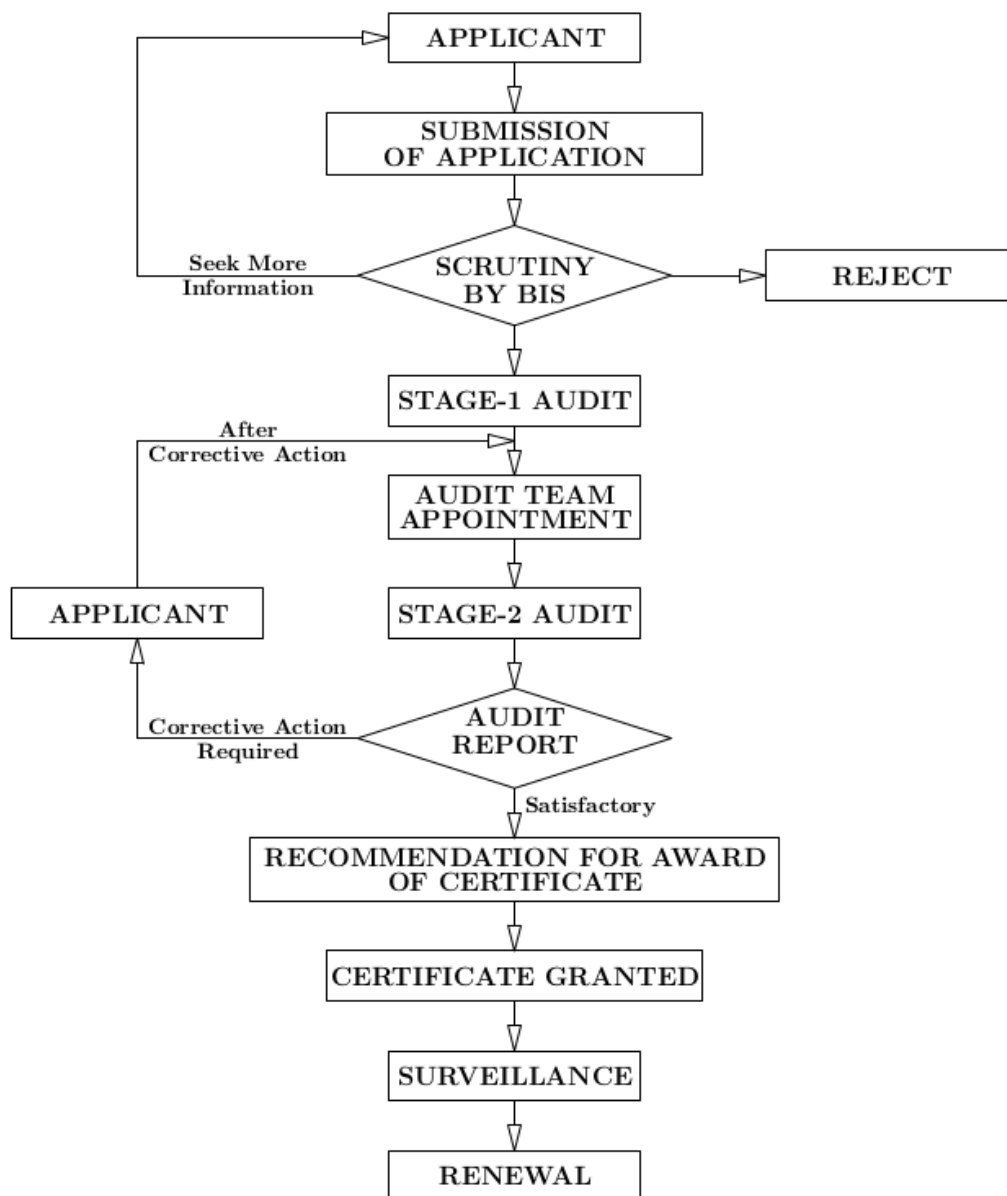
Under the Provisions of *BIS Act 1986*, any decision taken in respect of granting, withholding, renewal, suspension or cancellation of certification under the Bureau of Indian Standards Management Systems Certification Scheme can be appealed against. For the Procedure and Guidelines for making an appeal, contact Head (Management Systems Certification) at BIS Headquarters, 9 Bahadur Shah Zafar Marg, New Delhi - 110 002.

Note: BIS reserves the right to revise the terms and conditions and fees as and when necessary without notice.

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CERTIFICATION PROCESS



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Prescribed Applications

1. Quality Management System	[QMS] as per IS/SO 9001	- Form IV & V
2. Environment Management System	[EMS] as per IS/SO 14001	- Form IV & VII
3. Occupational Health & Safety Management System	[OHSMS] as per IS 18001	- Form IV & X
4. Food Safety Management System	[FMS] as per IS/SO 22001	- Form IV & XIII
5. Energy Management System	[EnMS] as per IS/ISO 50001	- Form IV & XV
6. Service Quality Management System	[SQMS] as per IS 15700	- Form IV & XIV
7. Hazard Analysis Quality Management System	[HACCP] as per IS 15000	- Form IV & XIII
8. Medical Device Management System	[MDMS] as per IS/ISO 13485	- Form IV & XVI
9. Social Accountability Management System	[SAMS] as per IS 16001	- Forms IV & XVII

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