



KIHT Certification Services
(Operating Under Kalam Institute of
Health Technology)

Certification Process

KIHT Certification Services (KCS)
KCS/PR07/Rev.01
Page 1 of 4

Table of contents	Page No.
1. Purpose	2
2. Scope of Applicability	2
3. Reference documents/standards	2
4. Responsibilities	2
5. Procedures	2
5.1 Granting Certification	2
5.2 Maintaining Certification	2
5.3 Reducing the scope of certification	3
5.4 Changes and Modifications to Certification	3
5.5 Issue of changed certificate	4
5.6 Modification of Certification Requirements	4
6. Records - Other Applicable documents	4
7. Revision Status	4



1. Purpose

The purpose of the procedure is to ensure a stable process for maintaining certification provided by KIHT Certification Services (KCS) to its clients.

2. Scope of Applicability

The procedure applies to all clients who would like to have certification from KCS within the scope of certification of KCS

3. Reference Documents/Standards (latest version is applicable unless otherwise mentioned)

- ISO/IEC 17021-1:2015 - Conformity assessment — Requirements for bodies providing audit and certification of management systems- Part 1: Requirements
- ISO/IEC 17021-3 - Conformity assessment — Requirements for bodies providing audit and certification of management systems — Part 3: Competence requirements for auditing and certification of quality management systems
- IAF MD 9 - Application of ISO/IEC 17021-1 in the Field of Medical Device Quality Management Systems
- IAF MD 2 - Transfer of Accredited Certification of Management Systems

4. Responsibilities

- The certification manager has the overall responsibility for the implementation of this procedure.
- Quality manager, Auditors, reviewer have the responsibility for the compliance of this procedure.

5. Procedures

5.1 Granting Certification

KCS grants the certificate based on the documentary evidence obtained from the client who fulfils all the requirements of management system information as per the required scope of certification.

The certification is granted and recorded in the list of the certified clients on the website provided:

- The customer has documented management systems that fulfil the requirement of applicable standards or other normative documents.
- That Internal Audit and Management Review cycle has been completed.
- The Client has taken the effective implementation of all corrective action identified due to Non-conformance raised by the audit team.
- There are no adverse reports/ information/ complaints/feedback with the KCS about the applicant regarding the quality and effectiveness of the implementation of the system.
- If an already certified client wishes to transfer their certificate from other certification body (CB) to KCS, the KCS will treat as a new client until the client is certified by a CB having accreditation from the accreditation board who is IAF-MLA signatory in applied QMS system certification scheme. In case of transfer of certificate request/application from the client of other Conformity Assessment Bodies (CAB) accredited by IAF MLA signatory accreditation board, KCS will follow all processes defined in IAF MD 02 before acceptance of the application.
- The applicant has paid all the fees.

5.2 Maintaining Certification

The KCS maintains certification based on the demonstration that the client continues to comply with the requirements of the management systems standards. It may contain a client's certification based on a positive conclusion by the audit team leader without further independent review, provided that

 <p>KIHT Certification Services (Operating Under Kalam Institute of Health Technology)</p>	Certification Process	KIHT Certification Services (KCS) KCS/PR07/Rev.01 Page 3 of 4
---	------------------------------	--

- a) For any major non-conformity or other situation that may lead to suspension or withdrawal of certification [PR14], the KCS has a system that requires the audit team leader to report to the certification body the need to initiate a review by appropriately competent personnel different from those who carried out the audit, to determine whether certification can be maintained.
- b) Certificate Manager of the KCS monitors its surveillance activities, including monitoring the reporting by its auditors, to confirm that the certification activity is operating effectively.

Maintaining Certification is allowed when during subsequent surveillance client has demonstrated that is continued to fulfil all requirements of the standard and scope of the certificate.

The certification is maintained provided:

- The certified organization continues to meet the criteria of certification and effective implementation of corrective action taken due to any non-conformity found during surveillance assessment has been verified
- There are no adverse reports/ information/ complaints/ feedback with the KCS about the applicant regarding the quality and effectiveness of the implementation of the system
- The client has paid all the outstanding dues

Special audits/ Short notice audits may be performed in accordance with special audit procedures [PR04].

5.3 Reducing scope of certification

The KCS shall reduce the scope of certification in the following situations:

- Failure to resolve the issues that have resulted in the suspension in a time established by the KCS
- Client's request
- Excluding the parts not meeting the requirements, when the client has persistently or seriously failed to meet the certification requirements for those parts of the scope of certification. Any such reduction is in line with the requirements of the standard used for certification.
- If correction or corrective action is not taken within the time agreed, certification could be reduced, suspended, or withdrawn.

KCS informs the customer in writing of reduction of the scope of certification through 'Reduction of Scope of Certification' and revises the list of certified customers. KCS updates the information on the KCS website to make it accessible to the public.

The customer is required to amend all advertising matters when the scope is reduced.

5.4 Changes and Modifications to Certification

- When KCS is informed that changes occur in the client's management system, the certification manager provides the Application form again to the customer to complete the form and submit it to KCS. After the review of the Application form submitted by the client, the certification manager determines the necessary action in accordance with modification.
- If applicable, the Certificate Manager shall perform the assessment for modification in accordance with the procedure for the auditing process which may require a special audit of the client.

 KIHT Certification Services (Operating Under Kalam Institute of Health Technology)	Certification Process	KIHT Certification Services (KCS) KCS/PR07/Rev.01 Page 4 of 4
---	------------------------------	--

- KCS shall have legally enforceable arrangements to ensure that the certified client informs the KCS, without delay, of matters that may affect the capability of the management system to continue to fulfil the requirements of the standard used for certification.

5.5 Issue of changed certificate

When change is approved by the KCS certificate manager, KCS shall retrieve the previous certificate and shall issue a new certificate. The list of customers is revised accordingly on the website. KCS shall report the changes to the Accreditation body if required. The new certificate would have the same certificate number and initial certification date, validity, and expiry date but the date of the issue would be the date of issue of the new revised certificate and will also include the revision number.

5.6 Modification of Certification Requirements

- If the certification requirements are changed, the following shall be processed within the specified period. KCS shall inform the Client about changed requirements in detail and one (1) month of the transitional period shall be observed.
- The client shall submit a documented implementation plan of changed requirements or its result in detail.
- Through ongoing surveillance, KCS shall verify the client's implementation and compliance with the changed system based on certification requirements changed, within 12 months.

6.0 Records - Other Applicable Document

- 1) List of External documents submitted by Client
- 2) Complaint and Appeal Register (F203, F204)
- 3) Application form (F01)

Revision Status

Rev. no	Date of approval	Clause/Para under change	Reason of Change
01	04.11.2023	Revision Status	Revision number column added in the revision Status

Prepared By: Quality Manager Date: 04-11-2023	Reviewed & Approved By: Certification Manager Date: 04-11-2023
--	---