



Sleep Laboratory Guidelines 2016

Table of Contents

Acknowledgement	3
I. Scope	4
II. Purpose	4
III. Definitions	4
IV. Acronyms	6
1. Introduction	7
2. Registration and licensure procedures	7
3. General design considerations	9
4. Professional requirements	11
5. Health records	13
6. Patient care and safety	13
References	15

Acknowledgement

Dubai Health Authority (DHA) is pleased to present the “Sleep Laboratory Guidelines”, which represents a milestone towards fulfilling the DHA strategic objective to “Improve quality standards in healthcare facilities”.

This document places an emphasis on facility design and service criteria with a focus on quality of services and safety of patients and healthcare professionals based on international standards of best practices in this domain, while taking into consideration the local and federal laws.

The Health Regulation Department (HRD) has developed this document in collaboration with Subject Matter Experts (SMEs). The contribution of these SMEs is invaluable and HRD would like to gratefully acknowledge these healthcare professionals and thank them for their dedication to quality in health and their commitment in undertaking such a complex task.

The Health Regulation Department

Dubai Health Authority

I. Scope

This document applies to health facilities, which are subject to licensure under the Dubai Health Authority (DHA) establishment law, including semi-governmental, private and health facilities operating in free zone areas, except facilities in Dubai Health Care City (DHCC), willing to provide sleep laboratory services.

DHA has the right to amend this document stipulated herein without prior notice. The latest version of which shall be published on the DHA website www.dha.gov.ae.

II. Purpose

This document outlines the basic mandatory requirements to ensure health facilities and healthcare professionals provide safe and quality care to patients with sleep disorders.

III. Definitions

Actigraphy is monitoring of movement, especially during sleep therapy to assess sleep disorders.

Belligerent means inclined or eager to fight; hostile or aggressive.

Circadian rhythm is a daily cycle of biological activity based on a 24-hour period and influenced by regular variations in the environment, such as the alternation of night and day.

CPAP titration is a type of in-laboratory sleep study used to calibrate continuous positive airway pressure (CPAP) therapy.

Healthcare professional is a healthcare personal working in healthcare facilities and required to be licensed as per the applicable laws in United Arab Emirates.

Hypersomnia is a sleep related disorder that causes excessive daytime sleepiness in people, often regardless of the presence of other sleeping disorders, or poor sleep hygiene.

Insomnia is a condition in which one has trouble falling or staying asleep. Some people with insomnia may fall asleep easily but wake up too soon. Other people may have the

opposite problem, or they have trouble with both falling asleep and staying asleep. The result is poor-quality sleep that does not leave one feeling refreshed when you wake up.

Licensure is issuing a license to operate a health facility to an individual, government, corporation, partnership, limited liability company, or other form of business operation that is legally responsible for the facility's operation.

Multiple sleep latency test is the measurement of the time interval from the onset of a nap to the onset of actual sleep, as monitored by electroencephalography (EEG) during a series of short naps.

Maintenance of wakefulness test is a test to measure the ability to stay awake for a defined period, (generally a 40 minute protocol is used), with the first epoch of sleep as the definition of sleep onset.

Parasomnia means general sleep disruptions from the rapid eye movement (REM) sleep cycle and non-REM sleep cycles. These disruptions can occur on a regular basis, or very rarely depending on the person. The disruptive events by them self may cause the affected person to wake up or partially wake, although during the actual event, one remains asleep. The most recognized parasomnias are talking while asleep, sleepwalking, night terrors and nightmares.

Patient is any individual who receives medical attention, care or treatment by any healthcare professional or admitted in a health facility.

Polysomnography (PSG) shall mean a type of sleep study, which records certain body functions as you sleep, or try to sleep. Polysomnography is used to diagnose sleep disorders.

Sleep apnea is an involuntary cessation of breathing that occurs while the patient is asleep. There are three types of sleep apnea: obstructive, central, and mixed.

Sleep disorders is problems with sleeping, including trouble falling or staying asleep, falling asleep at the wrong times, too much sleep, or abnormal behaviors during sleep.

Sleep Medicine is a medical specialty or subspecialty devoted to the diagnosis and therapy of sleep disturbances and disorders.

IV. Acronyms

AED	:	Automated Electronic Defibrillator
BLS	:	Basic Life Support
CO₂	:	Carbon-di-oxide
CPAP	:	Continuous Positive Airway Pressure
DHA	:	Dubai Health Authority
DHCC	:	Dubai Health Care City
EEG	:	Electroencephalogram
HRD	:	Health Regulation Department
MSLT	:	Multiple Sleep Latency Test
MWT	:	Maintenance of Wakefulness Test
O₂	:	Oxygen
PALS	:	Pediatric Advanced Life Support
PAP	:	Positive Airway Pressure
PSG	:	Polysomnogram
REM	:	Rapid Eye Movement
SME	:	Subject Matter Expert
UAE	:	United Arab Emirates

1. Introduction

A sleep laboratory conducts attended sleep studies like polysomnogram (PSG), multiple sleep latency test (MSLT) and maintenance of wakefulness test (MWT) which are tests that electronically transmits and records specific physical activities. The recordings become data that is analyzed by a physician trained in sleep medicine to determine if the patient has any sleep disorders.

Sticky patches with sensors called electrodes are placed on the patients scalp, face, chin, chest, limbs and finger. These sensors record brain activity, eye movements, breathing pattern, heart rate and rhythm, blood pressure and the amount of oxygen (O₂) in the blood. After acquiring the consent from the patient or the patient's guardian, the technician visually monitors and video records patients during sleep therapy for any abnormal activities.

- 1.1. Sleep laboratory services can be provided in:
 - 1.1.1. Hospital
 - 1.1.2. Outpatient facilities with one (1) of the following twenty-four (24) hours service:
 - 1.1.2.1. Neurology
 - 1.1.2.2. Otolaryngology
 - 1.1.2.3. Pediatric Pulmonology
 - 1.1.2.4. Pediatric Sleep Medicine
 - 1.1.2.5. Pulmonology
 - 1.1.2.6. Sleep Medicine

Note: Refer to the professional requirements of this document for further information

2. Registration and licensure procedures

- 2.1. To provide sleep laboratory services in the Emirate of Dubai the facility category application might be either:
 - 2.1.1. New facility license
 - 2.1.2. Add new specialty
- 2.2. Initial Approval

The applicant must create a username and password (for new facility) and submit an application through the online licensing system *SHERYAN* along with all necessary documents, which are as follows:

- 2.2.1. Schematic design drawings in AutoCAD format showing the proposed floor layout with measurement of the rooms and labelled providing the Sleep laboratory service.
- 2.2.2. A detailed business plan/ list of equipment, etc.
- 2.2.3. Undertaking letter from the owner in Arabic and English (for Add specialty)
- 2.2.4. Passport photocopy with residency visa for non-locals and UAE identity card (for new facility).
- 2.3. Based on the documents submitted, HRD will review the material to determine compliance and suitability for further processing. In case the application is rejected, a detailed report of rejection reasons will be provided.
- 2.4. Once the application is approved, an initial approval letter with defined activities will be issued which will be valid for six (6) months.
- 2.5. Final inspection

Upon completion of the facility setup requirements, the applicant shall submit an online request for final inspection, upon which HRD shall conduct an onsite pre-operational assessment. To obtain the DHA license, the applicant must meet the following:

- 2.5.1. Appoint a Medical Director (for new facility).
- 2.5.2. Employ licensed healthcare professionals to satisfy the functional program of the sleep laboratory.
- 2.5.3. Install and operate equipment required for provision of the proposed services in accordance with manufacturer specifications.
- 2.5.4. Develop policy and procedure documents for the following:
 - 2.5.4.1. Informed consent
 - 2.5.4.2. Infection control measures
 - 2.5.4.3. Patient health record
 - 2.5.4.4. Incident reporting

- 2.5.4.5. Patient acceptance criteria
- 2.5.4.6. Patient privacy
- 2.5.4.7. Patient own medication
- 2.5.5. The facility shall maintain treatment protocols for:
 - 2.5.5.1. Comprehensive polysomnography (PSG)
 - 2.5.5.2. Multiple sleep latency test (MSLT)
 - 2.5.5.3. Maintenance of wakefulness test (MWT)
 - 2.5.5.4. Titration of continuous positive airway pressure (CPAP) therapy
 - 2.5.5.5. Esophageal pressure monitoring, Actigraphy, end tidal CO₂ monitoring and transcutaneous CO₂ monitoring (if applicable).
- 2.5.6. Emergency plans for the following:
 - 2.5.6.1. Cardiac emergencies
 - 2.5.6.2. Neurologic emergencies, particularly seizures
 - 2.5.6.3. Psychiatric emergencies, particularly suicidal ideation
 - 2.5.6.4. Environmental emergencies including fire, weather, belligerent patients etc.
- 2.5.7. The facility shall maintain a written plan for monitoring equipment for electrical and mechanical safety, with monthly visual inspections for apparent defects. Annual inspections conducted for electrical safety and ground fault by certified electrician or biomedical engineer.
- 2.5.8. Based on the onsite pre-operational assessment visit and after meeting DHA requirement for healthcare professionals, the facility shall pay fees (when applicable) and HRD will issue “New facility license”/ “Add new specialty”.

3. General design considerations

The sleep laboratory shall have a patient preparation room, sleep therapy room(s) and control room(s).

3.1. Patient preparation room

3.1.1. Preparation of patient could be done in the sleep therapy room, but ideally, it should be done in a separate room with adequate ventilation and storage space for supplies.

3.1.2. Provide a sink to clean and disinfect electrodes and other monitors.

3.2. Sleep therapy room

3.2.1. The size of the sleep therapy room shall be not less than nine (9) square meters to accommodate emergency personnel access with a minimum of 0.60 meters of available clear space on three (3) sides of the bed.

3.2.2. All sleep therapy rooms shall be single occupancy, private and comfortable.

3.2.3. The floor to ceiling walls shall be made of hard material.

3.2.4. Provide a privacy door for every sleep therapy room that opens inwards and directly to a corridor or common use area such that the patient can access the sleep therapy room without passing through other sleep therapy rooms.

3.2.5. The sleep therapy rooms shall be in a quite area and low traffic section of the health facility.

3.2.6. The room should be preferably sunlight free to create a time free environment.

3.2.7. The sleep therapy rooms shall not have any obstructions in delivering emergency care.

3.2.8. The sleep therapy room shall have a bed with a mattress not smaller than a standard hospital bed.

3.2.9. The sleep therapy rooms shall have easy access to toilets. The ratio of sleep therapy rooms to toilets shall be 1:1.

3.2.10. In case the health facility provides treatment for handicapped patients, it shall have a sleep therapy room and toilet to accommodate these patients.

3.2.11. Each sleep therapy room shall have a mechanism for visual monitoring and video recording of patients during sleep therapy. Time delayed

photographs shall not be acceptable as a mechanism for visual monitoring.

- 3.2.12. The health facility shall maintain equipment for delivery of positive airway pressure (PAP) therapy for sleep apnea, which is controlled by a remote control.

3.3. Control room

- 3.3.1. The dimension of the control room shall not be less than 3.7 square meters.
- 3.3.2. It shall be located away from traffic area, to protect the privacy of patients during the test.
- 3.3.3. There shall be a two-way communication system between the sleep therapy room and the control room.
- 3.3.4. The control room shall host the polygraphic equipment capable of recording and storing physiological parameters using sensors and recommended or alternative derivations.
- 3.3.5. Phone numbers of important contacts should be visibly posted near the workstation, which shall include the number of the sleep laboratory service in-charge.

Note: The administrative areas and consultation rooms shall be separate from the sleep therapy rooms and must meet the DHA regulation criteria that can be found on the website www.dha.gov.ae.

4. Professional requirements

The facility shall employ and license sufficient healthcare professionals to meet the functional program of the twenty-four (24) hour service with special attention to security during the night. The number of sleep therapy rooms in the facility generally dictates the staffing requirements.

- 4.1. A sleep laboratory, service in-charge shall be a consultant/ specialist Physician in one of the categories as mentioned below, with certified training and experience in sleep medicine or holding an equivalent qualification to overlook the entire functioning of the sleep laboratory service provided.

- 4.2. Physicians who can operate and interpret sleep laboratory results shall be:
 - 4.2.1. Neurologist (with twelve (12) months training in sleep medicine)
 - 4.2.2. Otolaryngologist (with twelve (12) months training in sleep medicine)
 - 4.2.3. Pediatric Pulmonologist
 - 4.2.4. Pediatric Sleep Medicine Specialist
 - 4.2.5. Pulmonologist
 - 4.2.6. Sleep Medicine Specialist
- 4.3. The physician in-charge shall be:
 - 4.3.1. Responsible for the quality of sleep therapy including the proper operation and calibration of the equipment.
 - 4.3.2. Responsible for the training of all staff providing care.
 - 4.3.3. Be present in the health facility on a regular basis.
 - 4.3.4. Accessible for consultation and notification in the event of an emergency.
- 4.4. Pediatric sleep medicine physicians shall be employed to diagnose treat and manage pediatric patients with sleep disorders. They shall not manage adult patients with sleep disorders.
- 4.5. American board Sleep Medicine Specialist can assess and treat both adult and pediatric patients.
- 4.6. Polysomnographic Technologist
 - 4.6.1. The sleep facility shall employ appropriately trained and supervised polysomnographic technologist.
 - 4.6.2. The polysomnographic technologist shall document ongoing evaluation and management of every patient with sleep disorder.
 - 4.6.3. The polysomnographic technologist shall be responsible for close monitoring of the patient and shall have sufficient training to recognize potential emergencies such as life-threatening conditions like cardiac arrhythmias.
 - 4.6.4. The polysomnographic technologist should monitor for signals by the patient that they may be in distress. This can be verbal as well as behavioral.

- 4.6.5. The patient to technologist ratio should be 2:1 under most circumstances for attended polysomnography.
- 4.6.6. For infants, young children and older children/ adults with special needs the ratio of patient to technologist is 1:1.
- 4.6.7. The polysomnographic technologist shall maintain a valid Basic Life Support (BLS) certification.
- 4.6.8. The polysomnographic technologist treating pediatric patients shall maintain a valid Pediatric Advanced Life Support (PALS) certification.

5. Health records

- 5.1. All sleep laboratories shall maintain appropriate health records for patient evaluated by the facility and also for referred patients by other health facilities.
- 5.2. Health records shall document patient interaction, including initial evaluation, sleep therapy (if any), diagnosis, treatment, CPAP assessment and follow-up.
- 5.3. The health record shall include written indication that the physician has reviewed and approved the proposed evaluation.
- 5.4. Every evaluation shall be signed and stamped by the physician in case of paper based health records and signed off in case of electronic health records.

6. Patient care and safety

- 6.1. The safety of patients is the responsibility of the entire sleep laboratory team from the physician to the technologist directly monitoring the patient.
- 6.2. To provide comprehensive care the health facility may have a multidisciplinary medical advisory committee including a pulmonologist, pediatric pulmonologist, neurologist, psychiatrist, otolaryngologist, internal medicine, dentist and phycologist.
- 6.3. The majority of patients seen in the sleep laboratory take medications for various medical reasons. The facility shall maintain patient own medication policy to reinforce this.

- 6.4. All sleep laboratory shall have a quality assurance program with indicators like:
 - 6.4.1. Patient satisfaction
 - 6.4.2. Termination of procedures or refusal of treatment
 - 6.4.3. Timeliness of scoring
 - 6.4.4. Chart completion
- 6.5. The sleep laboratory shall be equipped with emergency equipment like emergency cart with defibrillator or Automated Electronic Defibrillator (AED).
- 6.6. Infection control should be a standard practice with effective hand sanitization and equipment disinfection practices to prevent the transmission of germs.
- 6.7. Hand sanitation should be performed before and after contact with each patient.
- 6.8. Provide hand rub stations at convenient locations throughout the sleep laboratory.
- 6.9. Arrangements should be in place for washing and disinfecting bed linens. Used bed linens, shall be handled in a manner that prevents contamination to the laboratory staff and other patients.
- 6.10. The facility shall maintain fire extinguishers. There shall be trained staff to respond to fire events. Orientation on the fire safety measures should be included in new staff induction program.
- 6.11. There shall be evacuation maps posted to indicate current locations marked with "You are here" to provide information regarding escape routes and fire exits.

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