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| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Report for Application for****Clinic Licence****under the Private Healthcare Facilities Ordinance (Cap. 633)**

|  |  |
| --- | --- |
| **Reference No:** |       |
|  |  |
| **Name of Clinic:** |       |
|  |  |

PHF 35 |

# Introduction

Under the Private Healthcare Facilities Ordinance (Cap. 633) (“the Ordinance”), four types of private healthcare facilities, namely hospitals, day procedure centres (DPC), clinics and health services establishments, are subject to regulation. A person who intends to operate a private healthcare facility is required to obtain a licence under the Ordinance.

To apply for a clinic licence, a completed application form together with a “Report for Application for Clinic Licence” (“the Report”) should be submitted to the Department of Health (DH).

*Points to note in completing the Report*

1. This report outlines the requirements for the clinic application under the Ordinance. Please review your clinic’s setup and check the appropriate box (☑). To proceed the application, please rectify any items where “No” are checked before submission.
2. Submission of documents to substantiate compliance is **NOT** required. However, relevant documents should be available on-site for inspection. (*see* **Annex)**
3. Equipment that directly relates to life saving is considered critical equipment (e.g. defibrillators, ventilators, etc.).
4. Where amendments to the Report are necessary, please inform DH by a covering letter/email stating the application **reference number** and the revised parts/items, and attach the revised pages at least **10 working days** before inspection.

**Department of Health**

# Personal Information Collection Statement

**Purpose of Collection**

1. DH collects personal data during the course of processing your application made under the Ordinance. The personal data provided will also be used by DH for the following purposes:
2. facilitating the implementation of the Ordinance;
3. establishing and maintaining a register under section 107 of the Ordinance for public inspection;
4. preparing statistics for the purpose of implementing the Ordinance without showing any personal data; and
5. facilitating communication among the government and yourself.
6. If you fail to provide the required information or the submitted information fails to clearly indicate that the private healthcare facility fulfils the requirements for the application concerned, DH may be unable to process the application.

**Classes of Transferees**

1. The personal data you provided are mainly for use within DH but they may also be disclosed to other Government bureaux/departments or relevant parties in the form and for the purposes mentioned in item 1 above, if required.

**Access to Personal Data**

1. You have the right of access and correction with respect to your personal data as provided for in sections 18 and 22 of and Principle 6 of Schedule 1 to the Personal Data (Privacy) Ordinance (Cap. 486). Your right of access includes the right to obtain a copy of your personal data provided under item 1. A fee may be imposed for complying with a data access request.

**Enquiries**

1. Enquiries concerning personal data provided, including the making of a request for access to and/or corrections of the personal data, should be addressed to:

|  |
| --- |
| Senior Executive Officer (Private Healthcare Facilities) |
| Office for Regulation of Private Healthcare Facilities |
| Department of Health |
| Room 402, 4/F, 14 Taikoo Wan Road |
| Taikoo Shing, Hong Kong  |
| (Enquiry Telephone Number：3107 8451) |

|  |
| --- |
| **Important Notice:** Under section 93 of the Private Healthcare Facilities Ordinance (Cap. 633), any person who furnishes in this application any statement or information that is false or misleading in a material particular may commit an offence. |

# Management and Governance

# Chief Medical Executive (CME)

|  |  |  |
| --- | --- | --- |
| Name in English |      (Surname) |      (Given names) |
| Name in Chinese |      (Surname) |      (Given names) |
| Qualifications |       |

# Arrangement in the absence of CME[[1]](#footnote-1)

# Particulars of deputising medical practitioner/dentist

[ ]  (a) Clinic **does not operate** during CME’s absence from duties

[ ]  (b) Clinic **operates** during CME’s absence from duties

Particulars of deputising medical practitioner/dentist in the absence of CME:

|  |  |  |
| --- | --- | --- |
| Name in English |      (Surname) |      (Given names) |
| Name in Chinese |      (Surname) |      (Given names) |
| Registration Number under Medical Registration Ordinance (Cap. 161) or Dentists Registration Ordinance (Cap. 156) |       |
| Qualifications |       |
| Telephone number |      (Daytime) |      (Emergency) |
| E-mail address |       |

# Emergency contact in the absence of CME

|  |  |  |
| --- | --- | --- |
| Name in English |      (Surname) |      (Given names) |
| Name in Chinese |      (Surname) |      (Given names) |
| Telephone number |      (Daytime) |      (Emergency) |
| E-mail address |       |

# Particulars of the registered dentist to assist CME in carrying out the day to day administration of the dental practice (For combined medical and dental practices ONLY)

|  |  |  |
| --- | --- | --- |
| Name in English |      (Surname) |      (Given names) |
| Name in Chinese |      (Surname) |      (Given names) |
| Registration Number under Dentists Registration Ordinance (Cap. 156) |       |
| Qualifications |       |
| Telephone number |       |
| E-mail address |       |

# For Clinic operated by the same licensee and under the administration of a Chief Medical Executive (CME) in condition stipulated in s50 of Cap 633 (i.e. group of 4 or more clinics with the same licensee): (if applicable)

Particulars of doctor/dentist who assist the CME in carrying out day to day administration of the clinic:

|  |  |  |
| --- | --- | --- |
| Name in English |      (Surname) |      (Given names) |
| Name in Chinese |      (Surname) |      (Given names) |
| Registration Number under Medical Registration Ordinance (Cap. 161) |       |
| Qualifications |       |
| Telephone number |       |
| E-mail address |       |

|  |  |  |
| --- | --- | --- |
| Name in English |      (Surname) |      (Given names) |
| Name in Chinese |      (Surname) |      (Given names) |
| Registration Number under Dentists Registration Ordinance (Cap. 156) |       |
| Qualifications |       |
| Telephone number |       |
| E-mail address |       |

# Staff training and supervision

|  |  |
| --- | --- |
|  | **Evidence to substantiate compliance** |
| 1. Regular check on the registration status/ practising certificate of professional personnel
 | [ ]  Yes | [ ]  No | Copy of certificates/record |
| Frequency: | Every       month(s) |
| 1. Job orientation programme for staff
 | [ ]  Yes | [ ]  No[ ]  NA | Record/policy of orientation programme |
| Duration:       |
| 1. Job orientation programme for other healthcare professional staff and other healthcare workers
 | [ ]  Yes | [ ]  No[ ]  NA | Record/policy of orientation programme |
| Duration:       |
| 1. All staff members are appropriately trained, including but not limited to training in the safe and proper use of medical equipment and assisting in medical procedures
 | [ ]  Yes | [ ]  No | Record/policy of training |

# Scope of Service

|  |
| --- |
| Clinical Service(s) provided in the Clinic  |
| Clinical services provided | For example, dental service                         |
| [ ]  | Vaccination service |
| [ ]   | Age range of patients: from       to       |
| [ ]  | Medical procedures involving sedation and anaesthesia (except those listed in column 2 of Schedule 3 of the Ordinance, which must be performed in Hospitals or Day Procedure Centres) |
| Operating Hours*(please specify hours)* | Monday to Friday: open from       to       / closed on      Saturday: [ ]  open from       to       / [ ]  closedSunday: [ ]  open from       to       / [ ]  closedPublic Holidays: [ ]  open from       to       / [ ]  closed |
| **For Mobile Clinic ONLY**Practising location(s) by the day and time of a week | Location 1(L1):      Location 2 (L2):      Location 3 (L3):      Location 4 (L4):      Location 5 (L5):      Location 6 (L6):                Please indicate the location(s) where the mobile clinic operates by the day and time of a week

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
|  | **Mon** | **Tue** | **Wed** | **Thu** | **Fri** | **Sat** | **Sun / Public Holiday** |
| **AM** | e.g. L1 | e.g. L2 | e.g. L1 | e.g. L2 | e.g. L1 | e.g. closed | e.g. closed |
| **PM** | e.g. L1 | e.g. L2 | e.g. L1 | e.g. L2 | e.g. L1 | e.g. closed | e.g. closed |

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# Physical Conditions

# Facility management

|  |  |
| --- | --- |
|  | **Evidence to substantiate compliance** |
| 1. There are adequate ventilation, lighting and signage for the safe operation of the clinic
 | [ ]  Yes | [ ]  No | Site environment |
| 1. There are patient-to-staff call systems or devices where a patient may be left alone temporarily
 | [ ]  Yes | [ ]  No | Call bell/call help mechanism |
| 1. There is a regular cleansing schedule for the clinic and records are maintained
 | [ ]  Yes | [ ]  No | Cleansing schedule/ record |
| 1. The premises of the clinic are maintained in good operational order and records of maintenance and repair are kept
 | [ ]  Yes | [ ]  No | Maintenance schedule/record |

# Equipment and store

|  |  |
| --- | --- |
|  | **Evidence to substantiate compliance** |
| 1. The clinic has the necessary and appropriate equipment which is used as intended for its purposes, in good working order and properly maintained
 | [ ]  Yes | [ ]  No | Maintenance schedule/record |
| 1. Records of maintenance and servicing of medical equipment are kept
 | [ ]  Yes | [ ]  No | Maintenance schedule/record |
| 1. Medical equipment, instruments, appliances, and materials of appropriate quantities are readily accessible
 | [ ]  Yes | [ ]  No | Critical/major equipment list |
| 1. Installation of dental compressed air and vacuum system is examined by an appointed examiner before it is put into use in accordance with the Boilers and Pressure Vessels Ordinance (Cap. 56)
 | [ ]  Yes | [ ]  No[ ]  NA | Document/record/ site environment |

# Facilities and equipment for critical care areas

[ ]  No operating room and recovery area is equipped (Please proceed to Section 4)

|  | **Evidence to substantiate compliance** |
| --- | --- |
| 1. The operating room is suitably designed, equipped and maintained for the purpose it is to be used; and maintained at acceptable level of sterility
 | [ ]  Yes | [ ]  No | Site environment |
| 1. The ceiling, walls and floors are made from materials that can be easily cleaned and disinfected as needed
 | [ ]  Yes | [ ]  No | Site environment |
| 1. The electrical system is regularly inspected and maintained, with documentation of repair and maintenance
 | [ ]  Yes | [ ]  No | Maintenance schedule/record |
| Frequency of inspection: | Every       month(s) |  |
| 1. The ventilation system is regularly inspected and maintained, with documentation of repair and maintenance
 | [ ]  Yes | [ ]  No | Maintenance schedule/record |
| Frequency of inspection: | Every       month(s)  |
| 1. The medical gas pipeline system is regularly inspected and maintained, with documentation of repair and maintenance
 | [ ]  Yes | [ ]  No | Maintenance schedule/record |
| Frequency of inspection: | Every       month(s) |
| 1. There is adequate area for scrub and gowning
 | [ ]  Yes | [ ]  No | Site environment |

# Service Delivery and Care Process

# Policies and procedures

|  |  |
| --- | --- |
|  | **Evidence to substantiate compliance** |
| 1. Frequency of reviewing policies and procedures
 | Every       year(s) | Document/record |
| 1. Frequency of circulating policies and procedures to staff
 | Every       month(s) | Schedule/record of circulation |

# Patients’ rights and identification

|  |  |
| --- | --- |
|  | **Evidence to substantiate compliance** |
| 1. There are policies and procedures to protect patients’ right
 | [ ]  Yes | [ ]  No | Document (such as patient charter) |
| 1. There are policies and procedures for patient identification
 | [ ]  Yes | [ ]  No | Form/document |
| 1. There are facilities and measures to protect for privacy of patients, e.g. screens, partitions, patient changing rooms
 | [ ]  Yes | [ ]  No | Site environment |
| 1. There is access for patients to obtain their own health records
 | [ ]  Yes | [ ]  No | Document/notice |

# Medical records

|  |  |
| --- | --- |
|  | **Evidence to substantiate compliance** |
| 1. There are policies and procedures for creation, management, handling, storage and destruction of medical records
 | [ ]  Yes | [ ]  No | Document/record |
| 1. All personal data are kept secure and protected from unauthorized access, alteration or loss
 | [ ]  Yes | [ ]  No | Records with personal data are locked in restricted access room |
| 1. Back-up storage of medical records are kept for medical records stored in the electronic format
 | [ ]  Yes | [ ]  No[ ]  NA | Back-up storage |

# Drug management

|  | **Evidence to substantiate compliance** |
| --- | --- |
| 1. Appropriate storage with restricted access are provided for medicines and controlled drugs to ensure security
 | [ ]  Yes | [ ]  No | Medicines are locked or kept in restricted access areaDangerous drugs are kept in locked receptacle |
| 1. Suitable storage facilities are provided for medicines in accordance with manufacturer’s recommendation
 | [ ]  Yes | [ ]  No | Fridge for cold chain medicineTemperature monitoring record for fridge (twice daily with high, low and real time temperature for vaccines and biologicals) (at least 3 days’ monitoring record for new clinic)Medicines are properly stored |
| 1. An up-to-date drug formulary is kept
 | [ ]  Yes | [ ]  No | Document |
| 1. All medicines supplied are registered pharmaceutical products in Hong Kong
 | [ ]  Yes | [ ]  No | Drug supply |
| 1. Drug procurement documents are kept
 | [ ]  Yes | [ ]  No | Document/record |
| 1. All medicines are clearly labelled and stored appropriately
 | [ ]  Yes | [ ]  No | Labelling of medicineMedicines for disposal/recall are stored separately from those ready for use  |
| 1. Expiry dates of medicines are checked on regular basis
 | [ ]  Yes | [ ]  No | Checking schedule/recordSegregated storage for expired medicines |
| 1. Medicines are dispensed under the supervision of a medical practitioner, dentist, or pharmacist
 | [ ]  Yes | [ ]  No[ ]  NA | Dispensing practice |
| 1. System is in place to monitor the accuracy of dispensing and administration of medicines
 | [ ]  Yes | [ ]  No | Clinic operational manuals/clinical guidelines/record |
| 1. Staff responsible for dispensing and administering medicines have received appropriate training
 | [ ]  Yes | [ ]  No | Training record |
| 1. Storage of medicines is segregated from food and other laboratory samples to avoid cross-contamination
 | [ ]  Yes | [ ]  No | Site environment |

# Pathology and radiology support

|  |  |
| --- | --- |
|  | **Evidence to substantiate compliance** |
| 1. Procedures for obtaining routine laboratory services are in place
 | [ ]  Yes | [ ]  No[ ]  NA | Form/document/ record |
| 1. Procedures for obtaining emergency laboratory services are in place
 | [ ]  Yes | [ ]  No[ ]  NA | Form/document/ record |
| 1. Procedures for obtaining routine radiology services are in place
 | [ ]  Yes | [ ]  No[ ]  NA | Form/document/ record |
| 1. Procedures for obtaining emergency radiology services are in place
 | [ ]  Yes | [ ]  No[ ]  NA | Form/document/ record |

# Procedural Sedation

[ ]  No procedural sedation performed in the facility. (Please proceed to Section 4.7)

(Procedural sedation should be performed in accordance with Guidelines on Procedural Sedation promulgated by the Hong Kong Academy of Medicine)

## Staffing for procedural sedation

|  | **Evidence to substantiate compliance** |
| --- | --- |
| 1. For each procedure with sedation, in addition to the medical practitioner responsible for the procedure, there is
 |  |  |
| 1. an appropriately trained staff in monitoring vital signs and procedural complications
 | [ ] Yes | [ ] No | Duty roster |
| 1. technical/nursing assistance as required
 | [ ] Yes | [ ] No | Duty roster |
| 1. Competency requirements set out by Hong Kong Academy of Medicine (HKAM) for medical practitioners responsible for the sedation and staff assisting in sedation process are met[[2]](#footnote-2)
 | [ ] Yes | [ ] No | Staff qualification/ credentialing policy |

## Facilities and equipment for procedural sedation

| All procedures are performed in a location equipped with: | **Evidence to substantiate compliance** |
| --- | --- |
| 1. source of oxygen and suitable devices for administering oxygen to spontaneously breathing patients
 | [ ] Yes | [ ] No | Oxygen supply |
| 1. source of oxygen with a suitable delivery system, a means of inflating the lungs, a supply of drugs for resuscitation, and a range of intravenous equipment and fluids for cardiopulmonary resuscitation
 | [ ] Yes | [ ] No | Resuscitation equipment and drugs |
| 1. drugs for the reversal of benzodiazepines and opioids
 | [ ] Yes | [ ] No | Drugs |
| 1. a tilting operating table, trolley or chair with ready access for induction and recovery of sedation
 | [ ] Yes | [ ] No | Venue for induction and recovery |
| 1. pulse oximeter and devices for the monitoring of vital signs
 | [ ] Yes | [ ] No | Equipment |
| 1. an ECG and a defibrillator
 | [ ] Yes | [ ] No | Equipment  |

## Monitoring and recovery for procedural sedation

|  | **Evidence to substantiate compliance** |
| --- | --- |
| 1. All patients are monitored continuously with pulse oximetry, which must give off visual and audible alarms when appropriate limits are transgressed
 | [ ] Yes | [ ] No | Equipment |
| 1. There is end-tidal carbon dioxide monitoring with capnography for patients where there is high risk of sudden unexpected loss of consciousness or when loss of consciousness has already occurred
 | [ ] Yes | [ ] No | Equipment  |
| 1. There are regular recordings of pulse rate, oxygen saturation and blood pressure throughout the procedure in all patients
 | [ ] Yes | [ ] No | Form/record |
| 1. Patient is monitored for an appropriate duration after the procedure in an area adequately equipped and staffed for recovery care and monitoring of patients
 | [ ] Yes | [ ] No | Form/record/ document |
| 1. Patient discharge is authorized by the medical practitioner providing the sedation after adequate assessment, or by another medical practitioner with proper delegation and handover
 | [ ] Yes | [ ] No | Form/record/ document |
| 1. A set of standard discharge criteria is adopted to facilitate a consistent and reliable assessment and a safe discharge
 | [ ] Yes | [ ] No[ ] NA | Form/document/ record |

# Patient safety incident reporting and learning system

|  | **Evidence to substantiate compliance** |
| --- | --- |
| 1. Written incident management and reporting system outlining the procedures to follow in the case of an incident or adverse event
 | [ ]  Yes | [ ]  No | Policy/record |
| 1. The CME reviews all incident reports, documents the review and quality improvement measures taken, and disseminates the lesson learnt regarding the adverse event identified to all staff
 | [ ]  Yes | [ ]  No | Document/record |

# Price information

|  |  |
| --- | --- |
|  | **Evidence to substantiate compliance** |
| 1. An up-to-date fee schedule covering all chargeable items and services is available in the clinic for reference of patients
 | [ ]  Yes | [ ]  No | Fee schedule |

# Complaint handling

|  |  |
| --- | --- |
|  | **Evidence to substantiate compliance** |
| 1. There is information provided for patients and their carers or representatives about the procedure for making complaints, and the process for managing and responding to any complaints
 | [ ]  Yes | [ ]  No | Notice |
| 1. The CME implements a mechanism consists of procedures for receiving, managing, responding to the complainant, and documentation,
 | [ ]  Yes | [ ]  No | Policy/document |
| 1. There is a specified time frame for initial response to the complainant
 | [ ]  Yes,       day(s) | [ ]  No | Document/record |

#  Telemedicine

[ ]  No Telemedicine service available. (Please proceed to Section 5)

|  |  |
| --- | --- |
|  | **Evidence to substantiate compliance** |
| 1. 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.
 | [ ]  Yes | [ ]  No | Document/record |
| 1. All staff providing telemedicine service have the necessary qualification and competence.
 | [ ]  Yes | [ ]  No | Training records  |
| 1. There are policies and procedures to safeguard privacy and security of data and records for telemedicine service
 | [ ]  Yes | [ ]  No[ ]  NA | Document/record |

# Infection Control

# Infection control facilities and equipment

|  | **Evidence to substantiate compliance** |
| --- | --- |
| 1. Hand hygiene facilities are readily available in all patient care areas
 | [ ]  Yes | [ ]  No | Site environment |
| 1. Appropriate and adequate stocks of personal protective equipment are available for use by staff
 | [ ]  Yes | [ ]  No | Stock list |
| 1. Reusable equipment and supplies used in invasive procedures are properly reprocessed by appropriate disinfection and sterilisation methods
 | [ ]  Yes | [ ]  No[ ]  NA | Disinfection and sterilisation record |
| 1. Where sterilisation by bench-top steam steriliser (autoclave) is performed, there is a system to monitor and record all sterilisation process
 | [ ]  Yes  | [ ]  No[ ]  NA | Sterilisation record |
| Type of bench-top steriliser | [ ]  Gravity Displacement (Type N steriliser)[ ]  Dynamic-air-removal (Type B/S steriliser)[ ]  Other:       |  |
| 1. Method for monitoring:
 | [ ]  Routine monitoring | Record/report |
| For routine monitoring: |  |  |
| i. Mechanical indicator for every load | [ ]  Yes  | [ ]  No | Mechanical indicator record (record of cycle time/exposure time, temperature and pressure, etc.) |
| ii. External chemical indicator  | Frequency:       | External chemical indicator record and mechanism |
| iii. Internal chemical indicator  | Frequency:       | Internal chemical indicator record and mechanism |
| iv. Biological indicator | Frequency:       | Biological indicator record |
| v. Steam penetration test | Type of test:      Frequency:      [ ]  NA | Steam penetration test record |
| vi. Other test(s)  | Type of test:      Frequency:      [ ]  NA | Other test record(s) |
| 1. Other method for monitoring
 | [ ]  Parametric release | Record/report |
| 1. Sterile equipment and supplies are stored in a clean and dry area
 | [ ]  Yes | [ ]  No | Monitoring equipment and record |
| * 1. Temperature: Stored below 24 oC
 | [ ]  Yes | [ ]  No |  |
| * 1. Frequency of temperature monitoring
 |       times daily |  |
| * 1. Humidity: Stored below 70%
 | [ ]  Yes | [ ]  No |  |
| * 1. Frequency of humidity monitoring
 |       times daily |  |
| 1. There is regular checking of expiry of sterile supplies
 | [ ]  Yes | [ ]  No[ ]  NA | Checking record |
| Frequency of checking: | Every       day(s) |
| 1. All sterilising equipment are regularly inspected and maintained with proper documentation
 | [ ]  Yes | [ ]  No[ ]  NA | Maintenance record |
| Frequency of checking: | Every       month(s) |
| 1. Sharps box is available in a convenient place for disposal of used sharps
 | [ ]  Yes | [ ]  No [ ]  NA | Site environment |

# Waste disposal

|  |  |
| --- | --- |
|  | **Evidence to substantiate compliance** |
| 1. Clinical waste are handled properly and safely according to written policies pursuant to the *Waste Disposal Ordinance* (Cap. 354)
 | [ ]  Yes | [ ]  No[ ]  NA | Document/record/ site environment |
| 1. Chemical waste are handled properly and safely according to written policies pursuant to the *Waste Disposal Ordinance* (Cap. 354)
 | [ ]  Yes | [ ]  No[ ]  NA | Document/record/ site environment |
| 1. Radioactive substances and waste are handled properly and safely pursuant to the *Radiation Ordinance* (Cap. 303)
 | [ ]  Yes | [ ]  No[ ]  NA | Document/record/ site environment |

# Infection control in dental practice (if applicable)

|  |  |
| --- | --- |
|  | **Evidence to substantiate compliance** |
| 1. Items not designed to be reused or cannot be sterilised (e.g. saliva ejectors, scalpel blades, needles, local anaesthetic cartridges, sutures, matrix bands, prophylaxis cups) are disposed of after use
 | [ ]  Yes | [ ]  No | Clinic operational manuals/clinical guidelines/site environment |
| 1. All dental handpieces that are detachable (including ultrasonic scalers) are sterilised after use
 | [ ]  Yes | [ ]  No | Clinic operational manuals/clinical guidelines/site environment |
| 1. Measures are taken to reduce aerosol and splatters generated during dental treatment
 | [ ]  Yes | [ ]  No | Site environment |
| 1. Dental laboratory items (e.g. impressions, appliances) are appropriately disinfected before sending to the dental laboratories. Measures are also taken to ensure that such items are disinfected before putting them in the patients’ mouths
 | [ ]  Yes | [ ]  No | Clinic operational manuals/clinical guidelines/site environment |
| 1. Measures are taken to protect X-ray equipment from contamination during taking and processing of radiographs. Contaminated X-ray equipment is appropriately disinfected
 | [ ]  Yes | [ ]  No | Clinic operational manuals/clinical guidelines/site environment |
| 1. Measures are taken to minimise microbial level in Dental Unit Waterlines. Sterile irrigation solution is used for all surgical procedures, such as dento-alveolar surgeries and implant placement
 | [ ]  Yes | [ ]  No | Clinic operational manuals/clinical guidelines/site environment |
| 1. Measures are taken to protect suction tubing and suction tip connector from contamination. Contaminated suction tubing and suction tip connector are appropriately disinfected. All the components of a suction system are cleaned and disinfected at least once a day
 | [ ]  Yes | [ ]  No | Clinic operational manuals/clinical guidelines/site environment |

# Risk management and contingency

|  | **Evidence to substantiate compliance** |
| --- | --- |
| 1. Written policies and procedures for resuscitation of patients
 | [ ]  Yes | [ ]  No | Policy/record |
| 1. Resuscitation equipment and emergency medications are easily accessible and checked at regular interval
 | [ ]  Yes | [ ]  No | Checking record |
| Frequency of checking: | Every       day(s)  |
| 1. Written protocol is in place for emergency transfer of patients to acute care hospitals when necessary
 | [ ]  Yes | [ ]  No | Policy/record |
| 1. Fire evacuation exercise is conducted at regular intervals and documented
 | [ ]  Yes | [ ]  No | Document/record |
| 1. Sufficient staff who are trained for cardiopulmonary resuscitation on duty while providing clinical service
 | [ ]  Yes | [ ]  No | 2 weeks’ roster and respective CPR training record |

 **Annex**

**List of documents, records and reports to be inspected**

(Submission of these documents is not required)

|  |
| --- |
| 1. ***Policies, procedures and operation guidelines:***
 |
| 1. Patient’s rights
 |
| 1. Patient identification
 |
| 1. Complaint handling
2. Creation, management, handling, storage, and destruction of medical records
 |
| 1. Incident management system
 |
| 1. Resuscitation of patients
 |
| 1. Fire and emergency response plan
 |
| 1. Emergency transfer of patients
 |
| 1. Waste disposal
 |
| 1. Provision of telemedicine *(if applicable)*
2. Standard of care delivered by telemedicine
3. Safeguard privacy and security of data and records
 |
| 1. Safe provision of procedural sedation *(if applicable)*
2. Staffing arrangement
3. Informed consent
4. Pre-sedation assessment
5. Pre-sedation instructions and care
6. Documentation of procedures
7. Recovery care
8. Patient discharge and care after discharge
9. Management of complications
10. Process before anaesthetic procedures
* Checking of consent forms
* Verification processes
* Accomplishment of pre-operative preparation
 |
| 1. Policy and procedures for obtaining pathology service *(if applicable)*
2. safety aspect of the laboratory;
3. maintenance of performance standards including quality control;
4. recording of all specimens received and processed by the laboratory;
5. arrangements for notification of urgent test results;
6. collection, labelling, transportation and storage of pathology specimen,;
7. protection of staff handling pathology specimens;
8. procurement of reagents;
9. checking on the expiry dates of reagents;
10. disposal of specimens and reagents; and
11. contingency plans for various emergencies including chemical spillage.
 |
| 1. Policy and procedures for obtaining radiology service *(if applicable)*
2. obtaining detailed clinical history such as history of allergy;
3. provision of thorough explanation before written consent is sought from the patient;
4. steps to be taken during the procedure and preparation;
5. possible occurrence of allergic reaction(s) after administration of contrast medium;
6. accurate labelling of all films/imaging records with the patient’s name, date of test performed and other identifiers;
7. safety procedures;
8. management of accident, emergency, or other adverse event;
9. incident reporting; and
10. application of infection control measures.
 |
| 1. Documentary records of MAC meeting *(if applicable)*
 |
| 1. ***Drug management***
2. Up-to-date drug formulary
3. Drug procurement record
4. Record on checking expiry dates of medicines
5. Dangerous drug register (if applicable)
6. Temperature monitoring record for cold chain medicine (if applicable)
 |
|  |
| 1. ***Up-to-date fee schedule***
 |
| 1. ***Copy of valid practicing certificate of registrable healthcare professionals***
 |
| 1. Medical practitioner(s)/dentist(s)
 |
| 1. Nursing staff
 |
| 1. Allied health professional
 |
| 1. ***Job orientation programme for new staff***
2. ***2 week staff roster***

 |
| 1. ***Record of relevant training***
2. dispensing and administration of medicines
3. use of medical equipment
4. assisting in procedures
5. resuscitation *(including for paediatric patients if applicable)*
6. credentialing of personnel involved in procedural sedation *(if applicable)*
 |
| 1. ***Report of fire evacuation exercise***
 |
| 1. ***Maintenance record of medical equipment***
 |
| 1. ***Incident report (including medication incident)***
 |
| 1. ***Record of clinical waste disposal***
2. ***Record of chemical waste disposal***
 |
| 1. ***Certificate in relation to fire safety e.g. FS172, FS251***
 |
|  |
| 1. ***Certificate in relation to electrical installation e.g. WR1, WR2*** *(if applicable)*
 |
|  |
| 1. ***Certificate in relation to dental compressed air and vacuum systems e.g. Form 2*** *(if applicable)*
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|  |
|  |

1. The CME is still held accountable for the medical management of the facility during his/her absence. [↑](#footnote-ref-1)
2. In addition to the healthcare staff named by the Guidelines on Procedural Sedation (2025), clinical assistants with relevant training or qualification in monitoring vital signs of patients undergoing sedation and procedural complications may also assume the role of such monitoring for patients undergoing procedural sedation, under the following conditions:

(a) hold a valid Basic Life Support certificate; and

(b) work under the direct supervision of the medical practitioner or dentist who retains personal responsibility for the monitoring. [↑](#footnote-ref-2)