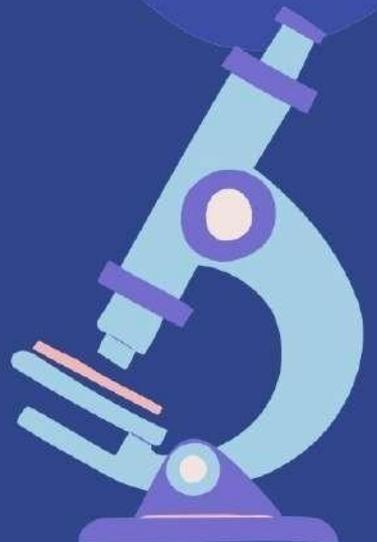
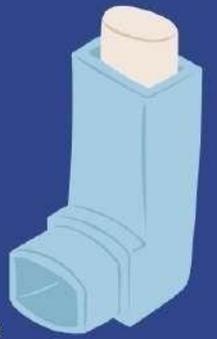


# KERALA STATE COUNCIL FOR CLINICAL ESTABLISHMENTS

**ASSESSOR'S GUIDELINES**



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### 1. INTRODUCTION

**The Kerala Clinical Establishments (Registration and Regulation) Act 2018** provides for registration and regulation of clinical establishments from all recognized systems of Medicine i.e. Modern Medicine including Dental, Laboratories, Diagnostic Center, Ayurveda, Yoga and Naturopathy, Homoeopathy, Siddha and Unani in the public and private sectors. This includes all establishments owned, controlled or managed by the Government, a Department of the Government, a trust (public or private), individual proprietorship, a partnership firm, corporation registered under a Central, Provincial or State Act (whether or not owned by the Government), a local authority. The objective of the Act is the improvement of public health by prescribing basic minimum standards for different categories of clinical establishments to ensure the provision of proper quality healthcare by the clinical establishments. The Act will also help to collect the required data and statistics from clinical establishments for better policy formulations, planning, implementation, response and evaluation. The Council has selected a panel of assessors for the inspection and assessment of standards of a clinical establishment. The panel selected has to examine whether a clinical establishment which has applied for permanent registration or for its renewal has the prescribed standards and whether it is able to maintain the said standards.

The assessment is carried out systematically for comprehensive review of clinical establishment services, functions and clinical establishment's quality management system. The objective evidence so collected forms the basis:

- ❖ For arriving at a judgment for recommendation of the team, to the District Authority
- ❖ For formulating the advice to assist the clinical establishment in its development.

This guide has been prepared based on the Kerala Clinical Establishments (Registration and Regulation) Act and Rules 2018, the Kerala Clinical Establishments (Registration and Regulation) Amendment Act 2022 and the Minimum Standards Rules published as SRO No. 503/2023 for Modern Medicine, Dental, Laboratory and Diagnostics centers, SRO No. 213/2024 for Ayurveda, SRO No. 215/2024 for Homoeopathy, SRO No.216/2024 for Siddha, SRO No. 214/2024 for Unani, SRO No. 217/2024 for Yoga and Naturopathy.

This document accordingly aims to:

- a. Provide the guidance to the Assessors during the assessment of clinical establishments.
- b. Ensure uniformity of assessment and reporting, and
- c. Eliminate ambiguities or doubts about the interpretation of requirements (s).

### 2. ROLE OF ASSESSMENT TEAM

The role of the Assessment team is to visit clinical establishments directly and conduct inspection and assess standards. The assessment report shall be submitted with specific recommendations of the team to the Authority within such time and in such format as the Council decides, after examining the evidence regarding the standards of clinical establishments and the information provided by the establishment.

The objective of the onsite assessment is to obtain evidence on compliance with respect to KCEA minimum standards.

Since clinical establishment permanent registration requires compliance with KCEA Minimum Standards the assessment team should consider conformances against these standards in the assessment. Thus, the members of the assessment team would be required to exercise their scientific judgmental skill and form their opinion regarding conformance with respect to minimum standards only. The assessment team consists primarily of a Team leader and Assessors. However, in some cases a technical expert may join the team to support on specific area. The Team shall manage the information regarding patients as confidential.

The assessment team deputed by the Authority may inspect clinical establishment at any reasonable time, in the manner specified below, namely: - (As per KCE Rules 2018)

- (i) to inspect the clinical establishment or part of it or its premises;
- (ii) to inspect any instruments, equipment, products, or things used or found in the clinical establishment and if necessary take samples and conduct test;
- (iii) to observe and examine the activities and other treatment practices carrying out in the clinical establishment without disturbing patients' privacy and disrupting treatment;
- (iv) to require the owner of the clinical establishment or operators of the establishment or any employee of the establishment to produce required documents or records;
- (v) to examine any records or documents, if thinks necessary and to collect copies or extracts thereof;
- (vi) to require the owner or any employee of the establishment to ensure the authenticity of such copies and make such copies available to the assessment team free of cost;
- (vii) to ask relevant questions and seek quick answers, or otherwise require and take statement of any person if necessary;
- (viii) to understand the actual situation of any matter enquire the owner of the establishment or any employee or patient of the establishment on relevant matters; and
- (ix) to ask relevant questions and elicit the best answers as per his knowledge and belief.

### **Role of Team Leader**

The number of assessors for assessing clinical establishment may vary from 1 to 6 members. If there is more than one member in the team, one may be assigned as team leader by the Authority. The team leader shall divide the work and distribute among the members of his team, fix the days of work, conduct assessment in such manner and submit report in such model and within such period, as ordered by the Authority. Before the start of Assessment the Team Leader should prepare an Assessment schedule which should include the departments/sections/areas/ activities to be assessed and assignment to various Assessors based on their expertise. The clinical establishment will be requested to assign guide/co-coordinator to accompany each assessor during the assessment. It is the responsibility of the team leader to prepare the final report on standard assessment and make recommendations. If any member of the team has any dissenting opinion on the final report so prepared, it shall be tendered to the team leader as a note and the team leader shall include the same along with his comments in the report. If the findings of the assessment team are not in conformity with the documents and information given in the application submitted for registration of clinical establishment and with the provisions of Act and the Rules made thereunder, the team leader shall submit that information together with the proposal for further action and recommendations to the Authority for necessary further actions. The Team Leader must sign all pages of the assessment report. The Team Leader is also required to monitor the performance of Assessor (s).

### **Role of Assessor**

The Assessors shall inspect and assess all physical facilities, equipment and furniture in use and all records related to the establishment, educational qualifications of the employees and its proof, information recorded in the application submitted for registration and the state of affairs for maintain the registration. Each Assessor should clearly understand the areas/ activities to be assessed by him. Assess and ensure that standards as fixed in accordance with the provisions of the Act and the rules are maintained. The report should be handed over to the Team Leader.

## **2. ON-SITE ASSESSMENT**

For the On Site Assessment, Authority appoints a Team Leader and assessors from the panel of empanelled Assessors. Scope and type of the clinical establishment is kept in mind while selecting the Team Leader. The number of assessors depends on the size of the clinical establishment. The Team should be present in the clinical establishment to be assessed at 9:30 am.

A communication is sent to all the team members with the following documents:

- Application form of the Clinical Establishment
- Documents submitted by Clinical Establishment.

Assessment Team shall meet and plan assessment programme. This shall include the distribution of work amongst the Assessors.

The assessment team/the Authority shall intimate the clinical establishment to be assessed, in writing or by electronic media or through any other mode, about the inspection, forty eight hours prior to the proposed date to conduct the assessment process. KSCCE assures that the team does not have any competitive position with the applicant organization. The Authority should ensure that assessors do not have any direct/ in-direct relationship with the organization or they/ or their organization. **The assessors should submit declaration of impartiality, confidentiality and integrity along with the submission of reports.**

### 3.1 Opening Meeting

- a) Team Leader and the team shall have an opening meeting with clinical establishment representatives where they get acquainted with the clinical establishment, departments / sections and their locations.
- b) The Team Leader shall explain the objective and scope of assessment and what is expected from the clinical establishment during the assessment.
- c) The Team Leader shall present the assessment schedule to clinical establishment representatives. The hospital/ clinical establishment will be requested to assign guide/coordinator to accompany each Assessor.

### 3.2 Assessment

The assessment activities include:

- **Orientation of assessors to the organization's services**  
The assessment procedure will start with an opening meeting. The assessors will explain the assessment process.
- **Document review**  
Document review includes review of statutory licenses and obligations as per checklist
- **Functional interview**
- **Infection control review**
- **Management of information / patient records review**
- **Staff qualification and education interview**
- **Facility tour**
- **Issue resolution**

The assessors shall inspect and assess all physical facilities, equipment and furniture in use and all records related to the establishment, educational qualifications of the employees and its proof, information recorded in the application submitted for registration and the state of affairs for maintaining the registration. All to be conducted as per checklist.

All persons connected with the running of the establishment shall be bound to supply clearly the full information regarding the functioning of the establishment to the assessment team. Any person or persons who obstructs the activities of the team or impedes the execution of duties of the team while conducting the process of assessment of clinical establishment shall be subjected to actions under section 28(1) of the Act and other laws in force.

Any person who is bound as per the Act or these rules or any orders or directions may be issued under it, does not give or refuses without reasonable cause, any information required by the assessment team or does not produce without delay any of the records, registers, reports, instruments, medical or medico-legal records, mandatory or confidential medical records etc. without delay or gives any information misleading the assessment team shall be subjected to actions as per section 28(2) of the Act.

While conducting assessment in the clinical establishment the team members shall take utmost care in the following matters, namely:-

- a. not to disturb or interrupt with the services providing to the patients; and
- b. Shall be cautious in keeping accuracy in assessment and maintaining discipline in behavior and work.

### **3.3 Compilation of Assessment Report**

- ❖ The Assessment Report should consist of checklist should be carefully filled in. The pages should be serially numbered.
- ❖ The Team Leader shall compile the observations from the assessors and summary on non-compliance from all the assessors.
- ❖ The Team Leader shall give the summary of the assessment in his final report
- ❖ Assessor has to provide deficiency both in the case of non-compliance as well as partial compliance.

### **3.4 Closing Meeting**

The Team Leader and other assessors shall have a meeting with the clinical establishment representatives

The closing meeting is to end with thanks giving for the co-operation and assistance provided by the hospital/ clinical establishment.

**3.5 Post Assessment**

- Team Leader shall send the report to District authority at the earliest (on the same day or next working day)

**3.6 Submission of Assessment Report**

Assessment report has to be submitted in Form 11

**Form 11**  
**[See rule 26(10)]**

**The Kerala Clinical Establishments (Registration and Regulation) Act, 2018**  
**Format for submitting assessment/Inspection Report**

Number of visits made with dates: \_\_\_\_\_

Names and other details of assessors/members of the inspection team: \_\_\_\_\_

Name of the clinical establishment visited: \_\_\_\_\_

Details for contact of clinical establishment visited \_\_\_\_\_

Procedure followed in inspection (kindly describe whom was met with, what records were examined, etc.) \_\_\_\_\_

Salient observations /findings: \_\_\_\_\_

Conclusions:

Specific recommendations:

1. To the Clinical Establishment
2. To the District Registering Authority

\* If there is no consensus among the members of the Inspection team, please specify.

Place:

Date

(Signature of assessors)

### **THE AUTHORITY**

- District Authority reviews the assessment report and seeks clarification and documentation from the Team Leader and clinical establishment, if required.
- District authority, on receipt of evidence of corrective action, if any, shall place the report for its consideration for registration.

### **4 FEEDBACK**

- Clinical establishments may submit feedback regarding the performance of the assessment team through email - [assessfeedback@myyahoo.com](mailto:assessfeedback@myyahoo.com)

## Decided Number of Assessors needed in a Team for Modern Medicine Clinical Establishments

SI No	Category	No. of Assessors needed				
		Doctors	Nurses	Administrators	Pharmacists	Laboratory Technician
<b>1</b>	<b>Primary Health Care Institutions</b>					
a	Clinic	1				1, if laboratory facility is available
b	Polyclinic	1	1			1, if laboratory facility is available
c	Day Care Centre	1	1			1, if laboratory facility is available
d	Hospital	1	1			1, if laboratory facility is available
<b>2</b>	<b>Secondary Health Care institutions</b>	1	1	1	1	1
<b>3</b>	<b>Tertiary Health Care institutions</b>	2	1	1	1	1

**Decided Number of Assessors needed in a Team for Laboratory Category & Diagnostic Services Category**

<b>Sl No.</b>	<b>Laboratory &amp; Diagnostic Services</b>	<b>No. of Assessors needed in a Team</b>
1	Level I	1
2	Level II	2
3	Level III	3

**Decided Number of Assessors needed in a Team for Dental Clinic/ Hospital**

<b>Sl No.</b>	<b>Dental Clinic/ Hospital</b>	<b>No. of Assessors needed in a Team</b>
1	1-3 Chairs	1
2	4-6 Chairs	2
3	7-12 Chairs	3
4	Dental Colleges/Hospital	4

## Number of Assessors needed in a Team for Ayurveda Clinical Establishments

Sl No.	Category	No. of Assessors needed in a Team	
<b>1. Primary HealthCare Institutions</b>			
		Doctor	Laboratory Technician (if laboratory facility is available)
a	Clinic	1	1
b	Polyclinic	2	1
c	Hospital (below 50 beds)	2	1
d	Therapy Centers	2	1
e	Specialty Centers	2	1
<b>2</b>	<b>Advanced Specialty Centers</b>	3	1
<b>3</b>	<b>Hospital (51-100 beds)</b>	3	1
<b>4</b>	<b>Hospital (above 100 beds)</b>	4	1

## Number of Assessors needed in a Team for Homoeopathy Clinical Establishments

Sl No.	Category	No. of Assessors needed in a Team	
<b>1. Primary HealthCare Institutions</b>			
		Doctor	Laboratory Technician (if laboratory facility is available)
a	Dispensary Type 1	1	1
b	Dispensary Type 2	1	1
c	Dispensary Type 3	1	1
d	Hospital (up to 25 beds)	2	1
<b>2</b>	<b>Hospital (26-100 beds)</b>	3	1
<b>3</b>	<b>Hospital (above 100 beds)</b>	4	1

### **Number of Assessors needed in a Team for Siddha Clinical Establishments**

SI No.	Category	No. of Assessors needed in aTeam	
<b>1. Primary HealthCare Institutions</b>			
		Doctor	Laboratory Technician (if laboratory facility is available)
a	Clinic/Dispensary	1	1
b	Specialty Clinic	2	1
c	Polyclinic	2	1
d	Therapy Centre	2	1
<b>2</b>	<b>Hospital</b>	<b>3</b>	<b>1</b>

### **Number of Assessors needed in a Team for Unani Clinical Establishments**

SI No.	Category	No. of Assessors needed in aTeam	
<b>1. Primary HealthCare Institutions</b>			
		Doctor	Laboratory Technician (if laboratory facility is available)
a	Clinic	1	1
b	Clinic with Regimen Therapy	2	1
c	Specialty Clinic	2	1
d	Hospital Type 1(A) (1-10 beds)	2	1
e	Hospital Type 1(B) (11-25 beds)	2	1
<b>2</b>	<b>Hospital Type 2 (25-50 beds)</b>	<b>3</b>	<b>1</b>
<b>3</b>	<b>Hospital Type 3 (Above 50 beds)</b>	<b>4</b>	<b>1</b>

**Number of Assessors needed in a Team for Yoga and Naturopathy Clinical Establishments**

SI No.	Category	No. of Assessors needed in aTeam	
<b>1. Primary HealthCare Institutions</b>			
		Doctor	Laboratory Technician (if laboratory facility is available)
a	Clinic	1	1
d	Hospital (1-10 beds)	2	1
e	Hospital (11-25 beds)	2	1
<b>2</b>	<b>Hospital Type 2 (26-50 beds)</b>	<b>3</b>	<b>1</b>
<b>3</b>	<b>Hospital Type 3 (Above 51 beds)</b>	<b>4</b>	<b>1</b>

# DECLARATION OF IMPARTIALITY, CONFIDENTIALITY & INTEGRITY

(to be filled in by each Assessor and enclosed with the Assessment report)

<b>Name</b>	
<b>Designation</b>	
<b>Organisation</b>	
<b>Address</b>	
<b>Capacity</b>	
<b>Clinical Establishment Assessed</b>	
<b>Date of visit(s)</b>	
<b>Type of visit</b>	<i>Assessment / Re-Assessment / Verification</i>

I \_\_\_\_\_, hereby

**declare that**

- i. I have not offered any consultancy, guidance, supervision or other services to the clinical establishment in any way.
- ii. I am not an ex-employee of the clinical establishment and am not related to any person of the management of the clinical establishment.
- iii. I will declare to the District Registering Authority that, my and/ or my immediate family's association with any of the clinical establishment that can affect the impartiality of the assessment process.
- iv. I got an opportunity to go through various documents of the above clinical establishment and other related information that might have been given by District Registering Authority. I undertake to maintain strict confidentiality of the information acquired in course of discharge of my responsibility and shall not disclose to any person other than that required by District Registering Authority.

Date:

Place:

Signature