



الهيئة الوطنية لتنظيم المهن والخدمات الصحية
NATIONAL HEALTH REGULATORY AUTHORITY

**A GUIDE TO THE APPLICATION PROCEDURE AND RULES
FOR LICENSING HEALTH CARE FACILITIES
IN THE
KINGDOM OF BAHRAIN**

***THE PURPOSE OF THIS DOCUMENT IS TO SET OUT THE REGISTRATION AND LICENSING PROCESS FOR A
FACILITY: APPLYING FOR A LICENSE AND COMPLYING WITH THE RULES AND REQUIREMENTS TO RETAIN A
LICENSE ON THE FACILITY REGISTER***

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PLEASE ENSURE YOU READ THE MOST UP-TO-DATE GUIDE AVAILABLE ON OUR WEBSITE

Introduction

To fulfil NHRA goal (**Regulated and accountable healthcare facilities**), we developed policies and procedures to outline the licensing process and to ensure that all facilities are compliant with the standards stated in Law No. (21) of 2015 regarding private health care facilities and Resolution No.(15), of 2017, regarding the technical and engineering standards required for licensing health care facilities.

The NHRA facility Licensing and Regulation Guide has been developed to serve as a reference for applicants during the preparation, consultation and inspection processes for a facility to be licensed and operated in the Kingdom of Bahrain.

It is designed to help you learn about the NHRA application processes, the regulations for facilities and the operational standards required in maintaining a facility.

This overview will provide important information about the NHRA, legislation, eligibility for licensing, how to request for a licensing inspection, inspection preparation, on-site inspection and the NHRA licensing rules.

The Healthcare Facilities (HCF) Licensing Department in NHRA primary function, is to receive and register requests for licensing and operation of health care facilities, this also includes any structural changes, amendments of the activities of licensed health facilities, approval on partial or total closure of the facility.

The procedure for issuing licenses has become more streamlined mainly due to the introduction of the SIJILAT online system of the Ministry of Trade and Commerce. Applicants can upload the required documents which can now be reviewed by the healthcare facilities licensing department. Upon completion of this review a preliminary license is issued. Subsequent to this, all remaining documents should be submitted by the applicants and a site inspection will be scheduled usually in a 2 week timeframe from the preliminary approval date. A final license will be issued after completion and verification of the above process.

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THE REGISTER

This section contains information about:

1. Relevant legislation / why register?
2. The License of Health Care Facilities and Definitions
3. Eligibility

1. RELEVANT LEGISLATION / WHY REGISTER?

1.1 Legal obligations

The NHRA and its responsibilities to license health care facilities are legally bound by the provisions in Legislative decree No. 38 of 2009. In addition to this law, the regulation and licensing of health care facilities is supported by Legislative Decree No. 21 of 2015 for Private Health care facilities

The legislation dictates that all health care facilities **must** be licensed to operate and provide healthcare services in the Kingdom of Bahrain, and they must fulfil the criteria set out in guidance and the relevant standards stated in resolution No. (15) for 2017, issued by the supreme council of health regarding the technical and engineering standards required for licensing health care facilities.

This guide to the application procedure and rules for licensing facilities in the Kingdom of Bahrain outlines the application process for licensees with regard to both licensing and on-going regulation.

In addition to the requirement for health care facilities to be licensed, all health care professionals working within a licensed facility are obliged to be licensed appropriately at all times when they practise their profession in the Kingdom of Bahrain and to comply with all other requirements in the Law. (See the NHRA Health Professional Regulations Licensing Procedures Manual 2017.

Understanding the legislation

All new applicants and existing license holders should be aware of the legislation relating to the registration and licensure of their facility. The legal terminology in the legislation can be confusing for anyone who is not familiar with the laws or with legislation in general. In this Guide, the NHRA has tried to convey the legal requirement in plain language but it is important to note that in the case of a dispute or discrepancy, the provisions of the law take precedence over any interpretation made in this guide.

1.2 Why should a health care facility be licensed?

If a facility is to provide any inpatient, outpatient/day consultations, medical services and treatments including prescribing medications, diagnostic services, day surgery, rehabilitation treatments, dental services, outpatients' specialist services or general practice services in the Kingdom of Bahrain, it is required by law to be licensed by the NHRA. It is a criminal offence for a facility to provide any healthcare services, treatments or prescriptions within the Kingdom of Bahrain, or to advertise its services, if it does not have a license, or its license is expired. Each facility licensee is responsible for ensuring that their license is current and appropriate for the type of facility they have. Failure to do so could result in penalty and criminal proceedings against them.

1.3 Unlicensed Health Care Facilities

Providing health care services and practising as a healthcare professional while unlicensed is an offence under Bahraini law. The NHRA will take action against any facility owner/licensee that is found to be operating while unlicensed. The NHRA could, at its discretion, decide to suspend or refuse an application for license following a period of unlicensed activity due to expiry or failure to meet the license requirements. The Public prosecutor may be informed of any unlicensed facilities or professional who, to the NHRA's knowledge is providing health care services.

2 THE LICENSE OF HEALTH CARE FACILITIES CATEGORIZATION AND DEFINATIONS

Types and Categorizations of Health Care facilities as issued in Resolution No. (15) for 2017 regarding the technical and engineering standards required for licensing health care facilities as follows:

Clinic:

General Practice clinic: Is a health care facility that provides general health care, general medical consultation and treatment services.

Specialized medical clinic: Is a health care facility that provides specialized health care, specialized medical consultation and treatment in one of the medical specialty.

24 hour clinic: A health care facility providing health care for 24 hours, 7 days a week and on the public holidays. This type of license will be provided to consultant physician/General dentist. A doctor should be available in each working shift of the clinic.

Clinic attached to a health facility: Is an attached clinic to the facility (hospital or medical Center) operated by a full time or part time consultant to provide health care and medical consultation services in only one of the medical specialty.

Medical Center:

The medical center is any facility that contains at least two clinics in the same medical specialization or in different specialties and is permitted to conduct minor surgeries requiring local anesthesia and don't require admission.

General medical centre: A health care facility providing health care with at least two different medical specialties.

General dental centre: A health care facility designed to provide oral and dental health care services, and includes at least two dental clinics

Specialized medical centre (Medicine & Dentistry): A health care facility consisting of more than one medical clinic in one or more sub-specialty.

24 hour General medical centre: A health care facility that provide health care for 24 hours, 7 days a week and on the public holidays. Two doctors should be available in each working shift of the centre

Radiology centre: A health care facility that conducts any radiological tests, including tests that require the use of colored medical materials. As well as the use of ultrasound, magnetic resonance and radioisotopes, and other medical radiation tests.

Laboratory: Is the prepared and equipped facility performing laboratory tests on individuals, body fluids, tissues, secretions or use of experimental animals to diagnose or prevent the disease or to determine the

health status of the individual or group of individuals. In terms of its scope of work, the laboratories are divided into the following four types:

Primary Laboratory: It performs simple/ basic laboratory tests for patients

Hospital & Centres' laboratory: It provides services to those who attend the centers and hospitals where the lab is located.

General laboratory: Performs laboratory tests on samples or for individuals referred by doctors from private clinics or other clinics of companies, organizations or hospitals. Their field of work includes various laboratory specialties such as microbiology, biochemistry, physical properties, blood and its components, pathology and others.

Specialized laboratory: Performs specialized laboratory tests on samples or for individuals referred by doctors from private clinics or other clinics of companies, organizations or hospitals. Their field of work is confined to one specialization of laboratory examinations.

2.2.6.5- Blood Collection Unit: Is a unit that provides blood collection services and the transfer of samples to the main laboratories.

Centers and clinics of allied health professionals and other health premises:

Alternative/ Complementary medicine Center: is a health care facility that provides a group of diverse medical and health care systems, practices, and products that are not presently considered to be part of conventional medicine and do not fall within the system of health care practice Modern preventive medicine.

Physiotherapy center: A health care facility prepared and equipped to provide physiotherapy services for the treatment and rehabilitation of diseases and physical disabilities using preventive, and therapeutic means of natural origin.

Nursing Care Center: Is a health care facility providing nursing and rehabilitation services for patients at their home.

Speech and Audiology Center: A center that evaluates and treats patients with problems and disabilities in speech and hearing.

Nutrition Center: A health facility providing nutritional advice and guidance to individuals and the society for prevention and/or treatment of diseases.

Psychology counseling center: A health facility that provides psychological, behavioral and social counseling services by specialists in the field and including services marital counseling and behavioral therapy for children and others.

Optic Center: A facility where medical lenses and contact lenses are measured, prepared and sold.

Mother and Child Education Center: A center specialized in motherhood and childhood cognitive and family therapy and counseling.

Prosthetics and Orthotics centre: A facility providing **Prosthetics and Orthotics** to individuals with disabilities to aid them to resume their functions and overcome their disability.

Tobacco Quitting Services: A facility that provides services for individuals wishing to quit tobacco use, in the form of individual or group therapy including behavioral and medical therapy (nicotine replacement therapy).

Rehabilitation Center: A health care facility that provides rehabilitation services or nursing care only in which admissions do not exceed 24 hours.

Health Care Unit: Is a facility established in schools, agencies and companies providing nursing and first aid services only.

Hospital

Categorization according to scope of service:

General Hospital: Any health care facility providing health services in all of the basic medical specialties or more, including Internal medicine, general surgery, paediatrics, obstetrics and gynaecology, and it includes admission service.

Specialized hospital: Any health care facility providing health services in one of the basic medical specialties or in one or more of the sub-specialties.

Teaching/ University Hospital: Any health care facility providing health services in all of the basic medical specialties and has accredited educational programs from a local, regional or international university/ educational council, through which interns, resident, physicians and other health professions are trained.

Rehabilitation Hospital: Is a health care facility that provides rehabilitation, long-term care or nursing care only including admission services.

One Day Surgery Hospital: Is a health care facility that provides its health services in surgery or any surgical sub-specialty for conditions that does not need more than 24 hours recovery period.

Categorizes according to bed capacity

- Hospital type (A) : 100 bed and more
- Hospital type (B) : 50 -100 bed
- Hospital type (C) : 50 bed and less

All types and categories of hospitals whether general, specialized or university hospitals should include the following minimal required scope of services:

- Emergency Section
- Laboratory / blood collection unit
- Radiology Section
- Pharmacy
- Operation theatre
- Outpatient clinic
- Inpatient wards
- Intensive care unit
- Isolating rooms
- Management services including (medical record, Administration offices and reception)

3. ELIGIBILITY

Eligibility criteria are outlined in the following legislation:

- Legislative Decree No. 21 of 2015 for Private Health care facilities
- Resolution No. (15) of 2017 for the technical and engineering standards for health care facilities.

APPLYING FOR A LICENSE

This section contains information about:

- 4 The Application Process**
- 5 The Application Form**
- 6 The License Proposal**
- 7 Fees**
- 8 The NHRA assessment process**
- 9 The NHRA decision-making process**
- 10 Additional Documentation**

4. THE APPLICATION PROCESS

There are 5 steps in the healthcare facility license application process:

- Step 1 – Application for preliminary approval
- Step 2 – Completing the project
- Step 3 – Inspection
- Step 4 – Final approval and license issuing
- Step 5 – operating the facility project

Step 1 - Application for Preliminary Approval

All new applications must be submitted on the License Application Form (see appendix 1) for the approval and licensing of all facilities.

Applicants should be familiar with the legislation relevant to licensing. It is recommended that applicants familiarize and address the requirements contained in this guide and develop their license proposal in consultation with the NHRA Health Care Facilities Licensure and Regulation Department.

To apply for preliminary approval, the applicant must:

- Submit applications after obtaining a commercial registration (CR) submitted through Ministry of Commerce web site (SIJILAT SYSTEM).
- Submit in hard or electronic copies the following Required documents for preliminary approval to health care facility HCF department:
 - 1. Application form (available from <http://www.nhra.bh>.)
 - 2. The name of the person officially authorized to represent the facility and to communicate with NHRA, and the evidence of authorization granted to him by the investor/facility owner.
 - 3. Project proposal and a detailed statement in all its aspects, including a list of the specialties and scope of services to be provided by the facility and the number of professionals expected to work in it.
 - 4. All engineering drawings for the project approved by an Engineering Center.
 - 5. Copy of passport or CPR.
 - 6. License to practice the profession in case of applying for the opening of a private clinic.

The application will be studied by HCF department and will communicate with applicant accordingly.

Step 2 – Completing the facility project

After obtaining the preliminary approval, the applicant should proceed with completion of the project according to approved condition and standards, and should finalize other required approvals from the concerned ministries or authorities such as environment, civil defence and municipality. The applicants could apply for professional licenses at this stage.

Step 3 - Inspection

When the project reaches the final stages, the applicant must submit an inspection request for HCF department to visit the facility (See appendix 3) and attach the following documents:

- Medical equipment approval granted by engineering & safety advisor in NHRA
- Municipality approval
- Civil Defense approval
- Approval by the public Authority for the Protection of Marine Resources, Environment and Wildlife in the case of Radiation Services

Upon receiving the form and documents, the HCF head will assign the inspection team and arrange for the visit. The inspection will be carried out to ensure all outstanding issues have been implemented and submit a report to HCF head.

Step 4- Final approval and license issuing

After completion and passing the final inspection, the applicant must submit the following documents:

1. License Fees invoice.
2. Name of the hospital administrative and medical directors.
3. List of licensed professionals.

Accordingly the final license certificate will be issued.

Step 5- Operating the facility

- The facility may only start operating after being fully equipped and all professionals who will be working in the facility has been licensed by professional license department.
- The facility should prepare the internal policies and procedures including its mission organizational structure, job description for all employees, their specialties, duties, and rights, staff uniforms and the facility working hours.
- The facility should declare to the public the costs of services and consultation fees before receiving the service.
- The license facility management must comply with the license granted to the facility and the activities contained therein.
- In the event of planning for any amendment to the facility structure or scope of its services, granted in the license, the management should notify NHRA in order to obtain the necessary approvals beforehand.

5. THE APPLICATION FORM

Whether applying for a license for the first time, renewing a license or making changes to the facility license requirements, the application process works as follows:

5.1 Complete the appropriate sections of the License Application Form (see appendix 1); ticking the appropriate boxes for new license, renewal of license or changes to license and completing the relevant sections.

- Applicants should follow the instructions on the form. Each relevant section of the form should be completed. Applicants should ensure that they write legibly, and personally sign and date the declaration on the application form.
- in case of new license the applicant must include the signatures of all relevant stakeholders,
- submit a comprehensive license proposal and submit all required documentation as requested.

Failure to provide all documentation in the required format will result in a delay in processing an application.

5.2 Once the applicant receives notification that they have received preliminary approval and are eligible to continue their application for consideration of a full license, they must submit the remaining documentation required and follow the inspection process.

5.3 Once the NHRA has received these documents in an acceptable format and the fees have been paid, the inspectors will conduct the final inspection before providing a report to the NHRA who will issue the facility license.

6. THE LICENSE PROPOSAL

In the best interests of patient care and public protection, the National Health Regulatory Authority (NHRA) seeks to ensure that the issue of quality and patient safety are systematically and comprehensively addressed, across all health care services in the Kingdom of Bahrain. Continuous quality assurance and improvement strategies should be evident within the proposal including:

- Strategic Direction and consideration of the Kingdom of Bahrain's overall goals in healthcare.
- Current international best practice.
- Management of operational performance including expected outcomes/adverse events/near misses.
- Development of quality assurance programs that reflect the use of NHRA standards.
- Risk management strategies.

The applicant/s is encouraged to discuss the development of the proposal and application, in particular the conceptual plans (design layout) and the continuous quality assurance/ improvement aspects, with the NHRA licensure inspectors prior to submission.

The Information required in the proposal should include:

- 6.1 Personal and professional details of the applicant and of the 'Board of Directors' if the applicant is or is to be a registered company/organisation.
- 6.2 Facility Name and Contact Details, (address, contact numbers etc.)
- 6.3 Outline of the facility proposal:
 - 6.3.1 A comprehensive statement of the strategic direction and goals of the facility
 - 6.3.2 Details of the proposed management team and organisational structure, if staff are already employed/identified, include their names and license numbers (if appropriate) beside their roles. In particular identify the Chief Operating Officer/Manager and Head of Nursing/Medicine/Allied Health, if this information is available.
 - 6.3.3 Identification of the proposed services and supporting services including service levels and responses to the requirements contained in the NHRA Health Care Facility Minimum Design Standards.
 - 6.3.4 Evidence of consideration of key demographic data to support the proposed location and services of the facility.
 - 6.3.5 Evidence of how you will comply with Infection Prevention and Control Standards, Medical Waste Standards, Fire Health and Safety Standards,
Outline of the Physical Facility Proposal: **(this section can be submitted before preliminary approval has been obtained)**
 - 6.3.6 A clear overview of the proposed site plan which specifically identifies the facility when constructed or renovated for use as a facility.
 - 6.3.7 The location of the proposed facility, including roads, frontages and adjoining properties.
 - 6.3.8 Architectural drawings: **(to be submitted before preliminary approval)**
 - 6.3.9 A proposed list of all medical devices that will require engineering approval for Installation, operation, performance and maintenance. Also confirmation that the Proposed devices conform to the importation requirements in the Kingdom of Bahrain.
 - 6.3.10 Details of any proposed leasing arrangements, including description of lease agreements.

7 FEES

Each health care facility license applicant must pay the appropriate fee to the NHRA, when submitting their application. **Fees are non-refundable.** *Please refer to Resolution No.(20) for 2016 regarding facility fees.*

For further information about fees and acceptable methods of payment are available on the NHRA's website at: www.nhra.bh

8. THE NHRA ASSESSMENT PROCESS

HCF department is responsible for receiving and reviewing all applications submitted for licensing health care facilities. The department should apply the following procedures for providing facility license

- 8.1 HCF reviews the submitted application and project proposal and other required documents, to ensure that the application meets NHRA conditions and standards. A meeting with the applicant could be arranged to discuss further details or conduct a site visit if needed. The preliminary approval will be

issued according to categorization and scope of service proposed by the applicant and approved by chairperson of HCF department.

- 8.2 If the initial application for a new facility to be established is successful, the NHRA shall issue a preliminary approval on SIJILAT site, with defined services and restrictions particular to the facility/applicant circumstances. This letter will be required to complete the procedures of authorities including but not limited to:
- 8.3 The preliminary approval will be given through SEJILAT site; **facility license application number** will be issued which should be quoted in all future transactions with the NHRA. Please allow a reasonable time for your initial application to reach the NHRA before receiving an acknowledgement.
- 8.4 The head of HCF will review the facility project and the required documents and accordingly, and should ensure that the facility has met all NHRA conditions and standards stated in resolution No. () for 2017, issued by supreme council of health, before recommending license approval.
- 8.5 HCF chairperson issues the license certificate and submits the certificate to NHRA Chief Executive Officer (CEO) for signature.
- 8.6 The license validity is for one year.

NB: Applications are processed as promptly as possible but this is only possible when a complete application is received.

Facilities must not commence practice within the Kingdom of Bahrain unless and until they are fully licensed. Preliminary approval does not confer a license to operate.

9 THE NHRA DECISION-MAKING PROCESS

- 9.1 All standard applications are processed by the NHRA staff and endorsed by the head of HCF department. Non-standard issues/applications are referred for more detailed consideration.
- 9.2 Refusing License renewal – Your Rights
 - 9.2.1. 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
 - 9.1.2. If the NHRA deems it necessary to complete some of the data or documents covered by the license application or to make amendments thereto, the applicant shall be notified within five days and may be increased for a period not exceeding 15 days from the date of submission of the application and NHRA should make a decision within 60 days from the date of submission.
 - 9.1.3. If the application is rejected, the decision to refuse the license shall be written in sufficient detail and accompanied by all the details, information and facts that led to the rejection of the license application. The person whose application was rejected may appeal against the decision to the NHRA within thirty days from the date of notification thereof, or after the (60) a day has passed from the date of submission without making a decision on the license application.
 - 9.2.4. NHRA shall decide on the appeal within thirty days from the date of filing the appeal, and notify the appellant of the decision against its appeal by a registered letter with the receipt of delivery, the expiry of this period without a making decision on the appeal shall constitute a rejection thereof.

9.2.5. Anyone who NHRA has expressly or implicitly denied his appeal may raise a case to the specialized court within sixty days from the date of notification of the rejection of his appeal or within sixty days of the expiry of the period of 30 days mentioned in paragraph (2.3) without making a decision on the appeal.

9.3 Incomplete Applications

Applicants should follow all instructions on the application form and ensure that they submit a business proposal and any supporting documentation in the requested format. A complete application should be submitted in order for the NHRA to consider the applicant's eligibility for a facility license. The NHRA reserves the right to:

- (a) return incomplete applications to the applicant at the correspondence address provided on their application; and/or
- (b) declare an application invalid if the applicant submits an incomplete application form and fails to provide any required information within a specified time period.

In these circumstances, if the applicant wishes to re-apply, they must submit a new, complete application.

9.4 Fraudulent Applications/Documentation

The NHRA will revoke the license of any facility that was licensed but was subsequently found to have submitted fraudulent documentation or misrepresented the facility functions and scope of services.

10 ADDITIONAL DOCUMENTATION

Following the NHRA's decision to grant preliminary approval, the NHRA reserves the right to seek further information or documentation from the applicant or make any enquiry/ies with any person(s) or body/ies regarding the application for a full facility license.

In certain circumstances, applicants are required to provide additional documentation. Examples of additional documentation that may be required by the NHRA are:

- Local municipality approval, including Water and Electricity Regulation approval, Civil defence approval and Roads approval.
- Radiation compliance approval for lead shielding installations, if applicable.
- Engineering approval for all proposed medical devices and installations from NHRA.
- public Authority for the Protection of Marine Resources, Environment and Wildlife in the case of Radiation Services

These are merely examples and not a comprehensive list of additional documentation that may be required. The NHRA also reserves the right to request an applicant to attend its offices where a personal interview is seen as appropriate to their application.

INFORMATION FOR LICENSED FACILITIES

This section contains information about:

- 11. Facility Licensure and Registration**
- 12. Obligation to notify the NHRA of changes in contact or other details**
- 13. Renewal Process**

11 FACILITY LICENSURE AND REGISTRATION

On being granted a license to operate, the license holder will be issued with a Certificate of Licensure, The Certificate of Licensure will display the following information about the licensee:

- License number
- Date of registration
- Category of License/type of facility
- Full name and title of owner
- Branch Name (if appropriate)
- “Conditions Attached”, if there are any conditions imposed on the license
- Address of the Facility
- Expiry date

This Certificate of Licensure must be displayed within the healthcare facility at all times.

The following information will be retained on the NHRA database and Register:

- type of facility, & Specialty
- license number,
- registration number,
- owners name,
- owners CPR, or CR. No.,
- contacts details for the owner,
- address of the facility,
- Manpower list - CPR- Job titles,
- Facility Structure – e.g. storage rooms, dispensaries, consultation rooms, compounding room etc..

12. OBLIGATION TO NOTIFY THE NHRA OF CHANGES IN CONTACT OR OTHER DETAILS

Legal Obligation on the Hospital Licensee

Licensees are legally obliged to inform the NHRA of any change in the details entered in the Register, e.g. change of address, change of ownership, change to person in charge, changes to the scope of services, changes in structure, temporary closure etc. To notify the NHRA of any of these changes, the licensee must complete the appropriate sections of the application form. (See appendix 1)

Change of Registered Name

Facility licensees may at any time apply to change their registered name, address or any other details. Where a licensee wishes to change their registered name, they should submit a request through SIJILAT site, quoting their current registered name, license number and their MOIC Commercial Registration number.

13. LICENSE RENEWAL PROCESS

1. Application

- The HCF department receives a stamped hard copy or electronic renewal application form from the facility.
- In case the facility wishes to do changes in the scope of services or add other activities or redesign the facility structure, it should submit the proposed change documents with the renewal application form.

2. Inspection

Head of HCF assign an inspection team to conduct an inspection visit to ensure that the facility is compliant with NHRA licensing regulations and standards. The team submits their inspection visit report to HCF head of department. A copy of the visit report should be sent to the facility and the original copy should be kept in the facility NHRA record.

3. Issuing the license

Upon receiving the final inspection report HCF head will decide on one of the following:

- **Full renewal:** when the facility is compliant with more than 80% of the licensing requirements and the remaining requirements are of minor priority that will not hinder granting the license.
- **Conditional license:** when the facility compliance is between 50% and 80%, and when the remaining requirements are of medium priority and requires a time frame to implement.
- **Deferred renewal:** when the facility compliance is less than 50%. Or when there is major and critical violation threatening patient safety.

If the decision was taken to grant **conditional license** renewal the following procedures will be followed:

1. The facility CEO will be interviewed by the HCF head and the report will be discussed with him/her.
2. The Facility CEO should submit within 2 weeks from receiving the inspection report a quality improvement plan showing the procedures and time frame to improve the partial or non-compliant license requirements.
3. The Facility CEO must sign a Pledge letter to ensure commitment to carry out the improvement required.
4. A time frame will be granted to carry out the improvement based on the size and type of the required improvements.
5. Another follow up inspection visit will be scheduled with the facility focusing on the partially and non-compliant areas.

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 next section).

NON COMPLIANCE AND SANCTIONS

This section contains information about:

- 14. The Principles of Non Compliance**
- 15. NHRA Non Compliance levels**
- 16. Law enforcement and Escalation**

14 THE PRINCIPLES OF NON COMPLIANCE

The NHRA's overarching concern and priority is to protect and promote the health, safety and welfare of people who use the healthcare services that we regulate, and to ensure the quality of care they receive. Owners and licensees of licensed health care facilities have a duty to make sure that the regulated activities they are responsible for are carried out and managed in a way that complies with legislation and our standards.

To facilitate shared responsibility and an open and transparent approach to regulation, the NHRA believes in a firm but fair approach to noncompliance. This is informed by the following principles:

14.1 Proportionality

Proportionality means relating noncompliance action to the risks identified. Sanctions will be identified using a proportionate manner and will be linked to risks relating to health and safety, or to the seriousness of the concern, which includes any actual or potential harm arising from a poor practice.

14.2 Targeting

Targeting means making sure that regulation is targeted primarily on the activities which give rise to the most serious risks or where the hazards/concerns are least well controlled; and that action is focused on the license holders who are responsible for the risk and who are best placed to control it – whether they are owners, employers, suppliers, or others.

14.2.1 The NHRA has a rolling program of annual inspections which is part of the regulatory license requirement. However additional inspections may take place as part of an investigation into incidents, complaints, near misses etc. these will take priority according to the nature and extent of risks posed by a license holder's operations.

14.2.3 The NHRA will monitor license holder's management competence. This is important, because a relatively low hazard site if poorly managed can entail greater risk to the public than a higher hazard site where proper and adequate risk control measures are in place. Certain sites will receive regular inspections so that the NHRA can give public assurance that such risks are properly controlled.

14.2.3 Any noncompliance action will be directed against the identified license holders of the facility. Where several license holders have responsibilities, such as both facility license holder and professional license holder, the NHRA may take action against more than one when it is appropriate to do so in accordance with this policy.

14.3 Consistency

Consistency of approach does not mean uniformity. It means taking a similar approach in similar circumstances to achieve similar ends across all healthcare facilities. Facility license holders managing similar risks will receive a consistent approach from the NHRA in the advice provided; the use of noncompliance actions, approvals etc.; decisions on whether to restrict or revoke a license; and in the response to incidents.

Decisions on noncompliance action are discretionary, involving judgment. The NHRA and its inspectors have arrangements in place to promote consistency in the exercise of discretion, including effective arrangements for liaison with other inspectors and escalation to senior management for decision making.

14.3 Transparency

Transparency means helping license holders to understand what is expected of them and what they should expect from the NHRA. It also means making clear to license holders not only what they have to do but, where this is relevant, what they don't. That means distinguishing between statutory licensing requirements and advice or guidance about what is desirable but not compulsory.

14.4 Accountability

The NHRA is accountable to the public for their actions. This means that it must have policies and standards against which they can be judged, and an effective and easily accessible mechanism for dealing with comments and handling complaints.

The NHRA will use its discretion in deciding whether incidents, proposals of ill health, or complaints should be investigated. Investigations that are undertaken will determine:

- causes;
- whether action has been taken or needs to be taken to prevent a recurrence and to secure compliance with the law and to ensure patient safety;
- lessons to be learnt and to influence the law and further guidance;
- what response is appropriate to a noncompliance of the standards and or the law.

15 NHRA NON COMPLIANCE LEVELS

The NHRA has developed a stepped approach in seeking to secure compliance with the law and licensing standards to ensure a proportionate response is taken to all non-compliant areas. The stepped approach and identified levels are outlined below:

15.1 Level 1 – Remedial Actions

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.

15.2 Level 2 - Improvement or Restrictive Practice Notices

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.

15.3 Level 3 - Restricted license conditions

Imposing, varying and removing conditions of the license is a flexible noncompliance process that we can use in a variety of different ways to keep people safe and ensure that legal requirements and standards are met. NHRA may decide to close or stop the violated services in the facility until improvement is taken place within the agreed time frame.

15.4 Level 4 – Suspension of license

We can suspend the license of a licensed person or licensed facility for a specified period of time, and also extend a period of suspension. Suspension of a facility license is a serious step that can have major consequences for the facility license holder. Suspension affects the whole health care facility where the relevant regulated activity is being carried out or managed. We will therefore give particular attention to the likely outcomes of taking this action. Suspension can, however, give a facility owner and /or license holder the chance to work towards achieving compliance and then resume carrying on and managing the on-going activity. We follow the same notice procedure described above when we wish to suspend the license.

We can also suspend or extend a period of suspension using urgent procedures. (see below).

15.5 Level 5 – Revoke/Remove the license

Our most powerful sanction is to revoke/remove a license. The removal of a license normally follows considerable efforts to get the facility license holders to comply with legal requirements and the licensing standards set down by the NHRA. Where necessary and in extreme proposals where it is thought that patient safety is severely compromised, we can use the removal of license process without first having followed other processes.

We can also remove the license using urgent procedures (see below).

15.5.1 At the NHRA's discretion, the license of any licensee who fails to pay the appropriate renewal fee and complete the renewal process within a specified period of time may be revoked. A renewal notice is sent to each licensee and a reminder is also sent, prior to revoking their license for non-payment of fees.

15.5.2 If a facility license is revoked, the facility must not practise or provide hospital services in the Kingdom of Bahrain unless and until they apply for and are issued with a new license.

15.6 Level 6 - Urgent procedures

When using our urgent powers to vary or impose conditions, or suspend/remove a license, we will issue an urgent notice/letter of action to the license holder. We will only take this step if we believe that if we do not, a person will, or may be, exposed to the risk of severe harm/potential death.

We will consider using urgent procedures to remove a license as a last resort where the problem cannot be resolved in any other way and where a person(s) is at serious risk to their life, health or wellbeing.

When using our powers to remove a license using urgent procedures, we will refer to the legal process. In these circumstances we will wherever possible:

- Tell the license holder in advance about our application to remove/revoke their license using urgent procedures,
- Only make an application without telling and involving the license holder in exceptional circumstances, such as when their whereabouts are not known and after considerable effort has been made to locate them
- Where we cannot give the facility license holder notice of our application, we will make a full and frank disclosure of all relevant evidence and confirm that we have done so in our application.

When serving an urgent notice of action on a license holder using urgent procedures, it will always include information about how the license holder can appeal against the urgent removal of license.

Where a license holder demonstrates 'low level' but continuous or frequent failure to comply with legal requirements and/or licensing standards, we will usually escalate our noncompliance action so that problems are dealt with swiftly and firmly. We will always follow up noncompliance action to ensure that compliance is achieved.

For further information about the NHRA's noncompliance and sanctions process, please see the NHRA's website at www.nhra.org.bh

16. Law 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 will cancel the facility 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 structural and safety requirements.
4. A court order was issued in relation to criminal act, or a court order was issued to shut down the facility.
5. In case were the facility was not operating for more than 6 months.

In the occurrence of the above conditions, NHRA will conduct an investigation with the owner/CEO. The facility management will be informed officially of the decision taken, and license 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 dispensary 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 major violations NHRA will refer the facility to the disciplinary committee according to decision no (15) for the year 2016. *See appendix 2.*

❖ **Reference: Please refer to Law No. (21) For the year 2015 regarding private health care facilities.**

17. OBTAINING A NEW LICENSE IF YOUR LICENSE HAS BEEN REVOKED

17.1 Obtaining a new license if your license was revoked for failing to renew

Health care facilities wishing to get a new license, after their last license was revoked for failing to renew should complete a new application, ticking the renewal box and submit it with all fees due and the required documentation to the NHRA.

17.2 Obtaining a new license if your license was revoked due to violation.

If a facility license is revoked following a finding that they have violated the law or are noncompliant with the licensing standards set by the NHRA, they can apply to have their license restored to the register when remedial action has been taken.

NOTE: On application for re-instatement, the facility license holder must submit the required documentation to the NHRA. The application for re-instatement will be reviewed and NHRA will make a decision either to grant or refuse the license. Applications will be considered on a case by case basis.

18. License Rejection and Appeal Process

18.1. 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

18.2. If the NHRA deems it necessary to complete some of the data or documents covered by the license application or to make amendments thereto, the applicant shall be notified within five days and may be increased for a period not exceeding 15 days from the date of submission of the application and NHRA should make a decision within 60 days from the date of submission.

18.3. If the application is rejected, the decision to refuse the license shall be written in sufficient detail and accompanied by all the details, information and facts that led to the rejection of the license application. The person whose application was rejected may appeal against the decision to the NHRA within thirty days from the date of notification thereof, or after the (60) a day has passed from the date of submission without making a decision on the license application.

18.4. NHRA shall decide on the appeal within thirty days from the date of filing the appeal, and notify the appellant of the decision against its appeal by a registered letter with the receipt of delivery, the expiry of this period without a making decision on the appeal shall constitute a rejection thereof.

18.5. Anyone who NHRA has expressly or implicitly denied his appeal may raise a case to the specialized court within sixty days from the date of notification of the rejection of his appeal or within sixty days of the expiry of the period of 30 days mentioned in paragraph (2.3) without making a decision on the appeal.

INFORMATION FOR EMPLOYERS

This section contains information about

19. Employing Healthcare Professionals

20. Visas and Work Permits

21. Complaints about Health Care facilities

19. EMPLOYING HEALTH CARE PROFESSIONALS

Facility license holders should ensure that all health care professionals employed are licensed with the NHRA in accordance with the law prior to allowing them to commence employment. The facility license holder could proceed with professional application after being granted the preliminary approval. Health care professionals must present to their employer a valid Certificate of Registration and License. The employer should record the registration status of all health care professionals employed by them, noting the date of expiry of their license, for the duration of the health care professional's employment. It greatly assists the NHRA to receive notification from employers when a licensed health care professional leaves their employment.

20. VISAS AND WORK PERMITS

The NHRA does not request visas or work permits as part of the registration process. It is the responsibility of every employer to ensure that each and every health care professional they employ holds the appropriate visa/permit for the purposes of practising their profession within the Kingdom.

21. COMPLAINTS ABOUT HEALTH CARE FACILITIES

Employers play a vital role in receiving, assessing, investigating and acting on complaints. Facilities should establish systems for managing complaints about their services or employees. In most cases, a complaint made to a facility should be dealt with by the facility. However, there are circumstances where it is appropriate and important for a facility to refer a matter to the NHRA. It is essential that facilities understand their role to avoid confusion, overlap, delay and inefficiency in the complaint management process. The NHRA has published guidelines for employers to help them understand their role in complaint management in relation to the NHRA. For further information, please contact the NHRA directly.

NOTE: THIS GUIDE MAY BE SUBJECT TO AMENDMENT/CHANGES IN WHOLE OR IN PART AT ANY TIME AT THE DISCRETION OF THE NHRA. THIS GUIDE DOES NOT CONSTITUTE AN OFFER OR GUARANTEE OF REGISTRATION/LICENSURE.

Tel: +973 17 11 33 33

Email : info@nhra.bhWebsite : www.nhra.bh

P.O.Box : 11464 , Manama

Kingdom of Bahrain



For office use : application number

.....

APPLICATION FOR FACILITY LICENSE**KIGDOM OF BAHRAIN**

IMPORTANT: Please follow these instructions completely. Failure to submit the necessary items/ information will delay the processing of your application. You must complete and submit all of the requested information.

Please tick the relevant box: and identify fee paid (The required fees must accompany the application)

New Facility	<input type="checkbox"/> Renewal / Reinstatement*
Change of Ownership	<input type="checkbox"/> Change of location
Change of facility name	<input type="checkbox"/> Change of person in charge
Change in Operational function	<input type="checkbox"/> Temporary closure
*if reinstatement , Due to :	<input type="checkbox"/> Adding services
Lapse of license or <input type="checkbox"/> Suspension or Revocation of license	<input type="checkbox"/> Others:

1. General

Facility Name:	Facility phone No. :
Type of facility : <input type="checkbox"/> Government <input type="checkbox"/> Private	
Owner of Facility:	contact mobile no.:
contact e-mail address:	
Authorized person:	contact mobile no.:
contact e-mail address:	His/her position in the facility:

2. For Renewal (only)

Facility License No:	Expiry Date:
Medical Director:	contact mobile no.:
contact e-mail address:	
Chief Executive Officer:	contact mobile no.:
contact e-mail address:	

Personnel:

Total Number of NHRA Licensed Medical Staff: <input type="checkbox"/>	Total Number of NHRA Licensed Doctors: <input type="checkbox"/>
Total Number of NHRA Licensed Nurses: <input type="checkbox"/>	Total Number of NHRA Licensed Pharmacist: <input type="checkbox"/>
Total Number of NHRA Licensed Allied Health Professionals: <input type="checkbox"/>	

3. (For both new and renewal of license) Choose the Type of Facility

<input type="checkbox"/> Hospital (Go to Section 3)	<input type="checkbox"/> Centers (Go to Section 4)	<input type="checkbox"/> Clinic (Go to Section 5)
<input type="checkbox"/> Laboratory (Go to Section 6)	<input type="checkbox"/> Physiotherapy Center (Go to Section 7)	
<input type="checkbox"/> Alternative / Commentary Centers (Go to Section 8)	<input type="checkbox"/> Unit (Go to Section 9)	<input type="checkbox"/> Others go to section 10
<input type="checkbox"/> Others mention such as optometry, maternal, etc. (go to section 11)		

3.Hospital :	
Total Number of Beds in the following departments:	
General "Medicine": <input type="checkbox"/>	Surgical: <input type="checkbox"/>
Pediatric: <input type="checkbox"/>	GYN &OBS: <input type="checkbox"/>
ICU: <input type="checkbox"/> <input type="checkbox"/> CCU:	NICU: <input type="checkbox"/>
Others:	
*Outpatient Services	*Inpatient Services
<input type="checkbox"/> Internal medicine	<input type="checkbox"/> Internal medicine
<input type="checkbox"/> Surgical (Mention sub-specialties if available) -----	<input type="checkbox"/> Surgical (Mention subspecialty if available) <input type="checkbox"/> -----
<input type="checkbox"/> Obstetrics and Gynecology	<input type="checkbox"/> Obstetrics and Gynecology
<input type="checkbox"/> Pediatrics: (Mention subspecialty if available) -----	<input type="checkbox"/> Pediatrics (Mention subspecialty if available) -----
<input type="checkbox"/> ENT	<input type="checkbox"/> ENT
<input type="checkbox"/> Dermatology	<input type="checkbox"/> Dermatology
<input type="checkbox"/> Ophthalmology	<input type="checkbox"/> Ophthalmology
<input type="checkbox"/> Psychiatry	<input type="checkbox"/> Psychiatry
<input type="checkbox"/> Orthopedic	<input type="checkbox"/> Orthopedic
<input type="checkbox"/> Dental (Mention subspecialty if available) ----- -----	<input type="checkbox"/> Dental (Mention subspecialty if available) ----- -
<input type="checkbox"/> Others: ○ ----- ○ ----- ○ ----- ○ -----	<input type="checkbox"/> Others ○ ----- ○ ----- ○ ----- ○ -----

Support Services**☐ **Physiotherapy**☐ **Alternative Medicine**☐ **Radiology**☐ **Plain x-rays**☐ **Specialized please specify**☐ **Laboratory**☐ **Blood Collection**☐ **Simple Laboratory**☐ **Specialized Laboratory**☐ **Pharmacy**☐ **Optometry**☐ **Nutrition**☐ **Ambulance**☐ **Emergency room**☐ **Resuscitation Room**☐ **ICU**☐ **NICU**☐ **Others (mention if available)*4. Centers****Type:** ☐ **General**☐ **Specialized**☐ **Dental**☐ **Availability of 24**
hour services**Total Number of Clinics:****Specialty : (Specify)****Scope of services:****Total No. of Medical staff:****NO of Doctors:****NO of Nurses:****NO of Allied Health:****Other staff: (specify):****Availability of Support Services :****Laboratory**☐ **available**☐ **not available****Pharmacy**☐ **available**☐ **not available****Radiology**☐ **available**☐ **not available****Other: (Specify)**

5.ClinicType: ☐ General ☐ Specialized ☐ Dental

Physician License NO:

Expiry date:

Scope of Services:

6.LaboratoryType: ☐ General ☐ Specialized ☐ Dental

Physician License NO:

No. of Lab technicians:

Scope of Services:

7.Physiotherapy Center

NO of Physiotherapist :

Scope of Services:

Other Stuff:

8.Alternative / Commentary Centers)

Scope of Services: (See decision No33 for 2016)

Total number of professionals:

9.Unit

Scope of Services:

Total number of professionals:

Professionals License NO: (in case of renewal)

Expiry date:

10.Other types of facility

Type of facility:

Scope of Services:

No. of Professionals per category:

Professionals License NO License NO: (in case of renewal)

DECLARATION

I/We the undersigned, certify that I/we am/are the person/s referred to in the foregoing application for licensure registration in the Kingdom of Bahrain, and that the statements herein are true to the best of my/our knowledge, information and belief.

I/we understand that, should I/we furnish any false information in this application, such act shall constitute cause for denial, suspension or revocation of the facility license in the Kingdom of Bahrain.

Signature

Date

PLEASE DO NOT SUBMIT YOUR APPLICATION UNTIL YOU CAN ENCLOSE ALL REQUIRED DOCUMENTATION.

CHECKLIST

Please use the check list to make sure that you have attached all necessary documents.

For preliminary approval

- ☐ Application from (available from <http://www.nhra.bh>)
- ☐ The name of the person officially authorized to represent the facility and to communicate with NHRA, and the evidence of authorization granted to him by the investor/ facility owner.
- ☐ Project personal and a detailed statement in all its aspects, including a list of the specialties and scope of service to be provide by the facility and the number of doctors expected to work in it.
- ☐ All engineering drawings for the project approved by an engineering center.
- ☐ Copy of the passport or CPR
- ☐ License to practice the profession in case of applying for the opening of a private clinic.

For final inspection

When the project reaches the final stages, the applicant must submit an interim inspection request for HCF department to visit the facility (see appendix) and attach the following documents:

- ☐ Medical equipment approval granted by engineering & safety advisor in NHRA
- ☐ Municipality approval
- ☐ Civil defense approval
- ☐ Approval by the public authority for the protection of marine resources, environment and the wildlife in the case of radiation services.

For Final approval

After completion and passing the final inspection must submit the following documents:

- ☐ License fees invoice
- ☐ Name of the hospital administrative and medical directors.
- ☐ List of licensed professionals



(Type) Health Care Facility License

License Proposal Template

National Health Regulatory Authority

Date _____

Table of Contents

Insert Table of contents when business proposal is complete

Introduction

In the best interests of patient care and public protection, the National Health Regulatory Authority (NHRA) seeks to ensure that the issue of quality and patient safety are systematically and comprehensively addressed, across all health care services in the Kingdom of Bahrain.

To this end all health care facility license applicants are required to complete a license proposal outlining key areas. Continuous quality assurance and improvement strategies should be evident within the proposal including:

- Current best practice
- Monitoring of outcome/ adverse events/near misses
- Development of local quality assurance programs that reflect the use of both internal and external standards and reviews. This can include NHRA accreditation or other recognised bodies.
- Risk management strategies

Applicants are encouraged to discuss the development of the proposal and application, in particular the conceptual plans (design layout) and the continuous quality assurance/ improvement aspects, with the NHRA HCF department prior to submission. However the discretion to grant or refuse to grant preliminary approval, a full license, or renewal of a license remains at all times with the NHRA.

This document has been designed as a template for producing a proposal for presenting to the NHRA. The proposal is a presentation of key facts to seek initial preliminary approval and then full licensure for a healthcare facility license.

Using this Template

To create a proposal from this template, simply do the following:

Delete this page.

Replace the title on the cover page with "License Proposal:" the name of your project, and the organization/facility information, including Type of facility, Facility Name, address and contact details

Complete the entire template when preliminary approval has been approved and entering into the full license application process

Each section contains brief instructions, shown in italics, which can be removed once your document is finalized.

Section 1: Authority Signatures

This section contains the signatures of key stakeholders, indicating that they agree with the business proposal as it is presented.

_____	_____	Date
Full name		
Main License Applicant		

_____	_____	Date
Full name		
Stakeholder		

_____	_____	Date
Full name		
Stakeholder		

_____	_____	Date
Full name		
Stakeholder		

Section 2: Executive Summary

Provide an executive summary (high level) that captures only the essential elements of the proposal being presented. Include the proposal's most pertinent facts in a clear, concise, and strategic overview. This should include a comprehensive statement of the strategic direction and underlying goals of the facility

Checklist:

The pertinent facts of the business proposal are provided in a clear and concise fashion.

Section 3: The Strategic Context

Health Care Needs and Desired Outcomes

Complete this section to identify the need (problem or opportunity) and the desired healthcare outcomes and service provision. Include identified need and any demographic evidence which supports the identified need and how the facility goals will fit with the strategic goals of healthcare in the Kingdom of Bahrain.

Section 4: Proposal

4.1 Describe the Proposal

Describe the Proposal (high level).

4.2 Organizational Structure and Overview

To build a strong rationale for a proposed healthcare facility, the current environment needs to be described. The organization/facility overview should include:

- 4.2.2 Mission
- 4.2.3 Strategic vision, goals, and service objectives
- 4.2.4 Proposed activities and scope of services,
- 4.2.5 Key stakeholders and clients
- 4.2.6 Proposed organizational structure, including details of the proposed management team, including names and professional experience when available.
- 4.2.7 Proposed capacity—financial and human resources including strategies for recruiting appropriately trained staff to the facility.

4.3 Scope of Services

Provide a complete description of the proposed services and supporting services including service levels, no of beds, clinic, and responses to the requirements contained in the NHRA Facility Minimum Design Standards and the NHRA Operational Licensing Standards that have been developed for specific facilities.

4.4 Implementation Considerations

Outline how the project will be implemented. Provide an implementation plan (strategic work plan) to demonstrate that the proposal has been appropriately thought through and that the proposals are within an acceptable degree of accuracy.

Demonstrate that the minimum design and building standards required in Bahrain are being considered within the design. You should also include evidence of how you will comply with Infection Prevention and Control Standards, Medical Waste Standards, Fire Health and Safety Standards, International Best Practice Standards.

4.2.2 Schedule and Approach

Identify the core work streams and associated milestones.

4.4.2 Anticipated Risk

Identify the risks anticipated with the project. Provide an option risk summary, which should include risk, probability, impact, mitigation and contingency, outcome, tolerance, and a risk assessment summary rating.

Section 5 – Physical Plans

5.1 Physical Facility Layout

A clear overview of the proposed site plan which specifically identifies the facility when constructed or renovated for use as a healthcare facility

5.1.1 Proposed Site Plan

This should include roads, frontages and adjoining properties and show the proposed facility when constructed or renovated for use. It must include the following architectural drawings: (3D drawings are optional)

- 5.1.1.1** *Architectural Drawings of the proposed plans, showing floor plans, elevations and sections titles of rooms and dimensions. Please refer to decision No. () for 2017*
- 5.1.1.2** *Architectural drawings of the proposed plan including the site plan, site boundaries, showing*
 - *Surrounding streets and accesses, total land area, total built up areas,*
 - *Car parking and car access(on ground and in building if applicable)*
- 5.1.1.3** *Pedestrian routes, access and ramps*
- 5.1.1.4** *Emergency access if required (ambulance, helicopter etc.)*
- 5.1.1.5** *Service routes, back door access, delivery access etc.*
- 5.1.1.6** *Details of any proposed leasing arrangements, including description of lease agreements.*

Section 7: Management and Capacity

7.1 Governance and Oversight

Identify and demonstrate the governance structures and oversight within the proposed facility. This should include organisational structures, committee structures, policies, procedures, operational management of high risk areas. Management of complaints/incidents and identified risks.

7.2 Performance Measurement Strategy

Indicate how the organization will address operational performance measurement for the facility post project implementation and benefits realization. This should include any proposed contracted activity, clinical and support services activity and identified high risk activity.

Section 8 - Appendices (TO BE ATTACHED IF REQUIRED)

CHECKLIST

Please use the check list to make sure that you have attached all necessary documents.

For preliminary approval

- ☐ Application from (available from <http://www.nhra.bh>)
- ☐ The name of the person officially authorized to represent the facility and to communicate with NHRA, and the evidence of authorization granted to him by the investor/ facility owner.
- ☐ Project personal and a detailed statement in all its aspects, including a list of the specialties and scope of service to be provide by the facility and the number of doctors expected to work in it.
- ☐ All engineering drawings for the project approved by an engineering center.
- ☐ Copy of the passport or CPR
- ☐ License to practice the profession in case of applying for the opening of a private clinic.

For final inspection

When the project reaches the final stages, the applicant must submit an interim inspection request for HCF department to visit the facility (see appendix) and attach the following documents:

- ☐ Medical equipment approval granted by engineering & safety advisor in NHRA
- ☐ Municipality approval
- ☐ Civil defense approval
- ☐ Approval by the public authority for the protection of marine resources, environment and the wildlife in the case of radiation services.

For Final approval

After completion and passing the final inspection must submit the following documents:

- ☐ License fees invoice
- ☐ Name of the hospital administrative and medical directors.
- ☐ List of licensed professionals

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APPENDIX 3 –INSPECTION REQUEST FORM



المهنة الوطنية لتنظيم المهن والخدمات الصحية
NATIONAL HEALTH REGULATORY AUTHORITY

NHRA INSPECTION REQUEST FORM

Application Details

Please ☐ New facility License ☐ Renewal Facility ☐ Adding new ☐ Other
select one: License service/specialty

New Facilities request: ☐ Interim Inspection Completion ☐ 100% Completion ☐

Type of facility

☐ Hospital ☐ Clinic / Centre ☐ Pharmacy ☐ Opticians
☐ Laboratory ☐ Radiology

Facility

Name: _____

Application

Reference _____

Number

License

Address: _____

applicants _____

name: _____

I hereby confirm that all the requirements are fulfilled and the NHRA has the authority to reject the facility license application if the Criteria are not met after two inspections. (there will be extra charge for additional inspections)

Signature: _____

For Official NHRA Use:

Coordinating _____ Date of _____
Inspector Inspection

Fulfils all requirements Yes / No

Notes:

USEFUL LINKS

Bahrain Websites:

- a. NHRA – www.nhra.bh
- b. E- Government, Kingdom of Bahrain <http://www.ega.gov.bh/>
- c. Ministry of Health, Kingdom of Bahrain <http://www.moh.gov.bh/en/>
- d. Civil Defence Authority, Kingdom of Bahrain. <http://www.moic.gov.bh>
- e. Electricity and Water Authority, Kingdom of Bahrain. <http://www.mew.gov.bh>

Other Countries:

- f. NFPA 99 (National Fire Protection Association) Manual for fire safety <http://www.nfpa.org>
- g. Heating, Refrigerating and Air Conditioning Engineers Incl.: HVAC-Design Manual for Hospitals and Clinics (www.ashrae.org)
- h. British Standards for Concrete Work-Part 1, 2 & Part 3 (Design and Construction of concrete works) (<http://www.bsstandards.co.uk>)
- i. British standards for Steel Work (Design and Construction of steel work) (<http://www.bsstandards.co.uk>)
- j. Lighting guide, Hospital and Health Care buildings, CIBSE, London (www.cibse.org)
- k. Requirements for Electrical Installations: IEE wiring Regulations (British standard) www.iee.org
- l. Planning, Design, and Construction of Health Care Environments, Published by the Joint Commission on Accreditation of Healthcare Organizations www.jointcommission.org
- m. Medical Gas Guidelines – HTM 02 part 1 & 2, <http://shj.co.uk/pdfs/divav.pdf>
- n. Food & Drug Administration. www.fda.gov
- o. Association for the Advancement of Medical Instrumentation. www.aami.org
- p. Institute of Electrical and Electronics Engineers. www.ieee.org
- q. European Union Medical Device Directive MDD http://ec.europa.eu/health/medicaldevices/documents/revision/index_en.htm
- r. Guidelines for Design and Construction of Health Care Facilities, The Facility Guidelines Institute, American Institute of Architects (AIA) <http://www.fgiguide.org>
- s. Australasian Health Facility Guidelines, Australasian Health Infrastructure Alliance, refer to website www.healthfacilityguidelines.com.au
- t. NHS Estates; Health Building Notes, Department of Health, U.K.