

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



Change Adapt Improve

INFORMATION BROCHURE
FOR
ACCREDITATION OF ASSISTED REPRODUCTIVE
TECHNOLOGY (ART) CENTRES

CONTENTS

Sl. No.	Title	Page No.
1.	About Quality and Accreditation Institute (QAI)	3
2.	Benefits of Accreditation	4
3.	Organisation Structure	5
4.	QAI's Centre for Accreditation of Health and Social Care	6
5.	Special Features of Accreditation	7
6.	Scope of Accreditation	8
7.	Eligibility and Preparation for Accreditation	9
8.	Accreditation Process	10
9.	Assessment Criteria and Fee Structure	13
10.	QAI-CAHSC Publications	13

1. About Quality and Accreditation Institute (QAI)

Quality and Accreditation Institute Pvt. Ltd. is incorporated by Registrar of Companies under the Companies Act 1956. QAI was set up to create an ecosystem of accreditation/ certification, education, training and quality improvement. We aim to provide a platform to stakeholders including professionals and organisations, associated with quality in any way, to share their wisdom and knowledge in order to make healthcare services delivering better outcomes. This will further provide tremendous opportunities to all concerned to learn and contribute in improving organisations. Different activities would be initiated under different verticals in a manner that they remain independent of each other. QAI aims to operate globally. One of the verticals set up within QAI is the Centre for Accreditation of Health and Social Care (CAHSC). It is responsible to run various accreditation/ certification activities in health and social care.

QAI endeavours to operate various accreditation programmes in the space of health and social care. We are aiming to provide value addition to such organisations through a unique process of self-assessment and peer review. We would assist organisations in moving forward on a self-regulated improvement journey.

Vision

Nurturing the largest global pool of organisations and people through quality and accreditation framework.

Mission

To conceive and deliver education, training, accreditation and related programmes in partnership with stakeholders using an approach of co-design and co-creation.

Values

Listener: Seek continuous feedback from stakeholders to address their concerns

Competitive: Look for viable options to benefit users of our services

Transparency: Clearly defined policies made available in public domain

Innovation: Continuously evolve using co-design and co-creation

International Affiliations

QAI is an institutional member of the International Society for Quality in Health Care (ISQua) (www.isqua.org).



QAI is a Board Member of the International Society for Telemedicine and eHealth (ISfTeH) (www.isfteh.org).



International Society for
Telemedicine & eHealth

2. Benefits of Accreditation

For Patients

- In an accredited healthcare facility (HCF), patient receives higher quality of care
- Safety of patient is given a priority
- Patients receive services by credentialed medical and nursing staff
- Rights of patients are respected and protected
- Patient satisfaction is regularly evaluated which provides an opportunity to patients to express about their experience
- Patients get an opportunity to be part of their own care

For Healthcare Facilities

- Accreditation enables the HCF in demonstrating commitment to deliver quality and safe patient care.
- Accreditation assures community about the quality of services and better health outcomes.
- Accreditation helps demonstrating that healthcare organisation functions in transparent and ethical manner.
- It also acts as a potential mechanism of risk management to safeguard provider from potential legal liability.
- It is a process to stimulate continual improvement.
- Act as a mechanism of self-regulation.
- It may provide opportunity for benchmarking by comparing their outcomes with other accredited organisations.

For Staff of Healthcare Facility

- Accreditation process provides opportunity to staff at all levels for their professional development
- It may help in building higher staff satisfaction because of good working environment, leadership opportunities and ownership of processes
- Being robust documentation and procedures in place, it also supports staff in building their confidence to deliver proper care

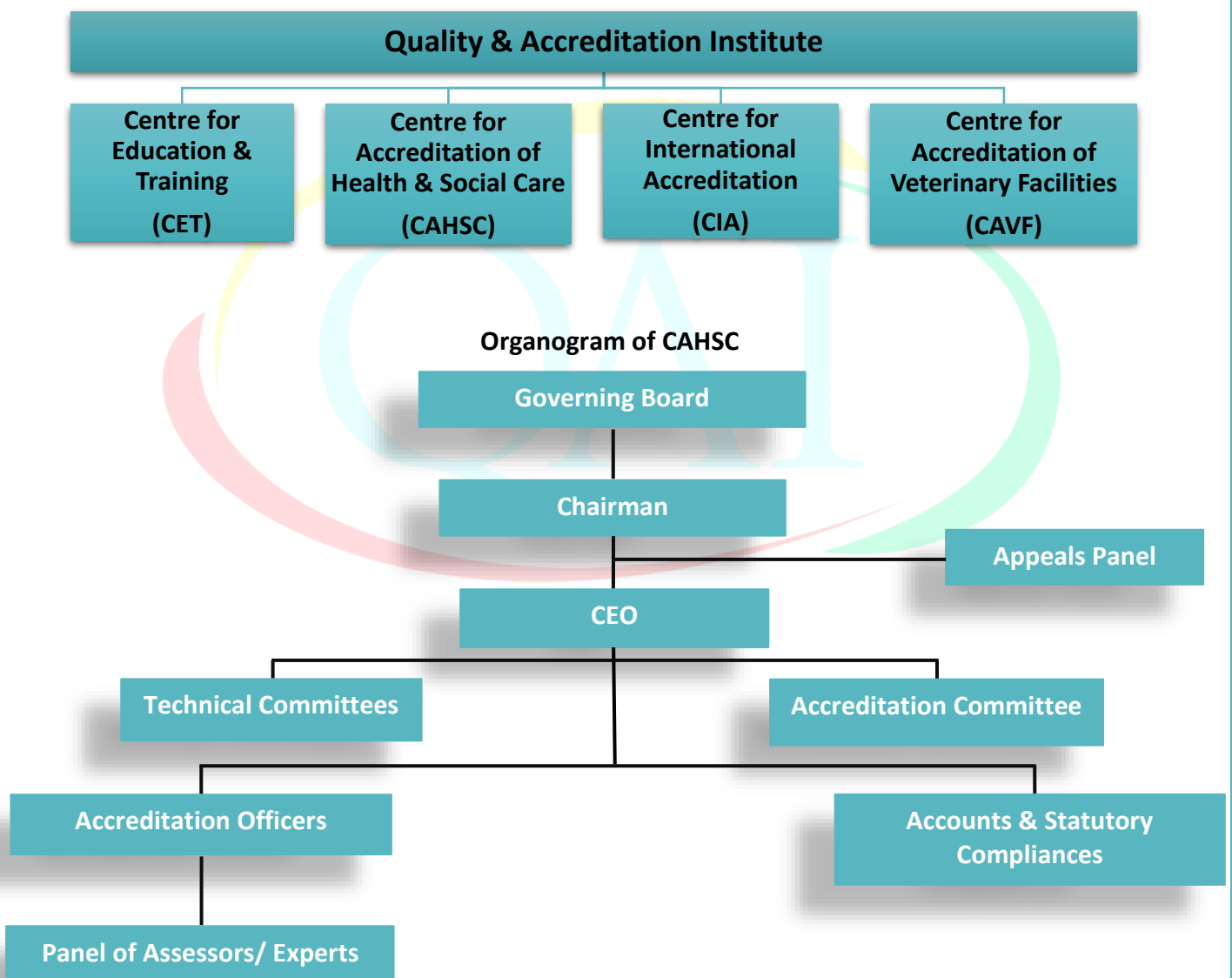
For Third Parties

- Accreditation provides an objective system of evaluation and empanelment by third parties like insurance companies, other payers, government etc.
- Accreditation helps in access to reliable and documented information on facilities, infrastructure, services and level of care.

3. Organisation Structure

The organisation structure of QAI’s Centre for Accreditation of Health and Social Care has been designed to meet the requirements of an effective and efficient accreditation system. The Centre is governed by a Board. The Board frames and approve policies and provide direction. CEO is the Member Secretary of the Board.

CAHSC operates its accreditation/certification process through a structured framework of competent staff, pool of empanelled Lead Assessors and Assessors covering specified expertise, technical committees and accreditation committee. Membership of various committees is drawn from reputed organisations, experts in the field, experienced assessors, academic institutions, important professional bodies, regulatory agencies/ bodies etc.

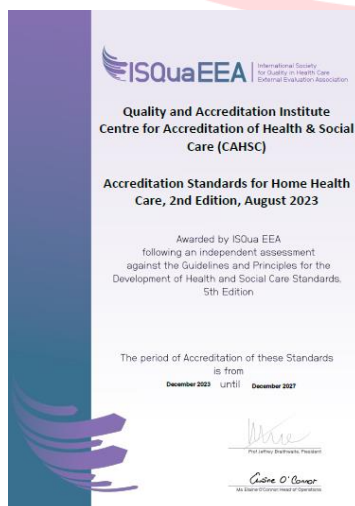


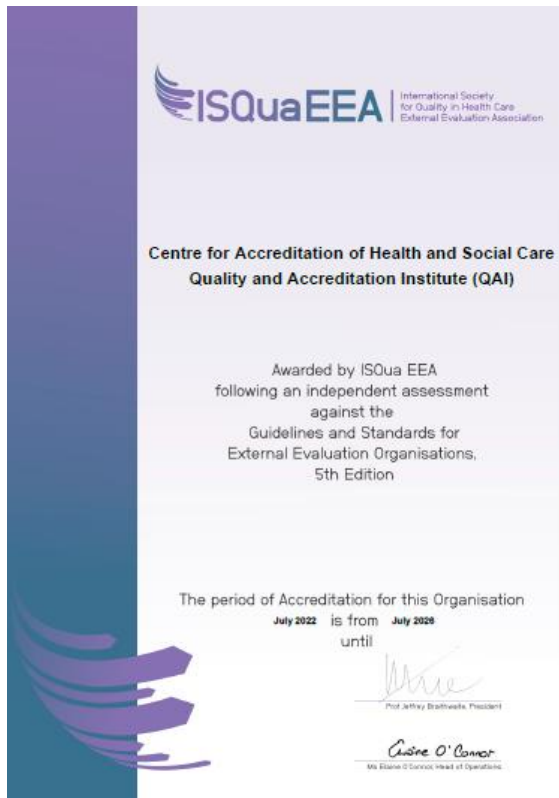
4. QAI's Centre for Accreditation of Health and Social Care (CAHSC)

It was set up to operate accreditation/ certification programmes in health and social care sector. Initially, it was targeted to launch those programmes which were not existing in India and there was a need felt by stakeholders to start such programmes. Currently, following accreditation/ certification/ recognition programmes are operational:

- Accreditation Programme for Hospitals
- Accreditation Programme for Small Hospitals
- Accreditation Programme for Assisted Reproductive Technology (ART)/ IVF Centres
- Accreditation Programme for Home Health Care
- Accreditation Programme for Dialysis Centres
- Accreditation Programme for Green Health Care Facility
- Accreditation Programme for Clinics
- Accreditation Programme for Ambulatory Care Facility (Dental/Eye/Imaging/Day Care Surgery Centres etc.)
- Accreditation Programme for Telehealth
- Recognition Programme for Telemedicine Practitioners
- Accreditation Programme for Hotels and Home Stays
- Accreditation Programme for Emergency Department
- Accreditation Programme for Transition Care/ Inpatient Rehabilitation Centre
- Certification Programme for Hospitals (Entry Level)
- WHO Patient Safety Friendly Hospital Standards Certification Programme
- Accreditation Programme for Primary and Advanced Stroke Centre

QAI becomes the first accreditation body in India to achieve ISQuaEEA Accreditation in less than five years of operations. QAI is the ONLY accreditation body in India having ISQua Accreditation as an Organisation and Two Sets of Standards.





QAI Accreditation is recognised by the Ministry of Health's Central Government Health Scheme (CGHS) for empanelment of Private Hospitals, Eye Centres, Dental Centres & Imaging Centres.

5. Special Features of Accreditation Programme

- Comprehensive Assessment Management System to allow quick turnaround time for the accreditation/ certification process as each step is linked to a defined period.
- Endorsement of a documented quality and improvement programme as per the intent of the standard.
- Based on comprehensive self-assessment and document review process providing opportunity to facility for a thorough review of their own documentation and implementation of requirements of standards.
- Rigorous Assessor Management System including a transparent monitoring and evaluation process.
- 'Client First' approach
- Harmonising local, national, regional and global framework
- HCF in SAARC nations enjoy same fee structure as for HCFs in India
- Blend of global strategy, experience and leadership
- Economic yet global benchmarking

6. Scope of Accreditation

Assisted Reproductive Technology (ART) including IVF Centres

Blastocyst Culture	Oocyte/Embryo/Blastocyst Cryopreservation
Counselling	Operation theatre
Donor Programme	Other procedures involving manipulation of gamete, embryo, and gonadal tissue
Embryo Biopsy	Ovarian Stimulation
Embryology Laboratory	Percutaneous Epididymal Sperm Aspiration (PESA)
Embryoscopy	Preimplantation Genetic Diagnosis (PGD)
Endometrial Biopsy	Preimplantation Genetic Testing (PGT)
Immunomodulation (Intralipid) Therapy	Reproductive Genetics
In Vitro Fertilization (IVF)	Semen Analysis (recognized standards e.g. WHO)
Intra Cytoplasmic Morphologically Selected Sperm Injection (IMSI)	Sperm cryopreservation
Intra Cytoplasmic Sperm Injection (ICSI)	Sperm DNA Fragmentation Index (DFI) Test
Intrauterine Insemination (IUI)	Sperm preparation (Fresh sample/ frozen sample/ MESA/ PESA/ TESE/ TESA/ Open Biopsy)
Laparoscopy & Hysteroscopy	Surrogacy
Laser Assisted Hatching	Testicular Sperm Aspiration (TESA)
Micro Epididymal Sperm Aspiration (MESA)	Testicular Sperm Extraction (TESE)
Oocyte retrieval	Ultrasonography

7. Eligibility and Preparation for Accreditation

7.1 Eligibility for Accreditation

The applicant HCF must check whether they are eligible to apply by looking at their size and scope of services. These standards are applicable to whole HCF and not a specific service/department of an HCF. HCF should be operating with a minimum of 30% occupancy and have implemented standards for at least two months before applying for Accreditation to have sufficient data and records to verify during the assessment.

7.2 Preparing for Accreditation

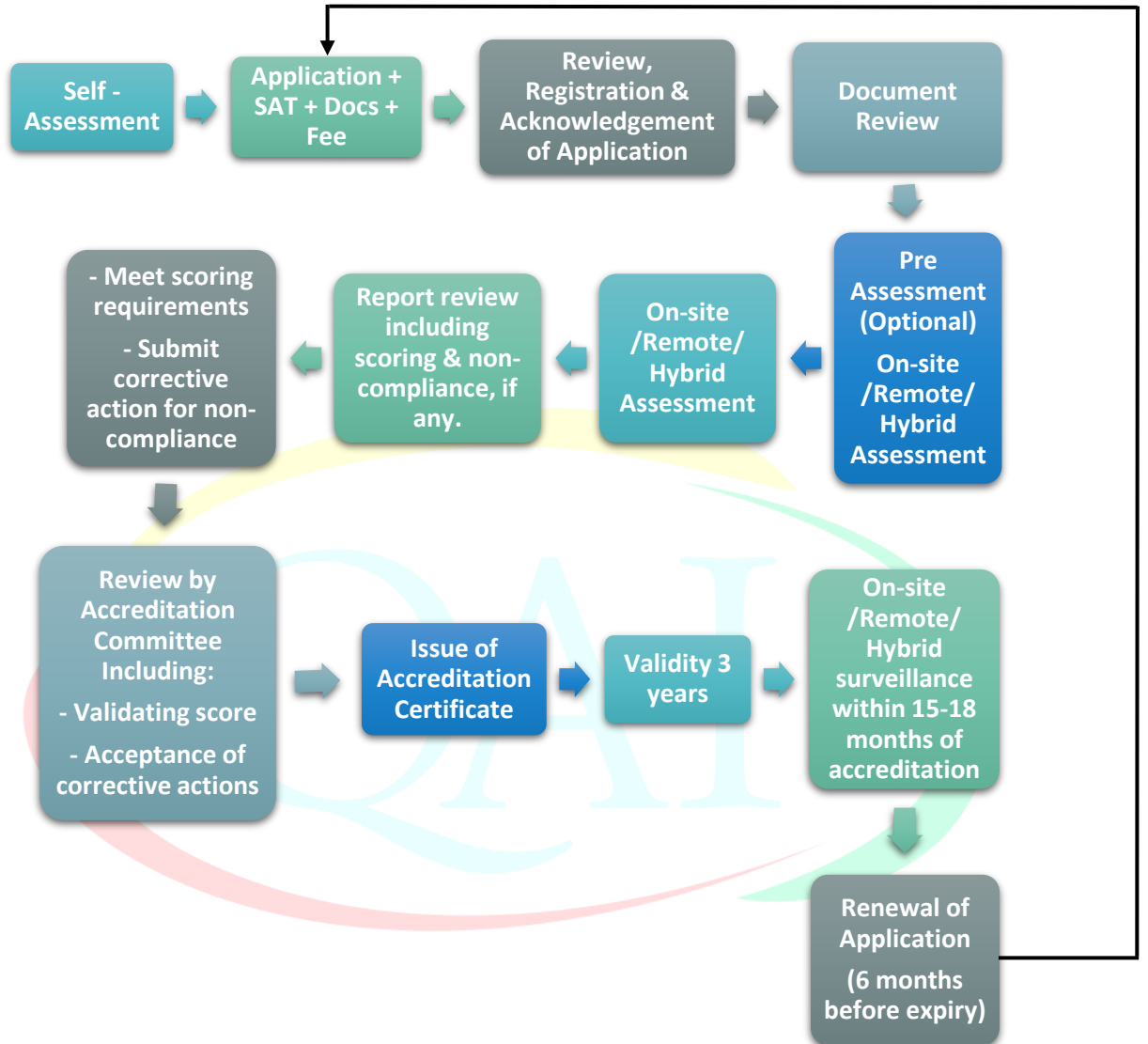
Management of the HCF shall first decide about getting Accreditation from QAI. It is important for the HCF to make a definite plan of action for obtaining Accreditation and nominate a person to co-ordinate all activities related to seeking Accreditation. The nominated official should be familiar with existing policies, procedures and documents of the HCF.

HCF must procure a copy of the relevant QAI Accreditation standards. A self-assessment tool can also be requested from the Secretariat. The HCF seeking Accreditation shall understand the QAI assessment process. The HCF shall ensure that all the requirements of the standard are implemented. The HCF may get its personnel trained in understanding and implementation of Accreditation standards. Such training programmes are conducted by QAI from time to time.



8. Accreditation Process

Accreditation process is shown below:



8.1 Self-Assessment

HCF first carries out self-assessment using self-assessment tool which is based on the requirements of the Accreditation standards. It gives an opportunity to the HCF to examine all its documentation and their implementation. It will also give a comprehensive view of its documentation to the Assessment Team. A self-assessment tool can be requested from the Secretariat.

8.2 Application

Applicant is requested to submit the following:

- Soft copy of completed application form (available on website)
- Soft copy of Self-assessment tool along with referenced documents
- Prescribed application fees
- Soft copy of signed QAI-CAHSC 003 'Terms and Conditions for Obtaining and Maintaining Accreditation/ Certification' (available on website)

8.3 Review, Registration and Acknowledgement of Application

CAHSC Secretariat on receipt of application form, self-assessment tool, referenced documents and the fees reviews the application for its completeness, and a unique ID number is allocated which is used for correspondence with the HCF. Secretariat may ask for additional information/ clarification(s) at this stage, if found necessary.

8.4 Document Review

Secretariat appoints an assessment team and share application form, self-assessment tool and any other relevant document provided by the HCF. CAHSC seeks HCF's acceptance for the proposed assessment team. The HCF can refuse any member of the proposed assessment team by giving specific reason(s) for their non-acceptance. Once the team and dates are finalised, lead assessor takes over to initiate the further process. The assessment team carry out document review by going through the application form, self-assessment tool and referenced documents, and provide feedback to the Secretariat. This feedback is shared with the HCF for taking necessary corrective actions.

8.5 Pre-Assessment (Optional):

QAI has introduced pre-assessment as optional. Those HCFs shall inform QAI while applying in case they wish to undergo pre-assessment. All HCFs are not required to undergo the same and can directly move to the final assessment. Appointed assessor or assessment team shall conduct the pre-assessment (remote/ hybrid/ on-site). Lead assessor shall submit the pre-assessment report to QAI. The HCF shall take corrective actions on the non-conformities raised by the lead assessor/ assessment team. The HCF shall be required to pay the pre-assessment fee as defined in the fee structure (programme wise).

8.6 Assessment

Appointed assessment team conducts the assessment (remote/ hybrid/ on-site). CAHSC may also nominate an observer which is either an assessor-in-training or a Secretariat staff. The assessment team keeps the secretariat in loop for any communication with the HCF. During assessment, the assessment team validate the scoring of self-assessment by reviewing documents, records, observation, interaction with staff and patients. The assessment report containing the findings of the assessment is prepared by the team. The non-compliances (a criterion receiving a score of 0 & 5), if identified are reported in the assessment report. The report is endorsed by the authorised signatory of the HCF. The report prepared by the assessment team is sent to CAHSC Secretariat. A copy of summary of assessment report and non-compliances, if any, are provided to the HCF at the end of the assessment.

8.7 Review of Assessment Report and Decision Making

The assessment report is reviewed by the Secretariat for its completeness, scoring and non-compliances, if any. If the HCF meets the scoring for accreditation, however there are non-compliances, the HCF is asked to submit corrective actions against those non-compliances. 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.

Once corrective actions are received, the report along with all documents is placed before the accreditation committee for its review and recommendation. All decisions taken by CAHSC regarding grant of accreditation are open to appeal by the HCF as per laid down appeal process.

8.8 Issue of Accreditation Certificate

If the recommendation of the accreditation committee results in the grant of accreditation, QAI-Secretariat processes for approval and issue of the accreditation certificate. Certificate has a unique number, name of accreditation standard, and period of accreditation i.e., dates of validity. The accreditation certificate is valid for three years. The certificate is issued under the signatures of the CEO and the Chair, CAHSC.

Accreditation Mark

Accredited HCF is authorised to use following accreditation mark subject to requirements specified in QAI CAHSC 019-Policy and guidelines for use of QAI accreditation/ certification mark.



ASSISTED REPRODUCTIVE TECHNOLOGY

8.9 Maintaining Accreditation

Compliance to applicable standards and other requirements

The accredited HCF at all times shall comply with the requirements of the standards as well as any other laid down requirements.

Terms and Conditions

The accredited HCF is required to comply at all times with the terms and conditions given in CAHSC 003 'Terms & Conditions for Obtaining and Maintaining Accreditation/Certification'. The HCF is required to submit a signed soft copy of the same before issue of the certificate.

Adverse Decision against the Healthcare Facility

If the HCF at any point of time does not comply with the applicable standards and/ or does not maintain the terms and conditions; or is not able to align itself to the modified criteria, CAHSC may take adverse decision against the HCF like abeyance, denial of accreditation, suspension or forced withdrawal as per laid down policy.

8.10 Surveillance

The accreditation certificate is valid for a period of three years. CAHSC shall conduct surveillance (Remote/ Hybrid/ On-site/ Desktop) within 15-18 months of accreditation. It is aimed at evaluating continued compliance with the applicable standards and other requirements stipulated from time to time. In addition to the regular surveillance, a surprise assessment may also be conducted to check compliance to the accreditation requirements.

8.11 Reassessment

The accredited HCF is subjected to re-assessment every three years for renewal of accreditation. The HCF has to apply six months before the expiry of accreditation in order to complete all formalities for renewal of accreditation before the expiry of the current accreditation so that continuity of the accreditation is maintained. The renewal application is submitted in the prescribed form along with required documents as mentioned in the application form. Rest of the process is same as for initial assessment.

Applicant ART Centre is requested to submit the application to info@qai.org.in

9. Assessment Criteria and Fee Structure

A uniform fee structure is maintained for all HCFs and the charges are maintained at a reasonable level so that HCFs are not denied participation in the accreditation process because of unreasonable financial conditions. The fee structure is kept simple and economical to facilitate maximum number of participations, less invoices and bank transactions. The information about the fee structure is given on the website.

10. QAI-CAHSC Publications

All relevant publications are available on our website www.qai.org.in.



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

709, Wave Silver Tower, Sector 18, Noida 201301, India

Email: info@qai.org.in Website: www.qai.org.in

Mobile No.: +91 8287841146

Ph. No.: +91 120 6664189

[LinkedIn](#) | [Twitter](#) | [Facebook](#) | [YouTube](#) | [Instagram](#)