Code of Practice

for Day Procedure Centres

(2023 Edition)

Department of Health

February 2023

Version History

Version	Effective Date
1	January 2020
2	January 2021
3	February 2022
4	February 2023

Promulgated by the Department of Health,
The Government of the Hong Kong Special Administrative Region

Table of Contents

Preface

The Private Healthcare Facilities Ordinance (the Ordinance) (Cap. 633) was gazetted on 30 November 2018 introducing a new regulatory regime for hospitals, day procedure centres, clinics and health services establishments. Pursuant to section 102 of the Ordinance, this Code of Practice for Day Procedure Centres (CoP) is issued by the Director of Health (the Director) to provide standards for all day procedure centres (DPCs) licensed under the Ordinance. The CoP sets out the licensing standards in respect of the governance, staffing, facilities and equipment, service delivery, quality and safety of care, infection control, and other matters related to the operation of a DPC.

This CoP is drawn up with reference to the sets of core and procedure-specific standards developed by the Project Steering Committee on Standards for Ambulatory Facilities (PSC), which have taken into account the legislation and regulatory standards of overseas jurisdictions with adaptation to local practice environment. The PSC was set up by the Department of Health and the Hong Kong Academy of Medicine in April 2015, co-opting members from the medical faculties of local universities, private hospitals and practitioners' associations. Eight Task Forces were formed under the PSC by nomination of the Hong Kong Academy of Medicine and constituent Colleges, comprising members who practise in hospital and/or ambulatory settings, and from both the public and private sectors, to make recommendations on procedure-specific standards for specialized services specified in Schedule 3 to the Ordinance. Pursuant to section 99 of the Ordinance, an Advisory Committee for Regulatory Standards for Private Healthcare Facilities (Advisory Committee) has been established in 2020 to regularly review and update the CoP when deemed necessary.

Compliance with the CoP is a condition for issuance and renewal of licences. Under section 47 of the Ordinance, the licensee of a DPC (the licensee) is wholly responsible for the operation of the DPC. The licensee is responsible, in particular, for setting up and enforcing policies, rules and procedures relating to the operation of the facility, the quality of care, and the safety of patients. He/she shall ensure the DPC is in compliance with the conditions of the licence, the CoP, and any direction that may be given by the Director by notice in writing as to how a DPC is to comply with the CoP pursuant to section 104 of the Ordinance.

Determination of compliance will be based on the standards stipulated in the CoP as well as any applicable technical guidelines, standards, and codes of practice. Where such guidelines, standards, or codes of practice are specified herein, the version specified applies unless an up-to-date version is approved by the Advisory Committee. The Director may also accept other guidelines, standards, or codes of practice if he/she is satisfied that they are capable of ensuring equivalent performance of the DPC. The responsibility of proving those other guidelines, standards, or codes of practice to be capable of ensuring equivalent performance rests with the licensee. The licensee is reminded to observe any other applicable legislation in the course of operating the DPC.

Department of Health
November 2020

Interpretation of Terms

The following provides the interpretation of terms under this CoP –

"Adverse Event" –

means an incident that resulted in harm to a patient.

"Certified Medical Physicist" –

means a person certified under the medical physicist certification scheme of the Hong Kong Association of Medical Physics or the Hong Kong Institution of Physicists in Medicine, or equivalent.

"Chief Medical Executive (CME)" –

means a person appointed by the licensee of a day procedure centre under section 49 of the Ordinance.

"Clinical Area" –

means any area in which patient treatment and care are delivered in the day procedure centre.

"Complaints Committee" –

means the Committee on Complaints against Private Healthcare Facilities established under section 71 of the Ordinance.

"Critical Care Area" –

means any area in a facility where failure of electrical power supply is likely to jeopardise the immediate safety or even cause major injury or death of patients or caregivers. Examples are operating room and recovery area.

"Day Procedure Centre (DPC)" –

means any premises described in section 5 of the Ordinance.

"Dental Practice" –

means the professional practice of a dentist.

"Dentist" –

means a dentist registered under the *Dentists Registration Ordinance* (Cap. 156).

"Enrolled Nurse" –

means a nurse enrolled under the *Nurses Registration Ordinance* (Cap. 164).

"Facility" –

means a day procedure centre.

"Healthcare Professional" –

means a person specified in Schedule 7 to the Ordinance, including a registered pharmacist, a registered dentist, an enrolled dental hygienist, a registered medical practitioner, a registered midwife, a registered nurse, an enrolled nurse, a registered medical laboratory technologist, a registered occupational therapist, a registered optometrist, a registered radiographer, a registered physiotherapist, a registered chiropractor, and a listed or registered Chinese medicine practitioner.

"Hospital" –

means any premises described in section 4 of the Ordinance.

"Licensee" –

means a holder of a licence, including a holder of a provisional licence, to operate a day procedure centre under the Ordinance.

"Medical Gas Pipeline System" –

means a system comprising sources of supply, a pipeline distribution system, terminal units (to which the user connects and disconnects medical equipment), and a warning and alarm system. It applies to medical gases, medical vacuum and anaesthetic gas scavenging disposal systems.

"Medical Practitioner" –

means a medical practitioner registered under the *Medical Registration Ordinance* (Cap. 161).

"Medical Record" –

means the formal documentation maintained by the day procedure centre on patients' history, physical findings, investigations, treatment, and clinical progress. It may be handwritten, printed, or electronically generated, and may include audio and visual recording.

"Medical Service" –

in relation to a patient, means a medical diagnosis, treatment (other than first aid treatment) or care for the patient given by a medical practitioner or a dentist.

"Medical Staff" –

means a medical practitioner or a dentist.

"Nurse"/"Nursing Staff"–

means a registered nurse or an enrolled nurse, registered or enrolled respectively, under the *Nurses Registration Ordinance* (Cap. 164) and who provides nursing care to patients in the day procedure centre.

"Operating Room" –

means a room described in Annex II which is permitted by the Director of Health in writing pursuant to section 70 of the Ordinance.

"Operator" –

means, in relation to a day procedure centre for which a licence is in force, the licensee of the facility.

"Ordinance" –

means the *Private Healthcare Facilities Ordinance* (Cap. 633).

"Patient" –

means an individual who is, or may be, suffering from a disease, injury or disability of mind or body, to whom healthcare service is provided, or on whom a medical procedure is carried out.

"Pharmacist" –

means a pharmacist registered under the *Pharmacy and Poisons Ordinance* (Cap. 138).

"Radiographer" –

means a radiographer registered under the *Supplementary Medical Professions Ordinance* (Cap. 359).

"Registered Nurse" –

means a nurse registered under the *Nurses Registration Ordinance* (Cap. 164).

"Scheduled Medical Procedure" –

means a medical procedure that is described in column 2 of Schedule 3 to the Ordinance; that is not a medical procedure described in column 3 of Schedule 3; and that is carried out in an ambulatory setting.

"Scope" –

in relation to services provided in a day procedure centre, includes the clinical and clinical supporting services provided in the facility.

"Service" –

includes those provided directly by employees of the day procedure centre, or indirectly through services that have been contracted out or run through a separate business contract at location of the registered address.

"Specialist" –

means a medical practitioner recognised in the Specialist Register by the Medical Council of Hong Kong.

"Specialized Ventilation System" –

means the ventilation system of an operating room in a facility.

Application

"Day procedure centres" (DPCs) refer to premises that do not form part of the premises of a hospital, and that are used, or intended to be used, for carrying out high-risk procedures. These procedures, referred to as Scheduled Medical Procedures, are defined in section 2 of the Ordinance, as a medical procedure that is (a) described in column 2 of Schedule 3 to the Ordinance; (b) not a medical procedure described in column 3 of the Schedule; and (c) carried out in an ambulatory setting (Annex I). Licensee of a DPC should observe the core standards as described in Chapter 1, and procedure-specific standards in Chapters 2 to 9 relevant to the class of scheduled medical procedures provided in their premises.

Where procedures are performed in an operating room, the requirements relating to operating room in *Chapter 2: Surgical Procedure* should be observed. The *Guidelines on Use of Operating Room for Surgical Procedures in Day Procedure Centres* (Annex II) also provide general guidance on the use of an operating room in a facility. Where dental compressed air and vacuum systems are installed in the facility, licensee may refer to the *Guidelines for Dental Compressed Air and Vacuum Systems* (Annex III) for general guidance on the design and installation of such systems. The feasibility of implementing the *Guidelines for Dental Compressed Air and Vacuum Systems* as a regulatory requirement would be reviewed as appropriate. Licensees are encouraged to observe the requirements set out in Annex III in preparation for its implementation.

General Principles on Inclusion of Medical Procedures to be Carried Out in a Day Procedure Centre (Scheduled Medical Procedures)

1. The risk of any procedure is defined by ANY one of the following three factors:
   (a) Risk of procedures;
   (b) Risk of anaesthesia involved; and
   (c) Patient's condition.[1]

2. Medical practitioners and dentists should take into account, in addition to the above factors, the age, body size and other physical conditions of the patient when deciding whether a medical procedure is high-risk and should be performed in DPC or in hospital.

3. Certain medical procedures should only be performed in hospital in view of their risks. Overall, medical procedures may be performed in DPC only if –
   (a) The patient is discharged in the same calendar day of admission;
   (b) The expected total duration of procedure and recovery requiring continuous confinement within the facility does not exceed 12 hours; and
   (c) Patient's condition is not Class IV or worse (i.e. Class IV or V) as classified by American Society of Anaesthesiologist (ASA) Physical Status Classification System.

[1] A procedure is considered high-risk if it is performed on a patient whose physical status is unstable Class III or worse as classified by the American Society of Anaesthesiologists (ASA) Physical Status Classification System.

Hospital-only Medical Procedures

Pursuant to section 103 of the Ordinance, the Director of Health specifies the following medical procedures that may only be carried out in a hospital:

(a) Administration of chemotherapy (cytotoxic) into body cavity or deep-seated organ;

(b) Image-guided core biopsy of deep-seated organ;

(c) Transarterial catheterisation or deep venous catheterisation;

(d) Continuous veno-venous haemofiltration or continuous veno-venous haemodiafiltration;

(e) Organ transplant [except corneal transplant] or complicated transplant procedures;

(f) Bronchoscopy or pleuroscopy;

(g) Therapeutic gastrointestinal endoscopy for children aged under 12 years old;

(h) Injection of sclerosing/embolisation agents into vascular/lymphatic compartment of deep-seated head and neck region;

(i) Blood transfusion;

(j) Radiotherapy for children aged under 18 years old;

(k) Frame-based stereotactic radiosurgery;

(l) Intra-operative radiotherapy;

(m) Total body irradiation;

(n) Half body irradiation;

(o) Total skin electron beam treatment;

(p) Brachytherapy; and

(q) Radionuclide therapy, except (i) iodine-131 therapy for thyrotoxicosis up to 400MBq; (ii) radium-223 therapy for advanced prostate cancer; and (iii) radiosynoviorthesis therapy

Chapter 1
Core Standards

1.1. Management/Governance

1.1.1. Chief medical executive

1.1.1.1. There is a chief medical executive (CME), who is a medical practitioner, at all times. If there is dental practice in the facility, there is a dentist in charge of such services. For a facility with dental practice only, the CME is a dentist. The facility appoints a medical practitioner or dentist, respectively, to deputise the CME in the latter's absence from duties.

1.1.1.2. The CME is held accountable for the medical management of the facility. He/she is responsible for the adoption and implementation of policies and procedures concerning healthcare services in the facility.

1.1.1.3. The CME ensures that the policies and procedures are consistent with the *Code of Professional Conduct* promulgated by the Medical Council of Hong Kong and/or the *Code of Professional Discipline for the Guidance of Dental Practitioners in Hong Kong* promulgated by the Dental Council of Hong Kong wherever applicable.

1.1.1.4. The CME ensures that all healthcare professionals working in the facility have the requisite qualifications, valid registration, training, and experience related to the healthcare services they provide.

1.1.2. Staff training and credentialing

1.1.2.1. All staff involved in clinical care are appropriately trained, including training in the use of any medical equipment and in assisting in medical procedures. There are at all times a sufficient number of suitably qualified and trained staff in the facility, taking into account the number and needs of patients, and types of services provided.

1.1.2.2. The CME ensures that the staff involved in clinical care are practising within their professional scope of practice and competence, and in accordance with the code of practice of relevant professions.

1.1.2.3. There is a process to recognise and regularly review employees' and visiting healthcare professionals' qualifications, training and competence.

1.1.2.4. The facility provides job orientation programme for new staff. Current operational manuals and clinical guidelines are easily accessible and available to staff for their reference.

1.1.3. Research

1.1.3.1. If clinical research is conducted on patients, the CME ensures that research ethics have been reviewed and the conduct of research is in accordance with standards that may be prescribed by relevant regulatory authorities. The CME also ensures that any clinical trial conducted is covered by a valid clinical trial certificate issued under relevant ordinance/regulations.

1.2. Physical Conditions

1.2.1. Facility management

1.2.1.1. The physical design, size, layout, and condition of the facility are appropriate for the safe and effective delivery of services and the needs of its patients.

1.2.1.2. All buildings, furniture, furnishings, fittings and equipment of the facility are maintained in good operational order.

1.2.1.3. The facility is kept clean and hygienic. Ventilation, lighting, and signage are adequate and appropriate.

1.2.1.4. The CME ensures that the construction and use of the facility are in compliance with relevant ordinances and regulations of the Laws of Hong Kong.

1.2.2. Equipment and store

1.2.2.1. All equipment used in the facility are used as intended for its purposes, in good working order, and properly maintained. Records of maintenance and servicing of medical equipment are kept.

1.2.2.2. Staff using medical equipment have completed training in the safe and proper use of the equipment.

1.2.2.3. The CME ensures that the facility has appropriate and readily accessible medical equipment, instruments, appliances, and materials that are necessary for the type and level of patient care it provides. The quantities stored are appropriate for the safe and effective provision of its services.

1.2.2.4. Equipment intended for single use are not reused.

1.2.3. Back-up power supply

1.2.3.1. Where high-risk procedures are conducted or life-support systems are used, back-up power supply is available for the life support systems, for recovering patients, and for safe completion or cessation of high-risk procedures.

1.3. Service Delivery and Care Process

1.3.1. Patients' rights

1.3.1.1. The facility establishes written policies and procedures to protect the rights of its patients.

1.3.1.2. Patients have the right to know the name and rank of staff providing services.

1.3.1.3. Patients have the right to be informed of the treatment planned for them and give informed consent to their treatment.

1.3.1.4. The privacy of patients is considered and respected by all staff of the facility.

1.3.1.5. Patients and their carers or representatives have the right to be informed about the procedures for making complaints, and the process of managing and responding to their complaints by the facility.

1.3.1.6. Patients have the right to access their own health records.

1.3.2. Patient identification

1.3.2.1. There are written policies and procedures for patient identification. There is appropriate verification process to ensure that the correct patient has the correct procedure performed on the correct site.

1.3.3. Medical records

1.3.3.1. There is a written policy in place for the creation, management, handling, storage, and destruction of all medical records.

1.3.3.2. For every patient, the CME ensures that complete, comprehensive, and accurate medical records are maintained and retained for specified minimum period.

1.3.3.3. Medical records include at least the following: unique identifier, patient's name, gender, date of birth, residential address, contact telephone number, drug allergy history, relevant consultation notes and investigation(s), treatment, and, where appropriate, sick leave and referral records.

1.3.3.4. All medical records are accurate, legible, and up-to-date. All entries in the record are dated and signed where appropriate.

1.3.3.5. Medical records are confidential and are kept secure. All stored personal data are protected from unauthorized access, alteration, or loss. The staff handling personal data are aware of the provisions of the *Personal Data (Privacy) Ordinance* (Cap. 486) and have due regard to their responsibilities under that Ordinance.

1.3.4. Drug management

1.3.4.1. The CME ensures that the handling and supply of medicines at the facility are in accordance with the requirements of the legislation in Hong Kong and prevailing guidelines promulgated by relevant regulatory authorities, including but not limited to the codes of professional conduct or discipline promulgated by the Medical Council of Hong Kong and the Dental Council of Hong Kong.

1.3.4.2. The facility provides drugs and biological products in a safe and effective manner to meet the needs of the patients and to adequately support the clinical services. The facility ensures proper vaccine storage and handling, with reference to the *Module on Immunisation* in the *Hong Kong Reference Framework for Preventive Care for Children in Primary Care Settings* (2019).

1.3.4.3. The CME ensures that there are written policies and procedures covering all aspects of medicine management, including but not limited to –

(a) ordering, procurement, receipt, storage, dispensing, labelling, administration, handling and disposal of medicines; and
(b) error and adverse incident reporting and management.

1.3.4.4. The CME keeps an up-to-date drug formulary. All medicines supplied are registered pharmaceutical products in Hong Kong. Drug procurement documents are kept appropriately for future reference and inspection.

1.3.4.5. All medicines are clearly labelled and stored appropriately. A system is in place to check the expiry dates of medicines. Expired medicines are not used for dispensing or administration and are disposed properly.

1.3.4.6. Medicines are dispensed under the supervision of a medical practitioner, dentist, or pharmacist. Staff responsible for dispensing and administering medicines have received appropriate training. A system is in place to monitor the accuracy of dispensing and administration of medicines.

1.3.5. Pathology and radiology support

1.3.5.1. The CME puts in place procedures for obtaining routine and emergency laboratory and radiology services to meet the needs of patient.

1.3.5.2. Where pathology or radiology service (including magnetic resonance imaging service) is provided in the facility, the requirements on equipment, service delivery and care process stipulated in the relevant chapters of the *Code of Practice for Private Hospitals*, where applicable, are complied with.

1.3.6. Special needs of paediatric patients

1.3.6.1. If the facility admits paediatric patients, the CME ensures that treatment is provided by persons who have appropriate qualifications, skills and experience in treating children. Resuscitation equipment and medication is made ready in accordance to the age of the patients.

1.3.7. Continuous quality improvement

1.3.7.1. The CME implements a system for reviewing the quality of services at appropriate intervals. Findings of the review are followed up to assure that effective corrective actions have been taken.

1.3.7.2. The CME ensures that policies and procedures relating to safe conduct of all

patient care activities are developed and implemented.

1.3.8. Patient safety incident reporting and learning system

1.3.8.1. The CME ensures that there is a written incident management and reporting system outlining the procedures to follow in the case of an incident or adverse event. The CME reviews all incident reports, documents the review, remedial and quality improvement measures taken, and disseminates the lesson learnt regarding the adverse event identified to all relevant staff. The CME also ensures all actions, including those instructed by the regulatory authority, are undertaken with documentation.

1.3.8.2. **Reportable events: sentinel events and serious untoward events**[2]

The CME ensures that any sentinel event or serious untoward event is reported to the Director of Health within 24 hours upon identification, and a full report is submitted to the Director of Health within 4 weeks. The reporting and management of incidents must comply with the *Guidance Notes for Reportable Sentinel Events and Serious Untoward Events of Day Procedure Centres Licensed under Private Healthcare Facilities Ordinance (Cap. 633)* promulgated by the Department of Health. Sentinel events and serious untoward events include:

Sentinel events

(a) Surgery/interventional procedure involving a wrong patient or body part;
(b) Retained instruments or other material after surgery/interventional procedure;
(c) Medication error resulting in major permanent loss of function or death;
(d) Intravascular gas embolism resulting in death or neurological damage; and
(e) Other adverse events resulting in permanent loss of function or death (excluding complications).

Serious untoward events

(a) Medication error which could have led to death or permanent harm or carries a significant public health risk; and
(b) Patient misidentification which could have led to death or permanent harm.

[2] As a transitional arrangement, the reporting requirements of sentinel events, serious untoward events and other reportable events will take effect from 1 July 2023.

1.3.8.3. **Other reportable events**[2]

The CME ensures that the following events are reported to the Director of Health upon identification:

(a) Unplanned transfer of a patient to a hospital directly from a day procedure centre during or after a planned procedure, which emergency management was required at the hospital; and

(b) Other events of public health significance (for example, radiation health incidents, or serious incidents, such as cessation of water or electricity supply, resulting in harm to patients who are receiving care in the facility).

1.3.9. Price information

1.3.9.1. Patients are informed of the charges of service whenever practicable. An up-to-date fee schedule covering all chargeable items are readily available for reference of patients at the admission or reception office, cashier, and where appropriate. If it is not possible to provide a fixed fee for a particular chargeable item, the fee could be presented in the form of a price range or could be marked to indicate that price information will be available upon request.

1.3.10. Complaint handling

1.3.10.1. The CME implements a mechanism for handling all complaints made by patients or persons representing the patient. The mechanism consists of procedures for receiving, managing, responding to the complainant, and documentation, with a specified time frame.

1.3.10.2. The CME ensures that patients and/or carers of patients are provided with information about the procedure for making complaints, and the process for managing and responding to any complaints.

1.3.10.3. If the Complaints Committee is considering a complaint, upon the request from the Complaints Committee, the CME provides any information or documents requested, in a timely manner, for concluding the case. The information provided to the Complaints Committee must be complete and accurate.

1.3.10.4. Upon request from the Complaints Committee, the CME ensures that investigation is conducted and the complainant is replied to. The CME

also ensures that reply and result of investigation are provided to the Complaints Committee within the stipulated timeframe.

1.3.10.5. The CME ensures that advice(s), if any, from the Complaints Committee on improvement measures are implemented.

1.3.11. Telemedicine

1.3.11.1. Telemedicine is the practice of medicine over a distance, in which interventions, diagnoses, therapeutic decisions, and subsequent treatment recommendations are based on patient data, documents and other information transmitted through telecommunication systems.

1.3.11.2. Where telemedicine is provided, there are policies and procedures in place to ensure overall standard of care delivered by telemedicine is not compromised as compared with in-person service.

1.3.11.3. All staff providing telemedicine service have the necessary qualification and competence. Staff and patients are able to identify each other in each encounter.

1.3.11.4. There are policies and procedures to safeguard privacy and security of data and records for telemedicine service.

1.3.12. Closure

1.3.12.1. If the licensee intends to cease operating the DPC before the licence expires, the licensee must make a request in writing to the Director of Health to cancel the licence. The licensee must make the request not less than 6 weeks before the intended date of cessation of operation.

1.3.12.2. The DPC must make proper arrangement where necessary for the patient affected to ensure the continuity of care given to them after its closure.

1.3.12.3. The DPC must follow the procedures as issued by the Department of Health for management of its closure.

1.4. Infection Control

1.4.1. Infection control policies and procedures

1.4.1.1. The CME ensures that there are written infection control policies, procedures, and guidance outlining the procedures to prevent or reduce the risk of a patient acquiring an infection while at the facility. Reference are made to guidelines promulgated by international or local health authorities (e.g. the Centre for Health Protection of the Department of Health).

1.4.1.2. The facility has an active infection control programme which includes measures to prevent, identify, and control infections.

1.4.1.3. Appropriate and adequate stocks of personal protective equipment are available for use by staff.

1.4.1.4. The CME reports to the Department of Health any unusual clustering of communicable diseases, in addition to the statutorily reportable infectious diseases stipulated in the *Prevention and Control of Disease Ordinance* (Cap. 599).

1.4.2. Cleaning, disinfection, and sterilisation of medical equipment

1.4.2.1. Reusable equipment and supplies used in operative or invasive procedure involving sterile tissue or vascular system are properly processed and rendered sterile by appropriate procedures of sterilisation. Sterile equipment and supplies are stored in a clean and dry area. There is a system for regular checking of expiry of sterile supplies.

1.4.2.2. There are written policies and procedures on the use of disposable equipment and on method of control to assure cleaning, disinfection and sterilisation of reusable equipment.

1.4.2.3. All sterilising equipment are regularly inspected and maintained with proper documentation. Relevant staff are appropriately trained in the use of the sterilising equipment.

1.4.3. Waste disposal

1.4.3.1. Clinical and chemical waste are handled properly and safely according to written policies and procedures promulgated by the Environmental

Protection Department pursuant to the *Waste Disposal Ordinance* (Cap. 354).

1.4.3.2. Radioactive waste is handled properly and safely according to the provisions of the *Radiation Ordinance* and the *Radioactive Substances Licence* issued by the Radiation Board in respect of the handling of the waste pursuant to the *Radiation Ordinance* (Cap. 303).

1.5. Resuscitation and Contingency

1.5.1. Risk management

1.5.1.1. The CME ensures that there is a written risk management policy and safety inspection procedures for the identification and assessment of risks and hazards in the facility and its services.

1.5.1.2. The CME ensures that there is a written emergency response policy outlining the procedures to be followed in the event of an emergency affecting the provision of services at the facility.

1.5.2. Resuscitation of patients

1.5.2.1. The CME ensures that there are written policies and procedures for resuscitation of patients and resuscitation facilities for emergencies. Resuscitation equipment are easily accessible and checked at regular interval. The CME ensures that there are sufficient staff who are trained for cardiopulmonary resuscitation on duty at all times. The facility carries out resuscitation drills regularly.

1.5.2.2. If the facility provides services to paediatric patients, there are resuscitation equipment and drugs appropriate for paediatric patients and staff with appropriate training and skills to perform the resuscitation.

1.5.3. Emergency transfer

1.5.3.1. There are written protocol in place for emergency transfer of patients to acute care hospitals when necessary.

1.5.3.2. Clinical records of sufficient content to ensure continuity of care should accompany the patient, but the preparation of records should not delay the transfer.

1.5.4. Fire safety and evacuation

1.5.4.1. The CME ensures that there are adequate precautions against the risk of fire.

1.5.4.2. The CME ensures that there is an internal fire and emergency response plan incorporating evacuation procedures. Fire evacuation exercise is conducted at regular intervals. Records of the drills are documented.

1.6. Healthcare Engineering Systems

1.6.1. Overview

1.6.1.1. Healthcare engineering systems, namely electrical installation, specialized ventilation system, and medical gas supplies, are essential systems for safe and effective delivery of medical services in healthcare facilities. Electrical installation serves to provide safe and reliable electrical supply and lighting to support the healthcare services therein. Specialized ventilation system is operated to achieve, in addition to human comfort, infection control and/or occupational safety purposes in healthcare environments. Medical gas pipeline systems are operated to ensure a safe and reliable provision of medical gases from the sources of supply to the clinical point-of-use.

1.6.1.2. The requirements of the design and installation of the healthcare engineering systems as specified in the CoP apply to new installations, existing installations, and additions and alterations to existing installations in the facility.[3]

1.6.2. Electrical installations

General requirements

1.6.2.1. The electrical installations of the facility are designed, installed, operated and maintained to provide safe and reliable electrical supply and lighting to support the healthcare services therein.

1.6.2.2. Fixed electrical installations comply with all relevant statutory requirements, including but not limited to those stipulated under the

[3] As a transitional arrangement, the requirements of the healthcare engineering systems as specified in section 1.6 will take effect from 1 January 2028.

following Ordinances and their subsidiary legislations and codes of practice:

(a) *Electricity Ordinance* (Cap. 406);
(b) *Buildings Ordinance* (Cap. 123);
(c) *Dangerous Goods Ordinance* (Cap. 295); and
(d) *Fire Services Ordinance* (Cap. 95).

1.6.2.3. A fixed electrical installation means a low or high voltage electrical installation that is fixed to premises but does not include any electrical equipment that is supplied with electricity after passing through a socket of the installation at which the supply can be disconnected without the use of a tool.

Design and installation

1.6.2.4. The electrical installations are designed and installed to meet the electrical demand of the facility.

1.6.2.5. The design and installation of the electrical installations in critical care areas meet internationally acceptable healthcare standards such as the *Health Technical Memorandum (HTM) 06-01* (2017 edition) - *Electrical services supply and distribution*, or equivalent.

1.6.2.6. Back-up power supply:

(a) Critical care areas are provided with back-up power supplies to ensure patient safety upon loss of the normal electrical power supplies. Back-up power supplies are available for the medical equipment for life support systems, recovering patients, and safe completion or cessation of surgical or high-risk procedures;
(b) Back-up power supplies for critical care area are provided by emergency generators and/or uninterruptible power supplies (UPS). The type, rating and back-up time of the back-up power supplies are selected to meet the back-up power requirements in accordance with the emergency response policy of the facility;
(c) Back-up power supplies connected to emergency generators are automatically available within 15 seconds upon loss of normal electrical power supply to the facility. The capacity of the emergency generators and the associated fuel supply systems is sufficient to support the essential services of the facility in accordance with its emergency response policy;
(d) Where back-up power supplies of critical medical equipment are

provided by emergency generator, a UPS system is also installed to ensure that there is continuous power supply to the critical medical equipment during the start-up time of an emergency generator;

(e) Back-up power supply connected to a UPS system is automatically available without break upon loss of normal electrical power supply to the supported services of the facility. A system of UPS and its batteries are sized with suitable back-up time for the services supported by them;

(f) A UPS system comprises safety features in accordance with the requirements of *BS EN IEC 62040-1*, or equivalent. The batteries of a UPS system are tested in accordance with the requirements of *BS EN 60896 Part 21* and *Part 22*, or equivalent;

(g) Operating lamps in operating rooms are supplied by UPS or built-in batteries with suitable back-up time for the clinical services; and

(h) All general lighting installations in critical care areas are provided with at least two different sources of supply, one of which is connected to back-up power supplies or secondary battery of light fitting to provide standby lighting. All points of standby lighting are capable of providing equal lumen output and distribution characteristics, giving equal intensity of light in all material directions at normal electricity supply.

1.6.2.7. In critical care areas, power supply continuity for life critical medical devices[4] is maintained in the event of a first fault to earth in the circuit by means of an isolated power supply (IPS). There is an alarm to alert clinical staff to a first fault to earth in a circuit.

1.6.2.8. The design and installation of the electrical installations for critical care areas are certified by a registered professional engineer in the electrical discipline or building services discipline under the *Engineers Registration Ordinance* (Cap. 409) to be in compliance with the CoP.

1.6.2.9. The fixed electrical installations of a facility are certified by a registered electrical worker/contractor to be in safe working order after completion of design and installation and before being energised for use in accordance with the *Electricity Ordinance* (Cap. 406) and its subsidiary legislations.

[4] Example of a life critical medical device is anaesthetic machine with ventilator for life support when general anaesthesia or major regional anaesthesia is performed.

Operation and maintenance

1.6.2.10. The electrical installations are properly operated and maintained, complying with all applicable statutory requirements, and taking into consideration of the guidance given in the manufacturers' recommendations and good trade practices.

1.6.2.11. Maintenance records are properly kept.

1.6.2.12. Back-up power supplies are maintained, inspected and tested regularly to ensure their proper functioning upon loss of the normal electrical power supply. Where the emergency generators and/or the UPS form part of the installations of the facility, on-load tests of emergency generators and discharge tests of batteries are scheduled and conducted effectively in coordination with the supported services.

1.6.2.13. The fixed electrical installations are inspected, tested and certified periodically by a registered electrical worker/contractor in accordance with the *Electricity Ordinance* (Cap. 406) and its subsidiary legislations.

1.6.3. Specialized ventilation systems

General requirements

1.6.3.1. The specialized ventilation systems are designed, installed, operated and maintained for purposes including but not limited to:
(a) the prevention of the spread of airborne infectious disease;
(b) the prevention and control of healthcare-associated infection; and
(c) the dilution and removal of contaminants and fumes where used.

1.6.3.2. Specialized ventilation systems comply with all relevant statutory requirements, including but not limited to those stipulated under the following Ordinances and their subsidiary legislations and codes of practice:
(a) *Buildings Ordinance* (Cap. 123);
(b) *Electricity Ordinance* (Cap. 406);
(c) *Fire Services Ordinance* (Cap. 95);
(d) *Building Energy Efficiency Ordinance* (Cap. 610); and
(e) *Public Health and Municipal Services Ordinance* (Cap. 132).

1.6.3.3. The relevant local guidance on ventilation, such as the *Recommendations on Prevention of Surgical Site Infection* and *Guide to Infection Control in*

Clinic Setting promulgated by the Centre for Health Protection of the Department of Health, are followed.

1.6.3.4. Where fresh water cooling towers are installed as part of the installations of the facility, the cooling towers comply with the requirements and guidelines in the *Fresh Water Cooling Towers Scheme* and *Code of Practice for Fresh Water Cooling Towers: Parts 1, 2 and 3* promulgated by the Electrical and Mechanical Services Department.

Design and installation

1.6.3.5. The design and installation of the specialized ventilation systems meet internationally acceptable healthcare standards such as *ANSI/ASHRAE/ASHE Standard 170-2021 – Ventilation of Health Care Facilities*, or *Health Technical Memorandum (HTM) 03-01* (2021 edition) – *Specialized ventilation for healthcare premises*, or equivalent.

1.6.3.6. Specialized ventilation systems provide appropriate pressure relationship, air change rate, filtration efficiency, temperature and relative humidity, and ensure air movement is generally from clean to less clean areas.

1.6.3.7. Operating rooms are ventilated according to the following specifications:

(a) ventilation design parameters;

Pressure Relationship to Adjacent Areas	**Minimum Outdoor ACH**	**Minimum Total ACH**	**Minimum Filter Efficiency**	**Design Temperature ºC**	**Design Relative Humidity %**
Positive (at least +2.5Pa)	4	20	MERV-16 or equivalent	20 - 24	20 - 60

Note: The minimum efficiency reporting value (MERV) is based on the testing method described in *ANSI/ASHRAE Standard 52.2*.

(b) recirculating devices with high-efficiency particulate air (HEPA) filters may be used to achieve the required room air changes per hour (ACH), provided the specified minimum outdoor ACH is supplied;

Note: HEPA filters are those filters that remove at least 99.97% of 0.3 micron sized particles at the rated flow in accordance with the testing methods of *IEST-RP-CC001.6*, or grade H13/H14 to *BS EN 1822*, or equivalent.

(c) air recirculated by means of room units is not used;

(d) each operating room has an individual temperature control;
(e) operating rooms are provided with a primary supply diffuser array to provide an air flow pattern over the patient and surgical team. The air flow is unidirectional and downwards; and
(f) the operating room is provided with at least two low sidewall return or exhaust grilles spaced at opposite corners or as far apart as possible.

1.6.3.8. The designed ventilation rate and pressure gradient in operating rooms are maintained by back-up power supply in the event of loss of normal electrical power supply. Where it is not feasible to maintain the designed ventilation rate and pressure gradient by back-up power supply, relevant operational protocol is established in the emergency response policy to ensure patient safety in that event.

1.6.3.9. Where outdoor air intakes are installed as part of the installations of the facility, the outdoor air intakes are situated away from any cooling towers, boiler flues, exhaust and vent discharges, and places where vehicle exhaust gases may be drawn in.

1.6.3.10. Where exhaust discharge outlets are installed as part of the installations of the facility, the exhaust discharge outlets are placed at a suitable location to minimise the recirculation of discharged air back into the building.

1.6.3.11. The design and installation of the specialized ventilation systems are certified by a registered professional engineer in the mechanical discipline or building services discipline under the *Engineers Registration Ordinance* (Cap. 409) to be in compliance with the CoP.

Operation and maintenance

1.6.3.12. The specialized ventilation systems are properly operated and maintained, complying with all applicable statutory requirements, and taking into consideration of the guidance given in internationally acceptable healthcare standards such as *ANSI/ASHRAE/ASHE Standard 170-2021, HTM 03-01* (2021 edition), or equivalent, the manufacturers' recommendations and good trade practices.

1.6.3.13. An ongoing routine maintenance of the specialized ventilation systems is in place to ensure proper functioning and adequate supply and exhaust of air in the designated areas of the facility. Documentation of repair and maintenance of the systems is kept.

1.6.3.14. Where fresh water cooling towers are installed as part of the installations of the facility, they are –

(a) maintained in a good and uncontaminated condition;

(b) monitored and controlled of their cooling water quality, including the presence of legionella and heterotrophic bacteria; and

(c) audited independently on their operation and maintenance every year.

1.6.3.15. Subject to infection control considerations, the specialized ventilation systems of the operating rooms may be set back or turned off during periods of non-use, provided that full ventilation is reinstated well in advance of the commencement of operation.

1.6.4. Medical gas supplies

General requirements

1.6.4.1. The manufacture, storage, supply and use of medical gases in the facility comply with all relevant statutory requirements, including but not limited to those stipulated under the following Ordinances and their subsidiary legislations and codes of practice:

(a) *Dangerous Goods Ordinance* (Cap. 295);

(b) *Fire Services Ordinance* (Cap. 95);

(c) *Electricity Ordinance* (Cap. 406); and

(d) *Boilers and Pressure Vessels Ordinance* (Cap. 56).

1.6.4.2. A person is appointed to assume overall management of medical gases. The relevant personnel is trained for safe supply, handling and use of medical gases.

1.6.4.3. An operational policy with emergency protocol in respect of medical gases (including medical gas leakage and contingency plan) is established in the facility and distributed to all personnel concerned.

1.6.4.4. The medical gases comply with prevailing specifications of the relevant gases as stated in the *Chinese Pharmacopoeia*, the *European Pharmacopoeia* or the *United States Pharmacopoeia*, where applicable, and are appropriate for medical use.

1.6.4.5. All personnel of the facility involved in the daily management and transport of medical gas cylinders or liquid gas containers have received training in the safe handling and storage of the gas cylinders and containers.

Operational management of medical gas supplies by compressed gas cylinders (CGCs) and liquefied gases in liquid gas containers (LGCs)

1.6.4.6. Medical gases supplied in CGCs and liquefied gases supplied in LGCs are procured from reputable sources.

1.6.4.7. The storage and use of medical gases and liquefied gases comply with the provisions of the *Dangerous Goods Ordinance* (Cap. 295) and its subsidiary regulations.

1.6.4.8. The use of naked flames either inside or in the vicinity of the storage area for medical gas or liquefied gas is prohibited. A notice to this effect in English and Chinese is conspicuously displayed inside and outside the storage area.

1.6.4.9. A system of regular checking of the expiry dates of each CGC in storage or in use is in place. Records of checking, order, return and receipt are kept.

1.6.4.10. The content of each CGC is identifiable by a specific colour code and label, and the content of each LGC is identifiable by a label.

1.6.4.11. A CGC identification colour chart is prominently displayed inside the storage area.

1.6.4.12. All reasonable precautions are taken to prevent tampering, and unauthorized access to CGCs and LGCs.

1.6.4.13. CGCs and LGCs are handled with care only by personnel who have been trained in cylinder or container handling.

1.6.4.14. A system of requisition and replacement of CGCs by clinical services with proper documentation is in place. CGCs that are no longer required for use, including empty and expired ones, have to be appropriately labelled and stored separately from ready-to-use CGCs, and returned to the supplier as soon as possible.

1.6.4.15. CGCs and LGCs are handled in accordance with the operating instructions with safety precautions available from the supplier.

Medical gas pipeline systems (MGPS)

1.6.4.16. The MGPS are designed, installed, operated and maintained to ensure a safe and reliable provision of medical gases in respect of quantity, identity, continuity and quality of supply to the nurses and clinical staff at the point-of-use.

Design and installation of MGPS

1.6.4.17. The design and installation of the MGPS meet internationally acceptable healthcare standards such as *Health Technical Memorandum (HTM) 02-01* (2006 edition) – *Medical gas pipeline systems*, or equivalent.

1.6.4.18. The capacities of the medical gas plants and manifolds are adequate to meet the gas demand.

1.6.4.19. All MGPS are provided with back-up sources of medical gas supply to ensure continuity and security of supply of medical gases during normal operation and contingent situations:

(a) all medical gas supplies comprise three sources of supply identified as "primary", "secondary" and "reserve" as defined in *HTM 02-01* (2006 edition), or equivalent;
(b) the supply systems are designed to achieve continuity of supply to the terminal units in normal conditions and in a single fault condition;
(c) types, capacities and locations of primary, secondary and reserve sources of supply are based on both system design parameters and the need for supply security;
(d) the continuity of medical gas supplies are maintained upon failure of the normal electrical power supply; and
(e) all medical air systems are supported by an appropriate, fully-automatic manifold.

1.6.4.20. MGPS plants and equipment are connected to the back-up power supply.

1.6.4.21. Terminal units are installed in various clinical areas to properly provide for the medical treatment processes therein. The pipeline distribution system is designed to deliver medical gases from the source of supply to the terminal units at the required flow rates and pressure.

(a) According to the type of medical gases to be supplied, the pipeline systems are designed in accordance with internationally acceptable

healthcare standards such as *HTM 02-01* (2006 edition), or equivalent, to ensure that the gas flows are adequate at each terminal unit.

(b) The design of the pipework system is based on the diversified flows and the permissible pressure loss from the source of supply to, and including, the terminal unit. The pipe sizes are selected to ensure that the pressure loss is below 5% of the nominal pipeline pressure.

1.6.4.22. Gas-specific connections, including terminal units, connectors, etc., are used throughout the pipeline systems.

1.6.4.23. A warning and alarm system is installed to monitor the safe and efficient operation of the MGPS. It serves to indicate the normal function of the MGPS, alert when routine replacement of cylinders or other engineering action(s) is required, and warn against abnormal conditions.

1.6.4.24. Testing and commissioning are conducted for new installations of MGPS, and additions or alterations to existing installations, to ensure that all the necessary safety and performance requirements of the MGPS are met. The tests and methods required are in accordance with *HTM 02-01* (2006 edition), or equivalent.

(a) The following tests and checks are carried out after installation of the MGPS is completed:

(i) tests for leakage on each MGPS;

(ii) tests of area valve service units (AVSUs) for closure, correct service and control of the terminal units in the zone: checks for correct labelling of AVSUs for zone reference, identity of terminal units controlled and indication of flow direction;

(iii) tests of line valve assemblies for closure and identification;

(iv) tests for cross-connection, flow, pressure drop, mechanical function and correct identity of the terminal units: checks for correct labelling and association with AVSUs;

(v) tests for mechanical function and identity of non-interchangeable screw thread connectors;

(vi) performance tests of the pipeline system;

(vii) functional tests of all supply systems;

(viii) checks of safety valve certification;

(ix) tests of warning systems;

(x) tests for particulate contamination/odour/taste; and

(xi) tests for anaesthetic gas scavenging disposal systems (if installed).

(b) The following tests are carried out after purging and filling with the working gas:
    (i) tests for particulate contamination;
    (ii) tests for gas identity; and
    (iii) tests for gas quality.

1.6.4.25. The initial pressure test on MGPS complies with Fire Services Department DG/TS/143(A) – *Requirements for Initial Pressure-testing of Medical Gas Piped Installation* where applicable.

1.6.4.26. The design and installation of the MGPS are certified by a registered professional engineer in the mechanical discipline or building services discipline under the *Engineers Registration Ordinance* (Cap. 409) to be in compliance with the CoP.

Operation and maintenance of MGPS

1.6.4.27. The MGPS are properly operated and maintained, complying with all applicable statutory requirements, and taking into consideration of the guidance given in internationally acceptable healthcare standards such as *HTM 02-01* (2006 edition), or equivalent, the manufacturers' recommendations and good trade practices.

1.6.4.28. An authorized person is appointed in writing by the CME of the facility for supervising the maintenance, repair and alteration work of the MGPS. The authorized person has received specialist training on MGPS, meeting the requirements of *HTM 02-01* (2006 edition), or equivalent.

1.6.4.29. All works on the existing MGPS of the facility are governed by a safety management system, such as a permit-to-work system as set out in *HTM 02-01* (2006 edition), or equivalent, to safeguard the integrity of the MGPS and hence patient safety, under the supervision of the authorized person. All work procedures and test records are documented. (A sample Permit-to-Work Form is provided in Annex IV.)

1.6.4.30. The MGPS are subject to a planned preventive maintenance schedule under the responsibility of the authorized person of the facility. Appropriate planned preventive maintenance works on the MGPS are conducted at regular intervals.

1.6.4.31. All engineering and facility management staff have received proper training

before operation and maintenance of the MGPS.

1.6.4.32. Annual inspection is conducted on the MGPS in accordance with Fire Services Department DG/TS/144(A) – *Requirement for Annual Inspection of Medical Gas Piped Installation* where applicable.

1.6.4.33. The facility has an emergency call-out service arrangement in place with a specialist contractor in MGPS to provide prompt onsite support in the event of any breakdown or other incidents related to MGPS.

Chapter 2
Surgical Procedure

2.1. Management/Governance

2.1.1. Staff requirement and training

2.1.1.1. An appropriate number of suitably qualified and experienced staff are in attendance during each surgical procedure.

2.1.1.2. Staff have received adequate training before assisting in new surgical procedures.

2.1.1.3. The CME develops and implements a policy to determine the scope of surgical procedures that may be performed in the facility with reference to the guidelines promulgated by the Hong Kong Academy of Medicine and/or its Colleges and taking into account of the following factors:

(a) risk of surgical infections;
(b) necessity to quickly and safely convert to an open surgical procedure due to complications or technical difficulties; and
(c) physical design, staffing and equipment resources of the facility.

2.1.1.4. For a facility equipped with operating room, a registered nurse who has relevant experience or training is assigned to oversee the day to day operation of the operating room.[5] A specialist may assume the role of overseeing the day to day operation of the operating room if he/she has the relevant experience or training.

2.2. Physical Conditions

2.2.1. Facility management

2.2.1.1. Doorways and corridors enable transfer of patients on wheelchair or stretchers.

[5] As a transitional arrangement, an experienced enrolled nurse overseeing the day to day operation of the operating room of an existing DPC may continue to assume such role under the supervision of a medical practitioner or a dentist. The DPC seeking to obtain a full licence under a statutory licensing system shall fully meet clause 2.1.1.4.

2.2.1.2. The following functional areas in a facility are separate:

(a) reception and waiting area;
(b) perioperative or procedural area;
(c) area for equipment reprocessing; and
(d) dirty utility room.

2.2.1.3. There is access control to pre-operative area, areas for conducting procedure and postoperative care area.

2.2.1.4. In a facility where procedures under deep sedation[6], general anaesthesia or major regional anaesthesia are performed, doorways within the relevant perioperative or procedural area permit transfer of patient on trolleys or stretchers with attachment.

2.2.1.5. The clinical areas have immediate access to hand-washing facilities.

2.2.2. Operative/procedural area

2.2.2.1. Surgical procedures are performed in a location that is spacious enough to accommodate all personnel, fittings and equipment required for the procedure without contamination and to allow the procedure and resuscitation to be carried out effectively.

2.2.2.2. The lighting is adequate for the procedure undertaken.

2.2.2.3. For a facility equipped with operating room,-

(a) each operating room is suitably designed, equipped and maintained for the purpose it is to be used;
(b) the operating room is maintained at acceptable level of sterility;
(c) the ceiling, walls and floors are made from materials that can be easily cleaned and disinfected as needed to meet infection control requirements;
(d) the operating room is equipped with specialized ventilation system of internationally acceptable standards of air quality, including but not limited to adequate number of fresh air exchange per hour, to prevent the spread of airborne infectious disease and to minimise surgical site infection;
(e) the ventilation system of the operating room is regularly inspected and

[6] The definition of "deep sedation" should refer to the *Guidelines on Procedural Sedation* (2020) promulgated by the Hong Kong Academy of Medicine.

maintained to ensure effective functioning for patient and staff safety. Documentation of repair and maintenance of the systems is kept; and

(f) adequate area for scrub and gowning is provided for operating room.

2.2.2.4. Where gaseous anaesthetic agents are used, appropriate gas administration devices and exhaust systems are in place, and relevant requirements on occupational safety should be observed.

2.2.3. Equipment reprocessing area and sterile stores

2.2.3.1. A one-way dirty to clean traffic flow is designated in the equipment reprocessing area to prevent contamination.

2.2.4. Equipment and store

2.2.4.1. The facility has the necessary equipment for supporting its scope of surgical services, including but not limited to:

(a) tilting table, trolley or chair that accommodates the procedures performed and provides for adequate range of movement for anaesthetic procedures;

(b) suitable devices for administering anaesthesia;

(c) surgical instruments;

(d) monitoring and resuscitation equipment; and

(e) any other special equipment required for a particular surgery to be performed.

2.2.4.2. There are adequate facilities and space for the collection and storage of specimens.

2.2.4.3. The facility is equipped with devices for monitoring vital signs of patients, such as blood pressure and oxygen saturation.

2.2.4.4. In a facility where procedures under sedation are performed, there are sufficient equipment for monitoring of patient in accordance with the *Guidelines on Procedural Sedation* (2020) promulgated by the Hong Kong Academy of Medicine.

2.2.4.5. In a facility where procedures under general anaesthesia or major regional anaesthesia are performed, there are sufficient equipment for monitoring of patient in accordance with the *Guidelines on Monitoring in Anaesthesia* (v5, 2017) promulgated by the Hong Kong College of Anaesthesiologists.

2.3. Service Delivery and Care Process

2.3.1. General

2.3.1.1. The CME ensures that written policies and procedures relating to the safe provision of surgical procedures and anaesthesia in the facility, including but not limited to the following, are in place and implemented:

(a) staffing arrangements for surgical procedures and anaesthesia;
(b) informed consent;
(c) pre-procedural assessment;
(d) pre-procedural instructions (e.g. fasting, medication) and care;
(e) documentation of procedures;
(f) patient discharge and care after discharge; and
(g) arrangement for post-operative complications (e.g. arrangement for inpatient care).

2.3.1.2. In developing policies and procedures in relation to high-risk anaesthetic procedures, reference is taken from relevant guidelines promulgated by the Hong Kong Academy of Medicine and the Hong Kong College of Anaesthesiologists.

2.3.2. Pre-procedure

2.3.2.1. Patients receiving surgical procedures are provided with information on the procedure and anaesthesia, including but not limited to the indication of the procedure, treatment alternative(s), the likely outcomes and risk of complications, before giving consent. Informed consent is documented in the medical record and/or in signed consent form.

2.3.2.2. Pre-procedural assessment is conducted by a medical practitioner. For patient undergoing procedure under sedation, there is a pre-sedation assessment in accordance to the *Guidelines on Procedural Sedation* (2020) promulgated by the Hong Kong Academy of Medicine. For patients undergoing general anaesthesia or major regional anaesthesia, the pre-anaesthetic assessment is in accordance with the *Guidelines on the Pre-anaesthetic Consultation* (v3, 2019) promulgated by the Hong Kong College of Anaesthesiologists. When it is not possible for the pre-sedation or pre-anaesthetic assessment to be done by the same medical practitioner who is responsible for the sedation or anaesthesia, there is an adequate documented mechanism for conveying findings of the consultation to the medical

practitioner performing the sedation or anaesthesia. The final assessment by the medical practitioner for performing the sedation or anaesthesia is documented.

2.3.2.3. Pre-procedural assessment includes, but is not limited to:

(a) history and physical examination;
(b) all current medications;
(c) allergies;
(d) relevant investigations and consultation(s) with other specialty if any; and
(e) fitness for the procedure and the sedation or anaesthesia to be performed.

2.3.2.4. Patients are given adequate instructions for pre-procedural preparation (e.g. fasting), and post-operative care and discharge (e.g. a responsible adult to escort and care for patient after sedation or anaesthesia).

2.3.2.5. The CME ensures that there are written policies and procedures on the following processes before surgical procedures:

(a) checking of consent forms;
(b) verification processes, including time-out, to ensure correct patient, surgical site, and procedure; and
(c) accomplishment of pre-operative preparation (e.g. fasting, pre-medication).

2.3.3. Intra-procedure

2.3.3.1. All general anaesthesia, neuroaxial block or major plexus block are administered only by an anaesthesiologist or by a trained medical practitioner under the supervision of an anaesthesiologist.

2.3.3.2. Staffing arrangements and monitoring of patients undergoing procedural sedation are in accordance with the *Guidelines on Procedural Sedation* (2020) promulgated by the Hong Kong Academy of Medicine.[7]

[7] In addition to the healthcare staff named by the *Guidelines on Procedural Sedation*, clinical assistants with relevant training or qualification in monitoring vital signs of patient undergoing sedation and procedural complications may also assume the role of such monitoring for patients undergoing procedural sedation, under the following conditions:

(a) holds a valid Basic Life Support (BLS) certificate; and
(b) works under the direct supervision of medical practitioner or dentist who retain personal responsibility for the monitoring.

2.3.3.3. In addition to 2.3.3.1, care process, staffing arrangement, and monitoring of patients undergoing general anaesthesia or major regional anaesthesia, and the documentation of the anaesthetic care are in accordance with the *Guidelines on Monitoring in Anaesthesia* (v5, 2017) promulgated by the Hong Kong College of Anaesthesiologists.

2.3.3.4. There are written policies and procedures on the counting of items used during the procedures, such as swabs, needles, blades, and other operative instruments and supplies, and what to do if items cannot be accounted for.

2.3.4. Post-procedure

2.3.4.1. A medical practitioner or registered nurse trained in post-anaesthetic care is in-charge of the operation of the recovery area. Staff working in the recovery area must be trained for their roles.

2.3.4.2. All patients after surgical procedures are observed for an adequate length of time commensurate with the anaesthesia given and the surgical procedure performed, and their fitness for discharge are determined by the medical practitioner in-charge of the patient, subject to 2.3.4.3.

2.3.4.3. Recovery of patients who have received sedation should be in accordance with *Guidelines on Procedural Sedation* (2020) promulgated by the Hong Kong Academy of Medicine or relevant guidelines promulgated by the Hong Kong College of Anaesthesiologists. Recovery of patients who have received general anaesthesia or major regional anaesthesia takes place in an area that is adequately equipped and staffed for post-anaesthetic care, in accordance with *Guidelines on Postanaesthetic Recovery Care* (v5, 2019) promulgated by the Hong Kong College of Anaesthesiologists.

2.3.4.4. The anaesthesiologist or the medical practitioner administering the sedation or anaesthesia, unless he/she has delegated another medical practitioner to take up the role, is responsible for supervising the recovery of the patient from sedation or anaesthesia. Medical or nursing staff trained in the post-anaesthetic care must be present at all times when a patient is in recovery and is/are able to promptly reach the supervising medical staff when need arises.

2.3.4.5. Monitoring of patients recovering from procedural sedation is in accordance with the *Guidelines on Procedural Sedation* (2020) promulgated by the Hong Kong Academy of Medicine.

2.3.4.6. Monitoring of patients recovering from general anaesthesia or major regional anaesthesia is in accordance with the *Guidelines on Postanaesthetic Recovery Care* (v5, 2019) promulgated by the Hong Kong College of Anaesthesiologists.

2.3.4.7. There are written policies and procedures for discharge of patients after procedures under sedation or anaesthesia, including but not limited to:
(a) discharge criteria;
(b) discharge instructions and advice (e.g. medication, care of post-operative site, complications, refraining from certain activities); and
(c) arrangements for enquiries or assistance outside operating hours.

2.3.4.8. For a patient who has received general anaesthesia, major regional anaesthesia or deep sedation, there is a responsible adult to escort him/her home.

2.3.4.9. There is written protocol on transfer of patients to hospital for those patients who are not fit to be discharged home after the procedure or sedation or anaesthesia.

2.3.5. Medical records

2.3.5.1. The following records are kept:
(a) detailed procedure or operation records of all procedures performed;
(b) investigation reports;
(c) consent forms;
(d) anaesthetic records;
(e) records of post-operative care and pre-discharge evaluation;
(f) pathology report, if specimen of body tissue or fluid was taken and sent for pathology; and
(g) outcome of the procedure.

2.3.5.2. Procedure or operation records include, but are not limited to:
(a) name(s) of the medical practitioner(s) performing the procedure and the assistant(s), if any;
(b) date, time, operation diagnosis, start and end time of the procedure, anaesthesia and sedation method, name, details of the procedure, surgical findings, and any tissue removed and/or sent for pathology;
(c) record of the name, dose, time, and route of administration of all medications and fluids given for the operation; and

(d) blood and other fluid losses of the patient at the conclusion of the surgery.

2.3.5.3. Without limiting 2.3.5.4 and 2.3.5.5, anaesthetic records include but are not limited to:

(a) name(s) of the medical practitioner(s) administering the anaesthesia; and

(b) the name, dose, route of administration of all anaesthetic drugs given.

2.3.5.4. For procedures under general anaesthesia or major regional anaesthesia, records of anaesthetic care are in accordance with the *Guidelines on Minimum Requirements for an Anaesthetic Record* (v4, 2017) promulgated by the Hong Kong College of Anaesthesiologists.

2.3.5.5. For procedures under sedation, records of anaesthetic care are in accordance with the *Guidelines on Procedural Sedation* (2020) promulgated by the Hong Kong Academy of Medicine.

2.3.6. Continuous quality improvement

2.3.6.1. The CME develops and implements policies and procedures to review the appropriateness of patient care, and monitoring of clinical performance and outcomes (e.g. surgical site infection, emergency transfer, unanticipated hospital admission).

2.4. Infection Control

2.4.1. Infection control policies and procedures

2.4.1.1. There are written infection control policies, procedures, and guidelines for prevention of surgical infection, including but not limited to:

(a) standard precautions;

(b) use of aseptic techniques;

(c) environmental cleansing and disinfection;

(d) cleaning, disinfection and sterilisation, and storage of surgical and/or anaesthetic equipment; and

(e) monitoring of effectiveness of infection control measures.

Reference is taken from guidelines promulgated by relevant health and professional authorities (e.g. *Recommendations on Prevention of Surgical*

Site Infection promulgated by the Centre for Health Protection of the Department of Health; *Guidelines on Infection Control in Anaesthesia* promulgated by the Hong Kong College of Anaesthesiologists).

2.5. Resuscitation and Contingency

2.5.1. Risk management

2.5.1.1. There are staff-to-staff communication systems for emergency in the operating/procedure room and recovery area.

2.5.1.2. There are patient-to-staff call systems or devices (e.g. call bells) where a patient may be left alone temporarily (e.g. patient changing room in the facility).

2.5.2. Resuscitation of patients

2.5.2.1. There are adequate and appropriate resuscitation equipment including but not limited to:

(a) device that can ventilate the lungs;
(b) oxygen supply;
(c) suction;
(d) basic intravenous setup; and
(e) defibrillator.

2.5.2.2. In a facility where procedural sedation is conducted, resuscitation equipment and emergency medications as required in the *Guidelines on Procedural Sedation* (2020), promulgated by the Hong Kong Academy of Medicine, are in place. Regular checks on their viability are conducted and documented.

2.5.2.3. In a facility where general anaesthesia or major regional anaesthesia is performed, resuscitation equipment as required in the *Recommended Minimum Facilities for Safe Anaesthetic Practice in Operating Suites* (v4, 2016), promulgated by the Hong Kong College of Anaesthesiologists, are in place.[8] Selection of medications to deal with emergency arising from anaesthesia shall be in consultation with an anaesthesiologist. Regular checks on their viability are conducted and documented.

[8] As a transitional arrangement, the requirement for operating room to have oxygen supply through oxygen pipe (with at least two outlets) for general anaesthesia or major regional anaesthesia must be complied with by 2022.

2.5.2.4. Emergency medications are stored in a designated and easily accessible area in the facility.

2.5.3. Emergency transfer

2.5.3.1. If the patient requires emergency transfer to a hospital, the anaesthesiologist and/or the surgeon is/are responsible for the care of the patient until the patient has been transferred to another appropriate medical staff.

2.5.3.2. There are policies and procedures in place for emergency transfer of patient to hospital for management of urgent adverse outcome.

2.5.3.3. Drills for emergency transfer are conducted at regular intervals and documented.

Chapter 3
Endoscopic Procedure

3.1. Management/Governance

3.1.1. Staff requirement and training

3.1.1.1. An appropriate number of suitably qualified and experienced staff are in attendance during each endoscopic procedure.

3.1.1.2. Staff have received adequate training before assisting in endoscopic procedures.

3.1.1.3. The CME develops and implements a policy to determine the scope of endoscopic procedures that may be performed in the facility with reference to the guidelines promulgated by the Hong Kong Academy of Medicine and/or its Colleges and taking into account of the following factors:
(a) risk of surgical infections;
(b) necessity to quickly and safely convert to an open surgical procedure due to complications or technical difficulties; and
(c) physical design, staffing and equipment resources of the facility.

3.2. Physical Conditions

3.2.1. Facility management

3.2.1.1. Doorways and corridors enable transfer of patients on wheelchair or stretchers.

3.2.1.2. The following functional areas in a facility are separate:
(a) reception and waiting area;
(b) perioperative or procedural area;
(c) area for equipment reprocessing; and
(d) dirty utility room.

3.2.1.3. There is access control to procedural area and recovery area, if applicable.

3.2.1.4. In a facility where procedures under deep sedation[9], general anaesthesia or major regional anaesthesia are performed, doorways within the relevant peri-operative/procedural area permit transfer of patient on trolleys or stretchers with attachment.

3.2.1.5. The clinical areas have immediate access to hand-washing facilities.

3.2.2. Procedural area

3.2.2.1. The procedure room shall be spacious enough to accommodate all personnel, fittings and equipment and to allow all procedures and resuscitation to be carried out effectively.

3.2.2.2. The lighting is adequate for the procedure undertaken.

3.2.2.3. The procedure room is suitably designed, equipped and maintained for the purpose it is to be used. The procedure room is maintained at acceptable level of cleanliness. The ceiling, walls and floors are made from materials that can be easily cleaned and disinfected as needed to meet infection control requirements.

3.2.2.4. Where gaseous anaesthetic agents are used, appropriate gas administration devices and exhaust systems are in place, and relevant requirements on occupational safety are observed.

3.2.2.5. Adequate area for scrub and gowning is provided in procedural area where applicable.

3.2.3. Equipment reprocessing area and sterile stores

3.2.3.1. A one-way dirty to clean traffic flow is designated in the equipment reprocessing area to prevent contamination.

3.2.4. Equipment and store

3.2.4.1. The facility has the necessary equipment for supporting its scope of endoscopic services, including but not limited to:

(a) tilting table, trolley or chair that accommodates the procedures performed and provides for adequate range of movement for anaesthetic

[9] The definition of "deep sedation" should refer to the *Guidelines on Procedural Sedation* (2020) promulgated by the Hong Kong Academy of Medicine.

procedures;

(b) suitable devices for administering anaesthesia;
(c) endoscopic instruments;
(d) monitoring and resuscitation equipment; and
(e) any other special equipment required for a particular endoscopic procedure to be performed.

3.2.4.2. There are adequate facilities and space for the collection and storage of specimens.

3.2.4.3. The facility is equipped with devices for monitoring vital signs of patients, such as blood pressure and oxygen saturation.

3.2.4.4. In a facility where procedures under sedation are performed, there are sufficient equipment for monitoring of patient in accordance with the *Guidelines on Procedural Sedation* (2020) promulgated by the Hong Kong Academy of Medicine.

3.2.4.5. In a facility where procedures under general anaesthesia or major regional anaesthesia are performed, there are sufficient equipment for monitoring of patient in accordance with the *Guidelines on Monitoring in Anaesthesia* (v5, 2017) promulgated by the Hong Kong College of Anaesthesiologists.

3.3. Service Delivery and Care Process

3.3.1. General

3.3.1.1. The CME ensures that written policies and procedures relating to the safe provision of endoscopic procedures and anaesthesia in the facility, including but not limited to the following, are in place and implemented:

(a) staffing arrangements for endoscopic procedures and anaesthesia;
(b) informed consent;
(c) pre-procedural assessment;
(d) pre-procedural instructions (e.g. fasting, medication) and care;
(e) documentation of procedures;
(f) patient discharge and care after discharge; and
(g) arrangement for post-procedural complications (e.g. arrangement for inpatient care).

3.3.1.2. In developing policies and procedures in relation to high-risk anaesthetic procedures, reference is taken from relevant guidelines promulgated by the Hong Kong Academy of Medicine and the Hong Kong College of Anaesthesiologists.

3.3.2. Pre-procedure

3.3.2.1. Patients receiving endoscopic procedures are provided with information on the procedure and anaesthesia, including but not limited to the indication of the procedure, treatment alternative(s), the likely outcomes and risk of complications, before giving consent. Informed consent is documented in the medical record and/or in signed consent form.

3.3.2.2. Pre-procedural assessment is conducted by a medical practitioner. For patient undergoing procedure under sedation, there is a pre-sedation assessment in accordance with the *Guidelines on Procedural Sedation* (2020) promulgated by the Hong Kong Academy of Medicine. For patient undergoing general anaesthesia or major regional anaesthesia, the pre-anaesthetic assessment is in accordance with the *Guidelines on the Pre-anaesthetic Consultation* (v3, 2019) promulgated by the Hong Kong College of Anaesthesiologists. When it is not possible for the pre-sedation or pre-anaesthetic assessment to be done by the same medical practitioner who is responsible for the sedation or anaesthesia, there is an adequate documented mechanism for conveying findings of the consultation to the medical practitioner performing the sedation or anaesthesia. The final assessment by the medical practitioner for performing the sedation or anaesthesia is documented.

3.3.2.3. Pre-procedural assessment includes, but is not limited to:

(a) history and physical examination;
(b) all current medications;
(c) allergies;
(d) relevant investigations and consultation(s) with other specialty if any; and
(e) fitness for the procedure and the sedation or anaesthesia to be performed.

3.3.2.4. Patients are given adequate instructions for pre-procedural preparation (e.g. fasting), and post-procedural care and discharge (e.g. a responsible adult to escort and care for patient after sedation or anaesthesia).

3.3.2.5. The CME ensures that there are written policies and procedures on the following processes before endoscopic procedures:
(a) checking of consent forms;
(b) verification processes, including time-out, to ensure correct patient, endoscopic procedure and site if applicable; and
(c) accomplishment of pre-procedural preparation (e.g. bowel preparation, pre-medication).

3.3.3. Intra-procedure

3.3.3.1. All general anaesthesia, neuroaxial block or major plexus block are administered only by an anaesthesiologist or by a trained medical practitioner under the supervision of an anaesthesiologist.

3.3.3.2. Staffing arrangements and monitoring of patients undergoing procedural sedation are in accordance with the *Guidelines on Procedural Sedation* (2020) promulgated by the Hong Kong Academy of Medicine.[10]

3.3.3.3. In addition to 3.3.3.1, care process, staffing arrangement and monitoring of patients undergoing general anaesthesia or major regional anaesthesia and the documentation of the anaesthetic care are in accordance with the *Guidelines on Monitoring in Anaesthesia* (v5, 2017) promulgated by the Hong Kong College of Anaesthesiologists.

3.3.3.4. For endoscopic procedures not involving any sedation and anaesthesia (except local anaesthesia), there is at least one personnel with relevant training or experience, and who is fully conversant with the equipment used, in each procedure room to assist in the endoscopic procedures.

3.3.3.5. There are written policies and procedures on the counting of items used during the procedures and what to do if items cannot be accounted for.

3.3.4. Post-procedure

3.3.4.1. All patients after endoscopic procedures are observed for an adequate length

[10] In addition to the healthcare staff named by the *Guidelines on Procedural Sedation*, clinical assistants with relevant training or qualification in monitoring vital signs of patient undergoing sedation and procedural complications may also assume the role of such monitoring for patients undergoing procedural sedation, under the following conditions:
(a) holds a valid Basic Life Support (BLS) certificate; and
(b) works under the direct supervision of medical practitioner or dentist who retain personal responsibility for the monitoring.

of time commensurate with the endoscopic procedure performed and the sedation or anaesthesia given, if any, and their fitness for discharge are determined by the medical practitioner in-charge of the patient, subject to 3.3.4.2.

3.3.4.2. Recovery of patients who have received sedation should be in accordance with *Guidelines on Procedural Sedation* (2020) promulgated by the Hong Kong Academy of Medicine or relevant guidelines promulgated by the Hong Kong College of Anaesthesiologists. Recovery of patients who have received general anaesthesia or major regional anaesthesia takes place in an area that is adequately equipped and staffed for post-anaesthetic care, in accordance with *Guidelines on Postanaesthetic Recovery Care* (v5, 2019) promulgated by the Hong Kong College of Anaesthesiologists.

3.3.4.3. A medical practitioner or registered nurse trained in post-anaesthetic care is in-charge of the operation of the recovery area. Staff working in the recovery area must be trained for their roles.

3.3.4.4. The anaesthesiologist or the medical practitioner administering the sedation or anaesthesia, unless he/she has delegated another medical practitioner to take up the role, is responsible for supervising the recovery of the patient from sedation or anaesthesia. Medical or nursing staff trained in the post-anaesthetic care must be present at all times when a patient is in recovery and is/are able to promptly reach the supervising medical staff when need arises.

3.3.4.5. Monitoring of patients recovering from procedural sedation is in accordance with the *Guidelines on Procedural Sedation* (2020) promulgated by the Hong Kong Academy of Medicine.

3.3.4.6. Monitoring of patients recovering from general anaesthesia or major regional anaesthesia is in accordance with the *Guidelines on Postanaesthetic Recovery Care* (v5, 2019) promulgated by the Hong Kong College of Anaesthesiologists.

3.3.4.7. There are written policies and procedures for discharge of patients after procedures under sedation or anaesthesia, including but not limited to:

(a) discharge criteria;
(b) discharge instructions and advice (e.g. medication, post-procedural care, complications, refraining from certain activities); and
(c) arrangements for enquiries or assistance outside operating hours.

3.3.4.8. For a patient who has received general anaesthesia, major regional anaesthesia or deep sedation, there is a responsible adult to escort him/her home.

3.3.4.9. There is written protocol on transfer of patients to hospital for those patients who are not fit to be discharged home after the procedure or sedation or anaesthesia.

3.3.5. Medical records

3.3.5.1. The following records are kept:

(a) detailed procedure or operation records of all procedures performed;
(b) investigation reports;
(c) consent forms;
(d) anaesthetic records;
(e) records of post-procedural care and pre-discharge evaluation;
(f) pathology report, if specimen of body tissue or fluid was taken and sent for pathology; and
(g) outcome of the procedure.

3.3.5.2. Procedure records include, but are not limited to:

(a) name(s) of the medical practitioner(s) performing the procedure and the assistant(s), if any;
(b) date, time, operation diagnosis, start time and end time of the procedure, anaesthesia and sedation method, name, details of the procedure, surgical findings, and any tissue removed and/or sent for pathology;
(c) record of the name, dose, time and route of administration of all medications and fluids given for the procedure; and
(d) blood and other fluid losses of the patient at the conclusion of the procedure, if applicable.

3.3.5.3. Without limiting 3.3.5.4 and 3.3.5.5, anaesthetic records include but are not limited to:

(a) name(s) of the medical practitioner(s) administering the anaesthesia; and
(b) the name, dose, route of administration of all anaesthetic drugs given.

3.3.5.4. For procedures under general anaesthesia or major regional anaesthesia, records of anaesthetic care are in accordance with the *Guidelines on Minimum Requirements for an Anaesthetic Record* (v4, 2017) promulgated

by the Hong Kong College of Anaesthesiologists.

3.3.5.5. For procedures under sedation, records of anaesthetic care are in accordance with the *Guidelines on Procedural Sedation* (2020) promulgated by the Hong Kong Academy of Medicine.

3.3.6. Continuous quality improvement

3.3.6.1. The CME develops and implements policies and procedures to review the appropriateness of patient care and monitoring of clinical performance and outcomes (e.g. complication, emergency transfer, unanticipated hospital admission).

3.4. Infection Control

3.4.1. Infection control policies and procedures

3.4.1.1. There are written infection control policies, procedures and guidelines for prevention of surgical infection, including but not limited to:

(a) standard precautions;
(b) use of aseptic techniques;
(c) environmental cleansing and disinfection;
(d) cleaning, disinfection and sterilisation, and storage of endoscopic and/or anaesthetic equipment; and
(e) monitoring of effectiveness of infection control measures.

Reference is taken from guidelines promulgated by relevant health and professional authorities (e.g. *Recommendations on Prevention of Surgical Site Infection* promulgated by the Centre for Health Protection of the Department of Health; *Guidelines on Infection Control in Anaesthesia* promulgated by the Hong Kong College of Anaesthesiologists).

3.4.2. Reprocessing of endoscopes

3.4.2.1. Disinfection or sterilisation of endoscopes is performed according to manufacturer's instructions.

3.4.2.2. Endoscopes and accessories (including all channels and valves) are thoroughly cleaned.

3.4.2.3. Endoscopes, accessories and goggles are disinfected by a high level disinfectant. Where applicable, endoscopes and accessories are sterilised according to manufacturer's instructions.

3.4.2.4. Endoscopes are rinsed thoroughly until it is free from disinfectant and according to manufacturer's instructions. Rinsing is performed prior to forced air drying or storage.

3.4.2.5. There is a system to regularly monitor the effectiveness of disinfection of endoscopes and accessories with documentation.

3.4.2.6. Endoscopes are stored hanging in a dry and well-ventilated area with valve and channel caps removed. If endoscopes are stored horizontally, there is alarm-monitored continuous air flow through each channel. Reprocessing is performed once the maximum allowable storage time has passed.

3.4.2.7. In reprocessing of endoscopes, reference is taken from occupational health and safety guidelines promulgated by the Labour Department (e.g. *Chemical Safety in the Workplace – Guidance Notes on Safe Use of Chemical Disinfectants*).

3.5. Resuscitation and Contingency

3.5.1. Risk management

3.5.1.1. There are staff-to-staff communication systems for emergency in the procedure room and recovery area.

3.5.1.2. There are patient-to-staff call systems or devices (e.g. call bells) where a patient may be left alone temporarily (e.g. patient changing room in the facility).

3.5.2. Resuscitation of patients

3.5.2.1. There are adequate and appropriate resuscitation equipment including but not limited to:

(a) device that can ventilate the lungs;
(b) oxygen supply;
(c) suction;
(d) basic intravenous setup; and

(e) defibrillator.

3.5.2.2. In a facility where procedural sedation is conducted, resuscitation equipment and emergency medications as required in the *Guidelines on Procedural Sedation* (2020), promulgated by the Hong Kong Academy of Medicine, are in place. Regular checks on their viability are conducted and documented.

3.5.2.3. In a facility where general anaesthesia or major regional anaesthesia is performed, resuscitation equipment as required in the *Recommended Minimum Facilities for Safe Anaesthetic Practice in Operating Suites* (v4, 2016), promulgated by the Hong Kong College of Anaesthesiologists, are in place.[11] Selection of medications to deal with emergency arising from anaesthesia shall be in consultation with an anaesthesiologist. Regular checks on their viability are conducted and documented.

3.5.2.4. Emergency medications are stored in a designated and easily accessible area in the facility.

3.5.3. Emergency transfer

3.5.3.1. If the patient requires emergency transfer to a hospital, the endoscopist and/or the anaesthesiologist is/are responsible for the care of the patient until the patient has been transferred to another appropriate medical staff.

3.5.3.2. There are policies and procedures in place for emergency transfer of patient to hospital for management of urgent adverse outcome.

3.5.3.3. Drills for emergency transfer are conducted at regular intervals and documented.

[11] As a transitional arrangement, the requirement for operating room to have oxygen supply through oxygen pipe (with at least two outlets) for general anaesthesia or major regional anaesthesia must be complied with by 2022.

Chapter 4
Dental Procedure

4.1. Management/Governance

4.1.1. Staff requirement and training

4.1.1.1. An appropriate number of suitably qualified and experienced staff are in attendance during each surgical procedure.

4.1.1.2. Staff have received adequate training before assisting in new surgical procedures.

4.1.1.3. The CME develops and implements a policy to determine the scope of surgical procedures that may be performed in the facility with reference to the guidelines promulgated by the Hong Kong Academy of Medicine and/or its Colleges and taking into account of the following factors:

(a) risk of surgical infections;
(b) necessity to quickly and safely convert to an open surgical procedure due to complications or technical difficulties; and
(c) physical design, staffing and equipment resources of the facility.

4.1.1.4. For a facility equipped with operating room, a registered nurse who has relevant experience or training is assigned to oversee the day to day operation of the operating room.[12] A specialist may assume the role of overseeing the day to day operation of the operating room if he/she has the relevant experience or training.

4.2. Physical Conditions

4.2.1. Facility management

4.2.1.1. Doorways and corridors enable transfer of patients on wheelchair or stretchers.

[12] As a transitional arrangement, an experienced enrolled nurse overseeing the day to day operation of the operating room of an existing DPC may continue to assume such role under the supervision of a medical practitioner or a dentist. The DPC seeking to obtain a full licence under a statutory licensing system shall fully meet clause 4.1.1.4.

4.2.1.2. The following functional areas in a facility are separate:
(a) reception and waiting area;
(b) perioperative or procedural area;
(c) area for equipment reprocessing; and
(d) dirty utility room.

4.2.1.3. There is access control to pre-operative area, areas for conducting procedure and postoperative care area.

4.2.1.4. In a facility where procedures under deep sedation[13], general anaesthesia or major regional anaesthesia are performed, doorways within the relevant perioperative or procedural area permit transfer of patient on trolleys or stretchers with attachment.

4.2.1.5. The clinical areas have immediate access to hand-washing facilities.

4.2.2. Operative/procedural area

4.2.2.1. Surgical procedures are performed in a location that is spacious enough to accommodate all personnel, fittings and equipment required for the procedure without contamination and to allow the procedure and resuscitation to be carried out effectively.

4.2.2.2. The lighting is adequate for the procedure undertaken.

4.2.2.3. For a facility equipped with operating room,-
(a) each operating room is suitably designed, equipped and maintained for the purpose it is to be used;
(b) the operating room is maintained at acceptable level of sterility;
(c) the ceiling, walls and floors are made from materials that can be easily cleaned and disinfected as needed to meet infection control requirements;
(d) the operating room is equipped with specialized ventilation system of internationally acceptable standards of air quality, including but not limited to adequate number of fresh air exchange per hour, to prevent the spread of airborne infectious disease and to minimise surgical site infection;
(e) the ventilation system of the operating room is regularly inspected and

[13] The definition of "deep sedation" should refer to the *Guidelines on Procedural Sedation* (2020) promulgated by the Hong Kong Academy of Medicine.

maintained to ensure effective functioning for patient and staff safety. Documentation of repair and maintenance of the systems is kept; and

(f) adequate area for scrub and gowning is provided for operating room.

4.2.2.4. Where gaseous anaesthetic agents are used, appropriate gas administration devices and exhaust systems are in place, and relevant requirements on occupational safety should be observed.

4.2.3. Equipment reprocessing area and sterile stores

4.2.3.1. A one-way dirty to clean traffic flow is designated in the equipment reprocessing area to prevent contamination.

4.2.4. Equipment and store

4.2.4.1. The facility has the necessary equipment for supporting its scope of surgical services, including but not limited to:

(a) tilting table, trolley or chair that accommodates the procedures performed and provides for adequate range of movement for anaesthetic procedures;

(b) suitable devices for administering anaesthesia;

(c) surgical instruments;

(d) monitoring and resuscitation equipment; and

(e) any other special equipment required for a particular surgery to be performed.

4.2.4.2. There are adequate facilities and space for the collection and storage of specimens.

4.2.4.3. The facility is equipped with devices for monitoring vital signs of patients, such as blood pressure and oxygen saturation.

4.2.4.4. In a facility where procedures under sedation are performed, there are sufficient equipment for monitoring of patient in accordance with the *Guidelines on Procedural Sedation* (2020) promulgated by the Hong Kong Academy of Medicine.

4.2.4.5. In a facility where procedures under general anaesthesia or major regional anaesthesia are performed, there are sufficient equipment for monitoring of patient in accordance with the *Guidelines on Monitoring in Anaesthesia* (v5, 2017) promulgated by the Hong Kong College of Anaesthesiologists.

4.3. Service Delivery and Care Process

4.3.1. General

4.3.1.1. The CME ensures that written policies and procedures relating to the safe provision of surgical procedures and anaesthesia in the facility, including but not limited to the following, are in place and implemented:

(a) staffing arrangements for surgical procedures and anaesthesia;
(b) informed consent;
(c) pre-procedural assessment;
(d) pre-procedural instructions (e.g. fasting, medication) and care;
(e) documentation of procedures;
(f) patient discharge and care after discharge; and
(g) arrangement for post-operative complications (e.g. arrangement for inpatient care).

4.3.1.2. In developing policies and procedures in relation to high-risk anaesthetic procedures, reference is taken from relevant guidelines promulgated by the Hong Kong Academy of Medicine and the Hong Kong College of Anaesthesiologists.

4.3.2. Pre-procedure

4.3.2.1. Patients receiving surgical procedures are provided with information on the procedure and anaesthesia, including but not limited to the indication of the procedure, treatment alternative(s), the likely outcomes and risk of complications, before giving consent. Informed consent is documented in the medical record and/or in signed consent form.

4.3.2.2. Pre-procedural assessment is conducted by a dentist or medical practitioner. For patient undergoing procedure under sedation, there is a pre-sedation assessment in accordance with the *Guidelines on Procedural Sedation* (2020) promulgated by the Hong Kong Academy of Medicine. For patient undergoing general anaesthesia or major regional anaesthesia, the pre-anaesthetic assessment is in accordance with the *Guidelines on the Pre-anaesthetic Consultation* (v3, 2019) promulgated by the Hong Kong College of Anaesthesiologists. When it is not possible for the pre-sedation or pre-anaesthetic assessment to be done by the same dentist or medical practitioner who is responsible for the sedation or anaesthesia, there is an adequate documented mechanism for conveying findings of the consultation to the

dentist or medical practitioner performing the sedation or anaesthesia. The final assessment by the dentist or medical practitioner for performing the sedation or anaesthesia is documented.

4.3.2.3. Pre-procedural assessment includes, but is not limited to:

(a) history and physical examination;
(b) all current medications;
(c) allergies;
(d) relevant investigations and consultation(s) with other specialty if any; and
(e) fitness for the procedure and the sedation or anaesthesia to be performed.

4.3.2.4. Patients are given adequate instructions for pre-procedural preparation (e.g. fasting), and post-operative care and discharge (e.g. a responsible adult to escort and care for patient after sedation or anaesthesia).

4.3.2.5. The CME ensures that there are written policies and procedures on the following processes before surgical procedures:

(a) checking of consent forms;
(b) verification processes, including time-out, to ensure correct patient, surgical site and procedure; and
(c) accomplishment of pre-operative preparation (e.g. fasting, pre-medication).

4.3.3. Intra-procedure

4.3.3.1. All general anaesthesia, neuroaxial block or major plexus block are administered only by an anaesthesiologist or by a trained medical practitioner under the supervision of an anaesthesiologist.

4.3.3.2. Staffing arrangements and monitoring of patients undergoing procedural sedation are in accordance with the *Guidelines on Procedural Sedation* (2020) promulgated by the Hong Kong Academy of Medicine.[14]

[14] In addition to the healthcare staff named by the *Guidelines on Procedural Sedation*, clinical assistants with relevant training or qualification in monitoring vital signs of patient undergoing sedation and procedural complications may also assume the role of such monitoring for patients undergoing procedural sedation, under the following conditions:
(a) holds a valid Basic Life Support (BLS) certificate; and
(b) works under the direct supervision of medical practitioner or dentist who retain personal responsibility for the monitoring.

4.3.3.3. In addition to 4.3.3.1, care process, staffing arrangement and monitoring of patients undergoing general anaesthesia or major regional anaesthesia and the documentation of the anaesthetic care are in accordance with the *Guidelines on Monitoring in Anaesthesia* (v5, 2017) promulgated by the Hong Kong College of Anaesthesiologists.

4.3.3.4. There are written policies and procedures on the counting of items used during the procedures, such as swabs, needles, blades and other operative instruments and supplies, and what to do if items cannot be accounted for. Where a dental surgery assistant is assigned to assist the dentist on the operating table during an operation, he/she must be trained and competent for the role and is under the direct supervision of the dentist or a registered nurse. The dentist or the registered nurse concerned shall be fully aware of the responsibility and accountability of their supervisory role.

4.3.4. Post-procedure

4.3.4.1. A dentist, medical practitioner or registered nurse trained in post-anaesthetic care is in-charge of the operation of the recovery area. Staff working in the recovery area must be trained for their roles.

4.3.4.2. All patients after surgical procedures are observed for an adequate length of time commensurate with the anaesthesia given and the surgical procedure performed, and their fitness for discharge are determined by the dentist or medical practitioner in-charge of the patient, subject to 4.3.4.3.

4.3.4.3. Recovery of patients who have received sedation should be in accordance with *Guidelines on Procedural Sedation* (2020) promulgated by the Hong Kong Academy of Medicine or relevant guidelines promulgated by the Hong Kong College of Anaesthesiologists. Recovery of patients who have received general anaesthesia or major regional anaesthesia takes place in an area that is adequately equipped and staffed for post-anaesthetic care, in accordance with *Guidelines on Postanaesthetic Recovery Care* (v5, 2019) promulgated by the Hong Kong College of Anaesthesiologists.

4.3.4.4. The anaesthesiologist, the medical practitioner, or the dentist administering the sedation or anaesthesia, unless he/she has delegated another medical practitioner or dentist to take up the role, is responsible for supervising the recovery of the patient from sedation or anaesthesia. Medical practitioner, dentist, or nurse trained in the post-anaesthetic care must be present at all

times when a patient is in recovery and is/are able to promptly reach the supervising medical practitioner or dentist when need arises.

4.3.4.5. Monitoring of patients recovering from procedural sedation is in accordance with the *Guidelines on Procedural Sedation* (2020) promulgated by the Hong Kong Academy of Medicine.

4.3.4.6. Monitoring of patients recovering from general anaesthesia or major regional anaesthesia is in accordance with the *Guidelines on Postanaesthetic Recovery Care* (v5, 2019) promulgated by the Hong Kong College of Anaesthesiologists.

4.3.4.7. There are written policies and procedures for discharge of patients after procedures under sedation or anaesthesia, including but not limited to:
(a) discharge criteria;
(b) discharge instructions and advice (e.g. medication, care of post-operative site, complications, refraining from certain activities); and
(c) arrangements for enquiries or assistance outside operating hours.

4.3.4.8. For a patient who has received general anaesthesia, major regional anaesthesia or deep sedation, there is a responsible adult to escort him/her home.

4.3.4.9. There is written protocol on transfer of patients to hospital for those patients who are not fit to be discharged home after the procedure or sedation or anaesthesia.

4.3.5. Medical records

4.3.5.1. The following records are kept:
(a) detailed procedure or operation records of all procedures performed;
(b) investigation reports;
(c) consent forms;
(d) anaesthetic records;
(e) records of post-operative care and pre-discharge evaluation;
(f) pathology report, if specimen of body tissue or fluid was taken and sent for pathology; and
(g) outcome of the procedure.

4.3.5.2. Procedure or operation records include, but are not limited to:
(a) name(s) of the dentist(s) and/or medical practitioner(s) performing the

procedure and the assistant(s), if any;

(b) date, time, operation diagnosis, start time and end time of the procedure, anaesthesia and sedation method, name, details of the procedure, surgical findings, and any tissue removed and/or sent for pathology;

(c) record of the name, dose, time and route of administration of all medications and fluids given for the operation; and

(d) blood and other fluid losses of the patient at the conclusion of the surgery.

4.3.5.3. Without limiting 4.3.5.4 and 4.3.5.5, anaesthetic records include but are not limited to:

(a) name(s) of the dentist(s) or the medical practitioner(s) administering the anaesthesia; and

(b) the name, dose, route of administration of all anaesthetic drugs given.

4.3.5.4. For procedures under general anaesthesia or major regional anaesthesia, records of anaesthetic care are in accordance with the *Guidelines on Minimum Requirements for an Anaesthetic Record* (v4, 2017) promulgated by the Hong Kong College of Anaesthesiologists.

4.3.5.5. For procedures under sedation, records of anaesthetic care are in accordance with the *Guidelines on Procedural Sedation* (2020) promulgated by the Hong Kong Academy of Medicine.

4.3.6. Continuous quality improvement

4.3.6.1. The CME develops and implements policies and procedures to review the appropriateness of patient care and monitoring of clinical performance and outcomes (e.g. surgical site infection, emergency transfer, unanticipated hospital admission).

4.4. Infection Control

4.4.1. Infection control policies and procedures

4.4.1.1. There are written infection control policies, procedures and guidelines for prevention of surgical infection, including but not limited to:

(a) standard precautions;

(b) use of aseptic techniques;

(c) environmental cleansing and disinfection;

(d) cleaning, disinfection and sterilisation, and storage of surgical and/or anaesthetic equipment; and
(e) monitoring of effectiveness of infection control measures.

Reference is taken from guidelines promulgated by relevant health and professional authorities (e.g. *Recommendations on Prevention of Surgical Site Infection* promulgated by the Centre for Health Protection of the Department of Health; *Guidelines on Infection Control in Anaesthesia* promulgated by the Hong Kong College of Anaesthesiologists).

4.5. Resuscitation and Contingency

4.5.1. Risk management

4.5.1.1. There are staff-to-staff communication systems for emergency in the operating/procedure room and recovery area.

4.5.1.2. There are patient-to-staff call systems or devices (e.g. call bells) where a patient may be left alone temporarily (e.g. patient changing room in the facility).

4.5.2. Resuscitation of patients

4.5.2.1. There are adequate and appropriate resuscitation equipment including but not limited to:
(a) device that can ventilate the lungs;
(b) oxygen supply;
(c) suction;
(d) basic intravenous setup; and
(e) defibrillator.

4.5.2.2. In a facility where procedural sedation is conducted, resuscitation equipment and emergency medications as required in the *Guidelines on Procedural Sedation* (2020), promulgated by the Hong Kong Academy of Medicine, are in place. Regular checks on their viability are conducted and documented.

4.5.2.3. In a facility where general anaesthesia or major regional anaesthesia is performed, resuscitation equipment as required in the *Recommended Minimum Facilities for Safe Anaesthetic Practice in Operating Suites* (v4, 2016), promulgated by the Hong Kong College of Anaesthesiologists, are in

place.[15] Selection of medications to deal with emergency arising from anaesthesia shall be in consultation with an anaesthesiologist. Regular checks on their viability are conducted and documented.

4.5.2.4. Emergency medications are stored in a designated and easily accessible area in the facility.

4.5.3. Emergency transfer

4.5.3.1. If the patient requires emergency transfer to a hospital, the dentist and/or the anaesthesiologist is/are responsible for the care of the patient until the patient has been transferred to another appropriate medical staff.

4.5.3.2. There are policies and procedures in place for emergency transfer of patient to hospital for management of urgent adverse outcome.

4.5.3.3. Drills for emergency transfer are conducted at regular intervals and documented.

[15] As a transitional arrangement, the requirement for operating room to have oxygen supply through oxygen pipe (with at least two outlets) for general anaesthesia or major regional anaesthesia must be complied with by 2022.

Chapter 5
Chemotherapy

5.1. Management/Governance

5.1.1. Staff requirement and training

5.1.1.1. A specialist in clinical oncology, medical oncology, haematology and haematological oncology, or other relevant specialties or subspecialties is appointed to be the CME of the chemotherapy (cytotoxic) service. Where the CME is not the specialist of the said qualification, a specialist with such qualification is appointed as an advisor for the service to regularly review the facilities, equipment, staff training, and the policies and procedures of the chemotherapy service.

5.1.1.2. For each patient attending the facility, there is a specialist in clinical oncology, medical oncology, haematology and haematological oncology, or other relevant specialties or subspecialties in charge of his or her chemotherapy (cytotoxic) treatment.

5.1.1.3. At all times when the facility is in operation, a medical practitioner should be contactable to render medical care and advice when needed and in emergency.

5.1.1.4. Where there is no medical practitioner immediately available for medical care when chemotherapy (cytotoxic) is administered, a registered nurse who has been trained in the practice of oncology nursing or administration of chemotherapy (cytotoxic) is available at all times as the duty nurse-in-charge to supervise nursing care of the service.

5.1.1.5. All nursing staff have received relevant training in the provision of chemotherapy (cytotoxic) service.

5.1.1.6. Dispensing of cytotoxic drugs is by or under the supervision of a pharmacist or medical practitioner.

5.1.1.7. Staff responsible for the reconstitution of cytotoxic drugs have received relevant training in infection control and proper use of isolator or biosafety

cabinet (BSC).

5.1.1.8. All staff have received training in health hazards of cytotoxic drugs, spillage handling techniques, and use of personal protective equipment.

5.2. Physical Conditions

5.2.1. Facility management

5.2.1.1. The preparation and administration of chemotherapy (cytotoxic) are conducted in separate and designated areas in the facility.

5.2.1.2. There is access control to areas where cytotoxic drugs are reconstituted or stored.

5.2.1.3. There is immediate access to hand washing facilities in clinical areas and areas where cytotoxic drugs are handled.

5.2.1.4. Where cytotoxic drugs are handled, the working surface should be smooth, washable and impervious to moisture.

5.2.1.5. The design of patient care areas should facilitate effective cleaning and disinfection.

5.2.2. Reconstitution facilities

5.2.2.1. Where cytotoxic drugs are handled, prevailing legislation relating to occupational health and safety and relevant guidelines promulgated by the Labour Department should be observed.

5.2.2.2. If cytotoxic drugs are reconstituted in the facility, a dedicated class II (Type A2 or B) or class III BSC or isolator should be used.

5.2.2.3. The isolator or BSC is installed according to manufacturer's recommendations and kept in good functional order. It should be regularly serviced and maintained. There is proper documentation of testing, repair, and maintenance.

5.2.2.4. Where a closed-system drug transfer device is used, the device should be used inside the isolator or BSC.

5.2.3. Equipment, store and transport

5.2.3.1. Cytotoxic drugs are stored in designated area with controlled access and are clearly labelled with warning signs in Chinese and English.

5.2.3.2. Labelled containers used for transport of cytotoxic drugs are impervious and protective against spillage, leakage, or breakage.

5.2.3.3. Cytotoxic spillage kits are readily accessible in areas where cytotoxic drugs are stored or handled.

5.2.3.4. Extravasation kits are readily accessible in areas where chemotherapy (cytotoxic) is administered by intravenous route.

5.3. Service Delivery and Care Process

5.3.1. General

5.3.1.1. The CME ensures that written policies and procedures relating to the safe provision of chemotherapy (cytotoxic) in the facility, including but not limited to the following, are in place and implemented:

(a) dispensing, reconstitution, and administration of cytotoxic drugs;
(b) handling, storage, transport, and disposal of cytotoxic drugs and related wastes;
(c) obtaining written consent from patient before commencement of chemotherapy (cytotoxic);
(d) verification of chemotherapy (cytotoxic) order for administration;
(e) assessment of patients' condition and clinical parameters prior to administration;
(f) monitoring of patients during administration;
(g) prevention and management of complications such as anaphylaxis and extravasation;
(h) accessible support for patients outside working hours;
(i) selection, maintenance, and appropriate use of personal protective equipment; and
(j) management of spillage or accidental contamination.

5.3.1.2. There are mechanisms in place to assess and document occupational health and safety risk related to handling of cytotoxic drugs, taking into account relevant guidance notes promulgated by the Labour Department. Such

assessments are performed regularly, and remedial measures are implemented where appropriate.

5.3.2. Medical Records

5.3.2.1. The following records are kept:

(a) treatment plan and prescription records, including but not limited to diagnosis, prescription, route of administration, dose or schedule modification, and duration of treatment;
(b) any known drug hypersensitivity or allergy;
(c) assessment of patients' condition prior to, during, and after administration;
(d) treatment-related reactions;
(e) relevant investigation reports; and
(f) consent forms.

5.4. Infection Control

5.4.1. Infection control policies and procedures

5.4.1.1. Written policies and procedures on infection control, which include but not limited to the followings, are in place and implemented:

(a) standard and transmission-based precautions;
(b) preparation and administration of parenteral drugs using aseptic techniques;
(c) safe injection practice and sharps handling;
(d) environmental cleansing and disinfection;
(e) cleaning, disinfection, and maintenance of reconstitution facilities;
(f) management of blood and body fluid spillage; and
(g) staff training.

5.5. Resuscitation and Contingency

5.5.1. Risk management

5.5.1.1. There are staff-to-staff communication systems for emergencies.

5.5.1.2. There are patient-to-staff call systems or devices (e.g. call bells) where a patient may be left alone temporarily (e.g. patient changing room in the

facility).

5.5.2. Resuscitation of patients

5.5.2.1. There are adequate and appropriate resuscitation equipment, including but not limited to:

(a) device that can ventilate the lungs;
(b) oxygen supply;
(c) suction;
(d) basic intravenous setup; and
(e) defibrillator.

5.5.2.2. Emergency medications are stored in a designated and easily accessible area in the facility. Regular checks on their viability are conducted and documented.

5.5.3. Emergency transfer

5.5.3.1. Policies and procedures are in place for emergency transfer of patient to hospital for management of urgent adverse outcomes.

5.5.3.2. Drills for emergency transfer are conducted at regular intervals and documented.

This page is intentionally left blank

Chapter 6
Haemodialysis

6.1. Management/Governance

6.1.1. Staff requirement and training

6.1.1.1. A specialist in nephrology is appointed to be the CME of the haemodialysis service. Alternatively, a specialist in nephrology is appointed as an advisor to review regularly the facilities, equipment, staff training, and policies and procedures of the haemodialysis service.

6.1.1.2. For each patient attending the facility, there is a specialist in nephrology in charge of his or her dialysis treatment.

6.1.1.3. At all times the facility is in operation, a medical practitioner should be contactable to render medical care and advice when needed and in emergency.

6.1.1.4. At all times the facility is in operation, a registered nurse who has completed one of the renal specialty courses recommended by the Hong Kong College of Physicians is assigned as the duty nurse-in-charge to supervise nursing care of the service. The nurse to patient ratio shall be at least 1:5.

6.1.1.5. All staff are trained in the provision of renal dialysis service. At least half of the nursing staff have completed one of the renal specialty courses recommended by the Hong Kong College of Physicians.

6.2. Physical Conditions

6.2.1. Facility management

6.2.1.1. There is sufficient circulating space around each bed or chair for nursing care to take place.

6.2.1.2. There are designated clean areas for the preparation, handling, and storage of medications, supplies, and equipment. Clean areas are separated from areas where contaminated or used supplies and equipment are handled or

stored.

6.2.1.3. The clinical areas have immediate access to hand washing facilities.

6.2.2. Equipment and store

6.2.2.1. The dialysis machines and water treatment systems are kept in good functional order. There is proper documentation of testing, repair and maintenance of dialysis machines, including back-up machines, and water treatment system.

6.2.2.2. Adequate number of unoccupied haemodialysis machine is available on-site as back-up.

6.3. Service Delivery and Care Process

6.3.1. General

6.3.1.1. The CME ensures that written policies and procedures relating to the safe provision of haemodialysis in the facility, including but not limited to the following, are in place and implemented:

(a) admission of patients to haemodialysis centre;
(b) management of patients with blood-borne infections;
(c) immunisation for susceptible patients and staff against infections;
(d) staffing arrangements for haemodialysis procedures;
(e) informed consent;
(f) initiation and termination of haemodialysis procedures;
(g) monitoring of patient conditions during dialysis;
(h) care of vascular access;
(i) operation of the haemodialysis machines and water treatment systems; and
(j) disinfection and rinsing of equipment.

6.3.1.2. Haemodialysis procedures must not be performed during disinfection procedures, and during maintenance and repair of relevant machines and systems.

6.3.2. Water quality

6.3.2.1. There are written policies and procedures for testing of water quality at

haemodialysis machines and at water treatment systems at regular intervals.

6.3.2.2. Testing of water quality should be performed and documented at regular intervals to ensure that the water quality meets internationally acceptable standards. The testing should include, but not limited to:

(a) microbiological contaminants (at least monthly for reverse osmosis water from the water treatment system; and monthly, rotating among machines so that each haemodialysis machine is tested at least annually, for dialysis fluid);

(b) endotoxin contaminants (at least monthly for reverse osmosis water from the water treatment system; and monthly, rotating among machines so that each haemodialysis machine is tested at least annually, for dialysis fluid); and

(c) inorganic contaminants (at least annually for reverse osmosis water from the water treatment system).

6.3.2.3. Alarm system is in place to monitor operation of water treatment system such as water level.

6.3.3. Disinfection

6.3.3.1. There are written policies and procedures on regular disinfection of water treatment and distribution systems, haemodialysis machines and equipment. Disinfection procedures are carried out according to the recommendations of manufacturers.

6.3.3.2. If chemical disinfection is performed, appropriate measures should be in place to test and document the absence of residual disinfectants in the system.

6.3.4. Prevention of blood-borne infections

6.3.4.1. There are protocols for serological testing of blood-borne viruses for patients. Testing are conducted prior to commencing haemodialysis, at regular intervals thereafter, and when clinically indicated, with results documented.

6.3.4.2. There are dedicated facilities and equipment for patients with hepatitis B or C. Patients with hepatitis B are dialysed with dedicated facilities and equipment in segregated area away from patients without hepatitis B.

6.3.4.3. If dialyser is reused, there are protocols on the cleaning and preparation before reuse. The dialyser should only be reused for the same patient.

6.3.4.4. Dialyser should not be reused in patients with hepatitis B or C.

6.3.5. Medical records

6.3.5.1. The following medical records are kept:

(a) haemodialysis orders;
(b) records of individual haemodialysis treatment, including treatment time and clinical observations;
(c) drug prescriptions;
(d) relevant investigation reports; and
(e) consent forms.

6.4. Infection Control

6.4.1. Infection control policies and procedures

6.4.1.1. Written policies and procedures on infection control, which include but not limited to the followings, are in place and implemented:

(a) standard and transmission based precautions;
(b) supply and use of personal protective equipment;
(c) environmental cleansing and disinfection;
(d) cleaning, disinfection and reprocessing of equipment;
(e) management of blood and body fluid spillage; and
(f) staff training.

Reference is taken from guidelines promulgated by relevant health and professional authorities, e.g. *Infection Control Guidelines on Nephrology Services in Hong Kong*.

6.4.1.2. There are policies and procedures for ensuring injection safety, proper sharps handling and disposal, and post-exposure management.

6.5. Resuscitation and Contingency

6.5.1. Risk management

6.5.1.1. There are patient-to-staff call systems or devices (e.g. call bells) for

emergency in the haemodialysis area and where a patient may be left alone temporarily (e.g. patient changing room in the facility).

6.5.1.2. There are written policies and procedures for handling emergencies within the service, including fire hazard and sudden interruption of electricity supply or water supply. Contingency plan is in place to allow for return of blood from dialysis machines during emergencies.

6.5.1.3. Written policies are in place for the arrangement for interruption of services, e.g., during adverse weather conditions.

6.5.1.4. There are clinical guidelines in place for management of disinfectant toxicity.

6.5.2. Resuscitation of patients

6.5.2.1. There are adequate and appropriate resuscitation equipment including but not limited to:

(a) device that can ventilate the lungs;
(b) oxygen supply;
(c) suction;
(d) basic intravenous setup; and
(e) defibrillator.

6.5.2.2. Emergency medications are stored in a designated and easily accessible area in the facility. Regular checks on their viability are conducted and documented.

6.5.3. Emergency transfer

6.5.3.1. There are policies and procedures in place for emergency transfer of patient to hospital for management of urgent adverse outcome.

6.5.3.2. Drills for emergency transfer are conducted at regular intervals and documented.

This page is intentionally left blank

Chapter 7
Interventional Radiology and Lithotripsy

7.1. Management/Governance

7.1.1. Staff requirement and training

7.1.1.1. An appropriate number of suitably qualified and experienced staff are in attendance during each interventional procedure.

7.1.1.2. Staff have received adequate training before assisting in new interventional procedures.

7.1.1.3. The CME develops and implements a policy to determine the scope of interventional procedures that may be performed in the facility with reference to the guidelines promulgated by the Hong Kong Academy of Medicine and/or its Colleges and taking into account of the following factors:

(a) risk of surgical infections;
(b) necessity to quickly and safely convert to an open surgical procedure due to complications or technical difficulties; and
(c) physical design, staffing and equipment resources of the facility.

7.1.1.4. For a facility equipped with operating room, a registered nurse who has relevant experience or training is assigned to oversee the day to day operation of the operating room.[16] A specialist may assume the role of overseeing the day to day operation of the operating room if he/she has the relevant experience or training.

7.2. Physical Conditions

7.2.1. Facility management

7.2.1.1. Doorways and corridors enable transfer of patients on wheelchair or

[16] As a transitional arrangement, an experienced enrolled nurse overseeing the day to day operation of the operating room of an existing DPC may continue to assume such role under the supervision of a medical practitioner or a dentist. The DPC seeking to obtain a full licence under a statutory licensing system shall fully meet clause 7.1.1.4.

stretchers.

7.2.1.2. The following functional areas in a facility are separate:
(a) reception and waiting area;
(b) perioperative or procedural area;
(c) area for equipment reprocessing; and
(d) dirty utility room.

7.2.1.3. There is access control to the procedural and/or peri-operative areas.

7.2.1.4. In a facility where procedures under deep sedation[17], general anaesthesia or major regional anaesthesia are performed, doorways within the relevant perioperative or procedural area permit transfer of patient on trolleys or stretchers with attachment.

7.2.1.5. The clinical areas have immediate access to hand-washing facilities.

7.2.1.6. The provision and use of irradiating apparatus should conform to the Radiation Ordinance (Cap. 303).

7.2.2. Operative/procedural area

7.2.2.1. Interventional procedures are performed in a location that is spacious enough to accommodate all personnel, fittings and equipment required for the procedure without contamination and to allow the procedure and resuscitation to be carried out effectively.

7.2.2.2. The lighting is adequate for the procedure undertaken.

7.2.2.3. For a facility equipped with operating room, -
(a) each operating room is suitably designed, equipped and maintained for the purpose it is to be used;
(b) the operating room is maintained at an acceptable level of sterility;
(c) the ceiling, walls and floors are made from materials that can be easily cleaned and disinfected as needed to meet infection control requirements;
(d) the operating room is equipped with specialized ventilation system of internationally acceptable standards of air quality, including but not

[17] The definition of "deep sedation" should refer to the *Guidelines on Procedural Sedation* (2020) promulgated by the Hong Kong Academy of Medicine.

limited to adequate number of fresh air exchange per hour, to prevent the spread of airborne infectious disease and to minimise surgical site infection;

(e) the ventilation system of the operating room is regularly inspected and maintained to ensure effective functioning for patient and staff safety. Documentation of repair and maintenance of the system is kept; and

(f) adequate area for scrub and gowning is provided for operating room.

7.2.2.4. Where gaseous anaesthetic agents are used, appropriate gas administration devices and exhaust systems are in place, and relevant requirements on occupational safety should be observed.

7.2.3. Equipment reprocessing area and sterile stores

7.2.3.1. A one-way dirty to clean traffic flow is designated in the equipment reprocessing area to prevent contamination.

7.2.4. Equipment and store

7.2.4.1. The facility has the necessary equipment for supporting its scope of interventional services, including but not limited to:

(a) tilting table, trolley or chair that accommodates the procedures performed and provides for adequate range of movement for anaesthetic procedures;

(b) suitable devices for administering anaesthesia;

(c) devices for specific imaging and/or interventional procedures;

(d) monitoring and resuscitation equipment; and

(e) appropriate radiation protective equipment for staff, patient and accompanying person.

7.2.4.2. There are adequate facilities and space for the collection and storage of specimens.

7.2.4.3. The facility is equipped with devices for monitoring vital signs of patients, such as blood pressure and oxygen saturation.

7.2.4.4. In a facility where procedures under sedation are performed, there are sufficient equipment for monitoring of patient in accordance with the *Guidelines on Procedural Sedation* (2020) promulgated by the Hong Kong Academy of Medicine.

7.2.4.5. In a facility where procedures under general anaesthesia or major regional anaesthesia are performed, there are sufficient equipment for monitoring of patient in accordance with the *Guidelines on Monitoring in Anaesthesia* (v5, 2017) promulgated by the Hong Kong College of Anaesthesiologists.

7.3. Service Delivery and Care Process

7.3.1. General

7.3.1.1. The CME ensures that written policies and procedures relating to the safe provision of interventional procedures and anaesthesia in the facility, including but not limited to the following, are in place and implemented:

(a) staffing arrangements for interventional procedures and anaesthesia, where applicable;
(b) informed consent;
(c) pre-procedural assessment;
(d) pre-procedural instructions (e.g. fasting, medication) and care;
(e) documentation of procedures;
(f) patient discharge and care after discharge; and
(g) management of complications (e.g. severe allergic reaction, arrangement for inpatient care).

7.3.1.2. In developing policies and procedures in relation to high-risk anaesthetic procedures, reference is taken from relevant guidelines promulgated by the Hong Kong Academy of Medicine and the Hong Kong College of Anaesthesiologists.

7.3.1.3. Where irradiating apparatus is used, licence under *Radiation Ordinance* (Cap. 303) is obtained.

7.3.2. Pre-procedure

7.3.2.1. Patients receiving interventional procedures are provided with information on the procedure and, where applicable, anaesthesia, including but not limited to the indication of the procedure, treatment alternative(s), the likely outcomes and risk of complications, before giving consent. Informed consent is documented in the medical record and/or in signed consent form.

7.3.2.2. Pre-procedural assessment is conducted by a medical practitioner. For patient undergoing procedure under sedation, there is a pre-sedation

assessment in accordance with the *Guidelines on Procedural Sedation* (2020) promulgated by the Hong Kong Academy of Medicine. For patient undergoing general anaesthesia or major regional anaesthesia, the pre-anaesthetic assessment is in accordance with the *Guidelines on the Pre-anaesthetic Consultation* (v3, 2019) promulgated by the Hong Kong College of Anaesthesiologists. When it is not possible for the pre-sedation or pre-anaesthetic assessment to be done by the same medical practitioner who is responsible for the sedation or anaesthesia, there is an adequate documented mechanism for conveying findings of the consultation to the medical practitioner performing the sedation or anaesthesia. The final assessment by the medical practitioner for performing the sedation or anaesthesia is documented.

7.3.2.3. Pre-procedural assessment includes, but is not limited to:

(a) history and physical examination;
(b) all current medications;
(c) allergies;
(d) implants (e.g. pacemakers) and possible contraindications to specific imaging procedures, where appropriate;
(e) relevant investigations and consultation(s) with other specialty if any; and
(f) fitness for the procedure and the sedation or anaesthesia to be performed.

7.3.2.4. Patients are given adequate instructions for pre-procedural preparation (e.g. fasting), and post-operative care and discharge (e.g. a responsible adult to escort and care for patient after sedation or anaesthesia).

7.3.2.5. The CME ensures that there are written policies and procedures on the following processes before interventional procedures:

(a) checking of consent forms;
(b) verification processes, including time-out, to ensure correct patient, procedural site and procedure; and
(c) accomplishment of pre-operative preparation (e.g. fasting, pre-medication).

7.3.3. Intra-procedure

7.3.3.1. All general anaesthesia, neuroaxial block or major plexus block are administered only by an anaesthesiologist or by a trained medical

practitioner under the supervision of an anaesthesiologist.

7.3.3.2. Staffing arrangements and monitoring of patients undergoing procedural sedation are in accordance with the *Guidelines on Procedural Sedation* (2020) promulgated by the Hong Kong Academy of Medicine.[18]

7.3.3.3. In addition to 7.3.3.1., care process, staffing arrangement and monitoring of patients undergoing general anaesthesia or major regional anaesthesia and the documentation of the anaesthetic care are in accordance with the *Guidelines on Monitoring in Anaesthesia* (v5, 2017) promulgated by the Hong Kong College of Anaesthesiologists.

7.3.3.4. Where applicable, there are written policies and procedures on the counting of items used during the procedures, such as guide wires, swabs, needles, blades and other operative instruments and supplies, and what to do if items cannot be accounted for.

7.3.4. Post-procedure

7.3.4.1. All patients after interventional procedures are observed for an adequate length of time commensurate with the interventional procedure performed and any sedation or anaesthesia given, and their fitness for discharge are determined by the medical practitioner in-charge of the patient, subject to 7.3.4.2.

7.3.4.2. Recovery of patients who have received sedation should be in accordance with *Guidelines on Procedural Sedation* (2020) promulgated by the Hong Kong Academy of Medicine or relevant guidelines promulgated by the Hong Kong College of Anaesthesiologists. Recovery of patients who have received general anaesthesia or major regional anaesthesia takes place in an area that is adequately equipped and staffed for post-anaesthetic care, in accordance with *Guidelines on Postanaesthetic Recovery Care* (v5, 2019) promulgated by the Hong Kong College of Anaesthesiologists. A medical practitioner or registered nurse trained in post-anaesthetic care is in-charge of the operation of the recovery area. Staff working in the recovery

[18] In addition to the healthcare staff named by the *Guidelines on Procedural Sedation*, clinical assistants with relevant training or qualification in monitoring vital signs of patient undergoing sedation and procedural complications may also assume the role of such monitoring for patients undergoing procedural sedation, under the following conditions:
(a) holds a valid Basic Life Support (BLS) certificate; and
(b) works under the direct supervision of medical practitioner or dentist who retain personal responsibility for the monitoring.

area must be trained for their roles.

7.3.4.3. The anaesthesiologist or the medical practitioner administering the sedation or anaesthesia, unless he/she has delegated another medical practitioner to take up the role, is responsible for supervising the recovery of the patient from sedation or anaesthesia. Medical or nursing staff trained in the post-anaesthetic care must be present at all times when a patient is in recovery and is/are able to promptly reach the supervising medical staff when need arises.

7.3.4.4. Monitoring of patients recovering from procedural sedation is in accordance with the *Guidelines on Procedural Sedation* (2020) promulgated by the Hong Kong Academy of Medicine.

7.3.4.5. Monitoring of patients recovering from general anaesthesia or major regional anaesthesia is in accordance with the *Guidelines on Postanaesthetic Recovery Care* (v5, 2019) promulgated by the Hong Kong College of Anaesthesiologists.

7.3.4.6. There are written policies and procedures for discharge of patients after procedures under sedation or anaesthesia, including but not limited to:
(a) discharge criteria;
(b) discharge instructions and advice (e.g. medication, care of post-operative site, complications, refraining from certain activities); and
(c) arrangements for enquiries or assistance outside operating hours.

7.3.4.7. For a patient who has received general anaesthesia, major regional anaesthesia or deep sedation, there is a responsible adult to escort him/her home.

7.3.4.8. There is written protocol on transfer of patients to hospital for those patients who are not fit to be discharged home after the procedure or sedation or anaesthesia.

7.3.5. Medical records

7.3.5.1. The following records are kept:
(a) detailed records of all procedures and operations performed;
(b) investigation reports;
(c) consent forms;
(d) anaesthetic records;

(e) records of post-operative care and pre-discharge evaluation;
(f) pathology report, if specimen of body tissue or fluid was taken and sent for pathology; and
(g) outcome of the procedure.

7.3.5.2. Procedure or operation records include, but are not limited to:
(a) name(s) of the medical practitioner(s) performing the procedure and the assistant(s), if any;
(b) date, time, operation diagnosis, start time and end time of the procedure, anaesthesia and sedation method, name, details of the procedure, surgical findings, and any tissue removed and/or sent for pathology;
(c) record of the name, dose, time and route of administration of all medications and fluids given for the operation; and
(d) blood and other fluid losses of the patient at the conclusion of the procedure.

7.3.5.3. Without limiting 7.3.5.4 and 7.3.5.5, anaesthetic records include but are not limited to:
(a) name(s) of the medical practitioner(s) administering the anaesthesia; and
(b) the name, dose, route of administration of all anaesthetic drugs given.

7.3.5.4. For procedures under general anaesthesia or major regional anaesthesia, records of anaesthetic care are in accordance with the *Guidelines on Minimum Requirements for an Anaesthetic Record* (v4, 2017) promulgated by the Hong Kong College of Anaesthesiologists.

7.3.5.5. For procedures under sedation, records of anaesthetic care are in accordance with the *Guidelines on Procedural Sedation* (2020) promulgated by the Hong Kong Academy of Medicine.

7.3.6. Continuous quality improvement

7.3.6.1. The CME develops and implements policies and procedures to review the appropriateness of patient care and monitoring of clinical performance and outcomes (e.g. surgical site infection, emergency transfer, unanticipated hospital admission).

7.4. Infection Control

7.4.1. Infection control policies and procedures

7.4.1.1. There are written infection control policies, procedures and guidelines for prevention of surgical infection, including but not limited to:

(a) standard precautions;
(b) use of aseptic techniques;
(c) environmental cleansing and disinfection;
(d) cleaning, disinfection and sterilisation, and storage of interventional and/or anaesthetic equipment; and
(e) monitoring of effectiveness of infection control measures.

Reference is taken from guidelines promulgated by relevant health and professional authorities (e.g. *Recommendations on Prevention of Surgical Site Infection* promulgated by the Centre for Health Protection of the Department of Health; *Guidelines on Infection Control in Anaesthesia* promulgated by the Hong Kong College of Anaesthesiologists).

7.5. Resuscitation and Contingency

7.5.1. Risk management

7.5.1.1. There are staff-to-staff communication systems for emergency in the operating or procedure room and recovery area.

7.5.1.2. There are patient-to-staff call systems or devices (e.g. call bells) where a patient may be left alone temporarily (e.g. patient changing room in the facility).

7.5.2. Resuscitation of patients

7.5.2.1. There are adequate and appropriate resuscitation equipment including but not limited to:

(a) device that can ventilate the lungs;
(b) oxygen supply;
(c) suction;
(d) basic intravenous setup; and
(e) defibrillator.

7.5.2.2. In a facility where procedural sedation is conducted, resuscitation equipment and emergency medications as required in the *Guidelines on Procedural Sedation* (2020), promulgated by the Hong Kong Academy of Medicine, are in place. Regular checks on their viability are conducted and documented.

7.5.2.3. In a facility where general anaesthesia or major regional anaesthesia is performed, resuscitation equipment as required in the *Recommended Minimum Facilities for Safe Anaesthetic Practice in Operating Suites* (v4, 2016), promulgated by the Hong Kong College of Anaesthesiologists, are in place.[19] Selection of medications to deal with emergency arising from anaesthesia shall be in consultation with an anaesthesiologist. Regular checks on their viability are conducted and documented.

7.5.2.4. Emergency medications are stored in a designated and easily accessible area in the facility.

7.5.3. Emergency transfer

7.5.3.1. If the patient requires emergency transfer to a hospital, the proceduralist and/or the anaesthesiologist is/are responsible for the care of the patient until the patient has been transferred to another appropriate medical staff.

7.5.3.2. There are policies and procedures in place for emergency transfer of patient to hospital for management of urgent adverse outcome.

7.5.3.3. Drills for emergency transfer are conducted at regular intervals and documented.

[19] As a transitional arrangement, the requirement for operating room to have oxygen supply through oxygen pipe (with at least two outlets) for general anaesthesia or major regional anaesthesia must be complied with by 2022.

Chapter 8
Anaesthetic Procedure

8.1. Management/Governance

8.1.1. Staff requirement and training

8.1.1.1. An appropriate number of suitably qualified and experienced staff are in attendance during each anaesthetic or sedation procedure.

8.1.1.2. For each patient undergoing general anaesthesia, neuroaxial block or major plexus block, a specialist in anaesthesiology is in charge of the anaesthetic care.

8.1.1.3. Where general anaesthesia, neuroaxial block or major plexus block is performed and the CME is not a specialist in anaesthesiology, a specialist in anaesthesiology is appointed as an advisor for the anaesthetic service to regularly review the facilities, equipment, staff training, and policies and procedures in relation to the anaesthetic care.

8.1.1.4. Where a recovery area is provided for the anaesthetic care, a medical practitioner, dentist, or registered nurse trained in post-anaesthetic care is in-charge of the operation of the recovery area. Staff working in the recovery area must be trained for their roles.

8.1.1.5. The CME develops and implements a policy to determine the scope of anaesthetic or sedation procedures that may be performed in the facility with reference to the guidelines promulgated by the Hong Kong Academy of Medicine and/or its Colleges and taking into account of the following factors:

(a) risk of anaesthetic or sedation procedures;
(b) type and risk of the procedures performed under the anaesthesia or sedation; and
(c) physical design, staffing and equipment resources of the facility.

8.2. Physical Conditions

8.2.1. Facility management

8.2.1.1. Doorways and corridors enable transfer of patients on wheelchair or stretchers.

8.2.1.2. The following functional areas in a facility are separate:
(a) reception and waiting area;
(b) procedural area;
(c) area for equipment reprocessing; and
(d) dirty utility room.

8.2.1.3. There is access control to procedural area and recovery area, if any.

8.2.1.4. In a facility where procedures under deep sedation[20], general anaesthesia or major regional anaesthesia are performed, doorways connecting the recovery area and procedural area permit transfer of patient on trolleys or stretchers with attachment.

8.2.1.5. The clinical areas have immediate access to hand-washing facilities.

8.2.2. Procedural area

8.2.2.1. Anaesthetic or sedation procedures are performed in a location that is spacious enough to accommodate all personnel, fittings and equipment required for the procedure without contamination and to allow the procedure and resuscitation to be carried out effectively.

8.2.2.2. The lighting is adequate for the procedure undertaken.

8.2.2.3. Where gaseous anaesthetic agents are used, appropriate gas administration devices and exhaust systems are in place, and relevant requirements on occupational safety should be observed.

8.2.2.4. Adequate area for scrub and gowning is provided, where applicable.

[20] The definition of "deep sedation" should refer to the *Guidelines on Procedural Sedation* (2020) promulgated by the Hong Kong Academy of Medicine.

8.2.3. Equipment reprocessing area and sterile stores

8.2.3.1. A one-way dirty to clean traffic flow is designated in the equipment reprocessing area to prevent contamination.

8.2.4. Equipment and store

8.2.4.1. The facility has the necessary equipment for supporting its scope of anaesthetic or sedation services, including but not limited to:

(a) tilting table, trolley or chair that accommodates the procedures performed and provides for adequate range of movement for anaesthetic or sedation procedures;
(b) suitable devices for administering anaesthesia or sedation; and
(c) monitoring and resuscitation equipment.

8.2.4.2. In a facility where procedures under sedation are performed, there are sufficient equipment for monitoring of patient in accordance with the *Guidelines on Procedural Sedation* (2020) promulgated by the Hong Kong Academy of Medicine.

8.2.4.3. In a facility where procedures under general anaesthesia or major regional anaesthesia are performed, there are sufficient equipment for monitoring of patient in accordance with the *Guidelines on Monitoring in Anaesthesia* (v5, 2017) promulgated by the Hong Kong College of Anaesthesiologists.

8.2.4.4. In a facility where anaesthesia or sedation procedures are provided to paediatric patients, equipment are appropriately sized for paediatric patients.

8.3. Service Delivery and Care Process

8.3.1. General

8.3.1.1. The CME ensures that written policies and procedures relating to the safe provision of anaesthetic or sedation procedures in the facility, including but not limited to the following, are in place and implemented:

(a) staffing arrangements for anaesthesia or sedation;
(b) informed consent;
(c) pre-procedural assessment;
(d) pre-procedural instructions (e.g. fasting, medication) and care;
(e) documentation of procedures;

(f) recovery care;
(g) patient discharge; and
(h) management of complications.

8.3.1.2. In developing policies and procedures in relation to high-risk anaesthetic procedures, reference is taken from relevant guidelines promulgated by the Hong Kong Academy of Medicine and the Hong Kong College of Anaesthesiologists.

8.3.2. Pre-procedure

8.3.2.1. Patients receiving anaesthetic or sedation procedures are provided with information on the procedure, including but not limited to the indication of the anaesthetic or sedation procedure, treatment alternative(s), the likely outcomes and risk of complications, before giving consent. Informed consent is documented in the medical record and/or in signed consent form.

8.3.2.2. Pre-procedural assessment is conducted by a medical practitioner or dentist. For patient undergoing procedure under sedation, there is a pre-sedation assessment in accordance with the *Guidelines on Procedural Sedation* (2020) promulgated by the Hong Kong Academy of Medicine. For patients undergoing general anaesthesia or major regional anaesthesia, the pre-anaesthetic assessment is in accordance with the *Guidelines on the Pre-anaesthetic Consultation* (v3, 2019) promulgated by the Hong Kong College of Anaesthesiologists. When it is not possible for the pre-sedation or pre-anaesthetic assessment to be done by the same medical practitioner or dentist who is responsible for the sedation or anaesthesia, there is an adequate documented mechanism for conveying findings of the consultation to the medical practitioner or dentist performing the sedation or anaesthesia. The final assessment by the medical practitioner or dentist for performing the sedation or anaesthesia is documented.

8.3.2.3. Patients are given adequate instructions for pre-procedural preparation (e.g. fasting), and care after anaesthesia or sedation (e.g. a responsible adult to escort and care for patient after anaesthesia or sedation).

8.3.2.4. The CME ensures that there are written policies and procedures on the following processes before anaesthetic or sedation procedures:
(a) checking of consent forms;
(b) verification processes, including time-out, to ensure correct patient,

procedural site and procedure; and

(c) accomplishment of pre-operative preparation (e.g. fasting, pre-medication).

8.3.3. Intra-procedure

8.3.3.1. All general anaesthesia, neuroaxial block or major plexus block are administered only by an anaesthesiologist or by a trained medical practitioner under the supervision of an anaesthesiologist.

8.3.3.2. Staffing arrangements and monitoring of patients undergoing procedural sedation are in accordance with the *Guidelines on Procedural Sedation* (2020) promulgated by the Hong Kong Academy of Medicine.[21]

8.3.3.3. In addition to 8.3.3.1, care process, staffing arrangement and monitoring of patients undergoing general anaesthesia or major regional anaesthesia and the documentation of the anaesthetic care are in accordance with the *Guidelines on Monitoring in Anaesthesia* (v5, 2017) promulgated by the Hong Kong College of Anaesthesiologists.

8.3.4. Post-procedure

8.3.4.1. All patients after anaesthetic or sedation procedures are observed for an adequate length of time commensurate with the anaesthesia or sedation given and the procedure performed, and their fitness for discharge are determined by the medical practitioner or dentist in-charge of the patient, subject to 8.3.4.2.

8.3.4.2. Recovery of patients who have received sedation should be in accordance with *Guidelines on Procedural Sedation* (2020) promulgated by the Hong Kong Academy of Medicine or relevant guidelines promulgated by the Hong Kong College of Anaesthesiologists. Recovery of patients who have received general anaesthesia or major regional anaesthesia takes place in an area that is adequately equipped and staffed for post-anaesthetic care, in accordance with *Guidelines on Postanaesthetic Recovery Care* (v5, 2019)

[21] In addition to the healthcare staff named by the *Guidelines on Procedural Sedation*, clinical assistants with relevant training or qualification in monitoring vital signs of patient undergoing sedation and procedural complications may also assume the role of such monitoring for patients undergoing procedural sedation, under the following conditions:

(a) holds a valid Basic Life Support (BLS) certificate; and

(b) works under the direct supervision of medical practitioner or dentist who retain personal responsibility for the monitoring.

promulgated by the Hong Kong College of Anaesthesiologists.

8.3.4.3. The anaesthesiologist, the medical practitioner, or the dentist administering the sedation or anaesthesia, unless he/she has delegated another medical practitioner or dentist to take up the role, is responsible for supervising the recovery of patient from anaesthesia or sedation. Medical practitioner, dentist or nurse trained in the post-anaesthetic care must be present at all times when a patient is in recovery and is/are able to promptly reach the supervising medical practitioner or dentist when need arises.

8.3.4.4. Monitoring of patients recovering from procedural sedation is in accordance with the *Guidelines on Procedural Sedation* (2020) promulgated by the Hong Kong Academy of Medicine.

8.3.4.5. Monitoring of patients recovering from general anaesthesia or major regional anaesthesia is in accordance with the *Guidelines on Postanaesthetic Recovery Care* (v5, 2019) promulgated by the Hong Kong College of Anaesthesiologists.

8.3.4.6. There are written policies and procedures for discharge of patients after procedures under anaesthesia or sedation, including but not limited to:
(a) discharge criteria;
(b) discharge instructions and advice (e.g. medication, care of post-operative site, complications, refraining from certain activities); and
(c) arrangements for enquiries or assistance outside operating hours.

8.3.4.7. For a patient who has received general anaesthesia, major regional anaesthesia or deep sedation, there is a responsible adult to escort him/her home.

8.3.4.8. There is written protocol on transfer of patients to hospital for those patients who are not fit to be discharged home after the procedure or anaesthesia or sedation.

8.3.5. Medical records

8.3.5.1. The following records are kept:
(a) detailed procedure or operation records of all procedures performed;
(b) investigation reports;
(c) consent forms;
(d) records for anaesthesia or sedation administered;

(e) records of post-operative care and pre-discharge evaluation; and
(f) outcome of the procedure.

8.3.5.2. Without limiting 8.3.5.3, records for anaesthesia or sedation include but are not limited to:
(a) name(s) of the medical practitioner(s) or dentist(s) and the assistant(s), if any, for performing the procedure and the anaesthesia or sedation;
(b) date, time, diagnosis, start time and end time of the procedure;
(c) record of the name, dose, time and route of administration of all medications, including all anaesthetic or sedation drugs, and fluids given for the procedure;
(d) blood and other fluid losses of the patient at the conclusion of the procedure; and
(e) regular readings from the monitored variables during anaesthesia or sedation, including those in the recovery phase, and other information as indicated (e.g. sedation-related complications).

8.3.5.3. For procedures under general anaesthesia or major regional anaesthesia, records of anaesthetic care are in accordance with the *Guidelines on Minimum Requirements for an Anaesthetic Record* (v4, 2017) promulgated by the Hong Kong College of Anaesthesiologists.

8.3.6. Continuous quality improvement

8.3.6.1. The CME develops and implements policies and procedures to review the appropriateness of patient care and monitoring of clinical performance and outcomes (e.g. complications attributable to anaesthesia or sedation, unanticipated hospital admission after anaesthesia or sedation).

8.4. Infection Control

8.4.1. Infection control policies and procedures

8.4.1.1. There are written infection control policies, procedures and guidelines for prevention of surgical infection, including but not limited to:
(a) standard precautions;
(b) use of aseptic techniques;
(c) environmental cleansing and disinfection;
(d) cleaning, disinfection and sterilisation, and storage of equipment as

appropriate; and

(e) monitoring of effectiveness of infection control measures.

Reference is taken from guidelines promulgated by relevant health and professional authorities (e.g. *Recommendations on Prevention of Surgical Site Infection* promulgated by the Centre for Health Protection of the Department of Health; *Guidelines on Infection Control in Anaesthesia* promulgated by the Hong Kong College of Anaesthesiologists).

8.5. Resuscitation and Contingency

8.5.1. Risk management

8.5.1.1. There are staff-to-staff communication systems for emergency in the operating or procedure room, and recovery area.

8.5.1.2. There are patient-to-staff call systems or devices (e.g. call bells) where a patient may be left alone temporarily (e.g. patient changing room in the facility).

8.5.2. Resuscitation of patients

8.5.2.1. There are adequate and appropriate resuscitation equipment including but not limited to:

(a) device that can ventilate the lungs;
(b) oxygen supply;
(c) suction;
(d) basic intravenous setup; and
(e) defibrillator.

8.5.2.2. In a facility where procedural sedation is conducted, resuscitation equipment and emergency medications as required in the *Guidelines on Procedural Sedation* (2020), promulgated by the Hong Kong Academy of Medicine, are in place. Regular checks on their viability are conducted and documented.

8.5.2.3. In a facility where general anaesthesia or major regional anaesthesia is performed, resuscitation equipment as required in the *Recommended Minimum Facilities for Safe Anaesthetic Practice in Operating Suites* (v4, 2016), promulgated by the Hong Kong College of Anaesthesiologists, are in

place.[22] Selection of medications to deal with emergency arising from anaesthesia shall be in consultation with an anaesthesiologist. Regular checks on their viability are conducted and documented.

8.5.2.4. Emergency medications are stored in a designated and easily accessible area in the facility.

8.5.3. Emergency transfer

8.5.3.1. If the patient requires emergency transfer to a hospital, the anaesthesiologist, and/or the medical practitioner or dentist performing the procedure, is/are responsible for the care of the patient until the patient has been transferred to another appropriate medical staff.

8.5.3.2. There are policies and procedures in place for emergency transfer of patient to hospital for management of urgent adverse outcome.

8.5.3.3. Drills for emergency transfer are conducted at regular intervals and documented.

[22] As a transitional arrangement, the requirement for operating room to have oxygen supply through oxygen pipe (with at least two outlets) for general anaesthesia or major regional anaesthesia must be complied with by 2022.

This page is intentionally left blank

Chapter 9
Radiotherapy

9.1. Management/Governance

9.1.1. Staff requirement and training

9.1.1.1. For a facility that provides external beam radiotherapy service, a specialist in clinical oncology is appointed to be the CME. For a facility that provides radionuclide therapy service, a specialist in nuclear medicine is appointed to be the CME. For a facility that provides both external beam radiotherapy and radionuclide therapy services, a specialist in clinical oncology is appointed to be the CME and a specialist in nuclear medicine is appointed as an advisor, or vice versa.

9.1.1.2. Where the CME is not the specialist of the said qualifications in 9.1.1.1., specialist(s) with such qualification(s) is/are appointed as advisor(s) for the service to regularly review the facilities, equipment, staff training, and policies and procedures of the radiotherapy service.

9.1.1.3. For each patient attending the facility, there is a specialist in clinical oncology or nuclear medicine in charge of his or her radiotherapy treatment.

9.1.1.4. At all times when the facility is in operation, a medical practitioner should be contactable to render medical care and advice when needed and in emergency.

9.1.1.5. Where there is no medical practitioner immediately available for medical care during radiotherapy treatment, a registered nurse is available at all times to provide support on patient care.

9.1.1.6. Certified medical physicist with relevant experience and training is available for-

(a) measurement of radiation used;
(b) calibration, commissioning, acceptance and optimisation of radiological equipment;
(c) verification and quality assurance of the equipment, the radiological procedures and treatment planning;

(d) advising and assisting to implement measures on radiation safety and protection; and
(e) training of staff on radiation protection.

9.1.1.7. Part I therapeutic radiographer with relevant experience and training is available at all times to take charge of the day to day operation of the service. A specialist in nuclear medicine may also assume the role of taking charge of the day to day operation of radionuclide service if he/she has the relevant experience or training.

9.1.1.8. Staff should handle irradiating apparatus and/or radioactive substances under and in accordance with licence issued under the *Radiation Ordinance* (Cap. 303).

9.2. Physical Conditions

9.2.1. Facility management

9.2.1.1. Each procedure room or preparation room is suitably designed, equipped, and maintained for the purpose to be used. The design conform to the requirements of the *Radiation Ordinance* (Cap. 303) where applicable.

9.2.1.2. There is access control to areas where irradiating apparatus is used, and/or where radioactive substances are handled or stored.

9.2.2. Equipment, store and transport

9.2.2.1. The possession and use of irradiating apparatus and radioactive substances, including the transportation, keeping, storage, and disposal of radioactive substances and wastes, conform to the requirements of the *Radiation Ordinance* (Cap. 303).

9.2.2.2. All equipment used for provision of radiotherapy, including treatment planning, delivery and monitoring, are appropriately commissioned, calibrated and kept in good functional order. Regular testing, repairing, maintenance and calibration of such equipment are performed, signed and documented by or under the personal supervision of a certified medical physicist.

9.2.2.3. Appropriate immobilisation device, shielding equipment and personal protective equipment are available where applicable.

9.3. Service Delivery and Care Process

9.3.1. General

9.3.1.1. The CME ensures that written policies and procedures relating to the safe provision of radiotherapy in the facility, including but not limited to the following, are in place and implemented:

(a) staffing arrangements;
(b) selection, maintenance, and appropriate use of personal protective equipment;
(c) obtaining written consent before the commencement of radiotherapy;
(d) quality assurance to ensure accurate delivery of targeted radiation doses to patients, including where applicable, individual treatment plans, simulation, localization, dose measurement and equipment such as irradiating apparatus and treatment planning system;
(e) assessment of patients' condition and clinical parameters prior to radiotherapy;
(f) supervision of patients during and monitoring of patient after the delivery of radiotherapy;
(g) interruption or modification of treatment plan; and
(h) where radionuclide therapy is provided,
    (i) handling, storage, transport, and disposal of radioactive substances and related wastes;
    (ii) dispensing and administration of radionuclide to patients;
    (iii) management of contaminations, patient excreta and spillage; and
    (iv) patient discharge arrangement and discharge instructions as relevant to the treatment prescribed.

9.3.1.2. Patients receiving radiotherapy are provided with information on the procedure, including but not limited to the indication of the procedure, treatment alternative(s), hazards involved, and the likely outcomes and risk of complications, before giving consent. Informed consent is documented in the medical record and/or in signed consent form.

9.3.1.3. The CME ensures that there are written policies and procedures on the following processes before radiotherapy:
(a) checking of consent forms;
(b) verification processes to ensure correct patient, treatment site, treatment plan and procedure; and
(c) verification of treatment protocols and treatment parameter of external beam radiotherapy equipment; and/or physical and chemical characteristics, dose and route of administration of radionuclides.

9.3.1.4. Patients are given adequate instructions for intra-procedural precautions (e.g. immobilisation) and post-procedural care and discharge (e.g. immobilisation for patient received radiosynoviorthesis therapy; handling of excreta following radionuclide therapy).

9.3.1.5. Where irradiating apparatus or radioactive substance is used, licence under *Radiation Ordinance* (Cap. 303) is obtained.

9.3.2. Medical Records

9.3.2.1. The following records are kept:
(a) treatment plan and prescription records, including but not limited to diagnosis, prescription, planned treatment dose and fractionation scheme, route of delivery, treatment aids used, delivered dose, and schedule modification;
(b) any known drug hypersensitivity or allergy;
(c) staff involved in the procedure;
(d) assessment of patients' condition prior to, during, and after radiotherapy;
(e) treatment-related adverse reactions;
(f) relevant investigation reports, simulation and imaging records; and
(g) consent forms.

9.3.3. Continuous quality improvement

9.3.3.1. The CME ensures that written policies and procedures for reviewing the appropriateness of patient care and for monitoring of clinical performance and outcomes (e.g. emergency transfer, unanticipated hospital admission) are implemented.

9.4. Infection Control

9.4.1. Infection control policies and procedures

9.4.1.1. Written policies and procedures on infection control, which include but not limited to the followings, are in place and implemented:
(a) standard and transmission-based precautions;
(b) preparation and administration of radionuclides using aseptic techniques, where applicable;
(c) environmental cleansing and disinfection; and
(d) monitoring the effectiveness of infection control measures.

9.5. Resuscitation and Contingency

9.5.1. Risk management

9.5.1.1. There are staff-to-staff communication systems for emergencies.

9.5.1.2. There are patient-to-staff communication systems or devices where a patient may be left alone temporarily (e.g. intercom system in procedure room, call bells in patient changing room).

9.5.1.3. There are written policies and procedures for handling emergencies within the service, including radiation incident, fire hazard, and sudden interruption of electricity supply.

9.5.2. Resuscitation of patients

9.5.2.1. There are adequate and appropriate resuscitation equipment, including but not limited to:
(a) device that can ventilate the lungs;
(b) oxygen supply;
(c) suction;
(d) basic intravenous setup; and
(e) defibrillator.

9.5.2.2. Emergency medications are stored in a designated and easily accessible area in the facility. Regular checks on their viability are conducted and documented.

9.5.3. Emergency transfer

9.5.3.1. Policies and procedures are in place for emergency transfer of patient to hospital for management of urgent adverse outcomes.

9.5.3.2. Drills for emergency transfer are conducted at regular intervals and documented.

Annex I

Classes of Specialized Services

(Reproduced from Schedule 3 to the *Private Healthcare Facilities Ordinance*)

Column 1 Class of specialized services	Column 2 Particular medical procedures	Column 3 Exceptions to medical procedures described in column 2
1. Surgical procedure	(a) Creation of surgical wound to allow access to major body cavity or viscus, including access to central large joints	(i) Needle injection (ii) Creation of surgical wound to allow access to peripheral joints distal to knee and elbow
	(b) Removal of tissue or fluid, or both, of a total volume of 500 mL or above	Suprapubic tap
	(c) Removal of tissue or fluid, or both, of any volume from deep seated organ in children under the age of 12 years	
	(d) Removal of tissue or fluid, or both, of any volume from thoracic cavity	Diagnostic pleural tapping
	(e) Insertion of prosthesis or implant	(i) Insertion of prosthesis in ear, nose and throat cavity (ii) Insertion of dental prosthesis and implant (iii) Insertion of facial implant (iv) Insertion of extra-ocular prosthesis and implant (v) Insertion of intrauterine or vaginal prosthesis (vi) Insertion of bulking agent of urethra (vii) Insertion of prostatic urethral stent (viii) Insertion of urethral sling (ix) Insertion of testicular prosthesis

Column 1 Class of specialized services	Column 2 Particular medical procedures	Column 3 Exceptions to medical procedures described in column 2
	(f) Core biopsy	(i) Core biopsy of superficial tissue excluding thyroid or salivary glands (ii) Core biopsy of superficial and peripheral muscle
	(g) Biopsy of deep-seated organ	
	(h) Lumbar puncture	
	(i) Transplant of any cell, tissue or organ, including autograft, allograft, xenograft, processed tissue or blood products (including platelet-rich plasma) and skin flap (including face lift)	(i) Skin graft less than 1% of total body surface area (ii) Transplant of conjunctival autograft (iii) Transplant procedure which primarily involves dento-alveolar region
	(j) Termination of pregnancy	
	(k) Dilation and curettage	
	(l) Circumcision with use of skin sutures in paediatric patients	
2. Endoscopic procedure	(a) Endoscopic procedure requiring image guidance	
	(b) Endoscopic procedure involving invasion of sterile cavity or gastrointestinal tract	Cystoscopy, and cystoscopic removal of ureteric catheter or stent, but not including other therapeutic cystoscopic procedure
	(c) Therapeutic endoscopic procedure	Minor therapeutic procedure such as removal of foreign body

Column 1 Class of specialized services	Column 2 Particular medical procedures	Column 3 Exceptions to medical procedures described in column 2
3. Dental procedure	Maxillofacial surgical procedure that extends beyond dento-alveolar process, including but not limited to— (a) Maxillary osteotomies and mandibular osteotomies (including angle reduction) (b) Open reduction and fixation of complex maxillofacial fracture (c) Surgical treatment of diagnosed malignancies (d) Surgical treatment of complex haemangioma (e) Surgery involving major salivary glands (f) Open surgery of temporomandibular joint (g) Harvesting of autogenous bone from outside oral cavity (h) Primary cleft lip and palate surgery	(i) Temporomandibular arthrocentesis (ii) Temporomandibular arthroscopy
4. Chemo-therapy	Administration of chemotherapy (cytotoxic) through parenteral routes regardless of therapeutic indication	
5. Haemo-dialysis	Haemodialysis	
6. Inter-ventional radiology and lithotripsy	(a) Extracorporeal shock wave lithotripsy (ESWL) requiring image guidance	
	(b) Image-guided core biopsy	(i) Image-guided core biopsy of superficial tissues excluding thyroid or salivary glands (ii) Image-guided core biopsy of superficial and peripheral muscle

Column 1 Class of specialized services	Column 2 Particular medical procedures	Column 3 Exceptions to medical procedures described in column 2
7. Anaesthetic procedure	(a) General anaesthesia (b) Neuroaxial blocks (including spinal, epidural and caudal) (c) Major plexus block (including cervical, brachial, lumbar and sacral) (d) Intravenous regional anaesthesia (e) Intercostal nerve block (f) Major nerve block— (i) Glossopharyngeal nerve, vagus nerve or their terminal branches (including superior, inferior and recurrent laryngeal nerves); (ii) Sciatic and femoral nerves; (iii) Posterior tibial nerve, pudendal nerve or para-cervical block (g) Use of sedative or analgesic drugs with reasonable expectation that it will, in the manner used, result in deep sedation for a significant percentage of a group of patients (h) Tumescent anaesthesia	
8. Radio-therapy	(a) External beam radiotherapy (b) Brachytherapy (c) Radionuclide therapy	

Annex II
Guidelines on Use of Operating Room for Surgical Procedures in Day Procedure Centres

---

This document aims to provide a general guidance on the use of an operating room, as defined below and based on prevailing international standards in respect of specialized ventilation for infection control, for day surgery in ambulatory setting.[23]

Medical practitioners and dentists must exercise professional judgment in deciding whether a procedure should be performed in or outside an operating room in ambulatory setting taking into account, among others, the nature of the procedure, patient's condition, the risks and consequences of infection, and the possibility of converting to open surgery.

Operating room is a room that meets the requirements of a restricted area and is designated and equipped with specialized ventilation, among others, for performing surgical or other invasive procedures that require aseptic surgical field. These procedures usually carry a high risk of infection (either by exposure of a usually sterile body cavity to the external environment or by implantation of a foreign object into a normally sterile site) or the consequences of infection can be devastating. In this context, procedures performed through orifices normally colonised with bacteria are not included. Any form of anaesthesia may be administered in an operating room. When gaseous anaesthetic agents are used, appropriate gas administration devices and exhaust systems are in place and requirements on occupational safety should be observed.

Restricted area is a designated space that can only be accessed through a semi-restricted area. The restricted access is primarily intended to support a high level of asepsis control. Traffic in the restricted area is limited to authorized personnel and patients. Personnel in restricted areas are required to wear surgical attire, and cover head and facial hair. Masks are required where open sterile supplies or scrubbed persons may be located.

---

[23] The prevailing international standards for ventilation of an operating room include, among others, *Health Technical Memorandum (HTM) 03-01* and *ANSI/ASHRAE/ASHE Standard 170*. For requirements on local application of prevailing international standards of specialized ventilation in operating room, licensee must refer to paragraph 1.6.3. on specialized ventilation systems in section 1.6 *Healthcare Engineering Systems*.

Examples of surgical and dental procedures that should be performed in an operating room:

- Implantation of intraocular lens
- Arthroscopy
- Suction and evacuation
- Dilatation and curettage
- Maxillofacial surgery

Examples of surgical and dental procedures that may be performed outside an operating room:

- Endoscopic procedures through natural orifices (e.g. GI endoscopy, cystoscopy, hysteroscopy) not involving insertion of implant or prosthesis into a sterile site
- Therapeutic pleural or abdominal tap
- Percutaneous biopsy of liver or kidney
- Colposcopy with loop electrosurgical excision procedure

The examples are provided for reference and not exhaustive.

References to Annex II

1. ANSI/ASHRAE/ASHE Standard 170-2021: Ventilation of health care facilities. Atlanta: ASHRAE; 2021.
2. Estates and Facilities Division, Department of Health. Health technical memorandum (HTM) 03-01: Specialised ventilation for healthcare premises. Part A - The concept, design, specification, installation and acceptance testing of healthcare ventilation systems. London: Department of Health and Social Care; 2021 Aug 31.
3. Humphreys H, Coia JE, Stacey A, Thomas M, Belli AM, Hoffman P, et al. Guidelines on the facilities required for minor surgical procedures and minimal access interventions. J Hosp Infect. 2012 Feb;80(2):103-9. doi: 10.1016/j.jhin.2011.11.010. Epub 2011 Dec 20.
4. Skues M. BADS Directory of procedures. 5th Ed. London: British Association of Day Surgery; 2016 Jun.

Annex III
Guidelines for Dental Compressed Air and Vacuum Systems

General requirements

1. A dental compressed air and vacuum system (DAVS) is a central system providing compressed air and/or vacuum suction, and comprises sources of supply and a pipeline distribution system connecting to the dental chair. This system is not applicable to portable compressed air equipment, portable suction source equipment, and the localised equipment forming part of a proprietary dental chair with compressor or vacuum pump unit, and interconnection tubing matched to the needs of the air instruments therein.

2. This *Guidelines for Dental Compressed Air and Vacuum Systems* provides general guidance on the design, installation, operation and maintenance of a DAVS in the facility for safe and effective delivery of healthcare services.

3. The manufacture, storage, supply and use of a DAVS in the facility comply with all relevant statutory requirements, including but not limited to those stipulated under the following Ordinances and their subsidiary legislations and codes of practice:
   (a) *Dangerous Goods Ordinance* (Cap. 295);
   (b) *Fire Services Ordinance* (Cap. 95);
   (c) *Electricity Ordinance* (Cap. 406); and
   (d) *Boilers and Pressure Vessels Ordinance* (Cap. 56).

4. An operational policy for the management of the DAVS is in place.

5. The design and installation of the DAVS meet internationally acceptable healthcare standards such as *Health Technical Memorandum (HTM) 2022 – Supplement 1* (2003 edition) – *Dental compressed air and vacuum systems*, or equivalent.

6. The capacities of the DAVS plants are adequate to meet the system demand of air flow and pressure for the safe operation of dental instruments.

7. The design and installation of the DAVS are certified by a registered professional engineer in the mechanical discipline or building services discipline under the *Engineers Registration Ordinance* (Cap. 409) to be in compliance with the CoP.

8. Testing and commissioning are conducted for new installations of DAVS, and additions or alterations to existing installations, to ensure that all the necessary safety and performance requirements of the DAVS are met. The following tests that meet internationally acceptable healthcare standards such as *HTM 2022 – Supplement 1* (2003 edition), or equivalent, are carried out:
   (a) functional tests;
   (b) tests for cross connection;
   (c) tests for leakage;
   (d) tests for flow and pressure;
   (e) tests for safety valves;
   (f) tests of warning system; and
   (g) tests for air quality.

Design and installation of dental compressed air system

9. The compressed air of a dental compressed air system is used to power the dental equipment and dental laboratory equipment, and to dry oral structures. This system comprises the following key components and accessories, or others with equivalent functions:
   (a) air inlet with filter;
   (b) compressor;
   (c) bacteria filter;
   (d) dryer;
   (e) oil and water separator;
   (f) air receiver with pressure gauge, pressure safety valve and drain;
   (g) pressure regulator;
   (h) pipeline and valves; and
   (i) gas-specific test point.

10. The dental compressed air system is designed to provide a minimum flow of 50 L/min continuously at the instrument connection end while maintaining a nominal pressure of 550 kPa.

11. The dental compressed air is clean and dry, appropriate for dental service use in all cases and properly treated to minimise the risk of contamination by micro-organisms to an acceptable level.

12. The bacteria filter is fitted at the downstream of the system and provides particle removal to 0.01 μm with a filtration efficiency of not less than 99.9999% under dispersed oil particulate test, at class U16 in accordance with *EN 1822*, or the manufacturer's recommendation.

13. Plants and equipment of dental compressed air system are provided with standby unit and connected to back-up power supply to ensure continuity and security of the system operation during normal and contingent situations. Where it is not feasible to provide standby unit or back-up power supply for the plants and equipment, an emergency response policy is established to ensure patient safety in that event.

14. The air receiver, its fittings and attachments are examined by an appointed examiner before they are put into use in accordance with the *Boilers and Pressure Vessels Ordinance* (Cap. 56).

Design and installation of dental vacuum system

15. The dental vacuum system is used to draw off saliva, secretions, tooth material and cooling water. This system comprises the following key components and accessories, or others with equivalent functions:
    (a) filter;
    (b) pump unit;
    (c) separator unit;
    (d) pipeline and valves;
    (e) drain; and
    (f) air outlet.

16. The dental vacuum system is designed to provide adequate suction pressure and air flow at each cannula connector for the dental treatment processes therein. The suction pipeline is also designed to carry the mixture of air, liquid and detritus at the required flow rate and pressure.

17. Where the air outlets are installed as part of the installations of the facility, they are either:
    (a) located outside the building on the condition that the air outlets are away from air intakes and opening windows to reduce the potential for the recirculation of discharged air back into the building, or
    (b) located inside the building on the condition that the exhaust line is provided with a filter complying with the following requirements or manufacturer's recommendation:
        (i) providing particle removal to 0.01 μm with a filtration efficiency of not less than 99.9999% under dispersed oil particulate test, at class U16 in accordance with *EN 1822* or equivalent; and
        (ii) removing unpleasant odours arising from the system.

18. Plants and equipment of dental vacuum system are provided with standby unit and connected to back-up power supply to ensure continuity and security of the system operation during normal and contingent situations. Where it is not feasible to provide standby unit or back-up power supply for the plants and equipment, an emergency response policy is established to ensure patient safety in that event.

Operation and maintenance of DAVS

19. The DAVS is properly operated and maintained, complying with all applicable statutory requirements, and taking into consideration of the guidance given in internationally acceptable healthcare standards such as *HTM 2022 – Supplement 1* (2003 edition*)* or equivalent, the manufacturers' recommendations and good trade practices. Unless otherwise specified by the manufacturer's recommendations, the following components and accessories of the DAVS are maintained and tests of air quality are performed regularly:
    (a) dental air compressors;
    (b) dental vacuum pumps;
    (c) receivers of air compressor;
    (d) filter elements;
    (e) dryer units;
    (f) drains and drain traps; and
    (g) separator units, where applicable.

20. The DAVS is subject to a planned preventive maintenance schedule under the responsibility of the facility. All the maintenance and test records, and as-fitted drawings are properly documented.

21. Where the DAVS is connected to and forms part of the installations of Medical Gas Pipeline Systems (MGPS), all the works on the DAVS of the facility are governed by a safety management system in accordance with the requirements of MGPS in other sections herein.

22. The facility has an emergency call-out service arrangement in place with a specialist contractor in DAVS to provide prompt onsite support in the event of any breakdown or other incidents related to DAVS.

Annex IV
Sample of Permit-to-Work Form

A sample of Permit-to-Work Form is shown on the next two pages for reference. The management of healthcare facility may design a suitable Permit-to-Work Form for use based on its operating model.

[Sample]

Permit To Work Form

Medical Gas pipeline Systems
Hazard Level:_____
Facility:_____ Permit No._____

Part 1 Description of work by authorized person ("AP(MGPS)") and permission to proceed from Designated Medical/Nursing Officer ("DMO/DNO")

The Following works is to be carried out.

_____

_____

Working drawing no._____ Work procedure no._____ Dated_____
Commencement hr/day_____ Completion hr/day_____
* the affected medical locations, pipelines and valves shall be highlighted on working drawing.
AP(MGPS) Name_____ Sign_____ Date_____ Time_____

Clinical/Nursing permission is required for this work and is granted by
DMO/DNO Name_____ Sign_____ Date_____ Time_____

Part 2 Acceptance of work and conditions by Competent Person (MGPS) ("CP(MGPS)")
I accept responsibility for the work as described.
No other work will be carried out by me or persons working under my control.
I am fully conversant with the work described and relevant health and safety requirement.
CP (MGPS) Name_____ Sign_____ Date_____ Time_____

Part 3 Confirmation of work completion, engineering test results and readiness for pharmaceutical testing
Works described in Part 1 has been completed and the following engineering test have been carried out

TEST	P/F	TEST	P/F

I have advised the AP(MGPS) of all works and tests carried out and provided details of installations
Test results are/are not satisfactory.
The installation has been left in a safe condition.
CP(MGPS) Name_____ Sign_____ Date_____ Time_____

The system is/is not ready for pharmaceutical testing, this Permit is hereby cancelled.
AP(MGPS) Name_____ Sign_____ Date_____ Time_____

Part 4 Pharmaceutical tests and authorization to use system by Quality Controller (MGPS) ("QC(MGPS") and AP(MGPS)

	O_2	N_2O	N_2O/O_2	MA	SA	VAC	AGSS
Test	P/F	P/F	P/F	P/F	P/F	P/F	P/F
Purging and filling							
Gas Identity							
Gas Quality							
Particulate meter							
Pipeline Odour							

The test results are/are not satisfactory. The system may/may not be taken into use.
QC(MGPS) Name_____ Sign_____ Date_____ Time_____
AP(MGPS) Name_____ Sign_____ Date_____ Time_____

Part 5 Acceptance of system status by Designated Medical/Nursing Officer
I declare that all aspects of the work have been explained to me. I hereby accept that the system is ready/not ready for service and I will undertake to advise all the appropriate staff of this service status.

DMO/DNO Name_____ Sign_____ Date_____ Time_____

References

Hong Kong

1. The Dental Council of Hong Kong. Code of professional discipline for the guidance of dental practitioners in Hong Kong. Hong Kong: The Dental Council of Hong Kong; 2019 Dec.
2. *Dentists Registration Ordinance* (Cap. 156). (HK).
3. Department of Health. Code of practice for clinics registered under the medical clinics ordinance. Hong Kong: Department of Health; 2010 Jan.
4. Department of Health. Code of practice for private hospitals. Hong Kong: Department of Health; 2019 Jun.
5. Department of Health. Code of practice for private hospitals, nursing homes and maternity homes. Hong Kong: Department of Health; 2016 Dec.
6. Department of Health. Consultation document: regulation of advanced therapy products. Hong Kong: Department of Health; 2018 Apr 3.
7. Department of Health. Consultation report: regulation of advanced therapy products. Hong Kong: Department of Health; 2018 Oct 30.
8. Department of Health. Module on immunisation. Hong Kong reference framework for preventive care for children in primary care settings. Hong Kong: Department of Health; 2019.
9. Department of Health. Standards for medical clinics (draft). Hong Kong: Department of Health; 2018 Jan.
10. Electrical and Mechanical Services Department. Code of practice for the electricity (wiring) regulations. Hong Kong: Electrical and Mechanical Services Department; 2020.
11. Electrical and Mechanical Services Department. Code of practice for fresh water cooling towers: Parts 1, 2 and 3. Hong Kong: Electrical and Mechanical Services Department; 2016.
12. Electrical and Mechanical Services Department. Fresh water cooling towers scheme brochure. Hong Kong: Electrical and Mechanical Services Department; 2016.
13. Hong Kong Academy of Medicine. Guidelines on procedural sedation. Hong Kong: HKAM; 2020 Jan 1.
14. The Hong Kong College of Anaesthesiologists. Guidelines on infection control in anaesthesia. HKCA-P15-v4. Hong Kong: HKCA; 2020 May.

15. The Hong Kong College of Anaesthesiologists. Guidelines on minimum requirements for an anaesthetic record. HKCA-T6-v4. Hong Kong: HKCA; 2017 Jun.
16. The Hong Kong College of Anaesthesiologists. Guidelines on monitored care by an anaesthesiologist. HKCA-P16-v2.2. Hong Kong: HKCA; 2019 Dec 13.
17. The Hong Kong College of Anaesthesiologists. Guidelines on monitoring in anaesthesia. HKCA-P1-v5. Hong Kong: HKCA; 2017 Jun.
18. The Hong Kong College of Anaesthesiologists. Guidelines on the pre-anaesthetic consultation. HKCA-P13-v3. Hong Kong: HKCA; 2019 Aug 21.
19. The Hong Kong College of Anaesthesiologists. Guidelines on post-anaesthetic recovery care. HKCA-P3-v5. Hong Kong: HKCA; 2019 Oct.
20. The Hong Kong College of Anaesthesiologists. Guidelines on quality assurance. HKCA-P7-v3. Hong Kong: HKCA; 2018 Sep.
21. The Hong Kong College of Anaesthesiologists. Guidelines for safe sedation for diagnostic and therapeutic procedures. HKCA-P2-v3. Hong Kong: HKCA; 2017 Jun.
22. The Hong Kong College of Anaesthesiologists. Recommendations for the perioperative care of patients selected for day care surgery. HKCA-P5-v3. Hong Kong: HKCA; 2017 Dec 19.
23. The Hong Kong College of Anaesthesiologists. Recommended minimum facilities for safe anaesthetic practice in operating suites. HKCA-T2-v4. Hong Kong: HKCA; 2016 Dec.
24. The Hong Kong College of Physicians, the Central Renal Committee of Hospital Authority of Hong Kong and the Hong Kong Society of Nephrology. Clinical practice guidelines for the provision of renal services in Hong Kong. Hong Kong: Nephrology. Vol 24 supp 1; 2019 Mar.
25. Hospital Authority. Code of practice on radiation safety 2011. Hong Kong: Hospital Authority; 2011.
26. *Hospitals, Nursing Homes and Maternity Homes Registration Ordinance* (Cap. 165). (HK).
27. *Human Reproductive Technology Ordinance* (Cap. 561). (HK).
28. Infection Control Branch, Centre for Health Protection, Department of Health. Guide to infection control in clinic setting November 2018. Hong Kong: Centre for Health Protection; 2020 Jun.
29. Infection Control Branch, Centre for Health Protection, Department of Health and Central Renal Committee, Hospital Authority. Infection control guidelines on nephrology services in Hong Kong 2018. Third Edition. (version 3.2). Hong Kong: Centre for Health Protection; 2019 Oct.
30. *Pharmacy and Poisons Ordinance* (Cap. 138). (HK).

31. *Personal Data (Privacy) Ordinance* (Cap. 486). (HK).
32. *Medical Clinics Ordinance* (Cap. 343). (HK).
33. Medical Council of Hong Kong. Code of professional conduct for the guidance of registered medical practitioners. Hong Kong: Medical Council of Hong Kong; 2016 Jan.
34. Medical Council of Hong Kong. Guidelines for all registered medical practitioners. Ethical guidelines on practice of telemedicine. Hong Kong: Medical Council of Hong Kong Newsletter Issue No. 26; 2019 Dec.
35. *Medical Registration Ordinance* (Cap. 161). (HK).
36. *Nurses Registration Ordinance* (Cap. 164). (HK).
37. *Prevention and Control of Disease Ordinance* (Cap. 599). (HK).
38. *The Radiation (Control of Irradiating Apparatus) Regulations* (Cap. 303B). (HK).
39. *Radiation Ordinance* (Cap. 303). (HK).
40. Scientific Committee on Infection Control, and Infection Control Branch, Centre for Health Protection, Department of Health. Recommendations on prevention of surgical site infection. 2nd Ed. Hong Kong: Centre for Health Protection, Department of Health; 2017 Sep (Addendum 02/2019).
41. *Supplementary Medical Professions Ordinance* (Cap. 359). (HK).
42. Occupational Safety and Health Branch, Labour Department. Chemical safety in the workplace – Guidance notes on personal protective equipment (PPE) for use and handling of chemicals. Hong Kong: Labour Department; 2009 Jan.
43. Occupational Safety and Health Branch, Labour Department. Chemical safety in the workplace – Guidance notes on risk assessment and fundamentals of establishing safety measures. Hong Kong: Labour Department; 2001 Sep.
44. *Waste Disposal Ordinance* (Cap. 354). (HK).
45. Working Group on Quality Assurance in Renal Services. Quality initiative recommendation in the provision of renal services. Hong Kong: Hong Kong College of Physicians and Central Renal Committee, Hospital Authority. [Cited 2017 Jun 1]

Australia

46. The Australasian Health Infrastructure Alliance. Australasian health facility guidelines. Part B – Health facility briefing and planning – Day surgery procedure unit. Revision 7.0. North Sydney: AHIA; 2022 March 29.
47. The Australasian Health Infrastructure Alliance. Australasian health facility guidelines. Part B – Health facility briefing and planning – Renal dialysis unit. Revision 7.0. North Sydney: AHIA; 2021 Feb 9.

48. Australian and New Zealand College of Anaesthetists. Guidelines on sedation and/or analgesia for diagnostic and interventional medical, dental or surgical procedures. Professional standards PS09. Melbourne: ANZCA; 2014.
49. Australian and New Zealand College of Anaesthetists. PS55(A) Position statement on minimum facilities for safe administration of anaesthesia in operating suites and other anaesthetising locations. Melbourne: ANZCA; 2021 Aug.
50. Australian and New Zealand College of Anaesthetists. Recommendations for the post-anaesthesia recovery room. Professional standards PS04. Melbourne: ANZCA; 2006 Aug.
51. The Australian Health Practitioner Regulation Agency (Ahpra) and National Boards. Telehealth guidance for practitioners. Melbourne: Ahpra; 2020 Jul 27.
52. Cancer Therapy Medication Safety Working Group. COSA guidelines for the safe prescribing, dispensing and administration of systemic cancer chemotherapy. Sydney: Cancer Council Australia. [Version URL: https://wiki.cancer.org.au/australiawiki/index.php?oldid=183289, cited 2018 Apr 8]. Available from: https://wiki.cancer.org.au/australia/COSA: Cancer_chemotherapy_medication_safety_guidelines
53. Gastroenterological Nurses College of Australia. Infection prevention and control in endoscopy 2021. Melbourne: Gastroenterological Society of Australia; 2021 Sep.
54. *Health Regulation 1996* (Current as at 2018 Dec 14). Part 4 Dispensary. Division 4 Dispensing of antineoplastic drugs. (QLD).
55. Medical Board of Australia. Guidelines: Technology-based patient consultations. Melbourne: Medical Board of Australia; 2012 Jan16.
56. Office of Industrial Relations, Workplace Health and Safety Queensland. Guide for handling cytotoxic drugs and related wastes. PN10522 Version 4. Queensland: Queensland Government, 2017 Feb.
57. *Private Health Facilities Act 1999*. (QLD)
58. *Private Health Facilities Regulation 2016*. (QLD).
59. *Private Health Facilities (Standards) Notice 2016*. (QLD)
60. Private Health Facilities Act 2007 No 9. (NSW)
61. *Private Health Facilities Regulation 2017*. (NSW)
62. *Private Health Facilities Regulation 2017*. Schedule 2 Licensing standards. Part 4 Chemotherapy class private health facilities. (NSW).
63. *Private Health Facilities Regulation 2017*. Schedule 2 Licensing standards. Part 15 Radiotherapy class private health facilities. (NSW).
64. Queensland Health. The clinical services capability framework for public and licensed private health facilities – anaesthetic services. CSCF v3.2. Queensland:

Queensland Government; 2017 May 15.
65. Queensland Health. The clinical services capability framework for public and licensed private health facilities – anaesthetic services – children's. CSCF v3.2. Queensland: Queensland Government; 2014 Dec.
66. Queensland Health. The clinical services capability framework for public and licensed private health facilities – cancer services – radiation oncology. CSCF v3.2. Queensland: Queensland Government; 2014 Dec.
67. Queensland Health. The clinical services capability framework for public and licensed private health facilities – medical imaging service. CSCF v3.2. Queensland: Queensland Government; 2014 Dec.
68. Queensland Health. The clinical services capability framework for public and licensed private health facilities – nuclear medicine service. CSCF v3.2. Queensland: Queensland Government; 2014 Dec.
69. Queensland Health. The clinical services capability framework for public and licensed private health facilities – perioperative. CSCF v3.2. Queensland: Queensland Government; 2017 Aug 28.
70. Queensland Health. The clinical services capability framework for public and licensed private health facilities – renal services. CSCF v3.2. Queensland: Queensland Government; 2016 May 13.
71. Standards Australia. AS2252.5:2017 – Controlled environments. Part 5: Cytotoxic drug safety cabinets (CDSC) – Design, construction, installation, testing and use. 2017 [Revised 27 Jul 2017; cited 2018 Aug 29]. Available from: https://infostore.saiglobal.com/en-au/Standards/AS-2252-5-2017-99379_SAIG_AS_AS_208939/
72. Standards Australia. AS/NZ4187:2003 – Cleaning, disinfecting and sterilizing reusable medical and surgical instruments and equipment, and maintenance of associated environments in health care facilities. 2003 [Cited 2016 Nov 8]. Available from: https://infostore.saiglobal.com/en-au/Standards/Product-Details-111440_SAIG_AS_AS_243773/?ProductID=111440_SAIG_AS_AS_243773
73. Statewide Renal Clinical Network. Clinical guideline – South Australian haemodialysis guidelines: routine water testing and reverse osmosis monitoring. Version 2.0. South Australia: SA Health, Government of South Australia; 2015 Jun.

Canada

74. Alberta Dental Association and College. Standard of Practice: Dental facilities accreditation. Alberta: ADAC; 2011 May.

75. Alberta Dental Association and College. Standard of Practice: Infection prevention and control standards and risk management for dentistry. Alberta: ADAC; 2010 Sep.
76. Alberta Dental Association and College [Internet]. Media release - 30 May 2017. Alberta: ADAC; 2017 [updated 2017 May 30; cited 2017 Jun 1]. Available from: http://www.dentalhealthalberta.ca/index/Pages/media-room
77. The College of Physicians and Surgeons of Ontario. Applying the out-of-hospital premises inspection program standards in endoscopy/colonoscopy premises. Ontario: CPSO; 2017 Jul.
78. The College of Physicians and Surgeons of Ontario. Independent health facilities: Clinical practice parameters and facility standards – Chronic kidney disease and dialysis. 1st Ed. Ontario: CPSO; 2010 Jul.
79. The College of Physicians and Surgeons of Ontario. Independent health facilities: Clinical practice parameters and facility standards – Hemodialysis. Ontario: CPSO; 2018 Jun.
80. The College of Physicians and Surgeons of Ontario. Independent health facilities: Clinical practice parameters and facility standards – Nuclear medicine (including PET/CT). Ontario: CPSO; 2018 Nov.
81. The College of Physicians and Surgeons of Ontario. Out of hospital premises inspection program – Program standards. Ontario: CPSO; 2017 Oct.
82. The College of Physicians and Surgeons of Ontario. Telemedicine. Ontario: CPSO; 2014 Dec.
83. The CSA Group and the Standards Council of Canada. CAN/CSA – ISO26722:16– Water treatment equipment for haemodialysis applications and related therapies. 2016 [Revised 1 Feb 2016; cited 2018 Aug 1]. Available from: http://www.scc.ca/en/standardsdb/standards/28294
84. Easty A, Coakley N, Cheng R, Cividino M, Savage P, Tozer R, White R. Safe handling of cytotoxics. Toronto (ON): Cancer Care Ontario; 2013 December 4 [In Review 2017 May]. Program in Evidence-Based Care Evidence-Based Series No.: 16-3 Version 2 IN REVIEW.
85. *Independent Health Facilities Act 1990*, R.S.O. 1990, C. I.3 (ON).
86. *Independent Health Facilities Act. Ontario Regulation 57/92.* General. (ON).
87. *Independent Health Facilities Act. R.R.O. 1990, Regulation 649.* Application and exemptions. (ON).
88. Infection Prevention and Control Program, Public Health Agency of Canada. Infection prevention and control guideline for flexible gastrointestinal endoscopy and flexible bronchoscopy. Ontario: PHAC; 2011 Feb.
89. The International Organization for Standardization. ISO 13959:2014 – Water for haemodialysis and related therapies. 2014 [Revised Apr 2014; Cited 2018

Aug 1]. Available from: https://www.iso.org/standard/61862.html
90. The Ministry of Labour Relations and Workplace Safety. Cytotoxic drugs guide 2021. Saskatchewan: WorkSafe Saskatchewan; 2021.
91. *Occupational Health and Safety Act. Ontario Regulation 67/93*. Health care and residential facilities. Section 97 Antineoplastic drugs. (ON).
92. *Occupational Health and Safety Regulation* (Current as at 2018 Jan 1). Part 6 – Substance specific requirements. (BC).
93. *Oversight of Health Facilities and Devices Act, 2017, S.O. 2017, C. 25. Schedule 9.* (ON).
94. Royal College of Dental Surgeons of Ontario. Standard of Practice: Use of sedation and general anesthesia in dental practice. Ontario: RCDSO; 2012 Jun (revised 2015 Apr).

Singapore

95. *Healthcare Services Act* (draft as of 2018 Dec 27). (SG).
96. Ministry of Health, Singapore. Directives for private ambulatory surgical centres providing ambulatory surgery: regulation 4(1) of the private hospitals and medical clinics regulations [Cap. 248, Rg1]. Singapore: Ministry of Health, Singapore; 2007 Jan 22.
97. Ministry of Health, Singapore. Guidelines for private healthcare institutions providing endoscopy: regulation 4 of the private hospitals and medical clinics regulations [Cap. 248, Rg1]. Singapore: Ministry of Health, Singapore; 2001 May.
98. Ministry of Health, Singapore. Guidelines for private healthcare institutions providing lithotripsy: regulation 4 of the private hospitals and medical clinics regulations [Cap. 248, Rg1]. Singapore: Ministry of Health, Singapore; 2000 Aug.
99. Ministry of Health, Singapore. Guidelines for private healthcare institutions providing renal dialysis: regulation 4 of the private hospitals and medical clinics regulations [Cap. 248, Rg 1]. Singapore: Ministry of Health, Singapore; 2001 Jun 1.
100. Ministry of Health, Singapore. Guidelines on safe sedation practice for non-anaesthesiologists. Singapore: Academy of Medicine, Singapore; 2014 May 19.
101. Ministry of Health, Singapore. National Telemedicine Guidelines. Singapore: Ministry of Health, Singapore; 2015 Jan 30.
102. Ministry of Health, Singapore. Specific licensing conditions for special care service (ambulatory surgery – liposuction) under regulation 37 and third schedule of the private hospitals and medical clinics regulations [Cap. 248, Rg

1]. Singapore: Ministry of Health, Singapore; 2008 Jul.
103. National Infection Prevention and Control Committee. The national infection prevention and control guidelines for acute healthcare facilities, 2017. Singapore: Ministry of Health, Singapore; 2017 Oct 24.
104. *Private Hospitals and Medical Clinics Act* (Cap. 248). (SG).
105. *Private Hospitals and Medical Clinics Regulations* (Cap. 248 Rg 1). (SG).

UK

106. The Association of Anaesthetists. Recommendations for standards of monitoring during anaesthesia and recovery 2021. Anaesthesia.2021; 76(10): 1426-1427.
107. British Standards Institution. BS EN 1089-3:2011. Transportable gas cylinders. Gas cylinder identification (excluding LPG). Colour coding. 2011 Aug 31.
108. *The Care Quality Commission (Registration) Regulations 2009*. (GB).
109. *The Care Quality Commission (Registration and Membership) (Amendment) Regulations 2012.* (GB).
110. Care Quality Commission. Clarification of regulatory methodology: PMS digital healthcare providers. London: Care Quality Commission; 2017 Mar.
111. The Chartered Institution of Building Services Engineers (CIBSE)/The Society of Light and Lighting (SLL). LG02: Lighting Guide 2: Hospitals and health care buildings – LG2. London: CIBSE; 2019 Sep.
112. Department of Health. Day surgery: operational guide. Waiting, booking and choice. London: Department of Health Publications; 2002 Aug.
113. Department of Health and Social Care. Health building note (HBN) 02-01: Cancer treatment facilities. London: Department of Health and Social Care; 2013 Mar 23.
114. Department of Health and Social Care. Health building note (HBN) 07-01. Satellite dialysis units: planning and design. Guidance on designing spaces outside of hospital renal units for adult patients who need maintenance dialysis. London: Department of Health and Social Care; 2013 Mar 20.
115. Department of Health and Social Care. Health building note (HBN) 14-01: Pharmacy and radiopharmacy facilities. London: Department of Health and Social Care; 2013 Mar 20.
116. Department of Health and Social Care. Health technical memorandum (HTM) 01-06: Decontamination of flexible endoscopes. London: Department of Health and Social Care; 2016 Jun 30.
117. Department of Health and Social Care. Health technical memorandum (HTM) 06-01: Electrical services supply and distribution. London: Department of

Health and Social Care; 2017 Apr 11.
118. Department of Health Estates and Facilities Division. Health building note (HBN) 10-02 Surgery: Day surgery facilities. London: The Stationery Office; 2007 May.
119. Estates and Facilities Division, Department of Health. Dental compressed air and vacuum systems. An update of HTM 2022 – supplement 1. London: The Stationary Office; 2003.
120. Estates and Facilities Division, Department of Health. Health Technical Memorandum (HTM) 02-01: Medical Gas pipeline systems. London: Department of Health and Social Care; 2006 May 1.
121. Estates and Facilities Division, Department of Health. Health technical memorandum (HTM) 03-01: Specialised ventilation for healthcare premises. London: Department of Health and Social Care; 2021 Aug 31.
122. Health and Safety Executive (HSE). Control of substances hazardous to health. The control of substances hazardous to health regulations 2002 (as amended) (COSHH). Approved code of practice and guidance (ACOP). L5 (6th Ed). London: Health and Safety Executive; 2013.
123. *Health and Social Care Act 2012*. (GB).
124. *The Health and Social Care Act 2008 (Regulated Activities) Regulations 2014*. (GB).
125. *The Health and Social Care Act 2008 (Regulated Activities) (Amendment) Regulations 2015*. (GB).
126. Humphreys H, Coia JE, Stacey A, Thomas M, Belli AM, Hoffman P, *et al*. Guidelines on the facilities required for minor surgical procedures and minimal access interventions. England and Wales: Healthcare Infection Society; 2012 Feb.
127. The Institution of Engineering and Technology (IET). Requirements for electrical installations BS 7671:2018 (IET wiring regulations, 18th Edition). London: IET; 2018 Jul 2.
128. *The Ionising Radiation (Medical Exposure) Regulations 2017*. (GB).
129. NHS Commissioning Board. NHS standard contract for cancer: chemotherapy (adult). Section B part 1 – service specification. B15/S/a. London: NHS England; 2013 Oct 1.
130. NHS England. Renal services. In centre haemodialysis (ICHD): main and satellite units. A06/S/a. London: NHS England. [cited 2017 Aug 1].
131. NHS Estate. Health building note (HBN) 6: Facilities for diagnostic imaging and interventional radiology. London: Department of Health and Social Care; 2001 Jan 1.
132. Paul Harris for IET Publications. Guide to electrical installations in medical

locations. London: IET; 2017.
133. The Renal Association and the Association of Renal Technologists. Guideline on water treatment systems, dialysis water and dialysis fluid quality for haemodialysis and related therapies. England: The Renal Association and The Association of Renal Technologists; 2016 Jan.
134. The Royal College of Anaesthetists. Guidelines for the provision of anaesthesia services for day surgery 2021. London: The Royal College of Anaesthetists; 2021 Mar 31.
135. The Quality Unit, Planning & Quality Division. [Revised] Guidance for the safe delivery of systemic anti-cancer therapy. CEL30(2012). Edinburgh: The Scottish Government; 2012 Jul.

US

136. *42 CFR Part 494. Conditions for Coverage for End-Stage Renal Disease Facilities*. (US).
137. ANSI/ASHRAE/ASHE Standard 170-2021: Ventilation of health care facilities. Atlanta: ASHRAE; 2021.
138. ASA House of Delegates/Executive Committee. ASA Physical Status Classification System. Washington D.C.: American Society of Anaesthesiologists; 2020 Dec 13. [Cited 2021 Feb 23]. Available from: https://www.asahq.org/standards-and-guidelines/asa-physical-status-classification-system
139. ASHRAE. HVAC Design manual for hospitals and clinics (second edition). Atlanta: ASHRAE; 2013.
140. Association for the Advancement of Medical Instrumentation (AAMI) and the American National Standards Institute. Dialysate for hemodialysis. ANSI/AAMI RD52:2004. Arlington: AAMI; 2004 Aug 9.
141. Centers for Disease Control and Prevention. Recommendations for preventing transmission of infections among chronic hemodialysis patients. MMWR 2001; 50(No. RR-5).
142. Facility Guidelines Institute. Guidelines for design and construction of outpatient facilities. 2018 Ed, US: Facility Guidelines Institute; 2018.
143. Jamil LH, Naveed M, Agrawal D, Fujii-Lau LL, Al-Haddad M, Buxbaum JL, et al. ASGE guideline on minimum staffing requirements for the performance of GI endoscopy. Gastrointest Endosc. 2020 Apr;91(4): 2020723-729.e17. doi: 10.1016/j.gie.2019.12.002. Epub 2020 Feb 6.
144. Joint Commission International. Joint commission international accreditation standards for hospital, 7th edition. US: joint commission international 2021.

145. National Institute for Occupational Safety and Health (NIOSH), Centres for Disease Control and Prevention. NIOSH Alert: Preventing occupational exposures to antineoplastic and other hazardous drugs in healthcare settings. Cincinnati: NIOSH; 2004 Sep.
146. *New York Codes, Rules and Regulations Title 10. Part 405 – Hospitals – Minimum Standards. Section 405.15 – Radiologic and Nuclear Medicine Services.* (NY).
147. *New York Codes, Rules and Regulations Title 10. Part 755 – Free-standing and off-site hospital based ambulatory surgery services*. (NY).
148. *New York State Public Health Law – Article 28. Hospitals*. (NY).
149. *New York State Public Health Law. Title II – A. Section 230-D. Office-Based Surgery*. (NY).
150. *New York State Public Health Law. Section 225. Part 16 - Ionizing Radiation.* (NY).
151. Novello AC, Pataki GE. New York State surgical and invasive procedure protocol for hospitals ~ diagnostic and treatment centers; ambulatory surgery centers ~ individual practitioners. New York: Division of Primary and Acute Care Services, Office of Health Systems Management, Department of Health, the State of New York, 2006 Sep.
152. *The Pennsylvania Code Title 28 Health and Safety. Subpart F. Ambulatory Surgical Facilities.* (PA).
153. *The Pennsylvania Code Title 28 Health and Safety. Chapter 115. Medical Record Service.* (PA).
154. *The Pennsylvania Code Title 28 Health and Safety. Chapter 127. Radiology Service.* (PA).
155. *The Pennsylvania Code Title 28 Health and Safety. Chapter 129. Nuclear Medicine Service.* (PA).
156. Pennsylvania Department of Health (PADH). Final telemedicine survey guidelines and Department of Health survey policy. Pennsylvania: PADH; 2016 Jan 15.
157. *The Public Health Code Part 222. Certificate of Need (CON) Review Standards for Urinary Extracorporeal Shockwave Lithotripsy (UESWL) Services.* (MI).
158. *Texas Administrative Code Title 25 Chapter 117. End Stage Renal Dialysis Facilities Licensing Rules.* (TX).
159. US Pharmacopoeia. USP General Chapter <797> Pharmaceutical compounding – sterile preparations. Rockville, MD: United States Pharmacopeial Convention, Inc; 2018 Sep 4.
160. US Pharmacopoeia. USP General Chapter <800> Hazardous drugs – handling in healthcare settings. Rockville, MD: United States Pharmacopeial

Convention, Inc; 2017 Sep 29.

Others

161. Kampen WU, Boddenberg-Pätzold, B., Fischer, M, Gabriel M, Klett R, Konijnenberg M, *et al*. The EANM guideline for radiosynoviorthesis. Eur J Nucl Med Mol Imaging. 2022 Jan;49(2):681-708.
162. International Organization for Standardization. ISO14644 Cleanrooms and associated controlled environments - Part 1 to 15.
163. International Organization for Standardization. ISO 23500-2:2019. Preparation and quality management of fluids for haemodialysis and related therapies — Part 2: Water treatment equipment for haemodialysis applications and related therapies. Geneva: ISO; 2019.
164. International Organization for Standardization. ISO 23500-3:2019. Preparation and quality management of fluids for haemodialysis and related therapies — Part 3: Water for haemodialysis and related therapies. Geneva: ISO; 2019.
165. Poeppel TD, Handkiewicz-Junak D, Andreeff M, Becherer A, Bockisch A, Fricke E, *et al*. EANM guideline for radionuclide therapy with radium-223 of metastatic castration-resistant prostate cancer. Eur J Nucl Med Mol Imaging. 2018 May;45(5):824-845. doi: 10.1007/s00259-017-3900-4. Epub 2017 Dec 12.
166. Stokkel MP, Handkiewicz Junak D, Lassmann M, Dietlein M, Luster M. EANM procedure guidelines for therapy of benign thyroid disease. Eur J Nucl Med Mol Imaging. 2010 Nov;37(11):2218-28. doi: 10.1007/s00259-010-1536-8. Epub 2010 Jul 13.
167. World Health Organization [Internet]. Implementation manual: WHO Surgical safety checklist 2009. Safe surgery saves lives. France: World Health Organization; 2009.