Global MCS	GLOBAL MANAGEMENT CERTIFICATION SERVICES PRIVATE LIMITED	Document No.	P-09
	PROCEDURE	Version.	5.00
	Certification System for Management Systems	Date of Issue	30.10.2023

	Name	Designation	Signature	Date
Reviewed & Approved By	K.Siva Naga Prasad	Managing Director		30.10.2023

Revision History

Version	Date	Description	Remarks
2.00	04.04.2016	Procedure revised based on the comments received from NABCB Assessors during Document Review. Document revised as per ISO 17021-1:2015	Also name changed
3.00	14.11.2016	Procedure revised to include the document review comments raised by IAS	
4.0	30.11.2020	MDQMS requirements were incorporated.	
5.0	30.10.2023	Revised to include the document review comments of UAF Assessor	

1.0 Purpose

To establish & maintain a procedure for the Initial certification, surveillance activities and recertification to ensure that all concerned personnel comply with the certification requirements for QMS, EMS,OHSAS,FSMS,MDQMS & ISMS.

2.0 Scope

All applicants and certified clients related to QMS, EMS,OHSAS,FSMS,MDQMS & ISMS

3.0 Responsibility & Authority

GM is overall responsible for the implementation.

4.0 Policy & Procedure

4.1 Initial Audit and certification

4.1.1 Application for Certification

GMCSPL requires the applicant to submit the 'Application for Certification' (F-01) with the necessary information to GMCSPL. The information may be made available through telephone/ letter/ meetings/ e-mails etc. and recorded by the GMCSPL personnel.

4.1.2 Application Review & Offer for Certification

Application and any supplementary information from the applicant is reviewed by the GM /an expert (F-64) if required and recorded as per Review of Application for Certification (F-02). If the application is accepted, the 'Certification Agreement' (F-03) is provided to the client with the terms and conditions defined in 'Certification Agreement' (F-03).

Audit objectives will be determined by GM and designated person(s), considering the Expert opinion based on the review of application and discuss had with client if required and includes.

a) determination of the conformity of the client's management system, or parts of it, with audit criteria;
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. Same is ensured by auditors during audits and reporting.

Audit scope covering extent and boundaries along with audit criteria also determined by GM, considers Expert guidance, and recorded in F-05.

GM, considering the expert guidance, plans the audit and nominates the audit team identifying their role as team leader, member or expert.

4.2 General requirements

a. The audit programme includes a two-stage initial audit, surveillance audits in the first and second years, and a recertification audit in the third year prior to the expiration of the certificate. The three–year certification cycle begins with the certification or

recertification decision. *The determination of the audit programme and any subsequent adjustment are made after application review/ pre transfer review and are based on the size of the client organization, the scope and complexity of its management system, products and processes as well as demonstrated level of management system effectiveness and the results of any previous audits. Where GMCSPL is taking account of certification or other audits already granted to the client, it collects sufficient, verifiable information to justify and record any adjustments to the audit programme during application review F-02/pre transfer review.*

b. GM selects and appoints the audit team, including the audit team leader designated as lead auditor by GMCSPL, taking into account the competence needed to achieve the objectives of the audit. The team includes at least one auditor/ technical expert who have qualification to assess the scope of certification as per 'technical area competency'. Audit team may consist of one qualified lead auditor only if he/ she meet all the competence criteria.

c. GM determines the time needed to plan and accomplish a complete and effective audit of the client's management system based on P-07. The audit time determined by the GMCSPL, and the justification for the determination, is recorded in F-02.

d. Where multi-site sampling is utilized for the audit of a client's management system covering the same activity in various locations, GM develops a sampling programme to ensure proper audit of the management system as per procedure P-07&P-16. The rationale for the sampling plan is documented for each client.

e. The tasks given to the audit team is defined and made known to the client organization, and require the audit team

   a. to examine and verify the structure, policies, processes, procedures, records and related documents of the client organization relevant to the management system,

   b. to determine that these meet all the requirements relevant to the intended scope of certification,

   c. to determine that the processes and procedures are established, implemented and maintained effectively, to provide a basis for confidence in the client's management system, and

   d. to communicate to the client, for its action, any inconsistencies between the client's policy, objectives and targets (consistent with the expectations in the relevant management system standard or other normative document) and the results.

f. GM sends the 'Audit Team Allocation Plan' (F-05) providing the name of and, when requested, make available background information on each member of the audit team, with sufficient time for the client organization to object to the appointment of any particular auditor or technical expert and for GMCSPL to reconstitute the team in response to any valid objection.

g. The Audit Team Allocation Plan (F-05) along with Audit Schedule (F-08) is communicated and the dates of the audit are agreed upon, in advance, with the client organization.

h. Team leader conducts opening and closing meeting in each assessment covering the agenda as per Checklist D-15 and records the attendance.

i. During the audit, The Team leader periodically assess audit progress and exchange information. The Team leader reassigns work as needed between the audit team members and periodically communicate the progress of the audit and any concerns to the client.

j. Where the available audit evidence indicates that the audit objectives are unattainable or suggests the presence of an immediate and significant risk (e.g. safety), the audit team leader reports this to the client and, if possible, to the GM to determine appropriate action. Such action may include reconfirmation or modification of the audit plan, changes to the audit objectives or audit scope, or termination of the audit. The audit team leader reports the outcome of the action taken to the GM

k. The audit team leader reviews with the client any need for changes to the audit scope which becomes apparent as on-site auditing activities progress and report this to the GM.

l. The presence and justification of observers during an audit activity is communicated to the client through Audit schedule F-08and plan F-05 prior to the conduct of the audit. The audit team Leader ensures that observers do not influence or interfere in the audit process or outcome of the audit.
NOTE Observers can be members of the client's organization, consultants, witnessing accreditation body personnel, regulators or other justified persons.

m. Each auditor is to be accompanied by a guide, unless otherwise agreed to by the audit team leader and the client. Guide(s) are assigned to the audit team to facilitate the audit. The audit team Lead ensures that guides do not influence or interfere in the audit process or outcome of the audit.
NOTE The responsibilities of a guide can include:
a) establishing contacts and timing for interviews;
b) arranging visits to specific parts of the site or organization;
c) ensuring that rules concerning site safety and security procedures are known and respected by the audit team members;
d) witnessing the audit on behalf of the client;
e) providing clarification or information as requested by an auditor.

n. Audit findings summarizing conformity and detailing nonconformity and its supporting audit evidence through audit checklist F-25 is to be recorded and reported to enable an informed certification decision to be made or the certification to be maintained

o. GMCSPL provides a written report for each audit F-11/F-09. The report is based on relevant guidance provided in ISO 19011. The audit team may identify opportunities for improvement but do not recommend specific solutions. Ownership of the audit report is maintained by GMCSPL.

p. The audit team leader ensures that the audit report is prepared after completion of audit before given any written recommendation and is responsible for its content. The audit report provides an accurate, concise and clear record of the audit to enable an informed certification decision to be made and includes or refers to the following:
a) GMCS identification;
b) The name and address of the client and the client's management representative;
c) The type of audit (e.g. initial, surveillance or recertification audit);
d) The audit criteria;
e) The audit objectives;
f) The audit scope, particularly identification of the organizational or functional units

or processes audited and the time of the audit;
g) Identification of the audit team leader, audit team members and any accompanying persons;
h) The dates and places where the audit activities (on site or offsite) were conducted;
i) Audit findings, evidence and conclusions, consistent with the requirements of the type of audit;
j) Any unresolved issues, if identified.

q. *GMCSPL requires the client to analyze the cause and describe the specific correction and corrective actions taken, or planned to be taken, to eliminate detected nonconformities, within a month time from the date of issuing the NCR. In case of Major non conformity during stage 2 audit, verification of correction and corrective action required either based on on site audit or virtual audit based on the findings. Failure to verify the implementation or correction and corrective action with in 6 months from stage 2 audit date GMCSPL will conduct the another stage 2 audit prior to recommending for certification*

r. *GMCS reviews the corrections, identified causes and corrective actions submitted by the client to determine if these are acceptable*. GMCS verifies the effectiveness of any correction and corrective actions taken. The evidence obtained to support the resolution of nonconformities is recorded. The client is informed of the result of the review and verification. Verification of effectiveness of correction and corrective action can be carried out based on a review of documentation provided by the client, or where necessary, through verification on-site.

s. The audited organization is informed if an additional full audit, an additional limited audit, or documented evidence (to be confirmed during future surveillance audits) is needed to verify effective correction and corrective actions. Normally, minor NCR are verified through documentary evidences but if the audit team decides that the minor nonconformity should be verified through follow-up visit, verification audit is performed

t. *Opportunities for improvement: Not a non conformity. If neglects it may lead to nonconformity in future.*
May be identified and recorded, unless prohibited by the requirements of a management system certification scheme. Audit findings, however, which are nonconformities specified below are not be recorded as opportunities for improvement. These may be issued to client, to take proper action on these issues to correct them.

u. GMCSPL classifies the nonconformities into two categories; 1.Major Nonconformity 2.Minor Nonconformity. The Criteria of classification of non-conformity, the corrective action timeframe and verification is as follows:

1. Major Non-conformity: Absence or failure to implement or maintain, one or more quality management system requirements or a situation, which raise significant doubt as to the quality of what the organization is supplying.
   Correction and corrective actions planned or taken have to be submitted within one month from the date of issuing the NCR. Audit team verifies the action taken by verification audit (follow-up visit) within three months. Certificate can't be granted until major NC(s) is/ are closed as per GMCSPL procedure P-09.

2. Minor Non-conformity: Any nonconformity, which is an isolated occurrence and is normally easily corrected and verified.

In case there are any NCs during recertification audit, lead auditor defines time limits for correction and corrective actions to be implemented prior to expiration of certification. In most cases recertification audit is planned in three months advance of the expiry of the certification.

If correction or corrective action is not taken within the time agreed certification could be reduced, suspended or withdrawn.

In case of conducting the follow up audit, the audit team shall verify all non-conformities found during the audit. The auditor days shall be at least 0.5 man-day.

If 3 (three) or more Major Non-conformities are found during the assessment, this assessment is considered “fail”. Certification assessment for “failed” customer is in accordance with the auditor days for Stage 2 audit.

4.3 Initial Certification Audit

The initial certification audit of a management system is conducted in two stages: stage 1 and stage 2.

4.3.1 Stage 1 audit

One of the audit team members conducts the stage 1 assessment:

a) to audit the client's management system documentation;
b) to evaluate the client's location and site-specific conditions and to undertake discussions with the client's personnel to determine the preparedness for the stage 2 audit;
c) to review the client's status and understanding regarding requirements of the standard, in particular with respect to the identification of key performance or significant aspects, processes, objectives and operation of the management system;
d) to collect necessary information regarding the scope of the management system, processes and location(s) of the client, and related statutory and regulatory aspects and compliance (e.g. quality, environmental, legal aspects of the client's operation, associated risks, etc.);
e) to review the allocation of resources for stage 2 audit and agree with the client on the details of the stage 2 audit;
f) to provide a focus for planning the stage 2 audit by gaining a sufficient understanding of the client's management system and site operations in the context of possible significant aspects;
g) to 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 the stage 2 audit.

For most management systems, at least part of the stage 1 audit is carried out at the client's premises in order to achieve the objectives stated above. However in exceptional

circumstances, stage 1 may be done without site visit and requesting documentation. The decision to not conduct site visit shall be justified and documented that may be based on the size and complexity of the organization indicated in the application review.
Wavier of stage 1 at site is limited to the categories specified as low addressed in Annexure 2, Classification of Business Sectors in Complexity Category of procedure P-07

In determining the interval between stage 1 and stage 2 audits, consideration is given to the needs of the client to resolve areas of concern identified during the stage 1 audit. Team leader may also need to revise its arrangements for stage 2.

However, in most cases this interval should not be less than a week without adequate justification. In exceptional cases stage 2 may be continued with stage 1 when there were no issues during stage 1 process.

4.3.2 Stage 2 audit

The purpose of the stage 2 audit is to evaluate the implementation, including effectiveness, of the client's management system. The stage 2 audit takes place at the site(s) of the client. It includes at least the following:

a) information and evidence about conformity to all requirements of the applicable management system standard or other normative document;
b) performance monitoring, measuring, reporting and reviewing against key performance objectives and targets (consistent with the expectations in the applicable management system standard or other normative document);
c) the client's management system and performance as regards legal compliance;
d) operational control of the client's processes;
e) internal auditing and management review;
f) management responsibility for the client's policies;
g) links between the normative requirements, policy, performance objectives and targets (consistent with the expectations in the applicable management system standard or other normative document), any applicable legal requirements, responsibilities, competence of personnel, operations, procedures, performance data and internal audit findings and conclusions.

4.3.3 Information for granting initial certification

a) The information provided by the audit team for the certification decision includes, as a minimum:

- the Certification Audit Report for stage 1 and stage 2 with all attachments,
- Comments on the nonconformities and, where applicable, the correction and corrective actions taken by the client,
- Confirmation of the information provided to GMCSPL used in the application review and
- A recommendation whether or not to grant certification, together with any conditions or observations.

4.4 Audit Conclusions

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

identification of any areas of concern that could be classified as a nonconformity during stage 2 by the auditor through F-11.

The audit team analyzes all information and audit evidence gathered during each audit, includes stage2 surveillance and recertification to review the audit findings and agree on the audit conclusions, identify necessary follow up actions and confirm the appropriateness of the Audit programme or identify any modifications required.

A closing meeting takes place between the audit team and the customer's management prior to leaving their premises as per 'Opening/Closing Meeting Checklist' (D-15). The audit team provides an oral/ written indication regarding the conformity of the applicant's management system with the certification requirements and provides an opportunity to the applicant organization to ask questions about the findings and their basis. The Final 'Certification Audit Report' is submitted to GMCSPL.

b. Copy of the 'Certification Audit Report' (F-09) on the outcome of the assessment is promptly brought to the customer attention by the GM, identifying any non- compliance to be discharged in order to comply with all of the certification requirements.

c. GM invites the customer to comment on the report and to describe the specific actions taken, or planned to be taken within a define time, to remedy any non-conformity with the certification requirements identified during the assessment, and also informs the customer of the need, if any, for full or partial re-assessment or whether a written declaration to be confirmed during surveillance will be considered adequate.

d. If the report authorized by GMCSPL differs from the above report, it is submitted to the customer with an explanation of differences from the previous report.

4.5 Actions prior to making a Decision & Decision on Certification

a) *Certification decision is normally taken by the MD/GM/Designated person(s) on the basis of an evaluation of the audit findings and conclusions and any other relevant information (e.g. public information, comments on the audit report from the client) as per Checklist for Certification Decision (F-19).*

b) *The Person(s) assigned for Certification Decision are employed by the GMCSPL or under legally enforceable agreed with GMCSPL or entities under control of GMCSPL*

c) *The information provided by the audit team is sufficient with respect to the certification requirements and the scope for certification is ensured by GM/MD/Designated person(s) through F-19.*

d) *GM/MD/Designated person(s) confirms through F-19, that Audit team leader reviewed, accepted, and verified the effectiveness of corrective and corrective action taken against major- non conformities & reviewed, accepted, and verified the effectiveness of corrective and corrective action planned in the event of minor Non-conformities*

e) It is ensured that those who have participated in the audit don't make the certification decision. If GM-Certification has participated in the audit, the decision on certification is taken by MD/Designated person(s) and if MD is part of audit certification decision will be by GM/Designated Person(s). If GM and MD are part of audit , Certification decision will be by Designated person(s) as per the Functional Competency matrix record F-64.

f) If Person(s) taking Decision/Team/Committee is not qualified in the applicable management standard (e.g. MDQMS), he is supported by a lead auditor qualified in the same.

g) Authority for granting, maintaining, extending, reducing, suspending or withdrawing certification is not delegated to an outside person or body.

h) In case the decision results in grant of certificate:

- The client is listed in the 'List of Certified Customers' (F-20) with the certification number.
- Certificate is issued in dual copies as per 'Form for Certificate' (F-50).
- The certificate bears the date of the formal decision by GMCSPL.
- Validity of the certificate starts from the date of certification decision and continues for the period as decided, up to a period of three years.
- 'Obligations of Certified customer' (D-03) is sent to the customer along with certificate describing the rights and duties of certified customers.

i) In case, grant of certificate is to be withheld, GMCSPL informs the customer with reasons and necessary actions required to be taken by the customer.

4.6 Surveillance activities

4.6.1 Review

a) Surveillance Intimation Letter F-69 will be sent to client at least one month before the surveillance due date and

b) Clients are requested to send the details of any changes in the organization had in the previous year

c) GM/MD reviews the changes intimated by the clients if any and prepares audit schedule

4.6.2 General

a) GM monitors the Surveillance activities.

b) Surveillance audits are planned as per audit program-F16'.

c) It is ensured that the date of the first surveillance audit following initial certification is not more than 12 months from the last date of stage 2 audit. GM may Adjust surveillance frequency based on the seasons or management system certification of limited duration, such adjustments for any case to be recorded and maintained.

d) If a certified client doesn't allow surveillance audit within the time period, it is put on suspension as per P-04. Under suspension, the client's management system certification is temporarily invalid. If the client doesn't accept the surveillance within three months of the suspension, its certification is withdrawn.

e) MD may allow an extension of maximum six months for suspension beyond 12 months in the following extreme circumstances:

- *Customer's change of Location under certification.*
- *Lockout/ Strike*
- *Natural disasters*
- *Any other reason as found reasonable*

f) Surveillance audit:

Surveillance audits are on-site audits, but are not necessarily full system audits, and are planned together with the other surveillance activities so that the GMCSPL can maintain confidence that the client's certified management system continues to fulfil

requirements between recertification audits. Each surveillance for the relevant management system standard and includes:

- internal audits and management review,
- a review of actions taken on nonconformities identified during the previous audit,
- treatment of complaints,
- effectiveness of the management system with regard to achieving the certified client's objectives,
- progress of planned activities aimed at continual improvement,
- continuing operational control,
- review of any changes, and
- use of marks and/or any other reference to certification.

h) Surveillance audits are performed in accordance with Audit Program F-16 and 'ongoing surveillance plan' (F-17).

i) Team Leader reports the result of on-going surveillance by submitting 'On-going Surveillance Report' (F-21).

j) GM may increase Surveillance frequencies based on the recommendation of the Team Leader in the following circumstances:-

a. Certified organization makes major modification to its management system or other changes that affect the basis for certification
b. The Corrective Action taken on the NCR(s) issued during previous assessment is not found effective.
c. Increase in the customer complaints
d. If Major NCR is found during a surveillance audit
e. Customer's request
f. Addition of employees

k) If needed, the additional assessment is conducted in accordance with the result of review of the effectiveness of client's Internal Audit and Management Review.

l) GM reviews each report as per 'checklist for on going surveillance F-18'.

4.7 Recertification

4.7.1 Review

a) Recertification Intimation Letter F-70 along with Application F-01 will be sent to client at least two months before the recertification due date and
b) Clients are requested to send the details of the organization through F-01.
c) GM/MD/Designated person reviews the details provided by the clients and prepares audit plan and schedule

4.7.2 Recertification Audit Planning

1) A recertification audit is planned and conducted to evaluate the continued fulfilment of all of the requirements of the relevant management system standard or other normative document. 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.
2) *The recertification audit considers the performance of the management system over the period of certification, and include the review of previous surveillance audit reports. This will be conducted during the audit by audit team.*

3) Normally recertification doesn't require stage I audit but may be required in situations where there have been significant changes to the management system, the client, or the context in which the management system is operating (e.g changes to legislation).
4) In the case of multiple sites or certification to multiple management system standards, the planning for the audit ensures adequate on-site audit coverage to provide confidence in the certification.

4.7.3 Recertification audit

1) The recertification audit includes an on-site audit that addresses the following.

- The effectiveness of the management system in its entirety in the light of internal and external changes and its continues relevance and applicability to the scope of certification;

- Demonstrated commitment to maintain the effectiveness and improvement of the management system in order to enhance overall performance ;
- Whether the operation of the certified management system contributes to the achievement of the organisation's policy and objectives.

2) When, during a recertification audit, instances of nonconformity or lack of evidence of conformity are identified, lead auditor defines the time limits for correction and corrective actions to be implemented prior to the expiration of the certificate.
3) When recertification activities are successfully completed prior to the expiry date of the existing certification, the expiry date of the new certification can be based on the expiry date of the existing certification. The issue date on a new certificate is on or after the recertification decision.
4) In case GMCSPL not completed the recertification audit or unable to verify the implementation of corrections and corrective actions for any major nonconformity prior to the expiry date of the certification, then recertification is not recommended and the validity of the certification cannot be extended. The clients to be informed and the consequences has to explained.

4.7.4 Recertification after expiry of certificate

If a client wishes to apply for re-certification after expiry of the certificate, it is processed as an initial certification if the gap crosses more than 6 months. if they approach with in 6 months' time, recertification can be performed provided that the outstanding recertification activities were completed, otherwise stage 2 has to conduct.
The effective date on the certificate is on or after the recertification decision and the expiry date is based on prior certification cycle

4.7.5 Issue of Certificate as a result of recertification

GM-Certification/MD/Designated Person(s)/Committee makes decision on renewing certification based on the results of the recertification audit, as well as the result of the review of the system over the period of certification and complaints received from the users of certification.

4.8 Special audits

4.8.1 Extensions to scope

GM-Certification, in response to an application for extension to the scope of a certification already granted, undertakes a review of the application and determines the necessary actions in accordance with 'Modification Table' (D-05) to decide whether or not extension may be granted. This may be conducted in conjunction with a surveillance audit.

4.8.2 Short-notice audits and Unannounced audits.

It may be necessary for GMCSPL 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 or if the clients ISMS makes major modifications to its system or other changes take place that could affect the basis of its certification.

In case of MDQMS clients short notice or unannounced audits takes place: if

a) Justifiable concerns about implementation of corrective actions or compliance with standard or regulations. b) post market surveillance data related to significant deficiency in MDQMS known to GMCSPL b) significant safety information of products known to GMCSPL c) Significant changes, affects the regulatory compliance as required by the regulations or known to GMCSPL.

Typical examples include but not limited to are

1) QMS- Impact and changes

- New ownership
- Design and/or manufacturing extensions
- New facility, site changes
- New processes, process changes
- QM management, personnel changes
- 2) Product related changes
- New Products, Categories
- Addition of new devise category

3) QMS and Product related changes

- Changes in standards, regulations
- Post market surveillance, vigilance.

In such cases Additional care is taken by the GM to avoid any conflict of interest as clients doesn't have the opportunity to object against any audit team members.

4.9 Use of Certificate, Certification Logo and Accreditation Mark

(1) GM-Certification ensures that GMCSPL complies with the conditions for use of Accreditation Mark.

(2) Customer's use of certificate and certification logo is controlled in accordance with Procedure P-05.

4.10 Access to records of complaints to customers

(1) The 'Certification Agreement' (F-03 include followings;

- Certified customer has to maintain records of complaints from its customers and resulting corrective action.
- Certified customer has to make available to GMCSPL the record of all complaints and corrective action taken, on request.

(2) Audit Team during surveillance audit/recertification audit checks customer complaints if any, and whether organization has investigated its own systems and procedures and taken appropriate corrective action.

5.0 Records

- Applicant and certified clients files
- List of Certified Customers F-20