

QAI CAHSC 101

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



Change Adapt Improve

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

Issue No. 08

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1. **About Quality and Accreditation Institute (QAI)**

Quality and Accreditation Institute is a private limited company incorporated by Registrar of Companies under the Companies Act 1956. QAI was set up to create an ecosystem of education, training, quality improvement and accreditation/ certification. It is believed that this organisation would 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 its Vision realised. This will further provide tremendous opportunities to all concerned to learn and contribute in improving organisations engaged with QAI. 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

Membership

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



QAI became the institutional member of the International Society for Telemedicine and eHealth (ISfTeH) (www.isfteh.org).



International Society for
Telemedicine & eHealth

2. **Benefits of Accreditation**

- Improvement in clinical practice and training activities.
- Recognition of your total quality management strategy through third party assessment distinguishing you from non-accredited centres.
- Provides opportunity for benchmarking.
- Enhanced level of assurance towards the safety and quality for patients approaching ART treatments, reassuring them about the standards of services provided.
- Safety and quality assurance in clinical and laboratory procedure.
- Displaying a mark of excellence which makes it easy for patient to identify the Centre/ HCF that offer quality processes hence ensuring privacy, confidentiality and uniform care as per best evidence practices.
- National and International acknowledgment of Good Medical Practices.

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

It is set up to operate accreditation/ certification programmes in health and social care sector. Primarily, it is targeted to launch those programmes which do not exist in India and there is a need felt by stakeholders to start such programmes. Currently, following accreditation/ certification/ recognition programmes have been developed: -

- Assisted Reproductive Technology (ART) including IVF Centres Accreditation Programme
- Home Health Care Accreditation Programme
- Dialysis Centres Accreditation Programme
- Green Health Care Facility Accreditation Programme
- Healthcare Facility Certification Programme
- WHO Patient Safety Friendly Hospital Standards Certification Programme
- Primary Care Clinic Accreditation Programme
- Ambulatory Care Facility Accreditation Programme
- Recognition Programme for Telemedicine Practitioners
- Accreditation Programme for Telehealth
- Accreditation Programme for Hotels and Home Stays
- Accreditation Programme for Emergency Department

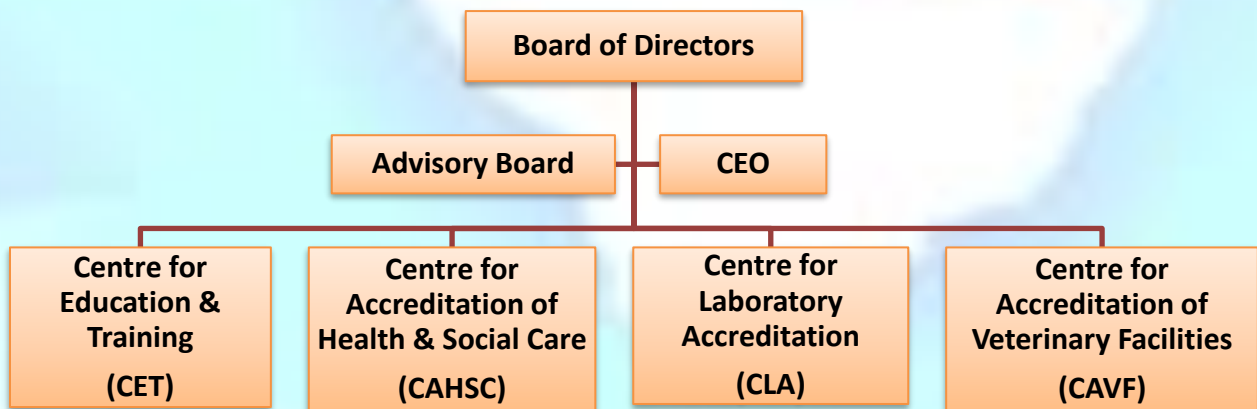
Following standards have achieved ISQua accreditation, making QAI the first and only accreditation body in India to get such recognition.

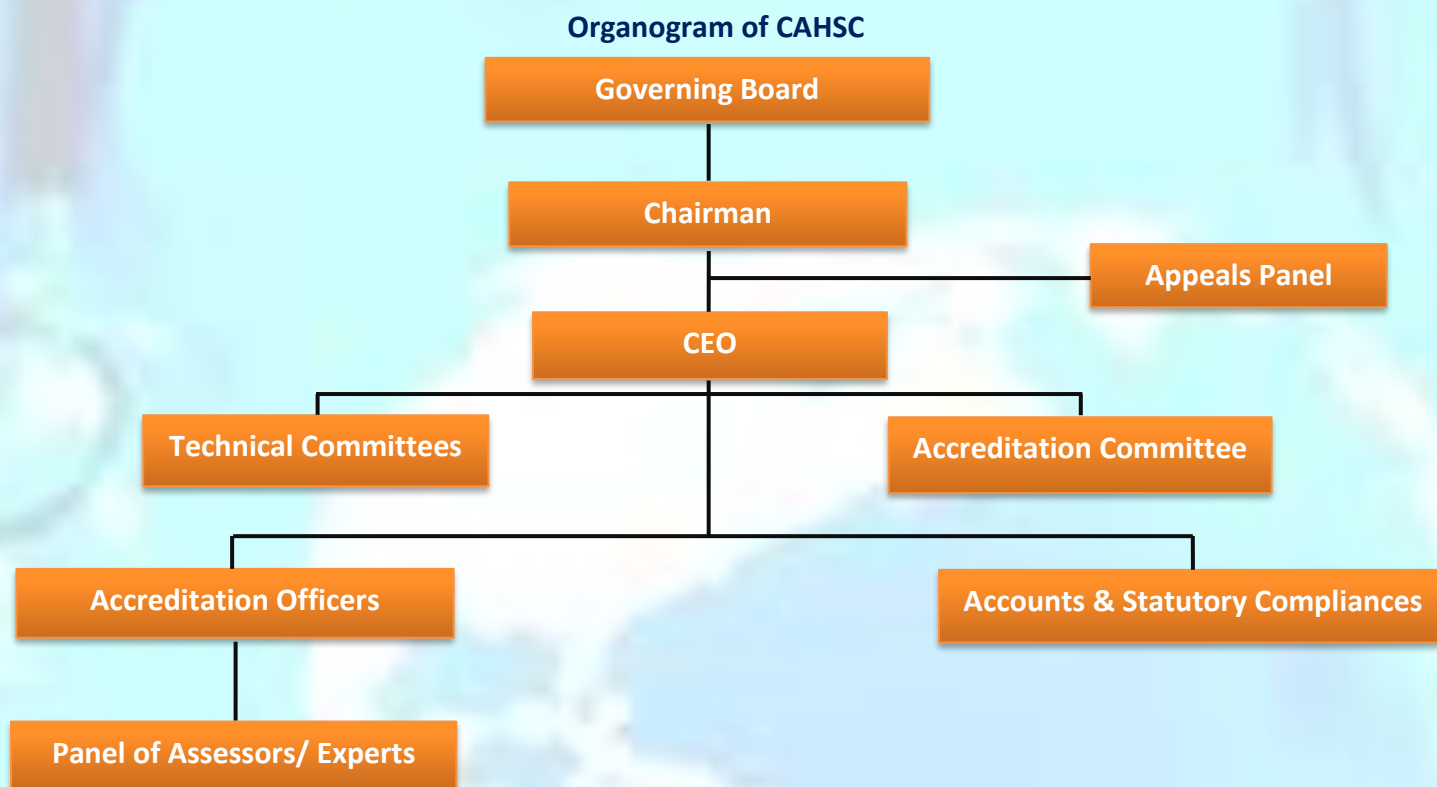


4. Organisation Structure

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 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.





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.
- No pre-assessment to reduce turn-around time, making it more cost effective and efficient.
- Based on comprehensive self-assessment and document review process providing opportunity to HCFs 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.
- Hear the voice of all keeping 'Client First'
- Harmonising local, national, regional and global framework
- Health care facility in SAARC nations enjoy same fee structure as for health care facilities in India
- Blend of global strategy, experience and leadership
- Economic yet global model

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. This can be done by looking at their scope of services and the accreditation standards available. The applicant is advised to implement standards for at least two months before applying for accreditation.

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 an e-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

Conceptualised an accreditation process which is simple and efficient as shown below:



8.1 Self-Assessment

HCF first carry 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 Facility. CAHSC seeks facility's acceptance for the proposed assessment team. The facility 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 facility for taking action.

8.5 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 facility. 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 facility. 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 facility at the end of the assessment.

8.6 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.

8.7 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.



8.8 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 accreditation 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.

8.9 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.

8.10 Reassessment

The accredited HCF is subjected to re-assessment every 3 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 with required documents as mentioned in the application form. Rest of the process is same as for initial assessment.

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 below:

Assessment criteria and fee structure for ART Centres

No. of embryos transfer in ART Centre (per year)	Assessment Criteria		Accreditation Fee	
	Final Assessment/ Renewal Assessment	Surveillance	Application Fee (Rs.)	Annual Accreditation Fee (Rs.)
Up to 300	Two-man days (2x1)	One-man day (1x1)	25000	125000
Above 300	Four-man days (2x2)	Two-man days (2x1)	50000	200000

NOTE: The man days given above for assessment and surveillance are indicative and may change depending on the facilities and the no. of embryos transfer in ART Centre (per year). A nominal fee may be charged for remote or hybrid assessment.

In addition to the above-mentioned fee, GST@18.0 % or as applicable from time to time to be paid.

Assessment Charges: In addition to the above fee, HCF shall bear the cost of following (in case of on-site/ hybrid assessment):

- Travel of the assessment team
- Accommodation and meals

Guidelines for Travel and Lodging:

- Travel to be made by Air in economy class (Apex fare) or by train in 2nd AC Class or by AC Bus/ Taxi.
- The HCF will provide the tickets for travel as per above guidelines. If the journey is made by own car, the re-imbursment will be as per company's rules or restricted to 2nd AC Class fare by train.
- The HCF shall also make arrangements for travel & lodging for the Assessment team. A single occupancy AC accommodation may be provided for each Assessor/ Observer in a reasonably good hotel/ guesthouse and arrangement for local transportation from temporary residence to the HCF and airport/ railway station/ bus stand.

Fee Payment:

All payments through Demand Draft/ Check/ Bank Transfer shall be made in favour of 'Quality and Accreditation Institute Pvt. Ltd.' payable at Noida/ New Delhi.

Bank Transfer details are:

Beneficiary name: Quality and Accreditation Institute Pvt. Ltd.

Beneficiary address: A-34, Sector 48, Noida-201304, India

Bank Account number: 003105031612

Bank Details: ICICI Bank Limited, K-1, Senior Mall, Sector 18, Noida-201301, India

Bank IFSC Code: ICIC0000031

Bank Swift Code: ICICINBBNRI

PAN No.: AADCI3230L

GSTIN: 09AADCI3230L1ZK

Note: Any bank charges for transfer of fee is to be paid by the sender.

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

Email: info@qai.org.in Website: www.qai.org.in
Twitter@QAI2017