1 PURPOSE:

These Standards define the requirements to ensure acceptable minimum levels of quality, performance, safety and reliability of Dental Services operating in Dubai Healthcare City (DHCC). These Standards define the Licensing Criteria, Qualified Personnel and Service Requirements for the provision of Dental Services in DHCC.

2 APPLICABILITY:

2.1 These Standards are applicable to all Healthcare Operators and Healthcare Professionals currently providing or intending to provide Dental Services within DHCC.

2.2 Healthcare Operator using Procedural Sedation and Analgesia within Dubai Healthcare City shall follow Standards for Procedural Sedation and Analgesia (PSA) in addition to these standards.

2.3 Healthcare Operators using Nitrous Oxide shall follow policy on Managing Anxious Children by use of Sedation in Pediatric Dentistry PP-HCO-004-03.

3 DEFINITIONS / ABBREVIATIONS:

3.1 ALARA: As Low as Reasonably Achievable

3.2 Dubai Healthcare City Authority (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.

3.3 DHCC: Dubai Healthcare City.

3.4 HCP: Healthcare Professionals

3.5 Dubai Healthcare City Authority - Regulatory (DHCR): is 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.

3.6 Dental Care or Dental Assistance: means that part of personal healthcare intended for individual prophylaxis, diagnosis, treatment of the diseases and/or conditions of the mouth and associated anatomical structures, and dental prosthetics.

3.7 Dental Director: means the Licensed Dentist who performs the leadership function of the Licensed Dental Facility.

3.8 Dental Laboratory shall mean a facility prepared for providing dental works like dentures, bridge, ceramics or other dental restorations such as implant, crowns based on the order of a dentist. Dental Laboratory can be established independently or within a health care facility providing dental services.

3.9 Dental Technician is one who makes appliances and restorative devices, such as bridges, dentures etc., to the specifications of a dentist.

3.10 FANR means Federal Authority for Nuclear Radiation, United Arab Emirates (UAE).

3.11 FGI: Facility Guidelines Institute

3.12 PPE: Personal Protective Equipment

3.13 Informed Consent: a process of communication between a person and a physician or other healthcare professional that results in the person’s authorization or agreement to undergo a specific medical intervention. It includes the principle that a physician
has a duty to inform his or her patients about the nature of a proposed or alternative treatment, procedure, test, or research, including the risks and benefits of each alternative and of not receiving it. An informed patient can then make a choice which procedure, if any, to undergo.

3.14 **RPO:** Radiation Protection Officer

3.15 **Safety:** means the condition of being protected against physical, psychological, or other types or consequences of failure, error, or harm, which could be considered non-desirable. This can take the form of being protected from the event or from exposure to something that causes health losses, for example, the use of a drug, or a procedure, or risk in the care environment.

3.16 **Scope of Practice of Dentistry:** means the Professional Practice involving the evaluation, diagnosis, prevention, or treatment, including non-surgical, surgical, or related procedures, of diseases, disorders, or conditions of the oral cavity, maxillofacial area, or the adjacent and associated structures, and the impact of the disease, disorder, or condition on the human body.

4 **LICENSURE OF DENTAL CLINICS:**

4.1 Dental services may be provided by DHCA Licensed Healthcare Operators holding a Clinical Operating Permit for Single and Multi-Specialty Outpatient Clinics, Outpatient Surgical Clinics, Hospitals and other Inpatient Healthcare Facilities in accordance with the requirements of the Standards defined herein. In issuing a Clinical Operating Permit and in renewing a Clinical Operating Permit, the Registry of Companies shall determine the appropriate ‘Type’, ‘Class’, ‘Scope’ and ‘Clinical Specialties’ for each Licensed Healthcare Operator providing Dental services. Clinical Specialties that can be provided within the scope of Dental Services are Endodontics, General Dentistry, Orthodontics, Pediatric Dentistry, Periodontics, Prosthodontics, Oral and Maxillofacial Surgery.

4.2 Each Licensed Healthcare Operator providing Dental Services shall provide such services in accordance with all applicable regulations, rules, policies and standards of DHCA.

5 **QUALIFIED PERSONNEL:**

5.1 Each Licensed Healthcare Operator providing Dental Services shall appoint qualified personnel and maintain staffing levels as required to ensure reliable and consistent care in compliance with these Standards, the DHCR Outpatient Clinic Quality Standards or the appointed accreditation organization’s standards, the DHCR Quality Oversight Policies, and any other applicable regulations, rules and standards.

5.2 Each Licensed Healthcare Operator providing Dental Services shall employ a Dental Director and an Administrative Manager. The Dental Director shall be a Licensed Dentist who may also serve as the Administrator.

5.3 The Dental Director shall have full time responsibility for oversight of all clinical services to ensure safe and quality healthcare service delivery as per the Standards for Outpatient Clinical Services.
5.4 The administrator responsibilities shall be stipulated in accordance to the requirements in the Standards for Outpatient Clinical Services.

5.5 All licensed Healthcare Professionals shall provide dental services within the scope of practice and standards of proficiency for their licensed category.

5.6 At least one competent HCP is assigned responsibility of coordinating the infection control program to ensure that all infection control and prevention policies and guidelines, sterilization policy are in place, staff adheres to certain practices such as immunizations, hand hygiene, sterilization monitoring, proper use of PPE and the facility complies with DHCR Infection control guidelines.

5.7 At least one individual is trained as a Radiation Protection Officer (RPO) and is assigned responsibility for coordinating Radiation Protection Safety Program and ensuring compliance to FANR requirements.

5.8 Each HCP providing care shall be given provision for ongoing professional development, regular in-house training and specific training for devices, products or equipment they are using in concurrent practice.

5.9 All Licensed Healthcare Professionals shall be currently certified in Basic Life Support (BLS).

5.10 Each Licensed Healthcare Operator shall determine the associated clinical risk in the provision of the Dental Services provided and ensure the availability of adequately trained and certified Licensed Healthcare Professionals in resuscitation procedures such as Advanced Cardiac Life Support (ACLS) and Pediatric Advanced Life Support (PALS) as appropriate.

5.11 If applicable, the roles and responsibilities of any student personnel attending the Licensed Healthcare Operator, must be clearly defined and clarified in writing. Approval shall be obtained from DHCR to have a trainee or student attending the Licensed Healthcare Operator.

6 PATIENT MANAGEMENT:

6.1 Each Licensed Healthcare Operator providing Dental Services shall manage patients care in accordance with these Standards, the DHCR Outpatient Clinic Standards, guidelines and all other applicable laws, regulations and standards.

6.2 Patient’s shall be accepted for healthcare services based on whether the facility’s scope of clinical activities, services and availability of suitably qualified and licensed healthcare professionals can meet the patient’s needs.

6.3 An oral and extra oral examination shall be conducted on all patients during the initial assessment to determine the proper diagnosis.

6.4 Standardized forms and templates shall be used for patient assessments and documentation in medical record.

6.5 Treatment for each patient shall be appropriate and based on the patient’s medical and dental history, examination, diagnosis, and discussion with the patient and/or parent (guardian), when applicable.

6.6 Patients suspected of tuberculosis or any other infectious disease should be isolated and treated accordingly.

6.7 Referrals should be made if necessary for proper diagnosis and treatment.
6.8 Pain assessment shall be completed for all patients throughout all phases of care, and support them by managing pain effectively.

6.9 Each Licensed Dentist shall document progress notes of the dental care given to a patient in the patient’s record. Progress notes shall be dated and signed by the Licensed Dentist treating the Patient.

6.10 Pre-procedural preparation shall include education to patients and carers, information regarding planned procedures and post procedural care, identification of medical risk factors and optimization of the patient’s condition.

6.11 A safety checklist shall be used for all dental invasive / surgical procedures.

6.12 Ionization radiation exposure to patients shall be limited or minimized by following ALARA (As Low as Reasonably Achievable) Principle.

6.13 Patient’s eyes shall be protected during dental procedures.

6.14 Barriers shall be established to prevent ingestion or inhalation of materials or small instruments.

6.15 Healthcare Professionals shall monitor the onset and progression of infection in the oral cavity of the patient.

6.16 Each Healthcare Operator providing Dental Services shall formulate policies and procedures that clearly outline the management of life threatening emergencies and care. These shall minimally include cardiopulmonary and anaphylactic emergencies and other unanticipated complications.

6.17 Policies and procedures to contain respiratory secretions in people who have signs and symptoms of a respiratory infection, beginning at point of entry to the dental setting shall be available and implemented.

6.18 Policies, procedures, and guidelines for safe injection practices (e.g. aseptic technique for parenteral medications) are available and implemented.

7 HEALTH INFORMATION MANAGEMENT:

7.1 Each Licensed Healthcare Operator providing Dental Services shall comply with DHCA regulations, policies and standards for the management of patient health information and medical records policy.

7.2 Each Licensed Healthcare Operator providing Dental Services shall ensure the confidentiality of patient health information as per the provisions of the DHCA Health Data Protection Regulation Numb (7) of 2013.

7.3 Each Licensed Healthcare Operator providing Dental Services shall plan and design information management processes to meet internal and external information needs. It shall ensure that the data and information needs of patients are met in a timely manner in a format that satisfy user expectations and with the desired frequency.

7.4 Standardized diagnosis codes, procedure codes, symbols, abbreviations, and definitions must be used.

7.5 Each Licensed Healthcare Operator providing Dental Services shall effectively manage the collection of health information. It shall also retrieve, disseminate, and transmit health information in useful formats.

7.6 Written documents, including policies, procedures, and programs, are managed in a consistent and uniform manner.
7.7 All Licensed Healthcare Professionals involved in the care of patients should have access as necessary to patients’ health information to plan, provide and document the care delivered.

7.8 Each Licensed Healthcare Operator providing Dental Services shall ensure that all patient Health Information is documented on official forms with the Healthcare Operator’s name.

7.9 Each licensed Healthcare Operator providing Dental Services shall ensure documented evidence in a patient’s medical record of any referrals to external healthcare services, Informed Consents (if applicable), and related healthcare management and outcomes to maintain continuity of care.

7.10 Each Licensed Healthcare Operator providing Dental Services shall meet all requirements for timely and regular submissions of data and information to DHCR as per applicable DHCA regulations, standards and policies.

7.11 Each Licensed Healthcare Operator providing Dental Services shall report clinical and managerial performance measures to DHCR Clinical Affairs Department to monitor and improve patient care and outcomes as defined in DHCR Performance Measures Policy.

8 PATIENTS RIGHTS AND RESPONSIBILITIES:

8.1 Each Licensed Healthcare Operator providing Dental Services shall provide patients and families with information regarding the DHCA Patients’ Rights and Responsibilities in accordance to Schedule two of the DHCA Governing Regulation Number (1) of 2013. This information shall also be displayed in English and Arabic throughout the facility for patients and visitors to review.

8.2 Each Licensed Healthcare Operator providing Dental Services is responsible for providing processes that support patients’ and families’ rights during care.

8.3 Patient Informed Consent shall be obtained through a defined process and carried out by trained staff in a manner and language the patient can understand in accordance to the DHCR Informed Consent Policy.

9 MINIMUM FACILITY REQUIREMENTS

9.1 Each Licensed Healthcare Operator providing Dental Services shall comply with the minimal facility requirements of the most current FGI Guidelines for Design and Construction of Hospitals and Outpatient Facilities. The design shall make provision for accessible, efficient, and safe clinical care in a secure, supportive and functional environment.

9.2 Each Licensed Healthcare Operator providing Dental Services shall ensure appropriate provisions for the separate management of pediatrics and the needs of parents / carers.

9.3 Each Licensed Healthcare Operator providing Dental Services shall have adequate equipment for safe, effective and efficient service to Patients, including appropriate sterilization equipment, diagnostic and radiographic equipment and supplies.

9.4 Medical equipment must be FDA, CE and/or IEC approved as appropriate and shall be registered in accordance with the UAE Ministry of Health Medical Devices Registration Guidelines.
9.5 All examination rooms, dressing rooms, and reception areas shall be built and maintained in a manner that ensures patient privacy during interviews, examinations, treatment, and consultations.

9.6 Each Healthcare Operator providing Dental Services shall ensure that treatment areas are of adequate size to allow for the presence of necessary equipment, patient and staff. It must also allow for the presence of emergency personnel and equipment and the safe care and transfer of the patient in case of a medical emergency.

9.7 Waiting areas shall ensure sufficient spaces throughout the facility with layouts sensitive to specific cultural needs.

9.8 Provisions for suitable and secure storage space for consumables, equipment, pharmaceutical drugs/products and medical records shall be provided.

9.9 If applicable, valid contracts for contracted services (e.g. hazardous waste removal, laboratory services, laundry, cleaning, sterilization) shall be maintained. A process to assure that contracted services are monitored for quality and patient safety shall be in place.

9.10 Utility systems must be routinely inspected, maintained, and improved.

9.11 A Safety Management Program must be established to manage risks in the environment and reduce the risk of injury to patients, staff and visitors.

9.12 Dental Radiology Requirements:

9.12.1 Healthcare Operators offering Dental Radiology Services shall get the approval/license from Federal Authority for Nuclear Regulation (FANR), UAE and comply with their regulations.

9.12.2 Individual monitoring for workers through dosimeters shall be conducted for any worker who is likely to receive more than 10% of the annual dose limit of 20mSv in any one year (i.e. 2mSv/yr) as per FANR requirements.

9.12.3 Risk assessment / evaluation shall be carried out for monitoring radiation exposure to the staff (For details see Appendix 1).

10 IN HOUSE STERILIZATION REQUIREMENTS:

10.1 Each Licensed Healthcare Operator providing Dental services shall have an assigned and dedicated area for sterilization.

10.2 Written policies and procedures on sterilization and manufacturer reprocessing instructions for reusable instruments shall be available to ensure reusable patient care instruments and devices are reprocessed appropriately.

10.3 The sterilization policy shall cover all the details and steps from collecting dirty instruments, transportation, cleaning, chemicals used and their dilutions, packaging and sterilization, storage etc.

10.4 The sterilization area shall consist of a decontamination zone and a clean working zone, physically separated.

10.5 The decontamination area shall be equipped with a countertop, hand washing station and a separate washing sink for instruments.

10.6 To avoid splash, the contaminated sink shall be separated from the clean work area by either a 4-foot distance from the edge of the sink or a separating wall or screen. If screen is used, it shall extend a minimum of 4 feet above the sink rim.

10.7 The clean work area shall be equipped with a countertop, sterilizer as required, hand washing station and built-in storage for supplies.
10.8 Automated cleaning equipment (e.g., ultrasonic cleaner, instrument washer, washer-disinfector) shall be used to remove debris to improve cleaning effectiveness and decrease worker exposure to blood.

10.9 Instruments shall be thoroughly cleaned according to manufacturer instructions and visually inspected for residual contamination before sterilization.

10.10 Sterile packs shall be labeled at a minimum with the sterilizer used, the cycle or load number, the date of sterilization, and if applicable an expiration date.

10.11 Reusable heat sensitive semi critical items that cannot be replaced by a heat stable or disposable alternative are high-level disinfected according to manufacturer’s instructions.

10.12 High-level disinfection products shall be used and maintained according to manufacturer instructions.

10.13 Dental hand pieces (including the low-speed motor) and other devices not permanently attached to air and waterlines are cleaned and heat-sterilized according to manufacturer instructions.

10.14 A chemical indicator shall be used inside each package. If the internal indicator is not visible from the outside, an exterior chemical indicator shall also be used on the package.

10.15 A biologic indicator (i.e., spore test) shall be used at least weekly and with every load containing implantable items.

10.16 A mechanical technique for sterilization monitoring shall include assessing cycle time, temperature, and pressure by observing the gauges or displays on the sterilizer and noting these parameters for each load. Printouts of these parameters shall be retained for monitoring purposes.

10.17 After sterilization clean supplies and instruments shall be stored in closed or covered cabinets and in a manner so that sterility is not compromised.

10.18 Sterile packages are inspected for integrity and compromised packages are reprocessed before use.

10.19 Instrument packs shall not be used if mechanical (e.g., time, temperature, pressure) or chemical indicators indicate inadequate processing (e.g., color change for chemical indicators).

10.20 Storage areas shall include provisions for ventilation, humidity, and temperature control.

10.21 Single-use devices shall be discarded after one use and not used for more than one patient.

10.22 Flash sterilization is not recommended in dental facilities.

10.23 Provisions for work-practice controls that minimize contact with sharp instruments (e.g., long-handled brush) and appropriate PPE (e.g., puncture- and chemical-resistant utility gloves) shall be available.

10.24 Healthcare Professionals responsible for reprocessing reusable dental instruments and devices shall be appropriately trained upon hiring, at least annually and whenever new equipment and processes are introduced.
11 REQUIREMENTS FOR DENTAL UNITS WATERLINES, BIOFILM CONTROL AND WATER QUALITY:

11.1.1 Dental unit water quality shall be maintained as per Dubai Municipality recommendation of Total Bacterial Count (TBC) of 200 CFU / mL as a maximum for contamination of water used in dental treatments.

11.1.2 Dental unit waterline treatment products / devices are used to ensure water meets local regulatory standards for drinking water for routine dental treatment output water.

11.1.3 Product manufacturer instructions (i.e. waterline treatment product, dental unit manufacturer) are followed for monitoring the water quality.

11.1.4 Sterile saline or sterile water shall be used as a coolant / irrigant when performing surgical procedures.

11.1.5 Manufactures recommendations shall be followed for the method of maintaining acceptable water quality, water delivery system and the recommended frequency of monitoring.

11.1.6 Monitoring of Water Quality of Dental Units shall be done at least quarterly unless the manufacturer recommends more frequent tests.

11.1.7 Appropriate measures should be taken to control formation of biofilm in waterlines and to control legionella bacteria.

12 QUALITY OVERSIGHT AND ACCREDITATION:

12.1 Each Licensed Healthcare Operator is required to successfully meet the DHCR Outpatient Clinic Quality Standards and to obtain Certification of Successful Completion of the Quality Survey performed by the Clinical Affairs Department of DHCR within (2) years of commencing operations, and maintain such certification throughout the term of its Clinical Operating Permit in accordance with the requirements of the DHCA Healthcare Operators Regulation number (4) of 2013.

12.2 Each Healthcare Operator shall establish quality assurance/ improvement program to monitor and review the quality of services provided by the Dental Services Facility in accordance with the requirements of the DHCA Healthcare Operators Regulation number (4) of 2013.

12.3 Each Healthcare Operator shall establish and approve a program for Quality and Safety that includes both patient and staff, and includes its Risk Management and Quality Control activities.

12.4 All staff members shall continuously participate in risk management and quality improvement activities.

12.5 Each Healthcare Operator providing Dental Services shall report all sentinel events to Clinical Affairs Department as per the applicable DHCR Sentinel Event policy.

13 DENTAL LABORATORY REQUIREMENTS:
13.1 Healthcare Operators operating a stand-alone dental lab must obtain a license / clinical operating permit from Dubai Healthcare City Authority- Regulatory (DHCR) to operate a dental laboratory in Dubai Healthcare City.

13.2 Stand-alone Dental Laboratories and Dental Labs operating within the Outpatient Dental Clinics shall be surveyed by the Quality Department of DHCR at their regular intervals of assessments i.e. Pre Operating Assessment, 6 Months Survey, 18 Months Survey and 2 years Comprehensive Surveys.

13.3 Dental Labs shall be equipped with appropriate equipment and supplies required to provide dental lab services.

13.4 All procedures carried out in the dental lab shall be done by or under the direction of qualified, skilled and experienced licensed dental technicians.

13.5 The lab shall be isolated from possible transmission of pathogens. Arrangements shall be made to prevent cross contamination from patients and HCP’s or other staff.

13.6 Any material or dental work entering or leaving the lab must maintain strict hygiene conditions. Proper disinfection of materials/ impressions entering and leaving the laboratory must be ensured.

13.7 Proper aspiration and ventilation shall be in place.

13.8 All relevant policies and procedures shall be in place to ensure operational quality and safety e.g. policy for receiving and delivery procedures etc.

14 REFERENCES AND RELATED DOCUMENTS


14.2 CDC Guidelines for Infection Control in Dental Health-Care Settings 2003, Morbidity and Mortality Weekly Report (MMWR) December 19, 2003 / 52(RR17);1-61

14.3 Dubai Healthcare City Authority-Regulatory, Standards for Procedural Sedation and Analgesia

14.4 Dubai Healthcare City Authority-Regulatory, Standards for Outpatient Clinical Services

14.5 Dental Laboratory Regulation, Health Regulation Department, Dubai Health Authority 2013.

14.6 Dubai Healthcare City Authority-Regulatory, Day Surgery Standards SD-HCO-002-01

14.7 Dubai Municipality Guidelines for the Control of Legionella in Dental Clinics 2009- DM-PH&SD-P7-TG05


14.10 Infection Prevention Checklist for Dental Settings, Basic Expectations for Safe Care, Centers for Disease Control & Prevention, March 2016


14.12 Personal Dosimetry in Dental Radiology, Radiological Protection Institute of Ireland, May 2011.

Appendix 1

The Risk Assessment:

A 10% evaluation is a documented evaluation by the facility that a worker is not likely to receive more than 10% of the annual occupational Dose limits in Article (10) of FANR-REG-24. This evaluation can be done on the basis of prior experience, such as doses measured by the licensee or doses measure by others in similar situations; area surveys; or a calculation, based upon source strength, distance, shielding, and time spent in the work area.

The Risk Assessment shall estimate all expected annual staff doses arising from the use of X-ray equipment in the practice and should take account of the following considerations:

- Identification of people at risk
- Realistic workload i.e., number of X-rays taken
- Type of X-ray unit(s) used
- Radiation output of the X-ray unit(s)
- Types of scans performed
- Layout of the surgery and structural shielding
- Operator position
- The likelihood of recording a reportable dose (i.e. an effective dose greater than 2 mSv in a year)
- Previous dose records for the staff performing similar work

This list is not exhaustive and other considerations, such as local policies, should also be taken into account.

The risk assessment shall be documented and retained on file by the dentist and may be requested during inspection by the local authorities.