



الهيئة الوطنية لتنظيم المهن والخدمات الصحية
NATIONAL HEALTH REGULATORY AUTHORITY

Report on Implementing Governance Procedures at the national Health Regulatory Authority

2021

❖ Introduction

The Authority believes that governance has an effective role in managing institutions and risks, and helps to direct institutional supervision, and to apply the principles of disclosure, transparency, accountability, resource management, enhance competitiveness, and raise efficiency and effectiveness. It also enhances confidence and the supervisory and oversight process and accountability and helps to improve performance and contributes to achieving the mission and goals of the authority.

Based on Resolution No. 13 of 2013 regarding the approval of the Governance Manual for Governmental Institutions and the Implementation Executive Program issued by the Honorable Council of Ministers, the Authority has begun implementing the principles of governance of government institutions by developing a strategy and performance indicators, updating its organizational structure and issuing decisions regulating its procedures, policies and guidelines for all operations in the authority, in addition to its commitment to the principles of transparency through publishing its annual reports, assessing risks and following up on performance.

The following report shows the mechanisms for implementing the principles of governance that the authority has implemented in 2020 based on the manual issued regarding the implementation program.

❖ The current situation

First: Responsibilities and terms of reference

A. Terms of reference:

The National Health Regulatory Authority is an independent body established by Law No. 38 of 2009. It undertakes the task of regulations of health services. Decree-Law No. 38 of 2009 stipulated the responsibilities as follows:

1. Propose policies for the development of health care and services systems in the Kingdom and get the approved by the Council of Ministers.
2. Issuing executive regulations and decisions related to organizing health professions and services, in a manner that does not contradict the laws in force.
3. Granting and renewing licenses for healthcare facilities and healthcare professionals.
4. Approval to conduct clinical trials.
5. Adopting conditions and standards for the quality of health services that health facilities must adhere to.
6. Determine the conditions and rules for using information in health facilities.
7. Establish rules for registering, pricing, and ensuring the quality of pharmaceutical products and drugs.
8. Monitoring health facilities to ensure their compliance with licensing conditions, ensuring the continued availability of health and technical conditions and standards, and safety requirements, and ensuring that medical devices and equipment used in these facilities meet the approved international standards and specifications.
9. Study patients' complaints and follow-up decisions taken on them.

10. Taking Disciplinary actions against professionals for medical errors and breaches of the provisions of the Law on Practice of the Profession or the principles, requirements, and ethics of the profession.

B. Organizational Chart:

1. Minister of Health:

The minister responsible for the Authority's activities before the Council of Ministers and the legislative authority.

2. The Supreme Council of Health - Authority's Board of Directors:

The supreme authority that handles the affairs of NHRA, approves plans and programs that govern its workflow, and supervises their implementation.

2.1 CEO:

The person in charge of managing the Authority's affairs, running its technical, administrative, and financial work, supervising its employees, and representing it before the judiciary system and in its links with others. The Chairman of the supreme council assumes direct supervision of the CEO.

2.1.1 Administrative, technical, and financial departments

The authority has an organizational structure approved by the Civil Service Bureau. The terms of reference and responsibilities of all departments and units and all employees of the authority have been defined, each according to his/her specific job in the organizational structure, which facilitates the distribution of work between them and clarifies the relationships between its occupants vertically and horizontally through which plans can be executed and managed. Risks, monitoring employee performance, improving enterprise performance, improving communication and the administrative process.

C. The internal policies of the Authority

The authority has set the internal policies for the term of reference of all departments and the mechanisms for carrying out the tasks in accordance with the rules and regulations governing each task, including:

1. Department of Healthcare profession regulations
2. Department of Health Facilities regulations
3. Complaints Unit
4. Clinical trials and Continuous Medical Education Unit
5. Department of Pharmaceutical Products regulations
6. Legal Affairs Unit
7. Accreditation unit
8. Department of medical devices Regulations

- 9. Insurance providers monitoring Unit
- 10. Department of Human and Financial Resources

D. Financial Policies and Procedures

The Authority's Financial Policies and Procedures have been developed and approved by the Prime Minister according to Decision No. (61) of 2016, in addition to the application of the unified financial guide issued by the Ministry of Finance and the relevant financial decisions issued by official government agencies, the most important of which is the subjection of all purchases made from the general budget of the authority to the approval of the Ministerial Committee for Financial and Economic Affairs and Financial Balance.

C. Departmental Policies and Procedures:

The policies and procedures to be followed for each task carried out by the departments have been established, which define the responsibilities for carrying out each task according to the laws and regulations. Internal policies are reviewed according to their validity date and updated on an ongoing basis by the concerned department.

H. Formation of administrative and technical committees:

The following technical committees have been formed in the authority, which are stipulated in the laws and regulations:

- Technical Committees to investigate medical error (doctors, dentists, allied professions, nursing, pharmacists)
- Disciplinary Committee for medical practitioners
- Accountability Committee for health facilities
- The Advisory Committee for the Classification of Categories of medical practitioners
- The Advisory Committee for Classification of Categories of Dentists
- Appeals Committee for professionals against whom disciplinary decisions have been issued
- Accreditation Committee
- Accreditation Appeals Committee
- Medicines Registration Committee

I. Issuing resolutions, regulations and guidelines

The Supreme Council of Health issued resolutions regulating a number of the authority's tasks as stipulated in the laws that regulate the work of the authority, including, but not limited to, a decision regarding due fees for facilities and professionals, licensure exams, and registration and pricing of medicines.

The authority has also issued many guidelines that clarify the policies and procedures required to submit requests to the authority, whether by business owners, professionals or importers.

Second: NHRA strategic and operational plans

1. The authority has updated its strategic plan including the vision, mission, and strategic objectives, and it has been linked to the National Health Plan and the Government Action Program and Vision 2030.
2. An operational plan has been developed to follow up on the planned initiatives.
3. Performance indicators have been set for all initiatives for measurement and follow-up sessions
4. The Authority has defined the values and principles which stipulates how the Authority performs its functions and achieves its objectives.
5. The Authority determines its annual budget based on the priorities of the initiatives stipulated in the operational plan.
6. Initiatives that require financial and human resources are implemented according to the availability of budget granted to the Authority and considering the government's fiscal balance program.

Third: Methods of communication

- The organizational structure of the authority defined the communication between the heads of departments and units and the distribution of tasks according to the administrative hierarchy in each department. The Office of the Executive Director also circulates all decisions issued to all employees of the authority for information. The authority has also developed joint electronic files between departments to exchange important information related to the implementation of joint tasks and their coordination between departments.
- The authority has updated its website, which contains all information, policies, statistics and procedures for all the authority's customers. All laws and decisions regulating the authority's work have been published in both Arabic and English.
- The authority's website includes a brief explanation of the tasks, policies and procedures followed by each department, as well as guides for submitting requests for each section, and means of communicating with the departments.
- Assigning an electronic platform for investors to provide all information and guidelines for submitting applications
- Opening an office for investors to answer all inquiries and follow up on their projects.
- Publishing electronic links to other governmental agencies related to investors that provide services and support to investors in the Kingdom of Bahrain.
- Posting an electronic evaluation on the site to obtain the opinions of the customers.
- Providing a box for complaints and suggestions for the customers at the reception, in addition to the authority's presence on the governmental complaint's platform "Tawasul".
- Assigning heads of divisions to open their offices for stakeholders or clients once a week to receive them and listen to their views on the services provided and the obstacles they face, and to exchange opinions about the opportunities and challenges to develop the performance and quality of the services provided.

Fourth: Risk Management

The authority conducted internal auditing and risk identification in 2016, and a plan was developed to address the mentioned risks based on auditing each of the authority's departments, most of which were concentrated in the absence of an electronic system. Accordingly, the authority's electronic system project has been approved by the end of 2020, and it is expected to start implementation in the first quarter of 2021. The authority will conduct an internal audit in 2021 if the required budget is available

Fifth: Disclosure and Transparency

1. The Authority publishes its annual reports, which shows the following:
 - The extent of achieving the objectives of the strategy
 - Human Resources
 - The Authority's budget
 - The results of the investigation of medical complaints
 - Disciplinary decisions implemented against healthcare professionals
 - Statistics of licensed health professionals and facilities
 - Statistics of registration and licensing of medical devices
 - Statistics of the violations detected in health facilities and pharmacies
 - Results of evaluation and accreditation of health institutions

2. The authority has designated a platform for open data to include lists of all the followings:
 - Licensed facilities and pharmacies
 - Licensed professionals
 - Licensed medications and their prices
 - Approved clinical trials
 - Approved continuous medical educations programs

3. The authority also publishes on its website all the policies, procedures, guidelines and regulatory decisions concerned with all the authority's tasks.

Fifth: measuring institutional performance

The authority has updated all its performance indicators for all procedures related to the tasks entrusted to it as part of the authority's strategy. The authority issues periodic reports to follow up the implementation of indicators and measures the performance index. The authority also issues the results of achieving performance indicators in its annual report, in addition to providing the Ministry of Finance with the budget execution performance report for the year in accordance with the General Budget Law.

Sixth: Internal Audit

The authority contracted with a private auditing company in 2016 and based on their report risks were monitored and identified and will continue to be audited periodically. Expected next audit by end of 2022>

Seventh: External Audit

The authority works to facilitate external auditing and cooperates with the National Audit Office and the Civil Service Bureau by providing all documents and data subject to auditing to express a professional opinion on these accounts, along with recommendations or notes, if any. The authority implements the applicable observations and recommendations that result from audits.

Eighth: Administrative committees

The following administrative committees were established at the authority:

- Internal Procurement Committee
- Employment Committee
- Job Performance Committee
- Incentives and Remuneration Committee
- Quality Committee
- Equal Opportunities Committee
- Administrative Appeal Committee
- Committee for internal and external training

Implemented 2020 Plans

1. Organizational Structure: The Authority has finalized its new organizational structure and is approved from the CSB

2. The strategic plan: The authority has updated its strategic plan for the years 2021-2025 and developed a semi-annual operational plan to monitor performance and implement initiatives.

3. Internal policies: The Authority has reviewed and updated the internal policies of all operations and procedures performed by the authority.

4. Digital transformation: @ new electronic systems have been launched by December 2021 “mehan” for professional licensing and “munshaat” for facility licensing.

Future 2022 Plans

- 1. Internal Audit:** The Authority will submit a request to the Ministry of Finance to contract with an external auditor to evaluate performance and identify risks on an annual basis.
- 2. Measuring institutional performance:** The Authority will work to obtain (2015: ISO 9001) in coordination with the Civil Service Bureau.
- 3. Digital transformation:** NHRA will continue to digitalize all its services, drug and medical devices registration electronic systems are part of our plan for the next 2 years>
- 4. Follow-up on governance procedures:** The Authority will issue an annual report related to monitoring the implementation of governance procedures and measuring their achievement.
- 5. Developing a business continuity plan:** The authority will develop business continuity plans, defining the main roles and responsibilities within them, analyzing the extent to which operations are affected by constraints and damages, risk management methods and strategies for restoring operations.