
 <b>GOVERNMENT OF DUBAI</b>	SOP	 سلطة مدينة دبي الطبية Dubai Healthcare City Authority Regulatory - النطاق التنظيمي
	<b><u>Standard Operating Procedure for Issuance of a New Non Clinical Operating Permit</u></b>	
Document #: SOP/RL/001/01		Review Date: 16 April 2020
Issue Date: 17 April 2017		Related Forms: <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No

## 1 **PURPOSE:**



The purpose of this document is to define and establish the Standard Operating Procedure (SOP) for a New Non Clinical Operating Permit (NOP). This NOP is issued to all eligible Non Clinical Facilities within Dubai Healthcare City.

## 2 **APPLICABILITY:**



The procedures outlined in this SOP are applicable to all Dubai Healthcare City – Regulatory (DHCR) departments.

## 3 **DEFINITIONS / ABBREVIATIONS:**



- 3.1 **Action:** includes failure to act;
- 3.2 **Applicant:** the applicant as defined in the specific Regulations that submit an application;
- 3.3 **Application:** An application for a License, a Provisional Approval Letter, or a Miscellaneous Permit made under the specific Regulations;
- 3.4 **Attestation:** The act of authenticating a document by an authorized person or authority with their official seal and signature;
- 3.5 **Branch:** The branch of a company or any other Entity or body formed outside DHCC under the laws and regulations applicable in its place of incorporation and authorized to conduct business through this branch inside DHCC;
- 3.6 **Business Plan:** A documented proposal of planned activities within the facility such as clinical programs, scope of services, commercial activities including all related details;
- 3.7 **Business Category:** A line of Non Clinical business, as determined in accordance with Decision 1 of the Healthcare Business Operators Regulation in DHCC
- 3.8 **Certificate:** For purposes of this Regulation, a certification bestowed upon a student after completion of extended training;
- 3.9 **Chairperson:** The Chairperson of the DHCA appointed under Article (8) of the Law;
- 3.10 **Non Clinical Activity:** A Healthcare Service that falls within a Business Category;
- 3.11 **Non Clinical Operating Permit Request:** A request by a Provisional Approval Letter Holder to convert its Provisional Approval Letter to a Non Clinical Operating Permit;
- 3.12 **Non Clinical Operating Permit (NOP):** The authorization issued by the Registry of Companies to a healthcare operator through Non Clinical Department allowing it to conduct one or more Non Clinical Activities;

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- 3.13 Commercial License (Trade License):** A license issued by the Registration & Licensing Department in DHCC allowing the client to carry out activities according to the Free Zone regulations;
- 3.14 Commercial Companies Law:** The UAE Law No. (8) of 1984 (as amended) in respect of Commercial Companies;
- 3.15 Commissioning:** The process of verifying and documenting that the Provisional Approval Letter Holder and all of its systems and assemblies are planned, designed, installed, tested, operated and maintained to meet the required Standards so that a License may be granted;
- 3.16 Design and Construction Guidelines:** As applicable at the time of application, (1) the current edition of the Facility Guidelines Institute "FGI" – Hospitals & Outpatient Facilities for Design and Construction of Hospital and Health Care Facilities, (2) DHCR Healthcare Facility Projects – Design Review Guidelines and such other guidelines of general professional acceptance that apply to specific Business Categories, provided that any such additional guidelines have been specifically identified as applicable by the Registry of Companies and adequate advance notice is provided that such guidelines may no longer be applicable;
- 3.17 DHCA:** The Dubai Healthcare City Authority established under Article (4) of the Law, and comprises the Chairperson, the DHCC Board of Directors and the Executive Body;
- 3.18 DHCC (Dubai Healthcare City):** The Dubai Healthcare City established in the Emirate of Dubai under Resolution No. (9) of 2003;
- 3.19 DHCR:** The regulatory arm of Dubai Healthcare City Authority. An independent licensing and regulatory authority for all healthcare providers, medical, educational and other business operating within DHCC;
- 3.20 DHCR Price List/ Fees structure 2016:** A document detailing all applicable current fees within DHCC as approved and published and amended from time to time;
- 3.21 Entity:** An organization, institution, or corporation other than a natural person;
- 3.22 Facility:** Any entity providing healthcare or non-healthcare services in DHCC. In DHCC, this is an all-inclusive term meaning a hospital, clinic, laboratory; pharmacy, restaurant, beauty salon, retail office, bank or other entity engaging in one or more clinical or Non Clinical activities;
- 3.23 Facilities Committee:** The committee set up under the purview of the Registry of Companies to carry out the day-to-day administrative functions of the Registry of Companies;
- 3.24 Non Clinical Facility Licensing Department:** The department set up under the purview of the Non Clinical Department to carry out the day-to-day administrative functions of the Registry of Companies;
- 3.25 Governing Regulation:** The DHCC Governing Regulation No. (1) of 2013, as in force from time to time;

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- 3.26 Healthcare Operators Regulation:** The DHCC Healthcare Operators Regulation No. (4) of 2013, as in force from time to time;
- 3.27 Initial Application:** The first time a prospective operator applies to establish a facility with DHCC;
- 3.28 IAF:** The Initial Application Form which is a template form outlining the details for submission by a prospective operator for review by the Facility Licensing Department & Facility Committee;
- 3.29 License:** A license issued by the Licensing Board with regard to healthcare professionals and Complementary and Alternative Medicine professionals or a license or permit issued by the Registry of Companies with regard to companies, including Clinical Operating Permits, Non Clinical Operating Permits, Research Permits and Education Permits;
- 3.30 Licensed Commercial Company:** A company registered under the Company Regulation and licensed under the Commercial Services Licensing Regulation to provide Commercial Services within DHCC;
- 3.31 Licensed Healthcare Operator:** A hospital, clinic, laboratory, pharmacy or other entity providing Healthcare Services in DHCC, holding a Clinical Operating Permit duly issued by the Registry of Companies in accordance with the Healthcare Operators Regulation and the applicable Rules, Standards and Policies;
- 3.32 Licensed Healthcare Professional:** A natural person engaged in a Healthcare Profession holding a License duly issued by the Licensing Board in accordance with the Healthcare Professionals Regulation and the applicable Rules, Standards and Policies;
- 3.33 Licensee:** A Licensed Healthcare Professional, Licensed Complementary and Alternative Medicine Professional, a Licensed Healthcare Operator, an Approved Education Operator, an Approved Research Operator, a Licensed Commercial Company, or a Non Clinical Operating Permit Holder;
- 3.34 Location:** The site within DHCC, including the physical facility or facilities associated therewith, at which a Licensed Healthcare Operator, an Approved Education Operator, an Approved Research Operator, or a Non Clinical Operating Permit Holder conducts or proposes to conduct activities under its License;
- 3.35 Policy:** A defined course of action determined by the DHCA and adopted in accordance with the provisions of this Governing Regulation, on the position, strategy or standing on a subject that shall be followed by those identified within the policy;
- 3.36 Provisional Approval Letter:** The approval issued to an Entity by the Registry of Companies to enable that Entity to:
- (1) Commence the activities required to meet the requirements of the Commissioning; and
  - (2) obtain a License in accordance with the specific Regulations;
- 3.37 Provisional Approval Letter Holder:** An Entity holding a Provisional Approval Letter;

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- 3.38 Register:** The register of Licensees maintained by the Registry of Companies under the Commercial Services Licensing Regulation or the register of companies maintained by the Registry of Companies under the Company Regulation, including the register of shareholders.
- 3.39 Registry of Companies:** The Registry of Companies established by Part Seven of this Governing Regulation;
- 3.40 Regulation:** Any regulation approved by the Chairperson under the Law, including any amendments to any such regulation.

#### **4 RESPONSIBILITY:**



- 4.1** Director of Non Clinical Facility Licensing - Oversight and final approval of the issuance of the New Operating Permit;
- 4.2 Non Clinical** Facility Department must ensure implementation through coordination and communication of the process for issuance of New Operating Permit;
- 4.3** All relevant departments such as Registration & Licensing, Facility Engineering, Professional Licensing Department, Quality Improvement and Health Informatics shall ensure accuracy of assessments, and report findings in a timely manner and where relevant participate in education sessions.

#### **5 PROCEDURE:**



##### **5.1 Initial Application**

Each prospective clinical business operator must submit an Initial Application Form (IAF) corresponding to the various types of segments applied for in DHCC such as Non Clinical Facilities. A business plan detailing the clinical scope of services and practice that the prospective clinical business operator wishes to provide in DHCC must accompany the IAF;

- 5.1.1** The prospective Non Clinical business operator must submit the initial clinical application form on the following link: <http://www.dhcr.gov.ae/en/E-Services/ServicesCatalogue?CTID=2> Payment of applicable fee will be in reference to proposed lease square footage for all clinical facilities documented as per the fee structure documented in the following link: <http://www.dhcr.gov.ae/Documents/DHCR%20Price%20List%20February%202016.pdf>
- 5.1.2** The Non Clinical Facility Licensing Department receives the application (scanned copy) and reviews its completeness and ensures that the Initial Non Clinical Application contains the following:
- Completed Initial Non Clinical Application with all relevant components completed;

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- b. Initial Application Fee payment notification by receipt or electronic confirmation by accounts department;
  - c. Completed Proposed Business plan with detailed Non Clinical program;
  - d. Related attachments such as Foreign Company / Parent Company's Certificate of Incorporation, UAE Trade License if applicable;
  - e. Additional documents such as CV's, Pass Port copies, Brochures, lease reservation document / title deed if applicable;
- 5.1.3** Non Clinical Facility Licensing Department senior executive / executive creates a file ID number in the following excel sheet located in the following folder - [\\Dhccdc02\dhccdfs\DHCC\CPQ\Facility Licensing & Standards\Facility Licensing - IAF & Operations\Operations\Client Documents\FLD\Serial number database](#)
- 5.1.4** Non Clinical Facility Licensing Department senior executive / executive creates a company file folder (corresponding to the file ID number) to save all related documents - [\\Dhccdc02\dhccdfs\DHCC\CPQ\Facility Licensing & Standards\Facility Licensing - IAF & Operations\Operations\Client Documents\FLD\Clients Info](#)
- 5.1.5** Non Clinical Facility Licensing Department senior executive / executive sends an email to prospective applicant acknowledging receipt of application and reference ID for all communications;
- 5.1.6** Non Clinical Facility Licensing Department executive sends request for clarification/Due Diligence/additional information by email /electronic system to applicant (if applicable);
- 5.1.7** Non Clinical Facility Licensing Department Executive validates the information received and prepares a review sheet of the initial application and saves it in the following location as per the Facility Committee meeting schedule-  
[\\Dhccdc02\dhccdfs\DHCC\CPQ\Facility Licensing & Standards\Facility Licensing - IAF & Operations\Operations\Client Documents\FLD\Facilities Committee Meeting\2016](#)
- 5.2 Facility Committee Review**
- 5.2.1** Non Clinical Facility Licensing Department executive prepares the Facility Committee agenda of items;
  - 5.2.2** Non Clinical Facility Licensing Department distributes the related initial Non Clinical application review sheet and related documents to the designated Facility committee members for review, discussion and decision making;
  - 5.2.3** Designated Facility Committee members review all initial Non Clinical applications during the meeting. When required clarification/Due

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Diligence/additional information by email is sent to the prospective Non Clinical business operator /applicant;

- 5.2.4 Name reservation request for prospective Non Clinical operator is submitted by Clinical Facility License Department senior executive/executive through the Dubai Media Free Zone Authority portal which is as follows- <https://dcca.secure.force.com/>;
- 5.2.5 Non Clinical Facility Licensing Department senior executive / executive will obtain required clarification /due diligence/additional information related to name reservation if applicable from the prospective applicant;
- 5.2.6 Upon receiving name reservation approval, a name reservation certificate is issued by Dubai Media Free Zone Authority;
- 5.2.7 Facility Committee members review Non Clinical applications during the Facility Committee meeting and provide decision to Facility Licensing Department for all the Non Clinical applications. Final Decisions can be rejected or approved.

### 5.3 Recommendations, restrictions and conditions

- 5.3.1 Where applicable all recommendations, restrictions and conditions are documented for each specific clinical application.



### 5.4 Decision

- 5.4.1 When the applicant receives an approved or declined decision, the Executive communicates with the prospective business operator /applicant the relevant denied decision;
- 5.4.2 Upon receiving an approval decision for specific initial applications Non Clinical Facility Department executive proceeds to communicate with the prospective Non Clinical business operator /applicant the relevant approval decision.

### 5.5 Issuance of Initial Provisional Approval Letters

- 5.5.1 This includes the following steps:
  - 5.5.1.1 Non Clinical Facility Licensing Department senior executive/ executive prepares initial provisional approval letters for all approval decisions as per Facility Committee decisions;
  - 5.5.1.2 All recommendations, restrictions and conditions are documented on the initial provisional approval letters for those specific clinical applications where applicable;
  - 5.5.1.3 Non Clinical Facility Licensing Department executive proceeds to communicate with the applicant the approval decision attaching the initial provisional approval and communicates to all relevant DHCC and DHCR members as applicable;



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**5.5.1.4** Applicant can now proceed to the next stage of issuance of lease / tenancy agreement.

## **6 ISSUANCE OF LEASE / TENANCY AGREEMENT**

**6.1** Applicant will proceed to issuance of Lease agreement with Sales & Leasing Department of DHCC for all DHCC owned buildings and DHCC managed Private buildings. Alternatively, for Private buildings applicant will proceed to respective representative for issuance of lease agreement;

**6.2** For all private buildings, applicant must get the lease agreement duly attested by Sales & Leasing Department of DHCC.

## **7 ISSUANCE OF COMMERCIAL LICENSE**

For all processes related to Commercial License Issuance refer to Registry of Companies Department.

## **8 DESIGN REVIEW AND ISSUANCE OF FIT OUT PERMI**

For all processes related to Design Review & Fit out Permit refer to Engineering Department.

## **9 HEALTH, SAFETY & FACILITY ENGINEERING INSPECTION**

**9.1** Health, Safety & Facility Engineering Inspection;

**9.1.1** Facility engineering departments will participate in the Facility Health, Safety & Facility Engineering Inspection as per the confirmed schedule;

**9.1.2** Facility Engineering will ensure that all Facility Inspections requirements are met and recorded;

**9.1.3** Facility Engineering forwards the inspection details of the Non Clinical facility to Registry Of Company for Non Clinical Operating Permit issuance.

## **10 NON CLINICAL OPERATING PERMITS**



**10.1** Upon passing the Health, safety & Engineering inspection, FLD prepares the Non Clinical Operating Permit;

**10.2** FLD communicates the Non Clinical operating permit fees as per the DHCR fee Structure to the Non Clinical facility operator;

**10.3** The Healthcare Operator provides FLD with a copy of the payment receipt for the Operating permit and all relevant members of DHCC;

**10.3** FLD issues the Non clinical operating permit after receiving the payment receipt from the Facility operator;

**10.4** Non Clinical Facility Licensing Department senior executive / executive updates

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the NOP database and creates a license number for the facility in the following folder -\\Dhccdc02\dhccdfs\DHCC\CPQ\Facility Licensing & Standards\Facility Licensing-

IAF&Operations\Operations\ClientDocuments\FLD\Clinical\updated Clinical operating client's database, based on the segment, activity, specialty and date of Non Clinical Operating Permit issuance. The validity duration of the clinical operating permit is for two years;

**10.5** Non Clinical Facility Licensing Department senior executive / executive prepares the Non Clinical Operating Permit, affixes the seal and sends an official E-Mail to the client informing them about the approved services, limitations and issuance and expiry dates. All related departments are copied in the email;

**10.6** Non Clinical Facility Licensing Department issues the Original Non Clinical Operating Permit to the Healthcare Business Operator and all related DHCC and DHCA-R members are informed.

#### **11 REFERENCES AND RELATED DOCUMENTS:**

DHCC Rule No. 1 of 2016

DHCR fees structure and Price List 2016

#### **12 RELATED FORMS & TEMPLATES:**

**12.1** Non Clinical initial application forms

**12.2** Non Clinical Operating Permit Template

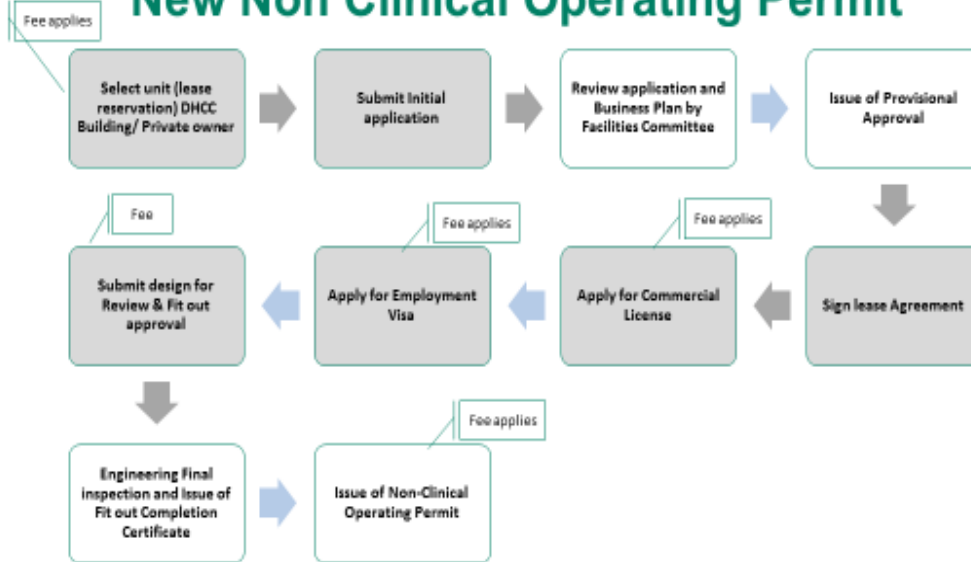
**12.3** Non Clinical Facility Process Flow Chart

#### **Appendix 1: Processes – New non clinical operating permit**

Modification of non-clinical operating permit



## New Non Clinical Operating Permit



- All new application should be submitted with business plan and Business plan

Applicant

DHCR



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