



الهيئة الوطنية لتنظيم المهن والخدمات الصحية NATIONAL HEALTH REGULATORY AUTHORITY

Inspection Policy 2017

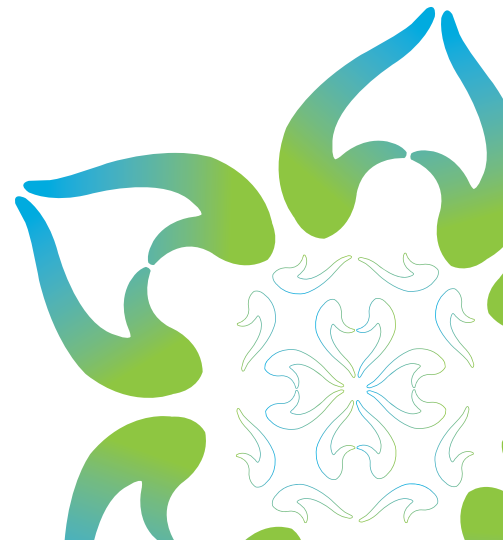


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Introduction

Inspection policy is developed to respond to the updates in **NHRA policies and procedures**. According to Law no. (21) of 2015 regarding private health care facilities, article (19) NHRA's responsibility for evaluating health services provided in all facilities in order to ensure quality and high performance of those services, and ensure compliance with regulations and standards related to patient safety, infection control and other technical standards. While article 20 specifies NHRA responsibilities for inspection to ensure compliance of private health facilities with the law and regulations issued to implement it. This clearly distinguishes the process of accreditation from licensing process.

NHRA has now separated the 2 processes, where surveyors (from NHRA staff or expert professionals contracting with NHRA) will be conducting accreditation every three years, while NHRA inspectors will be responsible for the annual licensing.

While accreditation will be focusing on quality performance standards, Inspection will be focusing on license requirements and ensuring that the facility is compliant with its scope of services.

This policy will provide health care facilities with information on the inspection process and what is expected from them in preparing for the inspection visit, during the inspection, and after the inspection conducted and report submitted.

It also assures that the health care facility's compliance with the license requirements is reviewed in a thorough, efficient, and consistent manner so that the inspectors have sufficient information and evidence to ascertain compliance with the law and the regulations and implement any noncompliance action as required.

1. Definitions

1. Inspection is defined as an official visit conducted by NHRA inspectors to health care facilities to ensure they are in compliance with the required healthcare licensing requirements.
2. Inspectors: are NHRA staff that has been assigned to conduct inspection by a decision issued from the chairman of the supreme council of Health.
3. Jurisdiction order: is the order granted to an inspector by the Minister of Justice to take actions related to violation of the laws.
4. Annual inspection: is the annual announced inspection carried out by NHRA for the purpose of renewal of license of health care facilities.
5. Unannounced inspection: is the inspection carried out in response to a complaint/violation.

2. Annual Inspection

2.1 Objective of the annual inspection

The objectives of the routine inspection are to ensure that all health care facilities in the Kingdom of Bahrain are inspected on a regular basis and are complying with the healthcare licensing requirements.

The chairperson of health care facility (HCF) section will prepare an annual inspection plan for all health care facilities. This plan will take in consideration the license expiry date of each facility in order to ensure that all facilities are inspected before license renewal.

The HCF chairperson should identify an inspection team to each facility and determine the size and composition of the inspection team depending on the size and scope of services in each facility. A lead inspector will be assigned in each team. The lead inspector's duty is to plan the inspection activity and schedule visits in accordance with the license expiry date. Each inspection visit will be carried out within 3 months of the license renewal date, in accordance with legislation. The relicense inspection visit is an announced inspection.

The chairperson is responsible to review all inspection reports and take a decision to renew the facility license accordingly.

2.2 Inspection Team

Each licensing / relicensing inspection is tailored to the type, size and range of services provided by the health care facility. The NHRA inspection team conducts the on-site inspection in order to determine the compliance with legislation

and the licensing requirements. The inspection team size and composition is based on a careful review of the following factors:

- The size of the health care facility to be inspected;
- The complexity and scope of the services provided; and
- Whether the facility has specialized services/ units or off-site clinics or locations.

Based on the above information, the HCF chairperson decides the length of the on-site inspection, the number and the disciplines of the inspectors.

The lead inspector will arrange in coordination with the facility the inspection dates and ensure that the health care facility knows the purpose of the inspection and the inspectors who will be attending for the inspection.

The lead inspector is responsible for assuring that all inspection preparation and activities are completed within the specified time frames and in a manner, consistent with the inspection policy and procedures.

2.3 Inspection process:

Pre-inspection -Before commencing the inspection, the facility CEO will be contacted to arrange for the inspection date and timing. The facility leadership/management team should be available on the day of inspection and a designated meeting room should be specified in order for the inspection team meet with the facility team.

- ❖ **Failure of the facility to commit itself to the inspection preparation will abort the inspection, which will result to delay in granting the relicense and the facility will be penalized for license expiry.**

Opening Conference – The objectives of the opening conference is to explain the scope of the inspection and what is expected from the health care facility during the inspection, orientation for the inspectors about the facility structure and services, obtaining the information needed to conduct the inspection and officially start the inspection process. The

opening conference is conducted by the entire inspection team and **should be attended by the health care facility leadership/management group.**

Information/Evidence Gathering - The objective of this task is to determine the facilities compliance with the NHRA licensing requirements and legislation through document review, observations, and interviews. This task consists of an organized, systematic, and consistent gathering of information necessary to make decisions concerning the facilities compliance during the inspection. The inspectors will use the inspection audit checklist specifying each service.

- ❖ **The Facility CEO and all staff should do their best to assist the inspectors to carry out their duties and should provide them with all the required information or document and records to avoid implementing the penalties stated in article (25)/6 of law no 21 for the year**

Closing Conference - The closing conference will be scheduled at the end of the inspection visit. It is attended by the facility leaders in addition to other staff members at the discretion of the Facility. The objective of the closing conference/meeting is to provide the facility with an initial overview of the outcome of the inspection in addition to key findings presented as recommendations for improvement. During the closing conference, members of the leadership group are encouraged to take this opportunity to comment and provide feedback on the findings for which there are issues of interpretation.

The lead inspector will present key recommendation for improvement. Other information will be provided when the inspection report is finalized. Key recommendations for improvement. Will focus on the following:

- High priority - those which the inspectors consider necessary to action as a matter of urgency and which will normally prevent the immediate license renewal. The Facility in this case need to make immediate improvement within 2 weeks' time.

edium priority - those which the inspectors have concerns about but which can be actioned in a longer time-frame. In this case a conditional renewal of the license could be granted.

Low priority – those which the inspectors consider would benefit the facility and would enhance the quality of the provision and foster best practice. These action points will not, on their own, normally affect the license renewal.

Further information should be provided when the inspection report.

The inspectors will often need to follow up on high priority non-compliant areas found during the inspection. Most of these will be addressed using remedial action, using the Inspection report and improvement action plan to work collaboratively with the facility.

Granting the license/re-license

1 Upon receiving the final inspection report NHRA HCF section will decide on one of the following:

- **Full renewal:** when the facility is compliant with all licensing requirements, and the remaining requirements are of minor priority that will not hinder granting the license.
- **Conditional license:** when the facility is not fully compliant with some of the requirements of medium priority and requires a time frame to implement changes.
- **Differed/denied renewal:** when the facility is totally non-compliant with license requirement or when there is major and critical violation threatening patient safety.

3.2 If the decision was taken to grant conditional license renewal, the facility CEO will be interviewed by the HCF chairperson and the report is discussed with him/her. The following procedures will be followed:

If the noncompliance is in high priority areas:

- The facility will be given a 2 weeks' notice letter indicating the immediate action to be taken.
- If the facility did not take the necessary action the license will not be renewed, and the necessary legal penalty should be taken as stated in law number 21 of the year 2015. (See page 13).

If the noncompliance was of medium to low priority:

The Facility CEO should submit within 2 weeks from receiving the inspection report an improvement plan showing the procedures and time frame to meet license requirements.

- The Facility CEO must sign a Pledge letter to ensure commitment to carry out the improvement required.
- A time frame will be granted to carry out the improvement based on the size and type of the required improvements.
- NHRA may decide to close or stop the violated services in the facility until improvement is taken place within the agreed time frame.

3.3 In both conditions, another follow up inspection visit should be scheduled with the facility to follow up compliance.

3.4 If the decision to defer license renewal was taken, the facility violations will be raised to NHRA CEO to take the necessary legal penalty as stated in law number 21 of the year 2015. (See page 13).

4. Unannounced inspection visit:

1. NHRA has the right at any time to conduct an unannounced inspection visit in response to a complaint or reported violation by any means.
2. The lead inspector in the team, who holds a jurisdiction order, will be assigned to lead the inspection and write a jurisdiction report stating the violation.
3. The assigned team will request to meet the CEO or administrator or doctor or the nurse in charge, and introduce himself and his team and the purpose of the visit.
4. Inspectors will at any time, during the inspection visit, will their best to carry out the inspection with minimal disturbance to the services and respect patient's privacy.
5. If the inspection requires interviewing a staff member this will be done away from the patients or visitors. In case of interviewing a physician, this will be done after he/she finishes the consultation and not during it.
6. Physician inspector with jurisdiction order has the right to enter a room with a patient inside, when it is mandatory to witness the violation in action, such as in case of conducting illegal operations or procedures.
7. Inspecting medical records will be carried out by physician inspector when needed.
8. NHRA inspectors have the full right granted to them by the law to demand any information or document even if is confidential.
9. In case the facility staff refuses to cooperate, or prevent inspection, the inspector will carry out the inspection irrespectively, and if necessary will call the police to help resume his/her duty. The facility staff should be clearly informed of the article in the law and the penalty that will be addressed to them as a result of their act. (*Article (25) of Law No. (21) for the year 2015*). In this case the lead inspector will write a jurisdiction report stating the violation of preventing NHRA staff from carrying their duty and sign the report from the responsible facility personal. The report will be raised to NHRA CEO to refer the facility to public prosecutor.

5. Enforcement and Escalation

Law no (21) for the year 2015 regarding private health care facilities, has regulated the action to be taken when dealing with facility violations as follows:

- **Article (10)** NHRA should cancel the license in the following conditions:
 1. Presenting false documents
 2. Lack of one of the conditions of licensing.
 3. Lack of one of the condition in relation to structure requirements.
 4. A court order was issued in relation to criminal act or a court order to shut down the facility.
 5. In case of granting a new licenses to build the facility and the owner failed to start the building during 6 months.
 6. In case were the facility was not operating for more than 6 months.

In this case NHRA will conduct an investigation with the owner or the CEO and the facility management will be informed officially of the decision made and the cancellation will be effective after 2 weeks from the notifications.

- **Article (21)** The NHRA can carry out an investigation on its own or upon the minister of health request or based on accountability committee or in response to a complaint. In this case NHRA has the right to request all the necessary documents and assign inspectors with jurisdiction order to inspect the facility.
- **Article (22):** In case of a severe violation NHRA will refer the facility to the disciplinary committee according to decision no (15) for the year 2016.

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