

# Quality and Accreditation Institute

## Centre for Accreditation of Health & Social Care



*Change Adapt Improve*

### INFORMATION BROCHURE FOR ACCREDITATION OF HEMATOPOIETIC CELL TRANSPLANTATION AND CELLULAR THERAPY (Product Collection, Processing and Administration)

## CONTENTS

Sl. No.	Title	Page No.
1.	About Quality and Accreditation Institute (QAI)	3
2.	Organisation Structure	5
3.	Accreditation Programmes	6
4.	Benefits of Accreditation	7
5.	QAI Accreditation Programme for HCT	8
6.	Accreditation Process	10
7.	Eligibility and Preparation for Accreditation	11
8.	Assessment Criteria and Fee Structure	13
9.	QAI-CAHSC Publications	14



## 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 quality & safety through accreditation/ certification, education, and training. We aim to provide a platform to stakeholders including professionals and organisations, associated with quality in some way, to share their wisdom and knowledge in order to support delivery of better services and products. This will further provide tremendous opportunities to all concerned to learn and contribute in improving organisations. Different activities were 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.

## 2. Centre for Accreditation of Health and Social Care (CAHSC)

QAI CAHSC 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, peer review and ongoing monitoring. Accreditation being a voluntary process, we encourage 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](http://www.isqua.org)).



QAI CAHSC is a member of the Accreditation Council of the International Society for Quality in Health Care External Evaluation Association (ISQuaEEA).

**QAI becomes the first accreditation body in India to achieve ISQuaEEA Organisation Accreditation in less than five years of operations.**

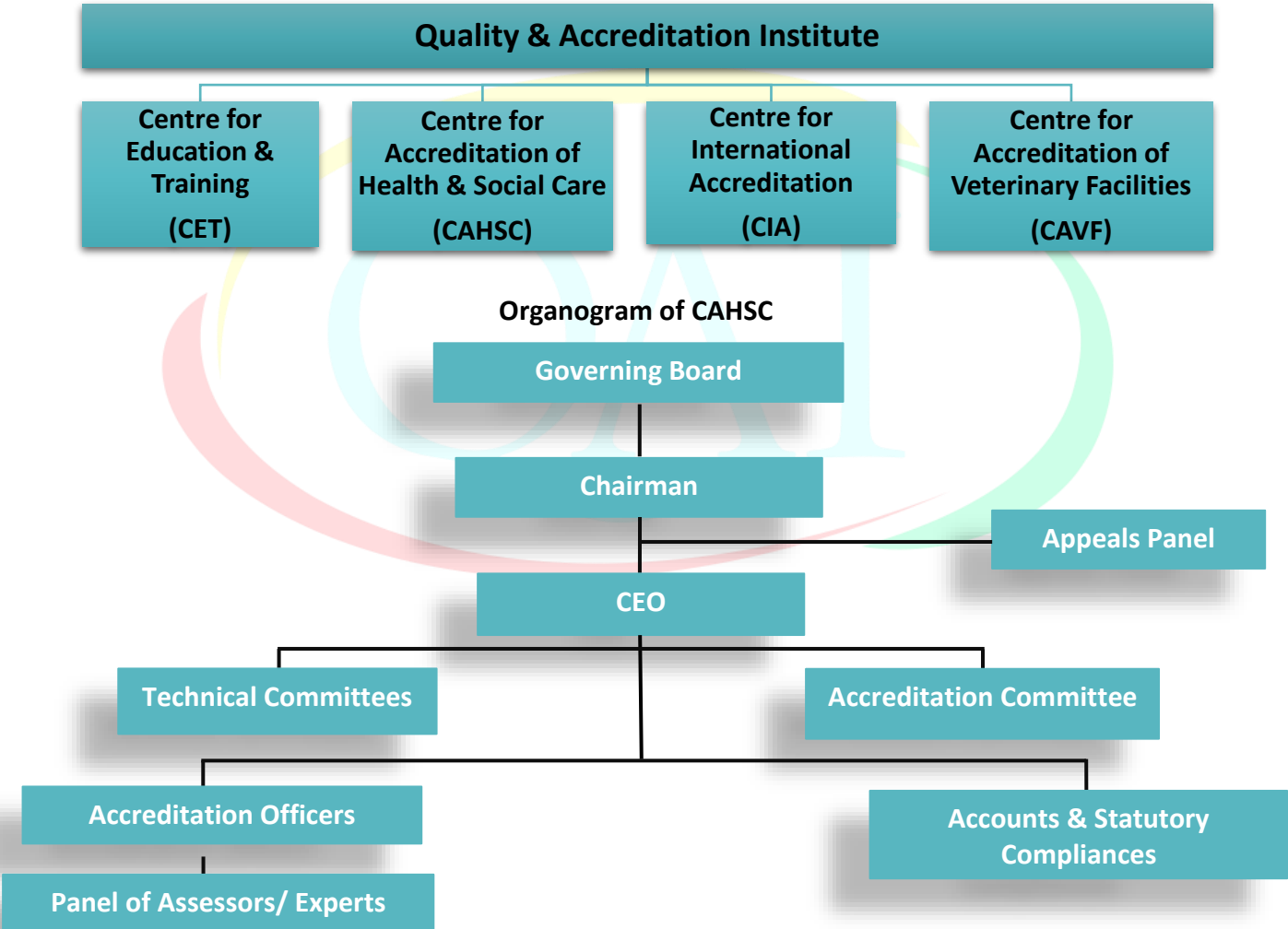


**QAI Accreditation is recognised by the Central Government Health Scheme (CGHS), Ministry of Health & Family Welfare, Govt. of India for empanelment of Private Hospitals, Eye Centres, Dental Centres & Imaging Centres.**

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.



### 3. Accreditation Programmes

QAI CAHSC has emerged as a Comprehensive Specialist Accreditation Body covering the entire patient care continuum i.e. pre-hospital, hospital and post-hospital care. 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 Centres)
- Accreditation Programme for Ambulatory Care Facility (Imaging Centres etc.)
- Accreditation Programme for Ambulatory Care Facility (Eye Care Centres)
- Accreditation Programme for Ambulatory Care Facility (Day Care Surgery Centres etc.)
- Accreditation Programme for Telehealth Services
- Accreditation Programme for Hotels and Home Stays
- Accreditation Programme for Emergency Department
- Accreditation Programme for Transition Care/ Inpatient Rehabilitation Centre
- Recognition Programme for Telemedicine Practitioners
- Accreditation Programme for Stroke Centres and Advanced Stroke Centres
- Accreditation Programme for Hair Transplant Clinics
- Accreditation Programme for Vision Centres
- Accreditation Programme for Healthcare Facilities as per QAI 7101<sup>plus</sup>
- Accreditation Programme for Medical Transport Organisations (MTOs)/ Ambulance Services
- Accreditation Programme for Care Homes (non-healthcare facilities)
- **Accreditation Programme for Hematopoietic Cell Transplantation & Cellular Therapy (HCT)**  
**-Product Collection, Processing, and Administration**
- Certification Programme for Hospitals and Small Hospitals (Entry Level)
- Certification Programme based on WHO Patient Safety Friendly Hospital Standards

### 4. Special Features of the QAI 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 peer 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
- Blend of global strategy, experience and leadership
- Economic yet global recognition

## 5. Benefits of the QAI Accreditation

### For Patients

- These standards are designed to protect patients by minimising risks, ensuring the high quality of care, and fostering a culture of continual improvement.
- It reassures patients that the facility they have chosen upholds rigorous safety protocols, employs qualified professionals, and utilise appropriate equipment and techniques.
- 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 HCT Facilities

- Accreditation enables the HCT facility in demonstrating commitment to deliver high quality and safe patient care.
- Accreditation assures community about the quality of services and better health outcomes.
- Accreditation helps demonstrating that the facility functions in transparent and ethical manner.
- It also acts as a potential mechanism of risk management to safeguard provider from potential legal liability.
- It stimulates continual improvement.
- Act as a mechanism of self-regulation and support applicable regulatory regime.
- It may provide opportunity for benchmarking by comparing their outcomes with other accredited facilities.
- QAI accreditation serves as a hallmark of trust, setting them apart in a competitive market.

### For Staff of HCT Facilities

- Accreditation process provides opportunity to staff at all levels for their professional development
- Helps 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
- Enables staff safety as a key component.

**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.
- Supports applicable regulators in regulatory compliance

**6. QAI Accreditation Programme for HCT**

QAI accreditation programme for HCT facilities is designed to cover a range of facilities and scope as given below.

**6.1 Types of Hematopoietic Cell Transplantation and Cellular Therapy (HCT) Facilities**

These accreditation standards are meant for the accreditation of the facilities involved in Collection, Processing and Administration of hematopoietic cellular therapy products. Collection facility may include bone marrow and/or apheresis collection. It may include collection of cellular products from donor (patient or another person). It may please be noted that a facility may involve in all or any of the following activities:

- a. Collection, processing, storage, distribution, administration
- b. Collection, processing, storage, administration
- c. Collection, processing, administration
- d. Collection, storage, administration
- e. Collection, administration
- f. Processing, storage, distribution
- g. Collection and distribution (for administration or to processing facility)
- h. Administration
- i. Manufacturing, storage, distribution
- j. Collection, processing, manufacturing, storage, distribution, administration

**6.2 Scope of the QAI Accreditation Standards**

QAI accreditation programme for HCT facilities covers the following scope:

- a. Hematopoietic progenitor cells (HPCs)
- b. Nucleated cells or mononuclear cells from any hematopoietic tissue source
- c. Immune effector cells (IECs)
- d. Genetically modified cells



### 6.3 Eligibility Requirements for the QAI Accreditation

The applicant HCT facility must check whether they are eligible to apply by looking at the following eligibility requirements.

#### A. Patient Volume:

1. The facility performs a minimum of 10 transplants per year.
2. For a new facility, compliance with these volume goals must be attained within the first three years of functioning.

#### B. Infrastructure and Facilities:

1. There must be a designated transplant unit with at least two or more designated transplant beds. The unit could be part of a facility for treating immune-suppressed patients that also include patients with acute leukaemia and other hematological disorders.
2. The transplant unit must have facilities in place to effectively manage these patients.
3. The necessary equipment and experience for *ex vivo* handling of marrow and/or PBSCs should be available. This includes at least the facilities with protocols for cryopreservation and management of ABO blood group incompatibility.
4. Twenty-four-hour, high-quality support from laboratories, blood bank, and radiology should be available. The facility for irradiation of cellular products, either in-house or outsourced, should be available.
5. Appropriate microbiology laboratory facilities, including bacteriology, virology, and mycology facilities, should always be available.
6. A radiotherapy unit with the ability to perform total body irradiation (TBI) should be available within the hospital or in its close proximity.
7. Intensive care unit (ICU), dialysis, bronchoscopy, and imaging facilities should be available for both adults and children within the institution.

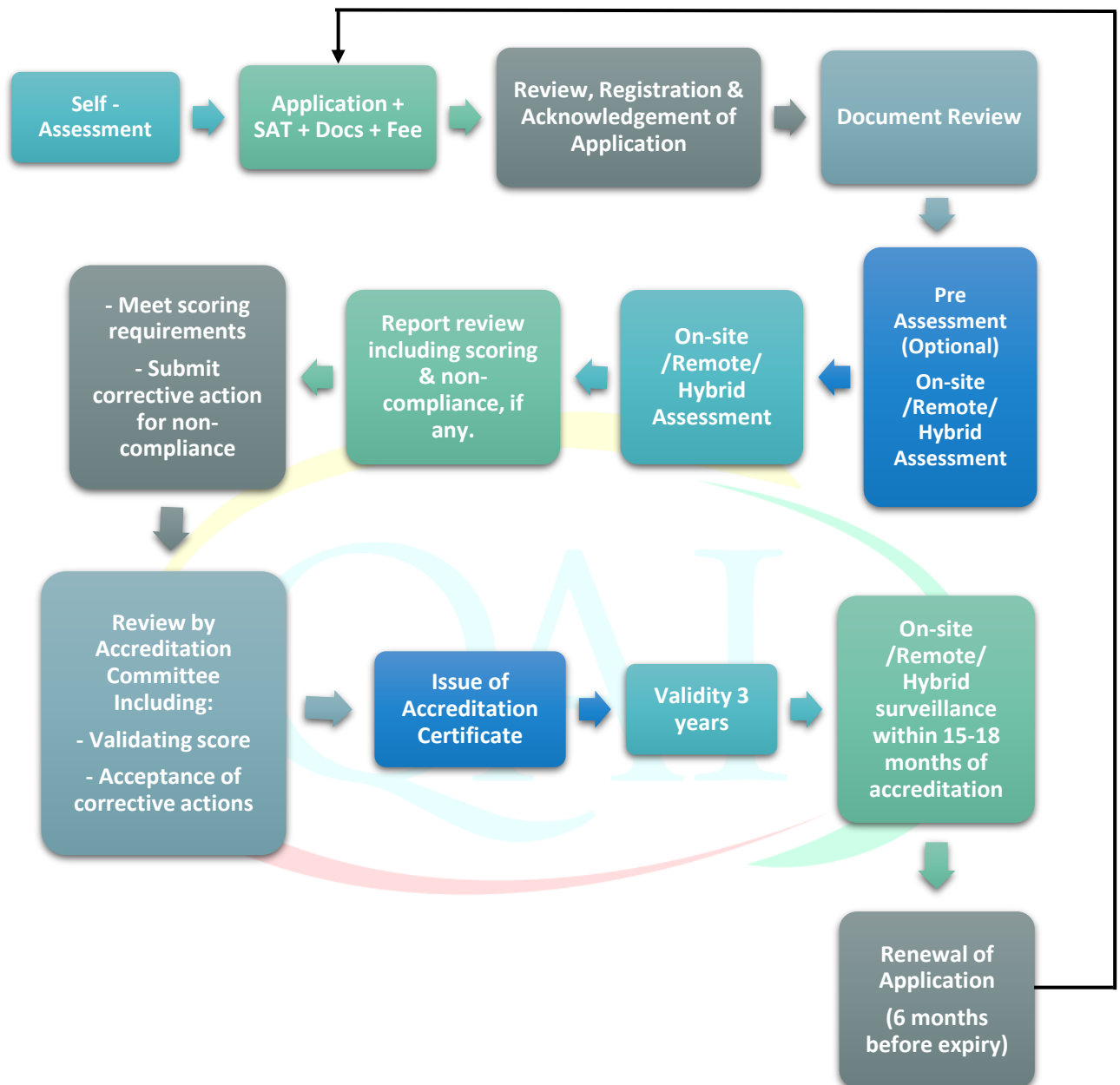
### 6.4 Preparing for Accreditation

Management of the Facility shall first decide about getting accreditation from QAI. It is important for the HCT facility 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 HCT.

**HCT facility must procure a copy of the QAI accreditation standards. A self-assessment tool can also be requested from the Secretariat.** The HCT facility shall ensure that all the requirements of the standard are implemented. The facility may get its personnel trained in understanding and implementation of accreditation standards by nominating staff to attend DIVE (Documentation-Implementation-Verification-Elevation) programme. Such DIVE training programmes are conducted by QAI from time to time.

## 7. Accreditation Process

Accreditation process is shown below:



### 7.1 Self-Assessment

HCT facility 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 facility 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.

### 7.2 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)

### 7.3 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 facility. Secretariat may ask for additional information/ clarification(s) at this stage, if found necessary.

### 7.4 Document Review

Secretariat appoints an assessment team and shares 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 necessary corrective actions.

### 7.5 Pre-Assessment (Optional):

QAI has introduced pre-assessment as optional. Those facilities shall inform QAI while applying in case they wish to undergo pre-assessment. Facility is not required to undergo the same and can directly move to the final assessment. Appointed assessment team shall conduct the pre-assessment (remote/ hybrid/ on-site). Lead assessor shall submit the pre-assessment report to QAI. The facility shall take corrective actions on the non-compliances raised by the assessment team. The facility shall be required to pay the required pre-assessment fee

## 7.6 Final 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.

## 7.7 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 facility meets the scoring for accreditation, however there are non-compliances, the facility is asked to submit corrective actions against those non-compliances. The facility 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 facility as per laid down appeal process.

## 7.8 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 facility 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.



HEMATOPOIETIC CELL TRANSPLANTATION AND CELLULAR THERAPY

## 7.9 Maintaining Accreditation

### Compliance to applicable standards and other requirements

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

### Terms and Conditions

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

### Adverse decision against the Healthcare Facility

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

## 7.10 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.

## 7.11 Reassessment

The accredited facility is subjected to re-assessment every three years for renewal of accreditation. The must 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.

**Applicant Facility is requested to submit the application to [info@qai.org.in](mailto:info@qai.org.in)**

## 8. Assessment Criteria and Fee Structure

A uniform assessment criteria and fee structure is developed. The fee structure is kept simple and economical to facilitate maximum number of participations, less invoices and bank transactions. The information about the fee can be requested by sending email to [info@qai.org.in](mailto:info@qai.org.in).

**9. QAI-CAHSC Publications**

All relevant publications are available on our website [www.qai.org.in](http://www.qai.org.in).



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