



GLOBAL MANAGEMENT CERTIFICATION SERVICES  
PRIVATE LIMITED

Document No.

P-08

PROCEDURE

Version.

4.00

CONTRACT REVIEW

Date of Issue

17.11.2023

	Name	Designation	Signature	Date
Reviewed & Approved By	K.Siva Naga Prasad	Managing Director		17.11.2023

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	30.11.2016	Revised as per the comments raised during office assessment by IAS	
4.00	17.11.2023	Revised as per the MD 02 latest version.	

**1 Purpose**

To define the manner that customer requirements are identified and how the certification body resources are matched and allocated for a certification contract.

**2 Scope**

This procedure shall be used for all proposed contracts to determine how the certification body will satisfy the proposed certification contract

**3 References**

ISO 17021 Clause 7 Certification body Personnel - planning and resources.

**4 Procedure**

**4.1 Initial Contract Review**

4.1.1 The GM Certification/MD/Designated Person(s) reviews the application based on their scopes authorisation, detailing the requirements for the contract review to ensure that the customer's requirements are understood and there is a competent resource available to deliver the Audits using Personnel scope competence matrix/Authorisation Matrix, F-64.

4.1.2 This review identifies;

NACE Code, industrial sector, Business sector, Technical sector, technical code, technical issues, processes, Risk classification of medical devices, regulatory requirements, National Medical Regulations that utilize ISO 13485, Organization/site activities, Products and services, use of ICT, safety requirements, environmental aspects etc.,

This information is obtained through the application (F-01) completed by the authorized person from the applicant organization.

4.1.3 Auditors are selected based on the competency of individuals for each technical area & each standard.

4.1.4 *While selecting composition of the audit team, following will be considered:*

*a) audit objectives, scope, criteria and estimated time of the audit;*

*b) whether the audit is a combined, integrated or joint audit;*

*c) the overall competence of the audit team needed to achieve the objectives of the audit;*

*d) certification requirements (including any applicable statutory, regulatory or contractual requirements);*

*e) language and culture;*

*f) whether the members of the audit team have previously audited the client's management system*

4.1.5 The team allocated shall be drawn from F-64, which identifies the individuals with the required skills for each technical areas and standards. The team can consist of one auditor or several auditors including any Technical Expert. The team must have collectively, all the above skills for each audit.

- 4.1.6 Availability of resource,  
Where a Technical expert is required to support the audit, GM selects one using Procedure P-03.
- 4.1.7 Audit man days will be determined by GM/Designated Person(s)/Team Lead/MD and prepares Audit team allocation plan.
- 4.1.8 The contract review results are recorded On completion of the contract review in review of application F-02.

## 4.2 Non scope applications

If it is identified that the application is not within the Accredited scope of the certification body at the initial contract review, the GM Certification rejects accredited certification and assesses the viability of expanding the Accreditation scope for this proposed certification contract.

That viability is based upon;

- i) What is the market potential?
- ii) what % of the market will we have if we do i).
- iii) what is the investment to expand against return, i.e. resource and time.
- iv) potential return over what period.
- v) what are the risks?
  - a) if we don't expand scope(do nothing)
  - b) what will competitors do?
  - c) contingency plans if we don't meet planned requirements
- vi) probability of success
- vii) benefits

If the GMCSPL MD/GM Certification decides to expand the Accreditation scope of the Certification Body capability to fulfil the contract then this is action by:

- i) Search of CV's, and skills matrix for relevant Auditor skills.
- ii) Advertise for Auditors with relevant skills and process as procedures P-03
- iii) Inform Accreditation body of wish to expand scope with what company when the Audit is liable to take place and who the Auditor team will be. In case of MDQMS GMCSPL to provide a detailed description of the technical area, e.g. with a list of medical devices and include their risk classification to the AB.
- iv) when GMCSPL applies for a scope of Accreditation for a technical area that has "other than specified above" in the description of technical area, GMCSPL provides a list of medical devices and include their risk classification to the AB.
- v) Fulfil AB requirements for scope extension which will possibly be:
  - a) interview of Auditors for new scope
  - b) witnessed Audit
  - c) Agree scope extension with no action from them

If the GMCSPL GM Certification decides not to expand the Accreditation scope of the Certification Body but decides to issue non accredited certificates then the GM

will communicate to the client about non availability of Accreditation for the scope but will issue a non accredited certificate.

### **4.3 Transfers from other Certification Body**

#### **4.3.1 Eligibility of a Certification for Transfer**

4.3.1.1 Only certification which is covered by an accreditation of an IAF or Regional MLA signatory at level 3 and where applicable level 4 and 5 are eligible for transfer. Organizations holding certification that is not covered by such accreditations are treated as new clients.

4.3.1.2 Only valid accredited certification are allowed for transfer. Certification which is known to be suspended are not be accepted for transfer.

4.3.1.3 In cases where certification has been granted by a certification body which has ceased trading or whose accreditation has expired, been suspended or withdrawn, the transfer shall be completed within 6 months or on expiration of the certification whichever is sooner. In such cases, GMCSPSPL informs the accreditation body, under whose accreditation it intends to issue the certification, prior to the transfer.

#### **4.3.2 Pre-Transfer Review**

4.3.2.1 GMCSPSPL has a process of getting information through F-01 for obtaining sufficient information in order to take a decision on certification and inform the transferring client of the process. This information as a minimum include arrangements regarding the certification cycle.

4.3.2.2 GMCSPSPL carry out a review of the certification of the transferring client. This review conducted by means of a documentation review and where identified as needed by this review, for example there are outstanding major nonconformities, shall include a pre-transfer visit to the transferring client to confirm the validity of the certification.

Note: The pre-transfer visit is not an audit.

4.3.2.3 GMCSPSPL uses the auditors qualified in the scheme and technical areas as recorded in F-64 for pre-transfer review. The review may be conducted by one or more persons. The individual or group conducting the pre-transfer visit shall have the same competence that is required for an audit team appropriate for the scope of certification being reviewed.

4.3.2.4 The review covers the following aspects as a minimum and the review and its findings shall be fully documented:

- (i) confirmation that the client's certification falls within the accredited scope of the issuing and accepting certification body;
- (ii) confirmation that the issuing certification body's accredited scope falls within its accreditation body's MLA scope;
- (iii) the reasons for seeking a transfer;
- (iv) that the site or sites wishing to transfer certification hold a valid accredited certification;
- (v) the initial certification or most recent recertification audit reports, and the latest surveillance report; the status of all outstanding nonconformities that may arise from them and any other available, relevant documentation regarding the certification process. If these audit reports are not made available or if the surveillance audit or recertification audit has not been completed as required by the issuing certification body's audit programme, then the organisation shall be treated as a new client;
- (vi) complaints received and action taken;
- (vii) considerations relevant to establishing an audit plan and an audit programme. The audit programme established by the issuing certification body should be reviewed if available.
- (viii) any current engagement by the transferring client with regulatory bodies relevant to the scope of the certification in respect of legal compliance.

#### **4.3.3 Transfer of Certification**

4.3.3.1 GMCSPSPL will not issue certification to the transferring client until:

- (i) it has verified the implementation of corrections and corrective actions in respect of all

outstanding major nonconformities; and

(ii) it has accepted the transferring client's plans for correction and corrective action for all outstanding minor nonconformities.

4.3.3.2 Where the pre-transfer review (document review and/or pre-transfer visit) identifies issues that prevent the completion of transfer, GMCSPL treats the transferring client as a new client.

The justification for this action to be explained to the transferring client and shall be documented by GMCSPL and the records maintained.

4.3.3.3 The normal certification decision making process is followed including that the personnel making the certification decision be different from those carrying out the pre-transfer review.

4.3.3.4 If no problems are identified by the pre-transfer review, the certification cycle shall be based on the previous certification cycle and GMCSPL establishes the audit programme for the remainder of the certification cycle.

GMCSPL can quote the organization's initial certification date on the certification documents with the indication that the organization was certified by a different certification body before a certain date.

Where the GMCSPL has had to treat the client as a new client as a result of the pre-transfer review, the certification cycle shall begin with the certification decision.

4.3.3.5 GMCSPL takes the decision on certification before any surveillance or recertification audits are initiated.

#### **4.3.4 Cooperation Between the Issuing Certification and GMCSPL**

4.3.4.1 The cooperation between the issuing and GMCSPL is essential for the effective process for transfer and the integrity of certification. When requested, the issuing certification body provides to GMCSPL all the documents and information required by this procedure. Where it has not been possible to communicate with the issuing certification body, GMCSPL records the reasons and make every effort to obtain necessary information from other sources.

4.3.4.2 The transferring client authorises that the issuing certification body provides the information sought by the GMCSPL. The issuing certification body shall not suspend or withdraw the organization's certification following the notification that the organization is transferring to the GMCSPL if the client continues to satisfy the requirements of certification.

4.3.4.3 GMCSPL and/or the transferring client can contact the accreditation body which accredits the issuing certification body where the issuing certification body

(i) has not provided the requested information to the GMCSPL, or

(ii) suspends or withdraws the transferring client's certification without cause

4.3.4.4 GMCSPL informs the issuing CB once issued the certification.

4.3.4.5 Same procedure is being followed in case any of the client requests transfer from GMCSPL to other CB and GMCSPL provides cooperation both with client and accepting CB.

#### **4.4 Change of Information on an Issued Certificate**

If a certificated client requests the certification body for a change of information on the certificate issued by GMCSPL. GM checks with the client the validity of the request and if the request is valid with documentation proof, the request will be approved. When approved an amended certificate is issued after the return of the old certificate.

If the request is for a change of scope then it shall usually be verified at the next surveillance audit and an amended certificate issued after successful completion of the surveillance audit.

If the request is urgent then an extra audit can be conducted.

#### **5.0 Quality Records**

Application F-01

Review of Application F-02

Pre Transfer Review F-26

Application for modification F-22