

Quality and Accreditation Institute
Centre for Accreditation of Health & Social Care



**POLICY AND PROCEDURES
FOR ASSESSMENT, SURVEILLANCE
AND REASSESSMENT OF HCF**

Issue No.: 04

Issue Date: February 2022

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Centre for Accreditation of Health & Social Care		
Doc. No.: QAI CAHSC 023	Policy and Procedures for Assessment, Surveillance and Reassessment of HCF	
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CHANGE HISTORY

Sl. No.	Doc No.	Current Issue No.	Revised Issue No.	Date of Issue	Reasons
1	CAHSC 023	01	02	December 2019 (7 December 2019)	Policy change for effective date of accreditation in 3.7
2	CAHSC 023	02	03	July 2020 (10 July 2020)	Change in types of assessment due to unavoidable circumstances like COVID-19
3	CAHSC 023	03	04	February 2022 (02 February 2022)	<ul style="list-style-type: none"> • Submission of action plan within 15 days replaced with submission of corrective actions within 90 days in clause 3.5 and 6 • Submission of action plan within 15 days replaced with submission of corrective actions within 60 days in clause 5

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1. Preparing for health care organisation (HCF) accreditation

In this document HCF means home health care, ART centre, dialysis centre, ambulatory care organisations, hospitals etc. HCF management should first decide about getting accreditation for its HCF from QAI. It is important for an HCF to make a definite plan of action for obtaining accreditation and nominate a responsible person to co-ordinate all activities related to seeking accreditation. The person nominated should be familiar with HCF's services, functions and existing quality system, if any.

A request can be made to QAI Secretariat for procurement of relevant QAI documents against the payment, if any. All documents are free downloadable except printed copy of standards and guidance book. A list of QAI documents is given on the website under each programme and general documents. Clarifications on any document/ process may be obtained from QAI Secretariat in person, by post, on telephone or through e-mail. The HCF get fully acquainted with relevant documents and understand the assessment procedure & methodology of making an application.

Before an application is made, it is required that HCF do the self-assessment using self-assessment tool to ascertain whether HCF fulfilling QAI accreditation requirements, if find the gaps, take necessary measures to fill those gaps.

Relevant requirements for QAI accreditation should be discussed amongst concerned staff of the HCFs. This will enable them to understand their weaknesses and strengths. The HCF must ensure that policies, procedures and other documents for various sections/ departments and services being provided are available and implemented.

The HCF interested in going for accreditation should understand the QAI assessment procedure and prepare accordingly.

2. Eligibility for applying for QAI Accreditation

The applicant HCF must apply for all its facilities and services being rendered from the specific location. QAI accreditation is only considered for HCF's entire activities and not for a part of it except for specific accreditation/ certification programmes like home health care, dialysis, ART, certain ambulatory care facilities e.g. medical imaging, physiotherapy etc. accreditation programmes, if they are part of a larger organisation. However, if these exceptional organisation/ services are operating as a standalone facility/ service then must apply for all its scope of services.

The applicant HCF must comply with all applicable Standards of QAI and regulatory/ statutory requirements.

The applicant HCF must have filled self-assessment tool kit against QAI Standards before the submission of application. Self-assessment tool is a mechanism of ensuring compliance to standards by the HCF themselves and therefore it would be easier for the assessment teams to verify those compliances during assessments (on-site/ remote/ hybrid). It also gives confidence to HCF about documentation and implementation of the requirements.

3. Accreditation Procedure

3.1 Application for accreditation/ certification

The HCF shall apply to QAI in the prescribed application form, along with self-assessment tool and supporting documents of the HCF in accordance with relevant accreditation/ certification standard. The application shall be accompanied with the prescribed application fee as detailed in the information brochures.

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For scoring in Self-assessment tool applicant organisation shall use the methodology given below:

- Compliance to the requirement: 10 (70 or >70% samples complying)
- Partial compliance to the requirement: 5 (30 to 69% samples complying)
- Non-compliance to the requirement: 0 (<30% samples complying)
- Not Applicable: NA (There may be a possibility that some of the standard/criterion is not relevant to a specific type of organisation based on its services, in such case that standard/criterion shall be rated as NA)

3.2 Registration and Acknowledgements of application

Within 10 days of receipt of the application from an HCF, the following actions shall be taken:

- Review application to see for which accreditation/certification programme application is made and accordingly allocate a Unique Registration Number
- Open a folder in the computer system and hard copy document file
- Update the database maintained
- Fee received as DD/ check is transferred to the QAI accounts section
- Performing completeness check of application including supporting documents and fee received on-line
- Examine the Self-Assessment tool/ Manuals to verify if all the requirements of standard have been adequately addressed
- Issue acknowledgement mentioning unique Registration number. If deficiencies are noticed, in application fees, application, or the self-assessment tool, it shall be recorded and the HCF be informed for corrective actions within 10 days.
- This unique Registration number shall be used for QAI's own recording system and also for correspondence with the HCF. All HCFs are advised to use this registration number while communicating with QAI
- QAI shall maintain confidentiality of application submitted by HCF.

3.3 Appointment of Lead Assessor

The Lead assessor shall have the overall responsibility of conducting the assessment and shall be responsible for conducting the on-site/ remote/ hybrid assessment of the concerned HCFs. Towards the task of assessment, he/she shall be assisted by a team of assessors commensurate with the scope of accreditation.

3.4 Assessment

Once the Lead Assessor has been selected, the concerned Officer shall constitute an assessment team for final assessment (on-site/ remote/ hybrid). The team shall include the Lead Assessor, assessor(s), technical expert(s) and observers or trainee assessors (if required) in order to cover the scope of accreditation. The HCF is informed about the team members and consent is taken to avoid any conflict of interest.

Thereafter the officer shall fix up dates for assessment of the HCF in consultation with the HCF and the assessment team. The Officer from QAI may also participate in the assessment as an observer/ coordinator during the assessment and convey his/ her observations to the Lead Assessor. The Officer is also required to provide clarification on QAI requirements to the Lead Assessor and other assessors, whenever necessary.

The HCF is informed about the assessment team and date(s). A copy of this communication is marked to the members of assessment team, along with the requisite documents. The

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assessors are required to reach the place of assessment, preferably a day before the start of assessment.

The assessment team assess the HCF's services and functions and verifies its compliance with the QAI Standards, for the purpose assessment team carries out various assessment activities (document/records review, visit to patient care area, functional interview, facility tours and special interviews etc.). The team will assess the extent of implementation of standards, the non-compliances, if identified are reported in the assessment report.

The assessors report shall be prepared in the formats prescribed by QAI as per the Assessors' Guide (QAI CAHSC 009) and to be sent by the Lead Assessor to QAI Secretariat, within 10 days of completion of assessment. The assessment team shall share the assessment report with the HCF representative after the assessment is over.

The assessment report shall contain the evaluation of manpower, all services, functions areas and departments/sections examined, non-compliances, if any found during assessment. The assessment report including score sheet based on self-assessment tool is prepared by the Lead assessor, in the formats prescribed. A copy of the report containing final summary, details of the non-compliances (NC/PC) observed during the assessment is handed over to the HCF by the Lead Assessor. Score sheet is not handed over to the HCF.

3.5 Scrutiny of assessment report

The assessment report and the scoresheet shall be examined by QAI and confirmed with the HCF that they have received a copy of the report. Officer shall seek any clarification, if required from assessment team or the HCF on the report. If the HCF meets the scoring for accreditation, however there are non-compliances, officer shall communicate to HCF to submit corrective actions against all non-compliances/ partial conformance (NCs & PCS) observed during assessment. The HCF shall get a time period of 90 days to submit all the corrective actions to QAI Secretariat. The corrective actions shall be reviewed by the respective Lead assessor/ assessor for the acceptance.

3.6 Accreditation committee

After satisfactory corrective action by the HCF, the Officer in QAI prepares a brief summary of all relevant information gathered during the processing of the application, the assessment report, additional information received from the HCF. The summary report is placed before the Accreditation Committee for their recommendation for grant of accreditation. In case the Accreditation Committee finds deficiencies in the assessment report to arrive at the decision, the Officer obtains clarification from the Lead assessor/ assessor/ HCF concerned.

The Accreditation Committee's observations on the assessment report and its recommendations shall be the deciding factors for grant of accreditation or otherwise. All decisions taken by the Accreditation Committee shall be recorded in the form of minutes. Based on the findings in the assessment report, the Accreditation Committee shall make appropriate recommendations regarding accreditation. For decision making following rule shall apply in addition to satisfactory corrective actions.

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Evaluation Criteria for accreditation decision:

- No zero is accepted in the regulatory/ legal requirements.
- The average score for individual standard must be ≥ 5 .
- The average score for individual chapter must be ≥ 7 .
- The overall average score for all chapters must be ≥ 7 .

3.7 Issue of accreditation certificate

When the recommendation of the accreditation committee results into accreditation, the officer concerned shall prepare an Accreditation Summary in the prescribed format provided in document QAI CAHSC 017. This accreditation summary along with scope of accreditation is submitted to Chairman for approval. Once Chairman has accorded his approval, the officer shall prepare the accreditation certificate and scope of accreditation. Accreditation certificate is digitally signed using the scanned signatures of the CEO and the Chairman. Accreditation certificate bears the signatures of the CEO and the Chairman while scope of accreditation only bears the signatures of the CEO. A unique certificate number shall be allotted to HCF. Certificate shall carry name of HCF, effective date of accreditation, date of expiry and unique certificate number. The effective date of accreditation will be the date of approval by the chairman. If the certificate pertains to the already accredited facility (renewal cases), 'Date of first Accreditation' shall also be mentioned above the accreditation date. Final certificate containing information as described above and duly signed by the Chief Executive Officer and the Chairman, QAI CAHSC is issued to the HCF.

The applicant HCF must make all payments due to QAI CAHSC, before the certificate is issued to the HCF.

Whenever, there is a change in the scope of accreditation as a result of surveillance, the same shall be issued after the recommendation of the Accreditation Committee.

4. Maintaining Accreditation/ Certification

4.1 Validity

The accreditation certificate shall be valid for a period of three years. On grant of accreditation, the HCF can use QAI accreditation mark on its letterheads, brochures and any other material issued to its customers. The guidelines for using QAI Accreditation/ Certification Mark are given in the document 'Policy and guidelines for use of QAI accreditation/ certification mark' (QAI CAHSC 019).

QAI shall conduct surveillance assessment (desktop/ on-site/ remote/ hybrid) within fifteen to eighteen months of accreditation and re-assessment (on-site/ remote/ hybrid) of the accredited HCF before the expiry of the accreditation certificate.

During the validity of accreditation, the HCF must continuously comply with the requirements of QAI Standards and 'Terms and condition for maintaining QAI accreditation/ Certification' (QAI CAHSC 003).

4.2 Extension/ Reduction of Scope of Accreditation/ Certification

The HCF during the validity of accreditation may enhance or reduce the scope of accreditation for which QAI shall assess during surveillance/ reassessment or organise a supplementary/

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special visit. The reduction of scope is only permitted if HCF ceases to provide services in that specific area.

4.3 Focus/ Surprise/ Verification/ Unannounced visit

Besides the regular (announced) surveillance and reassessment, QAI may also organise Focus/ Surprise/ Verification/ unannounced visit at any time because of any of the following reasons:

- **Changes in the accreditation standards and requirements**

If there is a change in the general accreditation criteria, QAI shall inform the HCF of this in writing indicating the transition period, which shall be at least 6 months. On receipt of the aforesaid information, the HCF must confirm to QAI, its willingness to modify its quality system in accordance with the changes. On confirmation from the HCF, QAI may conduct a verification visit to assess the implementation of the same.

- **Changes affecting the HCF operations**

In the event of the HCF informing QAI about any changes in the information affecting the HCFs activities and operations, such as equipment, accommodation, environment, scope of accreditation or changes in key managerial/ technical personnel, a verification visit may be conducted.

- **Misuse of accreditation mark**

Whenever any information regarding misuse of Accreditation Mark is received in QAI Secretariat, it shall be investigated and objective evidence of such misuse is collected and reported to the CEO QAI. Verification/ unannounced Verification visit shall be organised based on the severity of the outcome of the investigation.

- **Complaint against an HCF**

In case, a complaint has been received and the facts need to be verified. Complaint will be dealt with as per the policy.

- **Accreditation committee recommendation**

Based on the Accreditation Committee recommendation to cross checks the evidences/ documents submitted by HCF if that cast doubts on the authenticity.

5. Surveillance

QAI Secretariat shall inform the accredited HCF at the end of 12 months regarding the surveillance to be conducted within fifteen to eighteen months of obtaining accreditation. Surveillance assessment may be desktop review/ on-site/ remote/ hybrid, based on situations. In case surveillance is based on a desktop review, accredited healthcare facility is required to submit following information/ documents/ records for desktop surveillance. This is to ensure that the accredited HCF is maintaining the requirements of QAI standards and other applicable criteria.

A. Self-Assessment Tool (Latest)

A.1 Scoring by HCF

A.2 Evidence/ cross-reference to manuals/ documents

A.3 Updated/ renewed statutory requirements

B. Major Changes, if any

Any major changes in last one year (e.g., change in legal status, change in management and senior staff, change in scope, quality indicators etc.)

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C. Declaration by the Management (on the letter head)

A statement “This is to declare that that the HCF has been complying to the requirements of QAI standards and any other requirements prescribed by the QAI CAHSC since last on-site assessment”.

Surveillance is aimed at examining whether the accredited HCF is maintaining the requirements of QAI Standards and other applicable criteria.

The HCF during the validity of accreditation may request to enhance the scope of accreditation for which they should preferably apply two months before the conduct of surveillance.

The surveillance is similar to the first assessment. If the HCF meets the scoring, however there are non-compliances, officer shall communicate to HCF to submit corrective actions against all non-compliances/ partial conformance (NCs & PCS) observed during surveillance assessment. The HCF shall get a time period of 60 days to submit all the corrective actions to QAI Secretariat. The corrective actions shall be reviewed by the respective Lead assessor/ assessor for the acceptance. The summary of the surveillance report along with other relevant information shall be placed before the accreditation committee for their recommendation for continuation of accreditation or otherwise. QAI shall inform the HCF, in writing, about such decision.

6. Reassessment and Renewal of Accreditation

QAI Secretariat shall remind the HCF, 12 months before the expiry of accreditation for making application for renewal of accreditation to ensure that HCF applies for renewal.

The HCF may apply for renewal of accreditation by submitting an application in the prescribed form. The application shall be accompanied with the prescribed renewal fee, as detailed in the information brochure. The HCF may request for extension of scope of accreditation, which should explicitly be mentioned in the application form.

The request for renewal must be submitted at least six months before the expiry of the validity of accreditation. If the HCF does not apply for renewal of accreditation, three months before the expiry of accreditation, it shall be presumed that the HCF is no longer interested in accreditation and the accreditation status of the HCF shall expire on the validity date mentioned in the certificate. In such a case the HCF shall have to apply afresh and the continuity of the certificate shall be disturbed.

Once applied within the time frame given vide 6.3, the HCF must be prepared for assessment. QAI shall conduct the renewal assessment (on-site/ remote/ hybrid), based on situations anytime during this period to ensure that the decision on the renewal assessment can be arrived at before the expiry of the accreditation certificate. In circumstances, where the decision for renewal could not be arrived at before the expiry of the accreditation, QAI may take a decision to extend the certificate validity up to a period not exceeding three months.

The procedure for processing of renewal application is similar to that of first application. The procedure for the reassessment is similar to that of first assessment.

If the results of reassessment are positive and all non-compliances are submitted within 90 days after the reassessment and recommended by the accreditation committee before the expiry of the certificate, then the validity of the certificate is extended by another three years without any discontinuity.

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A new certificate of accreditation is issued on renewal; however, the certificate number remains the same.

7. Adverse Decisions

QAI may take an adverse decision on the accredited HCF, if the HCF at any time during the validity of accreditation, does not fulfil the requirements of QAI Standards and other relevant criteria. The conditions of taking adverse decisions, like a reduction in scope of accreditation, abeyance, suspension and forced withdrawal is described in the document 'Policies & Procedures for Dealing with Adverse Decisions' (QAI CAHSC 025).

In case of adverse decisions like inactive, abeyance, suspension and forced withdrawal, the HCF shall ensure that the use QAI accreditation mark is as per policy. The suspension and forced withdrawal status shall also be publicised.

In case the HCF's accreditation has been withdrawn by QAI, it is debarred to participate in the accreditation programme for a period of at least one year. The HCF may apply afresh by giving valid justification for earlier withdrawal and paying all fees & expenses, as applicable at that time.

8. Appeal

All adverse decisions taken by QAI regarding accreditation shall be open to appeal by the HCF, to the Chairman QAI as per laid down policy.

9. Publicity

QAI on its website shall publish details of applicant and accredited HCFs. Scope of accreditation & accreditation status with validity date of accreditation of the accredited HCFs shall be made available on our website.

10. Confidentiality

The members of the Board, Accreditation Committee, Assessors, Experts and QAI officials are required to maintain strict confidentiality of the information gathered regarding the HCFs from their various documents and any other related information that might have been given by QAI, during the process of accreditation. QAI shall impose the same obligation of maintaining secrecy on those, whom they entrust the tasks of a confidential nature, as described above. All such persons who have access to confidential information sign a declaration of confidentiality.

11. Liability

QAI shall not be responsible for any damages, which the HCF may suffer as a result of any action or negligence by those who are carrying out the tasks on behalf of QAI and any failure to the grant of accreditation or abeyance/ suspension/ forced withdrawal of the accreditation.

12. Amendments to the Policies and Procedures

QAI may at any time amend the policies and procedures related to grant of accreditation, maintaining accreditation, surveillance, renewal of accreditation and the adverse decisions thereon. QAI shall inform the HCFs regarding such amendments indicating the transition period set for compliance.

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