



---

# **GUIDELINES FOR INSPECTION OF EDUCATIONAL INSTITUTES AND HEALTH CENTERS - 2021**

**KINGDOM OF BHUTAN**

---

**BHUTAN MEDICAL AND HEALTH COUNCIL  
ROYAL GOVERNMENT OF BHUTAN**

# **GUIDELINES FOR INSPECTION OF EDUCATIONAL INSTITUTES AND HEALTH CENTERS**



**KINGDOM OF BHUTAN**

Bhutan Medical and Health Council  
Royal Government of Bhutan

©2021 Bhutan Medical and Health Council  
Government Autonomous Body  
Tel: -97-2-331102  
[www.bmhc.gov.bt](http://www.bmhc.gov.bt)

## **Table of Contents**

<b>Background</b>	<b>5</b>
<b>Scope and Application</b>	<b>5</b>
<b>Definitions</b>	<b>6</b>
<b>General Principles</b>	<b>6</b>
<b>Categories of Inspection</b>	<b>7</b>
<b>Inspection Team</b>	<b>8</b>
<b>Code of Conduct and Etiquette of the Inspection Team</b>	<b>9</b>
<b>Frequency and Duration of Inspection</b>	<b>9</b>
<b>Process Flow</b>	<b>10</b>
<b>Procedure of Inspection</b>	<b>10</b>
<b>Search Warrant</b>	<b>12</b>
<b>Documentation and Record keeping</b>	<b>12</b>
<b>References</b>	<b>13</b>
<b>Annexures</b>	<b>13</b>
<b>Tables</b>	<b>13</b>



## **1. Background**

The Bhutan Medical & Health Council (Council) is an autonomous government body which is empowered by the Bhutan Medical and Health Council Act 2002 to regulate the medical and health professionals and related matters. With the objective of strengthening public health safety, the Council is mandated to regulate the quality of education, training and practice of medical and health professionals which entails periodic monitoring of the institutes and health facilities.

Inspections are very useful to improve the quality of systems and services. There can be a lot of interaction and sharing of information between the inspectors and the employees of the organization during and after the inspections. The reports of the inspectors can be useful tools to understand the gaps in the system for corrective actions. Under Section (2) of Chapter III and Section (h) of Chapter VI the Act, the Council is empowered to frame rules, regulations and procedures as may be necessary from time to time. In addition, the Council is also empowered to appoint inspectors and advisors for submission of reports to the Council.

Challenges have been faced by officials in the planning, conduct and reporting of inspections due to lack of defined procedures. These guidelines define the processes of how the inspection is to be carried out in the educational and training institutes and the health facilities. The guidelines will be used as a guide by all the officials involved in the inspection of the educational, training institutes premises as well as places of practice in the healthcare centers (both public and private).

The main objective of the guidelines is to promote clarity, transparency and uniformity in the process of inspection, reporting, record keeping and follow-up actions.

## **2. Scope and Application**

This guideline is applicable to:

- 2.1 Inspection of medical and health education and training institutes;  
and
- 2.2 Inspection of public and private health centers.

### 3. Definitions

- 3.1 **Act:** It refers to the Medical and Health Council Act 2002, Kingdom of Bhutan.
- 3.2 **Inspection:** It refers to the process of visiting the premises (education institutes and healthcare facilities) for systematic collection of information, critical examination and evaluation of written evidence and observations. Inspections involve a visit to premises where the medical and health professionals are educated, trained or practiced usually to gather evidence to verify compliance to various rules, regulations, Standard Operating Procedures (SOP), guidelines, code of conduct etc. Inspection can involve evaluation of documents, interrogation, observation and measurements.
- 3.3 **Institution:** It refers to a private or public facility where health and medical professionals are trained.
- 3.4 **Inspector:** It refers to a qualified person who is appointed by the Council and is capable of rendering advice or recommendations to the Council with regards to specific terms of reference, such as monitoring and evaluation of health centers and institutes to assess for compliance with regulatory requirements.
- 3.5 **Health Center:** It refers to a public or private health facility where preventive, diagnostic, curative, rehabilitative health services are provided by registered medical and health professionals.
- 3.6 **Special Inspection:** It refers to inspection to investigate a complaint from public or health professionals as a result of some incidents, which can be ad-hoc.

### 4. General Principles

- 4.1 Reach our own judgements based on evidence after listening carefully to the views of users and service providers;
- 4.2 Focus on raising standards, stimulating improvement and supporting the delivery of objectives and expected outcomes;
- 4.3 Conduct inspection in an impartial and professional manner to foster a high degree of accountability and confidence in our system;
- 4.4 Establish clear standards and criteria against which institutes/health centers can be inspected;
- 4.5 Evaluate objectively, test assumptions, check the evidences and build up a picture of provision before drawing conclusions; and

4.6 Ensure that staff in institutes/health centers are aware of our regulations and complaints handling procedures.

## **5. Categories of Inspection**

The following are the different categories of inspections covered in these guidelines:

### **5.1 Inspection for Technical Approval for Registration**

This inspection is initiated upon receipt of an application for the new establishment or expansion of existing institute for training and education of medical and health professionals. This inspection is conducted to review the fulfilment and compliance to requirements as per the relevant standards prescribed by the Council.

### **5.2 Inspection for continuous/routine monitoring and evaluation**

This inspection is conducted as a part of the regular monitoring to assess the compliance to the Rules and Regulations. Routine inspection may be either announced or unannounced as deemed necessary.

### **5.3 Special Inspection**

Special inspection may be conducted in response to complaints, or requested by the concerned institute or health center to investigate the cause of the incident and identify corrective and preventive measures. This may also include inspections initiated by the Council to address specific areas of concern. Special inspection is conducted unannounced and at a short notice.

### **5.4 Follow up Inspection**

This type of inspection is conducted to assess the implementation of corrective and preventive actions that were recommended during the previous inspections. Follow up inspection may be either announced or unannounced as deemed necessary.



## **6. Inspection Team**

### **6.1 Inspection Team Composition**

The inspection team may be composed of one or more officials from the Council and other relevant agencies. As and when necessary, representatives from the private sector/CSOs may be included in the team. The team members should possess adequate experience and relevant qualifications. The inspection team should have a sound grasp of their terms of reference and inspection processes. The team leader will be selected from amongst the members.

### **6.2 Roles and Functions**

#### **6.2.1 Council Secretariat**

- Plan for inspection;
- Obtain approval for the inspection;
- Communicate to the relevant stakeholders;
- Arrange logistics and resources for the inspection;
- Brief the team leader and members; and
- Follow up post inspection.

#### **6.2.2 Inspection Team Leader**

- Lead the team during the inspection;
- Lead the meetings and discussions during the visits;
- Assign responsibilities to the team members;
- Chair and moderate the meetings;
- Build consensus and decide on the contents of the inspection report;
- Compile and submit inspection report;
- Inform Council Secretariat on any exigencies during the inspection.

### **6.2.3 Inspection Team Members**

- Follow code of conduct and ethics;
- Collect evidence and observation;
- Analyze the findings and write inspection report;
- Maintain records of the inspection and findings;
- Participate in the discussion; and
- Follow security norms and report any concerns to the team leader.

## **7. Code of Conduct and Etiquette of the Inspection Team**

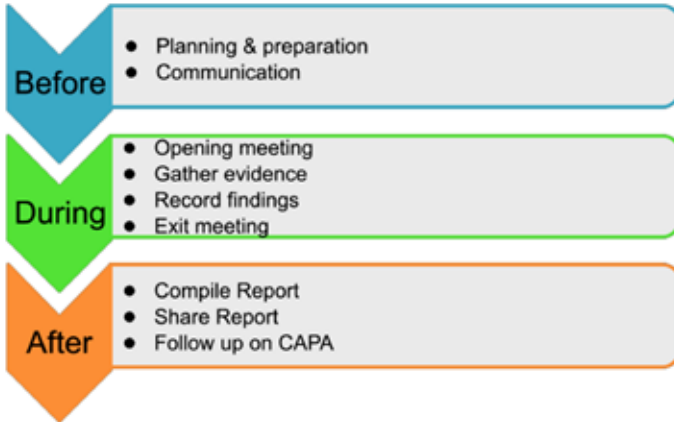
- Report to the inspection venue and meetings on time;
- Present in a professional attire and behave in good social manners;
- Collect evidence as per the procedures for objective analysis;
- Conduct review and assessments in an impartial manner;
- Communicate in a cordial and professional manner;
- Maintain confidentiality of the information collected and discussed during the inspection;
- Not solicit any bribes from the management and employees; and
- Respect the rules of inspection premises.

## **8. Frequency and Duration of Inspection**

Depending on the purpose, type and area of inspection; criticality of non-compliances and availability of resources, the frequency and length of inspection may vary from one inspection type to the other. Based on these parameters the Council shall decide the frequency and length of inspection.

The inspection period can be extended only after prior approval from the Council.

## 9. Process Flow



## 10. Procedure of Inspection

The following steps shall be followed before, during and after the inspection.

### 10.1 Planning and Preparation for the Inspection

Prior to the visit to the various premises for inspection, the Council shall ensure that all the necessary arrangements are made to ensure smooth implementation and conduct of the inspection. Inspection planning should consider all factors such as objective, resources, logistics, dates and area of inspection, tools, communication with the relevant stakeholders if required. Checklist for Inspection Planning (Annexure-1) should be used while planning the inspection.

### 10.2 Conducting Inspections

The inspection team should conduct opening and closing meetings before and after the inspection. The team leader should consider the following points during the opening meeting:

- Introduce the inspection team;
- Acknowledge for cooperation;
- Explain the scope, duration, methods and process of inspection;
- Solicit support from the management; and
- Discuss and clarify any issues.

### 10.3 During the Inspection

During the inspection, the team should gather evidences by:

- Reviewing the relevant areas (premises, equipment, documents etc.) as per checklist;
- Observing;
- Seeking clarification; and
- Taking notes and recording the findings.

While inspecting educational institutions, the team should use relevant checklist which are annexed in the standards of various educational programs. For other inspection, the team should use relevant checklist as annexed during the inspection:

- Checklist for Inspection of Private Healthcare Centers (Annexure-2)
- Checklist for Inspection of Public Healthcare Centers (Annexure-3)

*Note: For clearance/expansion of new or existing establishments, the checklist annexed in the standards of various educational programs will be followed. However, the checklist will vary with size of intake and new programs.*

## **10.4 Post Inspection Activities**

Upon completion of inspection, the team should conduct an exit meeting with the management and relevant personnel.

- Acknowledge the support;
- Share the preliminary inspection findings (include good practices and non-compliances);
- Allow to justify for the non-compliances and modify the findings if justified;
- Share and agree on the expected follow-up actions (CAPA; Table 3);
- Agree on a timeline for resolving non conformances; and
- Share a preliminary report and signed by both the parties.

After the exit meeting, the team should meet and consider the following:

- Compile and write the report;
- Submit the report to the Council;
- Follow up on missing information;
- Share the report with the institute/health center
- Follow up on Corrective Action and Preventive Action (Table 3)

## **11. Search Warrant**

If the inspection involves visit to any unauthorized premises located in private residences or property, the search warrant should be processed from the Court of Law.

## **12. Documentation and Record keeping**

All documents related to the inspection shall be documented for future reference for ten years. All the reports and documents shall be recorded as per the prescribed formats.

### **13. References**

- a) Quality Management System ISO 9001:2015
- b) Drug Regulatory Authority, Royal Government of Bhutan, Inspection Guidelines c) A guide to inspection in primary schools available online  
<https://assets.gov.ie/25257/0325129729314c5089d321c4cc197fb5.pdf>
- d) Executive Agency of the Scottish Government. (2011). Principles of Inspection And Review. Retrieved June 25, 2021, from  
<https://education.gov.scot/Documents/PrinciplesofInspectionandReview2010.pdf>.

### **14. Annexures**

- a) Annexure 1: Checklist for Inspection Planning
- b) Annexure 2: Checklist for Inspection of Private Healthcare Centers c) Annexure 3: Checklist for Inspection of Public Healthcare Centers d) Annexure 4: Summary of the inspection findings

### **15. Tables**

- a) Table 1: Compilation of human resources as per the HR standard b) Table 2: Human resources for the special services
- c) Table 3: Corrective Action and Preventive Action Reporting Form

## Annexure 1

### INSPECTION PLANNING FORM

Inspection Approval Number	
Type of premises	<input type="checkbox"/> Education and training institute <input type="checkbox"/> Government or private health center <input type="checkbox"/> Private health (diagnostic) center
Name of the premises	
Proposed dates for inspection	
Purpose of inspection	
Scope of inspection	
Types of inspection	<input type="checkbox"/> Approval Inspection <input type="checkbox"/> Special Inspection <input type="checkbox"/> Routine Inspection <input type="checkbox"/> Follow-up Inspection
Team Members	
Standards/checklist/ references for inspection	
Budget estimate	

Inspection plan submitted by:

.....  
 .....

(Name and Signature)

Approved by the Registrar:

.....

**Annexure 2**  
**CHECKLIST FOR INSPECTION OF PRIVATE**  
**DIAGNOSTIC CENTRES**

<b>A. GENERAL INFORMATION</b>	
Date of inspection	
Approval number	
Scope of inspection	

**Facility Details**

Name of the center	
Registration number	
Location & address	
Name of the proprietor	
Trade License No.	
Phone	E-mail
<input type="checkbox"/> Medical Clinic <input type="checkbox"/> Radiology <input type="checkbox"/> Dental clinic (stand-alone) <input type="checkbox"/> Laboratory <input type="checkbox"/> Pharmacy <input type="checkbox"/> Nutrition <input type="checkbox"/> Other facility, specify: .....  	



## A. GENERALASPECTS

Sl. No.	Area of Inspection	Observations	Remarks
1	Is there a legible signboard displayed at a promiscuous place?	<input type="checkbox"/> Yes <input type="checkbox"/> No	
2	Is the center adequately ventilated?	<input type="checkbox"/> Yes <input type="checkbox"/> No	
3	Is the center adequately lit?	<input type="checkbox"/> Yes <input type="checkbox"/> No	
4	Is there a proper drainage system?	<input type="checkbox"/> Yes <input type="checkbox"/> No	
5	Is there adequate water supply?	<input type="checkbox"/> Yes <input type="checkbox"/> No	
6	Are toilets clean and hygienic?	<input type="checkbox"/> Yes <input type="checkbox"/> No	
7	Is the space adequate for the operation of the establishment?	<input type="checkbox"/> Yes <input type="checkbox"/> No	

## B. GOVERNANCE AND MANAGEMENT

8	Is there a strategic plan with vision, mission, values and objectives?	<input type="checkbox"/> Yes <input type="checkbox"/> No	
9	Is there an organization chart?	<input type="checkbox"/> Yes <input type="checkbox"/> No	
10	Is there an approved list of services displayed?	<input type="checkbox"/> Yes <input type="checkbox"/> No	
11	Are the services provided as per the approved list?	<input type="checkbox"/> Yes <input type="checkbox"/> No	

## C. STAFF DETAILS

12	Is there a record of staff with qualifications and job descriptions?	<input type="checkbox"/> Yes <input type="checkbox"/> No	
13	Are all technical staff registered with the BMHC? <i>Check validity of BMHC Registration</i>	<input type="checkbox"/> Yes <input type="checkbox"/> No	
14	Are the staff wearing tags with name and BMHC Registration Number?	<input type="checkbox"/> Yes <input type="checkbox"/> No	

## D. COMPLAINT HANDLING

15	Is there a client feedback policy?	<input type="checkbox"/> Yes <input type="checkbox"/> No	
16	Are feedback and complaints documented and addressed?	<input type="checkbox"/> Yes <input type="checkbox"/> No	

<b>E. INFECTION PREVENTION AND CONTROL</b>			
17	Is there a dedicated cleaning schedule?	<input type="checkbox"/> Yes <input type="checkbox"/> No	
18	Does the center appear generally clean and odor free? (check for cobwebs and dust)	<input type="checkbox"/> Yes <input type="checkbox"/> No	
19	Is there a provision for handwashing with running water and soap?	<input type="checkbox"/> Yes <input type="checkbox"/> No	
20	Is there a written procedure for waste management?	<input type="checkbox"/> Yes <input type="checkbox"/> No	
21	Are wastes segregated in colour coded bins into infectious and noninfectious wastes?	<input type="checkbox"/> Yes <input type="checkbox"/> No	
22	Does the facility have a waste holding area?	<input type="checkbox"/> Yes <input type="checkbox"/> No	
23	Is there evidence of disinfectant use?	<input type="checkbox"/> Yes <input type="checkbox"/> No	
<b>F. LABORATORY</b>			
24	Are there SOPs for each test/ procedure performed? ( <i>Obtain the list of tests/procedures being performed and verify with the SOPs available</i> )	Yes <input type="checkbox"/> No <input type="checkbox"/>	
25	Are there SOPs or guidelines for laboratory quality management?	Yes <input type="checkbox"/> No <input type="checkbox"/>	
26	Is there a record of regular calibration/validation of equipment?	Yes <input type="checkbox"/> No <input type="checkbox"/>	
27	Is there a record of lab equipment management and maintenance?	Yes <input type="checkbox"/> No <input type="checkbox"/>	
28	Is there a patient record keeping and lab result tracking system?	Yes <input type="checkbox"/> No <input type="checkbox"/>	
29	Is there a system of recording, reporting and confirming panic values/positive tests results?	Yes <input type="checkbox"/> No <input type="checkbox"/>	
30	Is the quality control system in place?	Yes <input type="checkbox"/> No <input type="checkbox"/>	

31	Is the laboratory enrolled for the External Quality Assurance system?	Yes <input type="checkbox"/> No <input type="checkbox"/>	
32	Is there a documentation system for sample archiving, retrieval and disposal?	Yes <input type="checkbox"/> No <input type="checkbox"/>	
33	Are temperatures monitored and recorded?	Yes <input type="checkbox"/> No <input type="checkbox"/>	
34	Are adequate personal protective equipment available?	Yes <input type="checkbox"/> No <input type="checkbox"/>	
35	Are laboratory personnel in proper attire with lab coats?	Yes <input type="checkbox"/> No <input type="checkbox"/>	
<b>G. X-RAY, USG &amp; ECG</b>			
36	Are standard operating procedures available? <i>Obtain the list of tests/procedures performed and verify.</i>	Yes <input type="checkbox"/> No <input type="checkbox"/>	
37	Is precautionary warning notice displayed near the respective devices? <i>(for X-Ray services)</i>	Yes <input type="checkbox"/> No <input type="checkbox"/>	
38	Is there an adequate number of lead aprons for the radiographer and patients? <i>(for X-Ray services)</i>	Yes <input type="checkbox"/> No <input type="checkbox"/>	
39	Is there a system of monitoring radiation dose or radiation leakage? <i>(for X-Ray services)</i>	Yes <input type="checkbox"/> No <input type="checkbox"/>	
40	Are personal radiation dose monitoring badges worn daily and evaluated? <i>(for X-Ray services)</i>	Yes <input type="checkbox"/> No <input type="checkbox"/>	
41	Is there a system to assure quality of the images processed?	Yes <input type="checkbox"/> No <input type="checkbox"/>	
42	Is reporting, testing and calibrating done up-to-date and documented/ displayed?	Yes <input type="checkbox"/> No <input type="checkbox"/>	
43	Is the radioactive waste managed properly?	Yes <input type="checkbox"/> No <input type="checkbox"/>	

44	Is there a system for documentation and maintenance of equipment?	Yes <input type="checkbox"/> No <input type="checkbox"/>	
45	Are patient records maintained?	Yes <input type="checkbox"/> No <input type="checkbox"/>	
46	Is there a system of reporting and confirming panic values/positive tests results?	Yes <input type="checkbox"/> No <input type="checkbox"/>	

### Inspector details

Name .....

Designation .....

Signature .....

Date .....

### Annexure 3

## CHECKLIST FOR INSPECTION OF PUBLIC HEALTH CENTRES

<b>A. Health Centre Information</b>		
Name of Health Facility		
Level of Health Facility		
Dzongkhag		
Date of Visit		
<b>B. Human Resources</b>		
1	Are there adequate human resources as per the standards? <i>Compare the total number of each professional category against the standard. Use Table 1 to calculate the gaps.</i>	Yes <input type="checkbox"/> No <input type="checkbox"/>

	Standard	(Yes/No)	Remarks
1	<b>Infection Control and Waste Management</b>	Yes <input type="checkbox"/> No <input type="checkbox"/>	
	<b>1.1 Cleanliness</b>	Yes <input type="checkbox"/> No <input type="checkbox"/>	
	1.1.1 Is there a dedicated cleaning roster?	Yes <input type="checkbox"/> No <input type="checkbox"/>	
	1.1.2 Is there cleaning staff as per the HR standard of MOH?	Yes <input type="checkbox"/> No <input type="checkbox"/>	
	1.1.3 Is the floor area, walls, ceilings and rooms free of dust and unwanted items?	Yes <input type="checkbox"/> No <input type="checkbox"/>	
	1.1.4 Does the health facility appear generally clean and odor free across various departments?	Yes <input type="checkbox"/> No <input type="checkbox"/>	

	<b>1.2 Hand washing</b>		
	1.2.1 Is the sink available with clean running water?	Yes <input type="checkbox"/> No <input type="checkbox"/>	
	1.2.2 Is soap available at the hand washing area?	Yes <input type="checkbox"/> No <input type="checkbox"/>	
	1.2.3 Are alcohol-based hand rubs available at the point of care?	Yes <input type="checkbox"/> No <input type="checkbox"/>	
	1.2.4 Is a hand towel available?	Yes <input type="checkbox"/> No <input type="checkbox"/>	
	<b>1.3 Solid waste management</b>		
	1.3.1 Is there SOP for waste management?	Yes <input type="checkbox"/> No <input type="checkbox"/>	
	1.3.2 Are there color coded bins as per the standard?	Yes <input type="checkbox"/> No <input type="checkbox"/>	
	1.3.3 Is there proper segregation & disposal of pathological, radiological and pharmaceutical waste?	Yes <input type="checkbox"/> No <input type="checkbox"/>	
	1.3.4 Does the facility have a waste holding site?	Yes <input type="checkbox"/> No <input type="checkbox"/>	
	<b>1.4 Sterilization &amp; Disinfection</b>		
	1.4.1 Is there a central sterilization service unit/department?	Yes <input type="checkbox"/> No <input type="checkbox"/>	
	1.4.2 Is there SOP for sterilization?	Yes <input type="checkbox"/> No <input type="checkbox"/>	
	1.4.3 Is the equipment for sterilization functional?	Yes <input type="checkbox"/> No <input type="checkbox"/>	
	1.4.4 Are sterile supplies labeled and stored in designated areas?	Yes <input type="checkbox"/> No <input type="checkbox"/>	
	1.4.5 Is disinfection carried out regularly in the health center?	Yes <input type="checkbox"/> No <input type="checkbox"/>	
	1.4.6 Are disinfectants available?	Yes <input type="checkbox"/> No <input type="checkbox"/>	
	1.4.7 Are cleaning equipment available?	Yes <input type="checkbox"/> No <input type="checkbox"/>	

	1.4.8 Are cleaners aware of the standard concentration of the disinfectants?	Yes <input type="checkbox"/> No <input type="checkbox"/>	
<b>2</b>	<b>Patient Care</b>		
	2.1 Is there functional examination equipment? ( <i>Thermometer, tongue depressor, BP instrument, stethoscope, torch, weighing scale, privacy screen, examination bed</i> )	Yes <input type="checkbox"/> No <input type="checkbox"/>	
	2.2 Is there evidence of regular ward rounds being carried out?	Yes <input type="checkbox"/> No <input type="checkbox"/>	
	2.3 Is the patient record well documented (IPD, OPD, referrals)?	Yes <input type="checkbox"/> No <input type="checkbox"/>	
	2.4 Is the privacy of the patient being considered? <i>Observe the practices</i>	Yes <input type="checkbox"/> No <input type="checkbox"/>	
	2.5 Is the patient's confidentiality maintained? <i>Observe the practices/ interview</i>	Yes <input type="checkbox"/> No <input type="checkbox"/>	
	2.6 Is there a process for informed consent? ( <i>Check the documents / practice</i> )	Yes <input type="checkbox"/> No <input type="checkbox"/>	

<b>3</b>	<b>Quality Assurance</b>	<b>Yes/ No</b>	<b>Remarks</b>
	3.1 Does the facility have a trained and active quality improvement team?	Yes <input type="checkbox"/> No <input type="checkbox"/>	
	3.2 Are there records of meetings conducted for quality improvement?	Yes <input type="checkbox"/> No <input type="checkbox"/>	
	3.3 Is there evidence of recommendations of the QA meeting being implemented?	Yes <input type="checkbox"/> No <input type="checkbox"/>	
	3.4 Are meetings conducted to review mortality?	Yes <input type="checkbox"/> No <input type="checkbox"/>	
	3.5 Is there a record of regular monitoring and evaluation of infection control practices?	Yes <input type="checkbox"/> No <input type="checkbox"/>	

	3.6 Is there a written procedure to eliminate the medical errors?	Yes <input type="checkbox"/> No <input type="checkbox"/>	
--	-------------------------------------------------------------------	----------------------------------------------------------	--

<b>4</b>	<b>Equipment Management</b>		
	1.1 Is there a preventive maintenance plan for critical care equipment?	Yes <input type="checkbox"/> No <input type="checkbox"/>	
	1.2 Is calibration and validation of equipment carried out on a regular basis?	Yes <input type="checkbox"/> No <input type="checkbox"/>	
	1.3 Is there a list of all equipment in use?	Yes <input type="checkbox"/> No <input type="checkbox"/>	

<b>5</b>	<b>SOPs and Guidelines</b>		
	5.1 Are SOPs and guidelines available at all the work places?	Yes <input type="checkbox"/> No <input type="checkbox"/>	
	5.2 Are SOPs and guidelines implemented ?	Yes <input type="checkbox"/> No <input type="checkbox"/>	

<b>6</b>	<b>Good Prescribing and Dispensing Practices</b> <i>Examine at least 10 samples where applicable</i>		
	6.1 Are the prescriptions legible and complete?	Yes <input type="checkbox"/> No <input type="checkbox"/>	
	6.2 Are standard abbreviations used?	Yes <input type="checkbox"/> No <input type="checkbox"/>	
	6.3 Are the medicines prescribed in generic names?	Yes <input type="checkbox"/> No <input type="checkbox"/>	
	6.4 Are ICD codes used in the prescription?	Yes <input type="checkbox"/> No <input type="checkbox"/>	
	6.5 Are seal and BMHC registration numbers reflected in the prescription?	Yes <input type="checkbox"/> No <input type="checkbox"/>	
	6.6 Is dispensing carried out as per the SOP?	Yes <input type="checkbox"/> No <input type="checkbox"/>	



	6.7 Is there a system of prescription audit? Check documented evidence.	Yes <input type="checkbox"/> No <input type="checkbox"/>	
	6.8 Is there a system for medicine stock updates?	Yes <input type="checkbox"/> No <input type="checkbox"/>	
	6.9 Is the Hospital Therapeutic Committee meeting conducted periodically? ( <i>Check if conducted once in three months</i> )		

<b>7</b>	<b>Continuing Medical Education</b>		
	7.1 Is there a system of conducting in-house CME in the center?	Yes <input type="checkbox"/> No <input type="checkbox"/>	
	7.2 Are external CME opportunities given to relevant professionals as per the scope of practice?	Yes <input type="checkbox"/> No <input type="checkbox"/>	
	7.3 Are professionals placed in their workplace unit as per the scope of practice? Check for 10 people.	Yes <input type="checkbox"/> No <input type="checkbox"/>	
	<b>Human Resources for Special Services</b>	Yes <input type="checkbox"/> No <input type="checkbox"/>	
	Are human resources trained in special service areas? ( <i>special service areas include IUD, Cytology, Colposcopy, AICU, NICU, PICU, Dialysis, Perioperative care, Endoscopy, ECHO, Mammography, CATHLAB, MRI, Radiotherapy, CT scan, Kam-khab, Lay-nga.</i> ) <i>Use Table No.2 to record the findings</i>	Yes <input type="checkbox"/> No <input type="checkbox"/>	

<b>8</b>	<b>Occupational Safety &amp; Wellbeing</b>		
	8.1 Are appropriate PPE available in procedure rooms?	Yes <input type="checkbox"/> No <input type="checkbox"/>	
	8.2 Are PPE used by the health professional?	Yes <input type="checkbox"/> No <input type="checkbox"/>	
	8.3 Are TLD badges and lead aprons available in the radiology department?	Yes <input type="checkbox"/> No <input type="checkbox"/>	

	8.4 Is there reporting and recording of the incidents? (Example needle stick injuries, blood spills, etc)	Yes <input type="checkbox"/> No <input type="checkbox"/>	
	8.5 Is there a staff grievance redressal system?	Yes <input type="checkbox"/> No <input type="checkbox"/>	

9	<b>Emergency services</b>		
	9.1 Is there triage service?	Yes <input type="checkbox"/> No <input type="checkbox"/>	
	9.2 Is an emergency tray available at a designated site?	Yes <input type="checkbox"/> No <input type="checkbox"/>	
	9.3 Are there emergency drugs in the emergency tray as per the list? (Example adrenaline)	Yes <input type="checkbox"/> No <input type="checkbox"/>	
	9.4 Is there emergency equipment? (O2 cylinder, suction machine, ambubag etc.)? Refer ambulance guideline.	Yes <input type="checkbox"/> No <input type="checkbox"/>	
	9.5 Is the ambulance functional?	Yes <input type="checkbox"/> No <input type="checkbox"/>	
	9.6 Is there a budget for the ambulance fuel?	Yes <input type="checkbox"/> No <input type="checkbox"/>	

10	<b>C. Scope of Practice</b>		
	10.1. Are health professionals practicing as per their scope of practice? <i>List health professionals not adhering to the scope of practice and reasons if there is any.</i>	Yes <input type="checkbox"/> No <input type="checkbox"/>	

Name of Insector .....

Designation .....

Signature and Date .....

## Annexure 4

### Summary of the inspection findings

<b>A. Facility details</b>	
Name of facility/institution	
Phone number:	
Date of inspection:	

<b>B. Inspection team</b>				
Name	Designation	Agency	Email	Signature

<b>C. Findings and recommendations</b>
<p>Percent score of the facility/institution: .....</p> <p>Risk category of the facility: .....</p> <p>Notes on findings:</p>

**Recommendations:**

Recommended action (incentive or warning/sanction) (Refer the risk rating Table below for guidance):

.....

.....

Notes on recommendations:





**Table 3**

**Corrective Action and Preventive Action (CAPA) Reporting Form**

**Instruction:** *This form should be completed by management and sent to the BMHC*

Name of the Facility: .....

Date of Inspection: .....

Address of the Facility: .....

<b>Sl. No.</b>	<b>Observations</b>	<b>Possible Root Cause</b>	<b>Corrective Action and Preventive Action</b>	<b>Implementation timeline</b>

**Submitted by:**

Name: .....

Dated signature: .....

**Table 4****Risk rating matrix to guide decisions on risk categorization of facilities and the recommended regulatory actions**

<b>Score</b>	<b>Risk Category</b>	<b>Compliance Category</b>	<b>Recommended Regulatory Action</b>
0-10% *(and/or no valid license for private facilities)	Very High Risk	Non-Compliant	Close the facility. Recommend serious action where registration and licensing is absent/invalid.
11-30%	High Risk	Minimally compliant	Serve 3 months' notice for correction and conduct re-inspection. Facility can ask for re-inspection for purposes of re-categorization after corrections.
31-50%	Imminent High Risk	Partially Compliant	Serve 6 months' notice and conduct re-inspection Facility will be re-classified as High Risk if non-compliant. Facility can ask for re-inspection for purposes of re-categorization after corrections.
51-70%	Medium Risk	Substantially Compliant.	Serve 12 months' notice and conduct re-inspection.  Facility will be re-classified as Imminent High Risk if non-compliant. Facility can ask for re-inspection for purposes of re-categorization after corrections if improvement occurs before 12 months.
>70%	Low Risk	Fully Compliant	No re-inspection for one-two years.



**Table 5**  
**Compliance Rating Matrix**

<b>Rate</b>	<b>Description</b>	<b>Remarks</b>
Good	Quality of the provisions is good. There are significant strengths and very less weaknesses.	The quality as per the set standards. No major improvement is needed.
Satisfactory	Quality of provisions is adequate. The strengths outweigh the shortcomings. While the shortcomings do not have a significant negative impact they constrain the quality of the learning/ service experiences and should be addressed in order to achieve a better standard.	Satisfactory; adequate; appropriate provision although some possibilities for improvement exist; acceptable level of quality; improvement needed in some areas.
Fair	Although there are some strengths in the areas evaluated, deficiencies/ shortcomings that outweigh those strengths also exist. The facility will have to address certain deficiencies without delay in order to ensure that provision is satisfactory or better.	Fair; evident weaknesses that are impacting on learning/services. Less than satisfactory; experiencing difficulty; must improve in specified areas; action required to improve
Weak	There are serious deficiencies in the areas evaluated. Immediate and coordinated whole-facility action is required to address the areas of concern. In some cases, the intervention of other agencies may be required to support improvements.	Weak; unsatisfactory; insufficient; ineffective; poor; requiring significant change, development or improvement; experiencing significant difficulties