Code of Practice

for Private Hospitals

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Preface

The Code of Practice for Private Hospitals (the Code) is issued by the Director of Health under section 102 of the Private Healthcare Facilities Ordinance (Cap. 633) and applies to all private hospitals licensed under the Ordinance. It sets out the licensing standards in respect of the governance, staffing, facilities and equipment, service delivery, quality and safety of care, price transparency and other matters related to the operation of a hospital.

Under section 47 of Cap. 633, the licensee of a private hospital (the licensee) is wholly responsible for the operation of the hospital. 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 for, and the safety of patients. He shall ensure the hospital is in compliance with the conditions of the licence, the Code and any direction that may be given by the Director of Health by notice in writing as to how a hospital is to comply with the Code pursuant to section 104 of Cap. 633.

Determination of compliance will be based on the standards stipulated in the Code as well as any other applicable technical guidelines, standards, and codes issued by local and international authorities. Where such guidelines, standards, or codes are specified herein, the up-to-date version applies. The Director of Health may accept other standards, guidelines, or codes if he is satisfied that they are capable of ensuring equivalent performance of the hospital. The responsibility of proving those other standards, guidelines, or codes to be capable of ensuring equivalent performance rests with the licensee.

Compliance with the Code is a condition for issuance and renewal of licence. The licensee is reminded to observe any other applicable legislation in the course of operating the hospital.

Department of Health

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Interpretation of Terms

The following provides the interpretation of terms under the Code of Practice for Private Hospitals (the Code) –

"**adverse event**" –

means an incident that resulted in harm to a patient.

"**agency staff**" –

means a person who is not an employee of the hospital and who works for an agency not under the hospital or in his / her private capacity and is employed at the request of the patient or his / her family to deliver nursing / personal care. Examples of agency staff include private nurses and accompanying persons / chaperons.

"**Authorized Person**" –

means a person appointed in writing by the Chief Medical Executive of a hospital for supervising the operation, maintenance, repair and alteration work of the medical gas pipeline system(s).

"**Chief Medical Executive**" –

means a person appointed by the licensee of a hospital under section 49 of Cap. 633.

"**clinical staff**" –

means any person who delivers services related to the patient treatment and care in the hospital.

"**Complaints Committee**" –

means the Committee on Complaints against Private Healthcare Facilities established under section 71 of Cap. 633.

"**critical care area**" –

means an area in a hospital that provide life support or complex surgery, or 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 theatre / room, recovery area, cardiac catheterisation service, interventional angiography room, intensive care unit, high dependency unit, special care unit, cardiac care unit, labour room, and accident & emergency resuscitation bay / room, etc.

"**dental hygienist**" –

means a dental hygienist enrolled under the Ancillary Dental Workers (Dental Hygienists) Regulations (Cap. 156B).

"**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).

"**healthcare personnel**" –

means persons giving healthcare services in the hospital, including healthcare professional as defined in the Code.

"**healthcare professional**" –

means a person specified in Schedule 7 of Cap. 633.

"**hospital**" –

means any premises that are used, or intended to be used, for provision of medical services to patients with lodging, carrying out medical procedures on patients with lodging, receiving a pregnant woman for childbirth or a woman immediately after she gives birth to a child.

"**licensee**" –

means a holder of a licence to operate a hospital under Cap. 633.

"**Medical Advisory Committee**" –

means the committee established under section 57 of Cap. 633 for the hospital.

"**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 laboratory technologist**" –

means a medical laboratory technologist registered under the Supplementary Medical Professions Ordinance (Cap. 359).

"**medical practitioner**" –

means a medical practitioner registered under the Medical Registration Ordinance (Cap. 161). Under Chapters 3, 12, 28 and 33 of the Code, a medical practitioner shall also include a dentist registered under the Dentists Registration Ordinance (Cap. 156).

"**medical record**" –

means the formal documentation maintained by the hospital 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 registered medical practitioner or a registered dentist.

"**medical staff**" –

means registered medical practitioners or registered dentists who provide medical service for patients in the hospital and affiliated with the hospital as employees, partners or holders of admission privileges.

"**nurse**" –

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

"**occupational therapist**" –

means an occupational therapist registered under the Supplementary Medical Professions Ordinance (Cap. 359).

"**optometrist**" –

means an optometrist registered under the Supplementary Medical Professions Ordinance (Cap. 359).

"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.

"**patient safety incident**" –

means an event or circumstance that could have resulted, or did result, in unnecessary harm to a patient and includes adverse event.

"**pharmacist**" –

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

"**physiotherapist**" –

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

"**radiographer**" –

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

"**registered midwife**" –

means a person registered under the Midwives Registration Ordinance (Cap. 162).

"**registered nurse**" –

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

"**reportable event**" –

means an event stipulated under Clauses 6.4 and 6.5 of Chapter 6 of the Code.

"**services**" –

include those provided directly by employees of hospital, or through contractor of the hospital or run through a separate business contract at location of the registered address(es) of the hospital.

"**specialized ventilation area**" –

means an area in a hospital with special ventilation design for infection control and / or occupational safety. Examples are operating theatre / room, isolation room, bronchoscopy room, laboratory with biosafety risk, burns unit, labour room, aseptic preparation facilities, etc.

"**supporting care staff**" –

include but are not limited to healthcare assistants, personal care workers, clinic assistants, ward assistants, physiotherapy assistants and occupational therapy assistants who provide direct patient care under the supervision of nurses or other healthcare professionals.

PART I: GENERAL

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Section I – Corporate Governance

Chapter 1 Organisation and Administration

1.1 Overview

The licensee of a hospital is wholly responsible for the operation of the hospital. It is pertinent that the board of directors of the licensee takes an active role in monitoring the performance of the hospital in addition to decision-making.

1.2 General Requirements

1.2.1 The licensee must be a company or other body corporate, operated by a board of directors (however described). The licensee and the board of directors must be fit and proper persons to operate or exercise control over the hospital.

1.2.2 The hospital must have an organisational structure which includes all categories of staff. The structure also delineates the channels of communication, lines of authority and responsibility.

1.3 Board of Directors

1.3.1 The Board of Directors of the licensee (the "Board") oversees the management and operation of the hospital.

1.3.2 The Board must include a person -

(a) who is neither a registered medical practitioner nor a registered dentist; and

(b) who is not an employee of the hospital.

1.3.3 The Board is responsible for -

(a) the overall coordination and evaluation of activities within the hospital;

(b) setting up and enforcing rules, policies and procedures relating to the quality of patient care and patient safety, and for the operation of the hospital;
(c) ensuring compliance of the hospital with conditions of the licence;
(d) assuring that the quality and safety of care are evaluated through a quality management system and that identified problems are appropriately addressed;
(e) ensuring that information or document relating to the operation of the hospital is provided in a timely manner as requested by the Director of Health;
(f) overseeing the financial management of the hospital; and
(g) ensuring the hospital's compliance with relevant Ordinances and Laws of Hong Kong.

1.3.4 The licensee holds meetings at regular intervals, at least quarterly interval, to review the performance of the hospital.

1.3.5 The licensee pays regular visits to the hospital at intervals not less than six months to monitor the performance of the Chief Medical Executive and the management of the hospital. Such visits must be documented.

1.4 Appointment of Chief Medical Executive

1.4.1 The licensee must appoint a Chief Medical Executive (CME) to take charge of the day to day administration of the hospital.

1.4.2 The CME is, at all times when the hospital is in operation, responsible for -
(a) the day to day administration of the hospital; and
(b) the adoption and implementation of rules, policies and procedures concerning healthcare services provided in the hospital.

1.4.3 A CME must satisfy all the following applicable requirements -

(a) possessing the qualifications and experience necessary for administering the hospital;

(b) being physically and mentally fit to administer the hospital;

(c) being a person of integrity and good character; and

(d) being a registered medical practitioner who has been registered for not less than 15 years in Hong Kong.

1.4.4 The CME must equip himself / herself with updated knowledge in the administration of hospital.

1.4.5 On appointment of a CME, the licensee must provide him / her a letter of appointment specifying his / her duties as the CME.

1.4.6 If there is a change of the CME, the licensee must, before the expiry of 14 days after the change has occurred, notify the Director of Health in writing of the change, and the qualifications, training and experience of the CME appointed, or to be appointed, in replacement.

1.4.7 The licensee must appoint a person to deputise the CME in latter's absence from duties. The qualifications and experience of the deputising person must be appropriate to supervise the operation of the hospital.

1.4.8 The CME must keep and maintain the following types of registers in the form and way specified by the Director of Health -

(a) a staff register (as specified in Clause 2.2.7 of Chapter 2);

(b) a patients attendance register with information on the patient's name, identifier and personal particulars, and date of attendance;

(c) a hospital admission register with information on the patient's name, identifier and personal particulars, date of admission and date of discharge, transfer or death; and

(d) any other register that the Director of Health requires.

1.5 Appointment of Medical Advisory Committee

The licensee must establish and keep in operation the Medical Advisory Committee (MAC) for the hospital as detailed in Chapter 4. When there is any change in the membership of the MAC, the licensee must provide in writing to the Director of Health an updated list of the MAC members within 14 days of the change.

1.6 Policies and Procedures

1.6.1 Policies and procedures must be -

(a) clearly set out in an understandable language;

(b) documented in a policy manual readily accessible to staff;

(c) drawn up on the basis of adequate information and in consultation with relevant professionals;

(d) feasible of being implemented;

(e) in compliance with guidelines / codes / regulations / standards issued by professional bodies and Government; and

(f) not in conflict with relevant legislation.

1.6.2 Policies and procedures must be developed in the following areas -

(a) admission policy for patients;

(b) staff management;

(c) patient care;

(d) patient safety;

(e) patient identification;

(f) risk assessment;

(g) handling of information;
(h) patients' rights;
(i) complaints handling;
(j) charges;
(k) research activities;
(l) quality assurance activities; and
(m) specific requirements and handling procedures for each service.

1.6.3 The hospital must have policy to prohibit all forms of bribery and corruption, and to avoid situation with conflict of interest. Policies and procedures must be developed with reference to the guides and tools produced by the Independent Commission Against Corruption.

1.6.4 There must be kept a central register of policies and procedures that includes the title, issue date and review date of these documents.

1.6.5 There must be a mechanism to ensure staff are conversant with relevant procedures. Measures may include circulation of procedure manuals to staff concerned at regular intervals.

1.6.6 Evaluation must be carried out regularly on the practice adopted against the procedures to ensure effective implementation.

1.6.7 Policies and procedures must be reviewed at intervals not more than three years and revised as necessary to reflect the current scientific knowledge of services.

1.7 Clinical Governance

1.7.1 The hospital must establish a clinical governance system, under which it is accountable for continuously improving the quality of its services and safeguarding high standards of care.

1.7.2 The clinical governance for the hospital includes –

(a) delivery of patient-centred services;
(b) arrangements for accountability of quality;
(c) high standards of patient care and safety; and
(d) continuous improvement in patient services and care.

1.7.3 The hospital must establish clinical governance for monitoring and improving patient services in areas such as –

(a) patient feedback;
(b) risk assessment and quality assurance;
(c) multi-disciplinary audit;
(d) research and evaluation of patient services;
(e) human resource management; and
(f) professional development and training.

Chapter 2 Human Resource Management

2.1 Overview

The licensee must ensure that the staff or personnel who provide treatment and care in the hospital, are appropriately skilled, qualified and competent to do so.

2.2 General Requirements

2.2.1 There is at all times an appropriate number of suitably qualified and experienced persons in the hospital, taking into account the number and needs of patients and types of services provided.

2.2.2 All staff involved in clinical care must be appropriately trained including training in the use of any medical equipment and in assisting in medical procedures.

2.2.3 The Chief Medical Executive (CME) must ensure that the staff involved in clinical care are practising within their professional scope of practice and competence.

2.2.4 The CME must ensure that every healthcare professional working in the hospital has a valid practising certificate, or an enrolment that is still in force, for the professional capacity concerned; and that every healthcare personnel working in the hospital has the requisite qualifications, training and experience relevant to the healthcare services that the healthcare personnel provides.

2.2.5 Each person working in the hospital must –

(a) be suitably qualified;
(b) receive appropriate training and supervision;
(c) have received effective induction;

(d) be regularly appraised on his / her performance;
(e) be conversant with policies and procedures relevant to his / her duties; and
(f) be encouraged to undertake continuous professional development in his / her field of work.

2.2.6 Written and dated job description for different ranks and grades of staff must be available. A clearly defined organisation chart must be available so that the staff are aware of their responsibilities to facilitate team work.

2.2.7 A record must be kept for each employee with the following details –
(a) name and identifier of the person;
(b) details of his / her position and duties;
(c) date of employment and change in working locations;
(d) details of professional qualifications and valid registration with relevant professional regulatory body; and
(e) record and / or valid certificate of all training and educational activities.

2.2.8 The hospital must require all clinical staff to abide by relevant codes of professional practice.

2.2.9 A record of duty roster must be kept for all services / wards.

2.3 Medical Staff

2.3.1 The licensee of a hospital must ensure that there is at least one registered medical practitioner resident in the hospital at all times.

2.3.2 There must be a roster for medical practitioners to deal with emergencies. The roster must be devised in such a manner so as to avoid the same medical practitioner being put on duty for a prolonged period without replacement or backup.

2.3.3 Where the patient requests a specialist to provide the service, the medical staff providing the service must be one whose name has been included in the Specialist Register of the Medical Council of Hong Kong or the Dental Council of Hong Kong respectively, or the equivalent.

2.4 Medical Practitioners and Healthcare Professionals with Admission / Practising Privileges

2.4.1 For medical practitioners and healthcare professionals with admission or practising privilege, there must be a mechanism to –

(a) vet their fitness in terms of qualifications, experience and training;
(b) check the indemnification / medico-legal protection;
(c) monitor their performance;
(d) update them of current requirements of the hospital; and
(e) cancel their admission privileges if they are not fit or where the services provided are not of quality or that their performance violates the relevant codes of professional conduct and practice or that they have not complied with requirements of the hospital.

2.4.2 For medical practitioners and healthcare professionals who wish to carry out new procedures, techniques or treatment modalities, they must provide evidence of relevant training. Prior approval must be obtained from the Medical Advisory Committee.

2.4.3 There must be a mechanism for staff to report to the CME on irregular or unsatisfactory performance of medical practitioners and healthcare professionals.

2.4.4 A personal record must be kept for each of the medical practitioners and healthcare professionals and must include the following information –

(a) name and identifier of the person;

(b) details of professional qualifications and valid registration with relevant professional regulatory body; and

(c) the specialty permitted to be practised.

2.4.5 There must be a written agreement with medical practitioners and healthcare professionals setting out the details of practising privileges and his / her consent to comply with the rules and regulations of the hospital. Such agreement must be renewed on a regular basis.

2.4.6 The hospital must require all medical practitioners and healthcare professionals to place a copy of all clinical notes relating to the period of stay in the hospital in the patient's medical record.

2.4.7 The hospital must require all medical practitioners and healthcare professionals to respond to complaints raised against their performance.

2.4.8 The hospital must ensure that the communication arrangements of medical practitioners and healthcare professionals (for example, mobile phone and pager numbers) are accurately documented and updated where appropriate.

2.5 Nurses

2.5.1 There must be an overall nurse-in-charge who is a registered nurse with experience in nursing administration.

2.5.2 In the absence of the overall nurse-in-charge, another registered nurse must be authorized to act for him / her.

2.5.3 Where a registered nurse with relevant training is required to be available as the duty nurse-in-charge of a service provided by the hospital, there must be another registered nurse with relevant training who is authorized to act for him / her in his / her absence.

2.5.4 There must be a routine relieving mechanism and an emergency staff mobilisation plan in place to ensure adequate nursing manpower at all times and whenever necessary.

2.6 Supporting Care Staff

2.6.1 All supporting care staff must have undergone the relevant training and been assessed to be competent for undertaking their duties.

2.6.2 They must work under the supervision of nurses or other healthcare professionals.

2.6.3 Policies and procedures that are relevant to their areas of work must be presented in a form that they can understand.

2.7 Agency Staff

2.7.1 All agency staff must have an appropriate induction to the hospital and be made aware of current policies and procedures of the hospital.

2.7.2 The hospital must vet the qualification of agency staff if they are employed at the request of the patient or his / her family as professional staff. The performance of the agency staff must be monitored.

2.7.3 The staff of the hospital must not influence the patients or their family in employing agency staff.

2.7.4 Where a patient or his / her family wishes to employ agency staff, there must be written information made available to them on the qualifications and charges of different types of agency staff.

2.7.5 The patients or his / her family must be informed of the responsibilities of agency staff, the relationship of agency staff with the hospital and the legal liability in case of medical incidents arising from the performance of the agency staff concerned.

2.8 Health and Safety of Staff

2.8.1 The hospital must comply with the Occupational Safety and Health Ordinance (Cap. 509) to safeguard the health and safety of hospital staff.

2.8.2 A report and record on the accidents of staff on duty must be kept.

2.9 Staff Development and Education

2.9.1 There must be a job orientation programme to introduce the relevant aspects of the hospital service to new staff. The programme aims to prepare them for their role and responsibilities. This must include –

(a) information about the philosophy and objectives of the hospital and of each department / unit;

(b) information about the relationship between each department / unit and the hospital;

(c) duties and functions, lines of authority, areas of responsibility and methods of obtaining appropriate resources; and

(d) methods for evaluating the service provided as well as the performance of staff.

2.9.2 Orientation programmes must be conducted for services / specialties which demand special awareness of technology or safety.

2.9.3 Opportunities must be provided for staff to receive on-the-job training, in-service education and continuing education where appropriate.

2.9.4 Current operation manuals and clinical guidelines must be easily accessible and available to staff for their reference.

Chapter 3 Information Management

3.1 Medical Records

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

3.1.2 A comprehensive medical record must be maintained for each patient. All medical records must be accurate, sufficiently detailed, legible, current, complete and organised to enable –

(a) the medical practitioner responsible for the patient to provide continuing care to the patient, to review the diagnostic and therapeutic procedures performed and the patient's response to treatment;

(b) another medical practitioner or healthcare personnel to assume the care of the patient at any time or at times of emergency; and

(c) retrieval of information required for review and quality assurance activities.

3.1.3 The patient's name in full and a unique identifier such as patient / hospital number or alternative identifier must be displayed conspicuously on the record sheet for easy identification. The record of the patient comprises the following but is not limited to –

(a) patient's personal particulars and contact information, including gender, date of birth, residential address, contact telephone number;

(b) notes of all healthcare personnel and their identification, who have attended to the patient in the hospital, for example, admission notes, consultation notes and progress notes;

(c) prescription order form;

(d) observation charts and fluid balance charts;

(e) drug charts and history of allergy;

(f) reports of laboratory, radiological and diagnostic services;
(g) films or clinical photos;
(h) consent forms;
(i) anaesthetic records, including pre-operation assessment, pre- and post-anaesthesia record, date and place of operation;
(j) operation records including the histopathology report if tissue or body fluid was removed for examination, details of the site of the operative procedure, surgeon's signature;
(k) nursing care plans;
(l) any adverse events;
(m) sick leave and referral records; and
(n) discharge summary with diagnosis, key investigation results, treatment given and medications on discharge.

3.1.4 All entries in the patients' records must be dated and the time must be entered where appropriate. The entries must bear the signature of the service provider and the signature must be recognisable or traceable with specimen signature kept. Alternatively, the signature must be accompanied by the name of the signatory. Incorrect entry or error made must be crossed out and corrected where appropriate with the date and signature of the correcting officer.

3.1.5 Where the medical record is in an electronic format, there must be a mechanism to provide an audit trail on any amendments made on the record.

3.1.6 Audits on the content and completeness of patient medical records must be regularly conducted.

3.2 Storage and Destruction of Records

3.2.1 A policy must be set to retain medical records for a certain period of time. The period depends on the nature of the record and the likelihood of legal proceedings. The hospital should consult its legal advisor on how long specific types of records are stored.

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

3.2.3 Security measures and policies must be put in place for the safe handling and transmission of electronic information containing patients' data including, among others, electronic mails or those stored on removable media.

3.2.4 The electronic medical / patient record system of the hospital must be connectable with the Electronic Health System (eHealth).

3.2.5 For the use of electronic records, the hospital must devise risk management policy to protect data privacy, to ensure data integrity and to sustain provision of care to patients.

3.2.6 Destruction of records including electronic records or images containing patients' data must be undertaken in a secure manner.

3.3 Special Registers

3.3.1 A register of patients must be maintained. The registry can be in electronic or written format. The information to be included is as follows –

(a) the name, sex, date of birth, personal identifier, address and telephone number of each patient;

(b) the number given to identify the medical record of that particular admission, for example, hospital number;

(c) the date of admission; and

(d) the date of discharge, transfer or death.

3.3.2 A register must be maintained on the details of medical devices implanted that serves critical purposes. Pacemakers are examples of medical devices used for critical purpose. The register must contain the name or identifier of the patient, the brand, model, batch number and serial number of the device and the date of implant. This information is to allow subsequent tracing.

3.3.3 Registers must be maintained on the particulars of the patients receiving –

(a) items with human blood component, e.g. packed cell, platelet, fresh frozen plasma, etc.; and

(b) pharmaceutical products that are derived from human sources, e.g. albumin, clotting factors, and immunoglobulin, etc.

3.4 Regular Information for Submission to Director of Health

3.4.1 The licensee must submit the following information at regular intervals to the Director of Health –

(a) staffing situation;

(b) complaint digest;

(c) information related to price transparency measures as required under Chapter 33; and

(d) any other information related to the operation of the hospital, or as required by the Director of Health from time to time.

Section II – Clinical Governance

Chapter 4 Medical Advisory Committee

4.1 Composition

4.1.1 At least half of the members of the Medical Advisory Committee (MAC) must be registered medical practitioners or registered dentists, including at least one registered medical practitioner who is not employed by, or practising in, the hospital.

4.1.2 The chairperson of the MAC must be a registered medical practitioner, or, if the hospital has dental practice only, a registered dentist.

4.2 Function of the Committee

4.2.1 The MAC is to advise the licensee on the following -

(a) the qualifications of healthcare professional for providing services in the hospital and delineation of their clinical responsibilities;

(b) eligibility criteria for practising privileges of healthcare professional and review, renewal, restriction or withdrawal of practising privileges;

(c) all matters concerning medical diagnosis, treatment and care given, or to be given, in the hospital;

(d) all matters concerning the quality of care for, and the safety of, patients in the hospital; and

(e) whether or not to permit the introduction of new clinical techniques taking into consideration the training of healthcare professionals, the equipment required and the training / experience required of other supporting clinical staff.

4.2.2 The MAC must monitor and regularly review information collated on the clinical work undertaken at the hospital. Reviews include but are not limited to the following –

(a) any deaths reportable under the Coroners Ordinance (Cap. 504);

(b) clinical indicators, e.g. unplanned returns to operating theatre;

(c) clinical audits;

(d) adverse event; and

(e) complaints on performance of healthcare personnel.

4.2.3 The licensee and the Chief Medical Executive are responsible for ensuring that the advice given by the MAC of the hospital is properly implemented.

Chapter 5 Quality Management System

5.1 Overview

The licensee is responsible for setting up and enforcing rules, policies and procedures relating to the quality of care for, and the safety of, patients in the hospital. There must be an organisational structure with clear delineation of responsibilities for implementation of these rules, policies and procedures.

5.2 Quality Management

5.2.1 The hospital must conduct an ongoing quality assurance and improvement programme to objectively and systematically monitor and evaluate the quality and appropriateness of patient care, to resolve identified problems, and to pursue opportunities to improve patient care.

5.2.2 The hospital must have a written plan for the quality assurance and improvement programme. The plan must be reviewed by the Medical Advisory Committee (MAC) and endorsed by the Board of Directors.

5.2.3 The quality assurance and improvement programme must include monitoring and evaluation of data collected. Sources of data for monitoring and evaluation include but are not limited to medical records, incident reports, infection control records, and patient complaints.

5.2.4 The hospital must implement measures to resolve the problems or concerns identified. The effectiveness of these corrective measures must be evaluated.

5.3 Quality Committee

5.3.1 The hospital must establish a quality committee to conduct the quality assurance and improvement programme.

5.3.2 The quality committee must comprise medical staff and nurses and such other healthcare professional and administrative staff as appropriate.

5.3.3 The chairperson or members of the quality committee must have received training in conducting quality assurance activities.

5.3.4 The quality committee –

(a) prescribes standards of care and service;
(b) monitors and evaluates the quality and appropriateness of services, practices and procedures;
(c) identifies and resolves problems arising in connection with the services, practices and procedures;
(d) makes recommendations for quality improvement on the services, practices and procedures; and
(e) monitors the implementation of the recommendations.

The quality committee must document activities of the quality assurance and regularly review the quality assurance and improvement programme.

The quality committee must report to the MAC and the Board of Directors regularly.

Chapter 6 Risk Management

6.1 General Requirements

6.1.1 There must be a comprehensive written risk management policy and supporting procedures, covering the following –

(a) assessment of risks throughout the hospital;

(b) identification and analysis of and learning from incidents; and

(c) arrangement for responding to emergencies, for example, fire evacuation, cessation of water and electricity supply.

6.1.2 There must be an on-going process for identifying and reducing safety risks to patients and staff.

6.1.3 In the management of a serious incident, there must be –

(a) designated senior staff to co-ordinate the immediate response to the incident;

(b) alert procedures to deploy staff in response to an incident;

(c) procedures to communicate the nature of the incident to senior staff, family of the patient, regulatory authorities and media as appropriate (risk communications);

(d) investigation and audit after the incident; and

(e) implementation of recommendations to prevent future occurrence.

6.1.4 There must be contingency plans for emergencies such as fire and cessation of water or electricity supply, and they must be reviewed at regular intervals not exceeding three years. Regular drills must be conducted.

6.1.5 There must be staff-to-staff communication systems for emergency.

6.2 Resuscitation and Contingency

6.2.1 There must be at least one team of staff on duty at all times in the hospital and readily available to provide resuscitation. The team must comprise at least one medical practitioner. All team members must hold a valid certificate in Basic Life Support (BLS) or equivalent qualification and at least one medical practitioner must hold a valid certificate in Advanced Cardiac Life Support (ACLS) or equivalent qualification. Where children are admitted as inpatients, there must be at least a medical practitioner with a valid certificate in Paediatric Advanced Life Support (PALS) or equivalent qualification on duty at all times in the hospital and readily available to provide resuscitation.

6.2.2 The staff who need to provide resuscitation must receive updated training on a regular basis, with resuscitation drills carried out regularly. The hospital must conduct audit on the skills to assess the competence of staff concerned.

6.2.3 Resuscitation equipment must include at least the following items –

(a) bag valve mask (ambu bag);
(b) oxygen supply;
(c) suction;
(d) defibrillator;
(e) infusion drip sets and fluids; and
(f) drugs as advised by the Medical Advisory Committee.

6.2.4 Resuscitation equipment must be made easily accessible and staff must be made aware of its location.

6.2.5 Resuscitation equipment and medication must be made ready in accordance with the needs of patients of different ages. For example, where the hospital receives neonates or children,

paediatric dosage for medication must be made ready where practicable.

6.2.6 Resuscitation equipment must be checked and restocked to ensure all equipment remain in good working order at all times. Checks must be documented with staff's signature.

6.2.7 Written policies and procedures must be prepared in relation to resuscitation of patients.

6.2.8 Written policies and procedures must be put in place to guide the handling, use, and administration of blood and blood products for patients.

6.3 Patient Safety Incident Reporting and Learning System

6.3.1 The hospital must establish a reporting system for Patient Safety Incident. A Patient Safety Incident includes near miss, no harm incident or adverse event.

6.3.2 There must be a person appointed to coordinate risk assessment and promulgate information on risk identifications and solutions for Patient Safety Incident.

6.3.3 There must be written procedures for identification, reporting, analysis, and management of Patient Safety Incident. Lesson learnt and risk reduction measures must be disseminated to staff.

6.3.4 There must be policies and procedures on disclosure of adverse events to the patients concerned and / or their next of kin.

6.4 Reportable Events: Sentinel Events and Serious Untoward Events

The hospital must inform the Director of Health within 24 hours upon the identification of the following event(s), and submit full report 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" –

Sentinel Events

(a) Surgery / interventional procedure involving a wrong patient or body part;
(b) Retained instruments or other material after surgery / interventional procedure;
(c) ABO incompatibility blood transfusion;
(d) Medication error resulting in major permanent loss of function or death;
(e) Intravascular gas embolism resulting in death or neurological damage;
(f) Death of an inpatient from suicide (including home leave);
(g) Maternal death or serious morbidity associated with labour or delivery;
(h) Infant discharged to wrong family or infant abduction;
(i) 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;
(b) Patient misidentification which could have led to death or permanent harm.

6.5 Other Reportable Events

The hospital is required to inform the Director of Health upon the identification of the following event(s) –

(a) events of public health significance (for example, radiation health incidents);

(b) serious incidents affecting the operation of the hospital, for example, cessation of water and electricity supply;

(c) unusual clustering of communicable diseases, in addition to the statutorily reportable infectious diseases specified in the Prevention and Control of Disease Ordinance (Cap. 599).

Chapter 7 Complaints Management

7.1 Complaints Handling Procedures in the Hospital

7.1.1 The licensee must put in place a complaints handling procedure for receiving, managing and responding to complaints that are received against the hospital.

7.1.2 The licensee must ensure the complaints handling procedure is made known in an appropriate way to the patients of the hospital or persons acting on their behalf.

7.1.3 A notice on the channels for receiving complaints must be posted up for patients' information at the admission office, reception counter of individual service, cashier and reception hall. The notice must also include contact information of the Complaints Committee.

7.1.4 A time frame must be set for staff to provide initial response to complaints, for example, within 10 working days.

7.1.5 There must be a patient relation officer to handle complaints.

7.1.6 The licensee must ensure that –

(a) an investigation of the complaint is conducted and findings made;

(b) if the case requires, an improvement measure, whether general or specific to the complaint, is implemented; and

(c) the complainant is informed of the findings of the investigation and any improvement measure and follow-up action taken or to be taken.

7.1.7 A record of the details of the complaints received, investigation findings and actions taken must be kept.

7.1.8 The Chief Medical Executive must, on a monthly basis, provide to the Director of Health a complaint digest comprising the following –

(a) the complaints against the hospital received by the hospital;

(b) the findings of the investigations of the complaints; and

(c) the actions (including improvement measures) taken in response to the complaints.

7.1.9 Staff and related personnel of the hospital regularly must receive training on customer service improvement, such as mediation skills.

7.2 Complaints under Consideration by Complaints Committee

7.2.1 If the Complaints Committee is considering a complaint, upon the request from the Complaints Committee, the hospital must appoint a designated person for providing any information or documents requested and giving any assistance necessary, both in a timely manner, for concluding the case. The information provided to the Complaints Committee must be complete and accurate.

7.2.2 Upon the request from the Complaints Committee, the hospital must conduct investigation, reply to the complainant, and provide reply and result of investigation to the Complaints Committee within the stipulated time frame.

7.2.3 The hospital must implement the advice, if any, from the Complaints Committee on improvement measures.

Chapter 8 Clinical Research

8.1 Overview

The "Code of Professional Conduct for the Guidance of Registered Medical Practitioners" issued by the Medical Council of Hong Kong provides guidance on good clinical research practice. The hospital must set out its policy on whether clinical research is allowed on patients.

8.2 General Requirements

8.2.1 The hospital must set up an Ethics Committee to monitor clinical research, if there is any.

8.2.2 The purpose of the Ethics Committee is to review clinical research to safeguard the dignity, rights, safety and well-being of all actual or potential participants.

8.2.3 The Ethics Committee must provide independent and timely review of the ethics of proposed study.

8.2.4 Before any clinical research is to be carried out, a research proposal must be prepared and submitted to the Ethics Committee for approval.

8.2.5 The Ethics Committee must be multi-disciplinary and multi-sectoral in composition, including independent scientific expertise, professionals and specialists.

8.2.6 The Ethics Committee must have clear procedures in selecting and recruiting members. Conflicts of interests must be avoided when making appointments.

8.2.7 The licensee must ensure that any clinical drug trial conducted in the hospital is covered by a valid clinical trial certificate issued under the Pharmacy and Poisons Regulations (Cap. 138A) or the Chinese Medicine Ordinance (Cap. 549) as applicable.

8.2.8 The findings of the research or study conducted in the hospital must be reported to the Ethics Committee.

Section III – General Management

Chapter 9 Facility Management

9.1 General Requirements

The design and condition of the hospital must meet the purpose of the hospital and the needs of patient. All equipment in the hospital must be used as intended for its purpose, kept in good working order and properly maintained.

9.2 Physical Conditions

9.2.1 The physical design, size and layout of the hospital must be appropriate for the safe and effective delivery of services.

9.2.2 All areas must be designed, constructed, furnished and equipped to minimise the risk of transmitting infection, and facilitate implementation of infection prevention and control measures. The premises must be kept clean and hygienic.

9.2.3 There must be facilities for separation of clean and dirty items.

9.2.4 There must be adequate hand washing and sanitary facilities for staff and patients.

9.2.5 All buildings, furniture, furnishings, fittings and equipment of the hospital must be maintained in good operational order.

9.2.6 There must be mechanism in place for periodic inspection of all patient care buildings and physical facilities. This periodic inspection must be documented and help the management develop a plan to reduce evident risks and provide a safe and secure physical environment of care.

9.2.7 Lighting, temperature, humidity, ventilation and noise level must be appropriate to the facilities being used.

9.2.8 There must be patient-to-staff call systems or devices (e.g. call bells) in hospital beds and where a patient may be left alone temporarily (e.g. patient changing room, toilet or bathroom, etc.).

9.2.9 There must be facilities to provide for privacy of patients, where necessary (for example, screens).

9.2.10 Aids to facilitate the movement of the disabled (for examples, lifts and ramps) must be available where appropriate.

9.3 Equipment

9.3.1 There must be appropriate and sufficient quantities of medical equipment, instruments, appliances and materials that are necessary for the type and level of patient care provided.

9.3.2 All equipment used in the hospital must be appropriately procured, and properly installed, operated, maintained, and calibrated according to the manufacturer's recommendation. Maintenance and servicing records must be kept.

9.3.3 A register must be kept in respect of all medical equipment. Such register must include -

(a) the date of installation of the equipment;

(b) the model of the equipment and the name of the manufacturer;

(c) the name and contact telephone of the servicing agent; and

(d) details of the maintenance of the equipment and date of servicing.

9.3.4 There must be a planned preventive maintenance and replacement programme for critical or major equipment.

9.3.5 Equipment must not be modified unless the advice of the manufacturer or professional advice has been sought and no risk has been identified. Such advice must be documented.

9.3.6 All equipment must conform to the relevant health and safety requirement.

9.3.7 All equipment must be stored properly to ensure that at the time of use they are in optimum condition.

9.3.8 Medical equipment intended for single-use must not be reused.

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

9.3.10 Written procedures must be drawn up for use and for maintenance of different types of equipment.

9.3.11 There must be procedures for cleaning, disinfection, packaging, sterilisation, transportation and storage of reusable medical equipment.

9.3.12 Medical devices must be handled safely and decontaminated prior to re-use. Re-usable medical devices must be decontaminated in accordance with best practice requirements or manufacturer's recommendations.

9.4 Fire Safety

9.4.1 Advice must be sought from the Fire Services Department (FSD) or agencies approved by FSD on the measures on fire safety.

9.4.2 Adequate precautions against the risk of fire must be taken.

9.4.3 The use of fire-resistant materials for mattresses and upholstered furniture must be in line with standards prescribed by the FSD.

9.4.4 Procedures to be followed in the event of fire must be displayed in conspicuous places in the premises of the hospital.

9.4.5 Fire evacuation exercise must be conducted at regular intervals. Records of the drills must be made available for inspection.

9.4.6 The fire and smoke safety plans including systems related to early detection and suppression must be subject to regular testing and results must be documented.

9.5 Others

9.5.1 Where injectable or infusible products are provided in the hospital, the requirements stipulated in Chapter 28 of this Code, where applicable, must be complied with.

Chapter 10 Healthcare Engineering Systems

10.1 Overview

10.1.1 Healthcare engineering systems, namely electrical installation, specialized ventilation system, and medical gas supplies, are essential facilities 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 (MGPS) are operated to ensure a safe and reliable provision of medical gases from the sources of supply to the clinical point-of-use. These systems must be properly designed, installed, operated and maintained to meet the need of service and to ensure patient and staff safety.

10.1.2 The requirements of the design and installation of the healthcare engineering systems as specified in the Code apply to new installations, and additions and alterations to existing installations in the hospital. For existing healthcare engineering systems, the current version of the other guidelines, codes and standards, etc. applicable at the time of the commissioning of the installations applies.

10.2 Electrical Installations

General Requirements

10.2.1 The electrical installations of the hospital must be designed, installed, operated and maintained to provide safe and reliable electrical supply and lighting to support the healthcare services therein.

10.2.2 Fixed electrical installations must 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) Electricity Ordinance (Cap. 406);
(b) Buildings Ordinance (Cap. 123);
(c) Dangerous Goods Ordinance (Cap. 295); and
(d) Fire Services Ordinance (Cap. 95).

10.2.3 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.

10.2.4 A suitable person with relevant qualification / training and experience must be appointed to take overall charge of the management of the electrical installations of the hospital.

Design and Installation

10.2.5 The design and installation of the electrical installations in critical care areas must be of internationally acceptable healthcare standards such as the Health Technical Memorandum (HTM) 06-01 - "Electrical services supply and distribution", or equivalent.

10.2.6 The electrical installations must be designed and installed to meet the electrical demand of the hospital.

10.2.7 Back-up power supply -

(a) Critical care areas must be provided with back-up power supplies to ensure patient safety upon loss of the normal electrical power supplies.
(b) Backup power supplies must be available for the medical equipment for life support systems, recovering patients, and safe completion or cessation of surgical or high-risk procedures.

(c) Back-up power supplies for critical care area must be provided by emergency generators or emergency generators with uninterruptible power supplies (UPS). The type, rating and back-up time of the back-up power supplies must be selected to meet the back-up power requirements in accordance with the contingency plan for electricity suspension of the hospital. (Details on the back-up power supply requirements are provided in Annex 1)

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

10.2.9 The electrical installations must be designed to minimise the effect of an electrical fault to the clinical areas. The protective devices used must be able to achieve effective discrimination so that the smallest section of the affected electrical installation will be isolated in the event of an electrical fault.

10.2.10 The fixed electrical installations must be 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.

10.2.11 The design and installation of the electrical installations for critical care areas must be 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 Code.

Operation and Maintenance

10.2.12 The electrical installations must be properly operated and maintained, in compliance with all applicable statutory requirements, and taking into consideration of the guidance given in internationally acceptable healthcare standards such as HTM 06-01, or equivalent, the manufacturers' recommendations and good trade practices.

10.2.13 Maintenance records must be properly kept.

10.2.14 The electrical load profiles must be monitored, recorded and reviewed periodically to ensure adequacy of supply capacity of the fixed electrical installations.

10.2.15 Back-up power supplies must be maintained, inspected and tested regularly to ensure their proper functioning upon loss of the normal electrical power supply. On-load tests of emergency generators and discharge tests of batteries must be scheduled and conducted effectively in coordination with the supported services.

10.2.16 The fixed electrical installations must be inspected, tested and certified periodically by a registered electrical worker / contractor in accordance with the Electricity Ordinance (Cap. 406) and its subsidiary legislation.

10.3 Specialized Ventilation Systems

General Requirements

10.3.1 The specialized ventilation systems of the hospital must be designed, installed, operated and maintained for purposes including but not limited to –

(a) prevention of the spread of airborne infectious disease;

(b) prevention and control of healthcare-associated infection; and

(c) dilution and removal of contaminants and fumes where used.

10.3.2 Specialized ventilation systems must 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) Buildings Energy Efficiency Ordinance (Cap. 610); and
(e) Public Health and Municipal Services Ordinance (Cap. 132).

10.3.3 The guidance on ventilation in the "ICB Infection Control Guidelines" promulgated by the Centre for Health Protection of the Department of Health must be followed.

10.3.4 Where fresh water cooling towers are installed, the cooling towers must 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.

10.3.5 A suitable person with relevant qualification / training and experience must be appointed to take overall charge of the management of the specialized ventilation systems of the hospital.

<u>Design and Installation</u>

10.3.6 The design and installation of the specialized ventilation systems must be of internationally acceptable healthcare standards such as ANSI/ASHRAE/ASHE Standard 170 – "Ventilation of Health Care Facilities", or Health Technical Memorandum (HTM) 03-01 – "Specialised ventilation for healthcare premises", or equivalent.

10.3.7 In specialized ventilation areas, including but not limited to airborne infection isolation (AII) rooms, protective environment (PE) rooms, operating theatres / rooms and aseptic preparation facilities, the ventilation systems must 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. (Details on the specialized ventilation requirements for AII rooms, PE rooms and operating theatres / rooms are provided in Annex 2)

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

10.3.9 Outdoor air intakes must be situated away from any vehicle staging areas, exterior designated smoking area, cooling towers and all exhaust and vent discharges.

10.3.10 The discharge outlets from general extract systems must be placed at a suitable location to minimise the recirculation of discharged air back into the building. In addition, the discharges from AII rooms and local exhaust ventilation systems should be vertical and at sufficient height above roof level. (Details on the exhaust discharge requirements are provided in Annex 3)

10.3.11 The designed ventilation rate and pressure gradient in AII rooms, PE rooms and operating theatres / rooms must be maintained by back-up power supply in the event of loss of normal electrical power supply.

10.3.12 The number and arrangement of the chiller units and essential accessories of the central chilled water systems must be sufficient to support the facility operation plan upon a breakdown or routine maintenance of any one of the chiller units.

10.3.13 The design and installation of the specialized ventilation systems must be 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 Code.

Operation and Maintenance

10.3.14 The specialized ventilation systems must be properly operated and maintained, in compliance 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, HTM 03-01, or equivalent, the manufacturers' recommendations and good trade practices.

10.3.15 An ongoing routine maintenance of the specialized ventilation systems must be put in place to ensure proper functioning and adequate supply and exhaust of air in the designated areas of the hospital. Documentation of repair and maintenance of the systems must be kept.

10.3.16 The fresh water cooling towers, if any, must be –

(a) maintained in a good and uncontaminated condition;

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

(c) audited independently on their operation and maintenance annually.

10.3.17 Subject to infection control considerations, the number of air changes for areas that require a positive or negative pressure relationship can be reduced when the area is unoccupied, provided that the required pressure relationship to adjoining areas is maintained while the area is unoccupied and that the designed minimum number of air changes is re-established well in advance when the area becomes occupied.

10.4 Medical Gas Supplies

General Requirements

10.4.1 The manufacture, storage, supply and use of medical gases in the hospital must 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).

10.4.2 An operational policy with emergency protocol in respect of medical gases (including medical gas leakage and contingency plan) must be established and distributed to all personnel concerned.

10.4.3 The medical gases must comply with the prevailing specifications of the relevant gases as stated in the Pharmacopoeia of the People's Republic of China, the European Pharmacopoeia or the United States Pharmacopeia, where applicable, and must be appropriate for medical use in all cases.

10.4.4 A suitable person with relevant qualification / training and experience must be appointed to take overall charge of the management of medical gases supplies of the hospital.

10.4.5 All engineering and facility management staff must have received proper training before operation and maintenance of the medical gas pipeline systems.

10.4.6 All personnel of the hospital involved in the daily management and transport of medical gas cylinders / liquid gas containers must have received training in the safe handling and storage of the gas cylinders and containers.

Medical Gas Pipeline Systems (MGPS)

10.4.7 General requirements

(a) The MGPS of the hospital must be 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.

10.4.8 Design and installation

The following must be observed when designing and installing the MGPS -

(a) The design and installation of the MGPS must be of internationally acceptable healthcare standards such as Health Technical Memorandum (HTM) 02-01 – "Medical gas pipeline systems", or equivalent;

(b) The capacities of the medical gas plants and manifolds must be adequate to meet the gas demand;

(c) All MGPS must be 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. (Details on the back-up sources requirements are provided in Annex 4);

(d) MGPS plants and equipment must be connected to the back-up power supply;

(e) Terminal units must be installed in various clinical areas to properly provide for the medical treatment processes therein. The pipeline distribution system must be designed to deliver medical gases from the source of supply to the terminal units at the required flow rates and pressure –

(i) The pipeline systems must be designed in accordance with internationally acceptable healthcare standards such as HTM 02-01, or equivalent, to ensure that the gas flows are adequate at each terminal unit; and

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

(f) Gas-specific connections, including terminal units, connectors, etc., must be used throughout the pipeline systems;

(g) A warning and alarm system must be 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;

(h) Testing and commissioning must be 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 must be in accordance with HTM 02-01, or equivalent. (Details on the test requirements of MPGS are provided in Annex 5);

(i) The initial pressure test on MGPS must comply with Fire Services Department "DG/TS/143(A) – Requirements for Initial Pressure-testing of Medical Gas Piped Installation" where applicable;

(j) The design and installation of the MGPS must be 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 Code.

10.4.9 Operation and Maintenance

The following must be observed in the operation and maintenance of the MGPS –

(a) The MGPS must be properly operated and maintained, in compliance with all applicable statutory requirements and taking into consideration of the guidance given in internationally acceptable healthcare standards such as HTM 02-01, or equivalent, the manufacturers' recommendations and good trade practices;

(b) An Authorized Person must be appointed in writing by the CME of the hospital for supervising the operation, maintenance, repair and alteration work of the MGPS. The Authorized Person must have received specialist training on MGPS meeting the requirements of HTM 02-01, or equivalent;

(c) All works on the existing MGPS of the hospital must be governed by a safety management system, such as a permit-to-work system as set out in HTM 02-01, 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 must be documented. (A sample Permit-to-Work Form is provided in Annex 6);

(d) The MGPS must be subjected to a planned preventive maintenance schedule under the responsibility of the Authorized Person of the hospital. Appropriate planned preventive maintenance works on the MGPS must be conducted at regular intervals;

(e) Annual inspections must be 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;

(f) The hospital must have 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.

Operational Management of Medical Gas Supplies

10.4.10 This Section applies to medical gases supplied in compressed gas cylinders (CGCs), liquid gas containers (LGCs) and bulk liquid gas vessels (e.g. vacuum insulated evaporator).

10.4.11 Medical gases must be procured from reputable sources.

10.4.12 The storage and use of medical gases must comply with the Dangerous Goods Ordinance (Cap. 295) and its subsidiary regulations.

10.4.13 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 must be conspicuously displayed inside and outside the storage area.

10.4.14 A system of regular checking of the expiry date of each CGC in storage or in use must be in place. Records of checking, order, return, and receipt must be kept.

10.4.15 The content of each CGC must be identifiable by a specific colour code and label, and the content of each LGC must be identifiable by a label.

10.4.16 A CGC identification colour chart must be prominently displayed inside the storage area.

10.4.17 All reasonable precautions must be taken to prevent tampering, and unauthorized access to CGCs and LGCs.

10.4.18 CGCs and LGCs must be handled with care only by personnel who have been trained in cylinder or container handling.

10.4.19 A system must be instituted whereby all CGCs and LGCs are used in the order in which they are received.

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

10.4.21 CGCs and LGCs must be handled in accordance with the operating instructions with safety precautions available from the supplier.

<u>Dental compressed air and vacuum systems (DAVS)</u>

10.4.22 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, 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.

10.4.23 An operational policy for the management of the DAVS must be in place.

10.4.24 The design and installation of the DAVS must be of internationally acceptable healthcare standards such as Health Technical Memorandum (HTM) 2022 – Supplement 1 – "Dental compressed air and vacuum systems", or equivalent.

10.4.25 The design and installation of the DAVS must be 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 Code.

10.4.26 The DAVS must be properly operated and maintained, in compliance with all applicable statutory requirements, and taking into consideration the guidance given in internationally acceptable healthcare standards such as HTM 2022 – Supplement 1, or equivalent, the manufacturers' recommendations and good trade practices.

Chapter 11 Infection Control

11.1 General Requirements

11.1.1 The hospital must make infection prevention and control a priority. An infection control programme must be established to ensure the safety of both hospital staff and patients.

11.1.2 Written policies, procedures and guidance for the prevention and control of infection must be developed with reference to the relevant guidelines issued by local or international authorities, e.g. Centre for Health Protection of the Department of Health (CHP), including the following -

(a) standard and transmission based infection control precautions;
(b) use of personal protective equipment;
(c) safe injection practice and management of needle-stick injury;
(d) staff vaccination;
(e) isolation of patients suffering or suspected to be suffering from infectious disease;
(f) notification of suspected outbreak of infectious disease to CHP and management of the outbreaks;
(g) prevention and control of antimicrobial resistance;
(h) management of indwelling catheters;
(i) prevention of ventilator associated pneumonia;
(j) prevention of surgical site infection;
(k) management of spills or accidents with infectious substances;
(l) assessment of environmental infection risk during demolition, construction and renovation works;
(m) decontamination and reprocessing of re-usable medical devices;
(n) safe handling and disposal of clinical waste, cytotoxic waste and chemical waste;
(o) management of laundry and linen;

(p) collection, packaging, handling and delivery of laboratory specimens; and

(q) operation of catering service.

11.1.3 The hospital must establish a high level infection control committee and infection control team for implementation of infection prevention and control measures.

11.1.4 The hospital must ensure that appropriate isolation facilities are in place for patients with infectious diseases.

11.1.5 The hospital must maintain appropriate and adequate stocks of personal protective equipment for use by staff.

11.2 Infection Control Committee

11.2.1 The infection control committee must develop infection control policies, endorse infection control guidelines and monitor the work of the infection control team in carrying out the infection control programmes.

11.2.2 The infection control committee must include at least one member who is a specialist in clinical microbiology and infection, infectious disease, public health medicine, or equivalent.

11.3 Infection Control Team

11.3.1 The infection control team must organise, implement and monitor infection control practice of the hospital. The team must also monitor the incidents and trends of infections among patients and staff as well as infection control activities.

11.3.2 The infection control team must be headed by a trained infection control practitioner. Members of the infection control team must have received training in infection control.

11.3.3 The infection control team must advise on the following issues -

(a) early stage planning relating to the building services and purchase of medical equipment; and

(b) contracting-out process for services which have implications for infection control, for example, laundry, housekeeping, waste disposal, catering, sterile supplies and maintenance of ventilation system.

11.3.4 The work of infection control team must be supported by timely medical support and microbiological service.

11.3.5 The infection control team must undertake on-going activities and surveillance to monitor nosocomial infections, outbreaks of infectious diseases and to detect multi-drug resistant organisms.

11.3.6 The infection control team must be involved in training of staff on all aspects of infection control and prevention.

11.3.7 The infection control team must keep abreast of the situation of infectious diseases in the community and implement appropriate infection control measures.

PART II: CLINICAL SERVICES

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Section I – General Service Requirements

Chapter 12 Service Delivery and Care Process

12.1 Overview

Patients with certain clinical conditions warrant special attention. It is essential for the licensee to identify the type of conditions that warrants special attention; and to plan and monitor the service accordingly. For individual patients, the medical practitioner-in-charge of the patient assumes the most important role in delivering appropriate care.

12.2 Rights of Patients

12.2.1 Patients have the right to be treated with dignity. All services must be delivered without discrimination on the basis of age, sex, religion, ethnicity and disability of the patient.

12.2.2 There must be written policies and procedures to protect the following rights of the patients –

(a) the right to obtain information on one's own diagnosis, treatment, progress and investigation results;

(b) the right to obtain information necessary to give informed consent to any investigation, procedure, surgery or other treatment modalities; such information includes clear and comprehensive information about the procedure, its effectiveness and any risks associated with it and any alternatives to the treatment recommended;

(c) the right to refuse treatment after being explained of the consequence;

(d) the right to confidentiality in all communications and records related to one's own care;

(e) the right to refuse experimentation or participation in teaching programmes;

(f) the right to access their own medical records;

(g) the right to obtain a medical report or a copy of the medical record from the hospital and the attending medical practitioner after paying respective processing charges;

(h) the right to know the name and rank of the staff providing services;

(i) the right to know the qualifications of the medical practitioner providing the service;

(j) the right to be informed of any public health measures taken in the hospital and to take appropriate measures to protect their health.

12.2.3 Consent must be sought from the patient in respect of the consultation or care provided by healthcare personnel other than the medical practitioner-in-charge. The need for continuing consultation or care must be reviewed at suitable intervals and agreed by the patient.

12.2.4 Patients and their next of kin or representatives must have the right to be informed about the procedures for making complaints and the process of managing and responding to their complaints by the hospital.

12.2.5 For Reportable Event, the hospital must inform the patient concerned and / or their next of kin that the Department of Health is looking into the matter and provide them with the relevant written notice in the prescribed format.

12.2.6 There must be appropriate facilities to ensure privacy and to meet the special needs of patients.

12.2.7 Staff must wear badges with full name and post title to identify themselves. The staff badge must be visible to the clients.

12.2.8 There must be appropriate measures to protect patients' personal belongings from theft or loss and also measures to protect patients from assault by visitors, other patients, and staff. This responsibility is particularly relevant to infants, children, the elderly, and others unable to protect themselves or signal for help.

12.3 Care of Patients in General

12.3.1 There must be a medical practitioner who is in charge of the patient and accountable for the care of the patient during his / her stay in the hospital. The medical practitioner is responsible for coordinating medical services to be provided to the patient.

12.3.2 For patients who are admitted by a medical practitioner with admission privilege, that medical practitioner assumes the role of the medical practitioner-in-charge of the patient. When there is a change in the medical practitioner-in-charge, the patient must be informed accordingly.

12.3.3 The management of the hospital must ensure that patients receive timely assessment of their health problems and appropriate treatment and care.

12.3.4 During the stay of the patient in the hospital, the medical practitioner-in-charge must regularly follow up the patient taking into consideration of the patient's clinical condition.

12.3.5 Patients must be properly assessed by a medical practitioner prior to undergoing any intervention.

12.3.6 Assessments and / or procedures performed must be documented in the patient's records and readily made available to those responsible for the patient's care.

12.3.7 Patients and / or families must be informed about the outcomes of care and treatment including unanticipated outcomes.

12.4 Care of Geriatric Patients

12.4.1 The staff must have a basic understanding of the needs of the elderly.

12.4.2 Guidelines must be developed for –

(a) feeding the elderly especially for those with swallowing difficulty;
(b) restraining for the elderly who are likely to fall or cause injury to self or others;
(c) skin care, oral and dental hygiene of each patient;
(d) early detection of abnormal behaviour or condition;
(e) care of bedridden patients;
(f) care of demented patients;
(g) care of incontinent patients; and
(h) insertion and care of indwelling catheter.

12.5 Care of Paediatric Patients

12.5.1 Treatment must be provided by medical practitioners who have appropriate qualifications, skills and experience in treating children.

12.5.2 Arrangements must be made to meet the medical, physical, psychological and social needs arising from the age of the child.

12.5.3 All staff who care for or treat children must be trained to recognise the signs and symptoms of child abuse and initiate appropriate action by taking reference from the latest guidelines related to child abuse issued by the Social Welfare Department, for example, "Protecting Children from Maltreatment – Procedural Guide for Multi-disciplinary Co-operation (Revised 2020)".

12.5.4 Toys provided for use by children must be safe and cleaned after use.

12.5.5 Where the hospital caters for neonates, there must be policies and procedures to support breastfeeding, such as rooming-in facilities and a breastfeeding support team.

12.6 Care of Patients with Mental Problems or Violent Behaviour

12.6.1 There must be policies and procedures to –

(a) assess the patient's inclination to violence and self-harm;

(b) assess the quality, safety, appropriateness and security of the service facilities to prevent the patient harming himself / herself or other person;

(c) provide training to enable staff to manage such patients;

(d) communicate the patient's condition to staff who are taking care of the patient;

(e) manage a disturbed patient;

(f) prescribe the use of restrains, rapid sedation and emergency medication where applicable; and

(g) report incidents or self-harm.

12.6.2 The attending medical practitioner must carry out an examination on the mental condition of the patient suspected to have suicidal tendency and take appropriate action. Staff

must monitor the condition of the patient and increase vigilance where appropriate.

12.6.3 Where the hospital provides psychiatric inpatient service, there must be at all times an appropriate number of Registered Nurses (Psychiatric) providing nursing care.

12.7 Care of Patients who Require Physical Restraint

12.7.1 Use of restraints is discouraged and must only be used as the last resort to prevent patient from injuring himself / herself or others or to prevent the patient from falling.

12.7.2 Restraints must be applied by a nurse only after having consulted a medical practitioner who has assessed the suitability of using restraints, the type and the maximum duration. The need for restraint must be documented in the patient's clinical record.

12.7.3 Where restrainers are to be used, the informed consent of the patient or his / her next-of-kin or other authorized representative must be obtained.

12.7.4 Written policies and procedures must be developed on the use of restrainers to ensure the proper use of restraint.

12.7.5 The restraint must allow a patient to breathe freely. Minimal movement of body and limbs is permitted.

12.7.6 The condition of the patient, including the circulation and skin integrity, must be checked on a regular basis to ensure that the patient is safe from the risk of strangulation. There must be a record to document such checking.

12.8 Care of Patients who Require Palliative Care

12.8.1 The size of the multi-professional team must commensurate with the scale of service being provided.

12.8.2 All team members must be trained in the assessment of palliative care needs for people with different physical, psychological, social, religious and cultural needs.

12.8.3 All team members must have received training and updating in communication skills including the breaking of bad news.

12.8.4 There must be appropriate equipment and facilities for symptom management, rehabilitation or terminal care.

12.8.5 There must be written policy and procedures on : -

(a) access to palliative care, pain management and / or other support services, e.g. bereavement support;

(b) end-of-life care, including decision making;

(c) the development and use of advance care plans or directives; and

(d) recognition and recording of advance directives.

12.9 Use of Telemedicine

12.9.1 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.

12.9.2 Where the hospital provides telemedicine service, the hospital must have policies and procedures in place to ensure that the overall standard of care delivered by telemedicine is not compromised as compared with in-person service.

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

12.10 Care of Patients who have Received Sedation or Anaesthesia

12.10.1 Where conscious (moderate) sedation, deep sedation, general anaesthesia or major regional anaesthesia is performed, it must be performed in accordance with the relevant guidelines published by the Hong Kong Academy of Medicine and its colleges, where applicable.

12.10.2 All general anaesthesia, spinal anaesthesia, epidural anaesthesia, deep sedation, or potent anaesthetic agents[1] with no specific antagonists must be provided only by an anaesthesiologist or a trained medical practitioner under the supervision of an anaesthesiologist.

[1] Examples of potent anaesthetic agents with no specific antagonists should refer to the "Guidelines on Procedural Sedation" promulgated by the Hong Kong Academy of Medicine.

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Section II – Specific Service Requirements

Chapter 13 Accident and Emergency Services

13.1 Staff Requirement and Training

13.1.1 A specialist in emergency medicine or relevant specialty must be appointed to take overall charge of the accident & emergency (A&E) services and to review regularly the facilities, equipment and staff training of the services.

13.1.2 There must be at least one medical practitioner who is a specialist in emergency medicine on duty in the A&E department at all times during the operating hours to provide A&E services.

13.1.3 A registered nurse who has been trained in the practice of emergency nursing must be available at all times as the duty nurse-in-charge to supervise nursing care of the services.

13.1.4 The hospital must have a policy in place to mobilise additional staff to attend to emergency situations.

13.1.5 The hospital must maintain an up-to-date roster of specialists who are readily available to render consultation service and necessary assistance.

13.1.6 Where appropriate, there must be a combination of medical practitioners and nurses who hold valid certificates in the following areas or equivalent on duty at all times –

(a) Advanced Trauma Life Support (ATLS);
(b) Advanced Cardiac Life Support (ACLS);
(c) Trauma Nursing Care Course (TNCC); and
(d) Paediatrics Advanced Life Support (PALS).

13.1.7 There must be an on-going review of staffing levels and skills, facilities and equipment required for the operation of the emergency services. Drills on emergency care must be conducted at regular intervals across various disciplines in the hospital to ensure staff preparedness and competence in dealing with emergency patients.

13.2 Physical Conditions

13.2.1 The design, facilities, fixtures and fittings of the A&E services must be able to cope with all services it provides and offer patients and staff a comfortable and safe environment.

13.2.2 There must be adequate facilities and equipment for consultation, resuscitation, acute treatment, minor operation, monitoring, etc. within the A&E services. Each room for carrying out the respective care must be designed, equipped and maintained to appropriate standards to meet patients' needs. Clear signage about the patient pathway, facilities and services must be available.

13.2.3 An emergency call system must be available to call for assistance.

13.2.4 There must be a designated area, which is appropriately designed and ventilated, for managing suspected or probable patients with airborne infectious disease(s) to ensure a safe environment of care for patients and staff.

13.3 Equipment

13.3.1 All medical equipment and supplies for life support must be appropriate for different ages and readily available, for example, resuscitation equipment including oxygen supply and bag valve mask (ambu bag), vacuum suction, portable ventilator, basic intravenous setup and medication for resuscitation. For resuscitation, a defibrillator must be available.

13.3.2 Mechanism must be in place to ensure that the oxygen and suction equipment, emergency electricity supply, etc. are functioning.

13.3.3 Appropriate number of emergency trolleys for resuscitation must be in place at all times.

13.3.4 Blood storage facilities must be in close proximity to the emergency services. The blood bank of the hospital must keep an adequate stock of blood of common blood types and blood derivatives to cope with contingency.

13.4 Service Delivery and Care Process

13.4.1 Hospitals operating A&E services must provide, on a 24-hour basis, an adequate range of services including pathology service, radiology service, operating theatre service, pharmacy and dispensing services, intensive care service, cardiac services and other related supporting services appropriate to the needs of emergency patients.

13.4.2 There must be policies and procedures guiding a patient's admission to the emergency services and appropriate referral or transfer of the patient to another unit of the hospital or another institution to meet the patient's imminent care needs. There must also be a policy guiding the discharge of patient.

13.4.3 The hospital must put in place a triage system so that priority for assessment and treatment is given based on the patient's condition at the time of admission.

13.4.4 Assessments of emergency patients must be completed in a timely manner.

13.4.5 All patients must be informed about their rights in a manner they can understand. Emergency patients and families must receive adequate information about the patients' condition, proposed treatment(s), and specialists involved so that they can make appropriate decisions. Informed consent must be obtained before surgery, anaesthesia, use of blood and blood products, and other high-risk treatments and procedures.

13.4.6 Apart from timely receiving information on the proposed care and the expected outcomes of that care, an A&E patient and his / her family or relatives can also receive information on the expected charges for the care. Suitable staff must be readily available to answer patient or his / her family's enquiry about the expected fees and charges.

13.4.7 Where a patient's condition warrants care or treatment in another institution, the hospital must make appropriate transport arrangement through a well-managed process that ensures patient safety. Hospital must have established effective communication and collaboration with Fire Services Department or other emergency ambulance services such as St John Ambulance, for transportation of patients to or from the A&E services of the hospital.

13.4.8 There must be written policies and procedures regarding the handling of major incidents and disaster management. Relevant hospital staff must be trained to familiarise themselves with the policies and procedures at regular intervals.

13.4.9 In addition to the requirements in "Medical Records" in Chapter 3 of the Code, the following points must be observed in documenting a patient's records -

(a) all assessments, procedures, treatments and other care performed and written in the patient's records become a part of the hospital medical records system;

(b) the past medical records of the emergency patient, if available, are retrieved for use; and

(c) mechanism is in place to enable easy retrieval of the past medical records of the emergency patient preferably within 24 hours of admission.

Chapter 14 Allied Health Services

14.1 Staff Requirement and Training

14.1.1 An occupational therapist, physiotherapist and optometrist with registration under the Supplementary Medical Professions Ordinance (Cap. 359) must be appointed to take overall charge of respective services and to review regularly the facilities, equipment and staff training of the services. For other services where the allied health professionals are not required to be registered under Cap. 359, the staff concerned must have received relevant training with records of training kept.

14.1.2 Adequate supervision on assistants and other supportive personnel must be provided by qualified allied health professionals.

14.2 Physical Conditions

Adequate space must be provided for storing equipment and supplies.

14.3 Equipment

14.3.1 There must be sufficient equipment and supplies appropriate to the needs and the services offered.

14.3.2 All equipment must be maintained at regular intervals with records.

14.4 Service Delivery and Care Process

14.4.1 There must be written policies and procedures on the handling of equipment and instructions for patients.

14.4.2 Where the treatment involves the manipulation of aids / equipment by patients themselves, the patients must be briefed on the proper handling of the equipment and the associated risk.

14.4.3 Precautions or contraindications must be relayed to patients before specific types of treatments are contemplated.

14.4.4 Treatment and advice given must be documented in the patient's medical record.

Chapter 15 Aseptic Preparation Service

15.1 Overview

15.1.1 Aseptic preparation service refers to a service where sterile products are prepared using aseptic technique. Such products include but are not limited to parenteral nutrition, cytotoxic drugs, eye drops, cell and tissue products, and radiopharmaceuticals.

15.1.2 This chapter does not apply to the simple reconstitution or preparation of a commercially manufactured sterile product in accordance with directions contained in the approved labelling provided by the product's manufacturer for immediate administration to a particular patient in a clinical setting (e.g. ward, operating theatre, outpatient clinic, etc.).

15.1.3 All applicable license(s) for operation of such service must be in place.

15.2 Staff Requirement and Training

15.2.1 A pharmacist or a medical practitioner with relevant qualification / training, and experience must be appointed to take overall charge of the service and to review regularly the facilities, equipment and staff training of the services.

15.2.2 Staff involved with the aseptic preparation must have relevant qualification / training. All staff participating in the aseptic preparation service must be appropriately trained and assessed, with reference to guidelines issued by local or international authorities, prior to undertaking the tasks they are assigned to perform.

15.2.3 Periodic and documented reassessment of the aseptic technique of staff must be undertaken, and retraining must be provided as appropriate.

15.2.4 There must be pre-defined responsibilities to each grade / rank of staff.

15.3 Physical Conditions

15.3.1 The service unit must be appropriately situated, designed, built, equipped, used, and maintained for the intended activities, with reference to applicable international standards.

15.3.2 The service unit must be of sufficient size to accommodate all personnel, fittings and equipment required for operation without contamination and to enable an appropriate workflow and segregation of activities.

15.3.3 Aseptic preparation activities must be carried out in dedicated areas with controlled access. Cytotoxic drugs or radiopharmaceuticals must be prepared in a designated area.

15.3.4 There must be appropriate ventilation system which provides appropriate environment that is suitable for the intended activities, including but not limited to adequate number of air changes, permitted number of particles, temperature and pressure differential to adjacent area. The ventilation system of the service unit must be regularly inspected and maintained to ensure effective functioning for patient and staff safety.

15.3.5 Environmental monitoring (e.g. temperature, air change, differential pressure, particle count, microbial count, etc.) must be regularly performed with reference to guidelines issued by local or international authorities and at pre-defined intervals.

15.4 Equipment

15.4.1 There must be appropriate equipment for intended activities which is installed, calibrated, operated, and maintained in accordance with manufacturer's recommendations and applicable local or international guidelines.

15.4.2 Dedicated class II (Type A2 or B), class III biosafety cabinets (BSC) or isolator must be used for reconstitution of cytotoxic drugs.

15.4.3 Appropriate personal protective equipment must be available to reduce exposure to cytotoxic and radioactive drugs. Appropriate clean room clothing must be available where necessary.

15.4.4 Environmental monitoring of the aseptic working environment within the laminar flow cabinets, biosafety cabinets or isolators (e.g. air change, differential pressure, particle count, microbial count, etc.) must be performed at predefined interval and maintained with reference to guidelines issued by local or international authorities.

15.5 Service Delivery and Care Process

15.5.1 There must be written policies and procedures developed with reference to guidelines issued by local or international authorities and implemented on service delivery and care process, including the following –

(a) control of access to specified work areas;

(b) cleaning and disinfection of equipment and work areas;
(c) environmental surveillance of the aseptic preparation areas and devices and action for deviation;
(d) procurement, receipt, handling and storage of starting materials, equipment, devices used, and preparation of in-house reagents / materials, etc.;
(e) quality control for starting material and products;
(f) packaging, release and transport of products;
(g) handling of spillage of chemical, radioactive and cytotoxic drug;
(h) cryopreservation, storage and distribution / disposal of prepared products as applicable;
(i) infection control practice;
(j) donor eligibility criteria (for cell and tissue products), including but not limited to infectious disease testing;
(k) reporting and management of adverse event and product complaints and products tracking mechanisms; and
(l) risk assessment of the operations at the service.

15.5.2 The preparation and release of each individual product for use in patient must be under the supervision of a pharmacist or a medical practitioner.

15.5.3 Written policies and procedures on detailed product processing, labelling, checking, release procedures and recording, including details of staff involved must be in place.

15.5.4 Tracking mechanism for products and related starting materials from the source to processing and final deposition (e.g. patient) must be established.

15.5.5 Contingency plans must be established for detection of product failure through monitoring systems, recalls and alerts.

15.5.6 A quality assurance system must be set up to ensure the products are prepared in such a way that they are fit for their intended purposes and that their quality consistently complies with the defined requirements, including but not limited to requirements for audits.

Chapter 16 Cardiac Catheterisation Service

16.1 Staff Requirement and Training

16.1.1 A specialist in cardiology or relevant specialty must be appointed to take overall charge of the service and to review regularly the facilities, equipment and staff training of the service.

16.1.2 A radiographer who has received relevant training must be assigned to provide support in each procedure room at time of operation.

16.1.3 A registered nurse who has been trained in the practice of invasive diagnostic / interventional cardiology must be available at all times as the duty nurse-in-charge to supervise nursing care of the service.

16.1.4 Nurses who have received relevant training must be assigned to assist the medical practitioner, provide care and support to the patient.

16.1.5 There must be a medical practitioner or nurse who holds a valid certificate in Advanced Cardiac Life Support (ACLS) or equivalent on duty in the cardiac catheterisation service when the service is in operation.

16.2 Physical Conditions

16.2.1 The service unit must include a scrub up area, a procedure room and a recovery area.

16.2.2 An emergency call system must be available to call for assistance. There must be adequate staff to carry out emergency procedures in a timely manner.

16.3 Equipment

16.3.1 There must be emergency trolley and defibrillator standby for resuscitation purpose.

16.3.2 All relevant staff must be provided with dosimeter to continuously monitor their radiation exposure level according to the Radiation Ordinance (Cap. 303) while engaging in radiation work or handling of radioactive substances.

16.4 Service Delivery and Care Process

16.4.1 The service must take place in a hospital with facilities for major operations and intensive care service.

16.4.2 There must be written policies and procedures for –

(a) admission and aftercare of patients including patient education programmes; and

(b) aseptic practices and radiological safety.

Chapter 17 Chemotherapy Service

17.1 Staff Requirement and Training

17.1.1 A specialist in clinical oncology, medical oncology, haematology and haematological oncology, or relevant specialties must be appointed to take overall charge of the service and to review regularly the facilities, equipment and staff training of the service.

17.1.2 Chemotherapy services must be provided under the direction of a specialist.

17.1.3 A registered nurse who has been trained in the practice of oncology nursing must be available at all times as the duty nurse-in-charge to supervise nursing care of the service.

17.1.4 Nurses who have received relevant training must be assigned to provide care and support to the patient.

17.2 Physical Conditions

The process for preparation of cytotoxic drugs must be carried out in a safe environment with appropriate ventilation.

17.3 Equipment

Equipment must be readily available to manage emergencies including anaphylaxis, extravasation, cardiac arrest and spillage of cytotoxic drugs.

17.4 Service Delivery and Care Process

There must be written policies and procedures for –

(a) obtaining written consent from patient before commencement of chemotherapy;
(b) precautions for the preparation of cytotoxic drugs;
(c) administration of cytotoxic drugs;
(d) prevention and treatment of complications arising from chemotherapy;
(e) giving advice to patients on side effects or complications;
(f) use, handling, storage and disposal of chemotherapeutic agents;
(g) handling of body wastes;
(h) dealing with spillage or accidental contamination; and
(i) managing emergencies including anaphylaxis, extravasation and cardiac arrest.

Chapter 18 Chinese Medicine Service

18.1 Staff Requirement and Training

18.1.1 A registered Chinese medicine practitioner with valid practicing certificate must be appointed to take overall charge of the service and to review regularly the facilities, equipment and staff training of the service.

18.1.2 Healthcare Personnel who are designated to provide patient care and carry out clinical observations and other procedures must have received appropriate training in Chinese medicine.

18.1.3 Dispensers trained in Chinese medicine must be designated to prepare Chinese medicines in accordance with a prescription given by a registered / listed Chinese medicine practitioner.

18.1.4 Investigation must be prescribed and carried out by appropriate trained personnel.

18.1.5 Interpretation of investigation results must be carried out by trained personnel.

18.2 Physical Conditions

There must be adequate space and facilities, which are appropriate to meet the needs of the Chinese medicine service.

18.3 Equipment

There must be adequate medical equipment or instruments, and supplies, which are appropriate to meet the needs of the Chinese medicine service.

18.4 Service Delivery and Care Process

18.4.1 Hospitals that provide traditional Chinese medicine service must comply with the Chinese Medicine Ordinance (Cap. 549), relevant guidelines and codes promulgated from time to time by the Chinese Medicine Council of Hong Kong and the Department of Health.

18.4.2 If a Chinese medicine dispensary conducts retail business of Chinese herbal medicines, the dispensary must hold a valid retailer licence in Chinese herbal medicines under the Chinese Medicine Ordinance (Cap. 549).

18.4.3 For Chinese medicine dispensary operating without a retailer licence in Chinese herbal medicines, the registered Chinese medicine practitioner-in-charge of the service must take the overall responsibility of the operation of the Chinese medicine dispensary. In addition, individual Chinese medicine practitioner is also professionally responsible for the Chinese medicines dispensed to patients under his / her care (including Chinese medicines dispensed directly by himself / herself or by dispensers and other staff who are under his / her supervision).

18.4.4 Where patients are managed by both registered Chinese medicine practitioner and medical practitioner-in-charge, the treatment plan must be agreed by both parties in consultation with the patient for the best interest of the patients. Policy and procedures for administration and consumption of Chinese medicines must be in place.

18.4.5 The conduct of clinical trial of proprietary Chinese medicine must be in compliance with the guidelines for "Good Clinical Practice for Proprietary Chinese Medicines" issued by the Chinese Medicine Council of Hong Kong.

18.4.6 If an adverse event is suspected to be associated with the use of Chinese medicines, it must be notified to the Central Notification Office (CENO) of the Centre for Health Protection of the Department of Health.

Dispensing of Chinese Medicines

18.4.7 Where the service involves dispensing of herbal medicines or Chinese medicine granules for prescription, etc., policies and procedures must be developed with any relevant references issued and updated from time to time by the Chinese Medicine Council of Hong Kong.

18.4.8 Where herbal medicines are decocted for patients, the following means and facilities must be in place –

(a) appropriate area with good ventilation for decocting;
(b) appropriate decocting devices and utensils; and
(c) appropriate storage of sample after decocting, for example, residues of decocted herbal medicines or herbal broth to allow for examination when necessary, and to enhance the traceability of herbal medicines.

Storage of Chinese Medicines

18.4.9 The store room must be maintained in a sanitary condition, kept cool, dry and well ventilated. Appropriate measures must be taken for the control of insects, rodents, mould, humidity and contamination.

18.4.10 Any Chinese herbal medicine belonging to Schedule 1 of the Chinese Medicine Ordinance (Cap. 549) must be properly stored and separated from other medicines.

18.4.11 Chinese medicines must be separately stored from other substances. Chinese medicines for internal use must be stored separately from those for external use.

18.4.12 Proper procurement records must be kept to allow tracing.

When Performing Acupuncture, Moxibustion, Cupping and Other Procedures

18.4.13 There must be an appropriate accommodation for patient privacy. The following areas must be observed –

(a) disposable acupuncture needles are not reused;

(b) acupuncture needles which are intended to be reused are properly sterilised before reuse. Appropriate sterilisation is carried out in accordance with the instructions given by the manufacturer, for example, autoclaving;

(c) appropriate containers for the disposal of acupuncture needles are used, for example, sharps boxes. The disposal procedure makes reference from the prevailing guidelines;

(d) reusable clinical equipment such as glass cups and derma rollers is cleaned, disinfected and / or sterilised as appropriate and properly stored;

(e) personnel responsible for performing sterilisation procedures is adequately trained; and

(f) operation of the clinical apparatus is well maintained and records of periodical inspection are kept.

Medical Record

18.4.14 Medical records must be kept in accordance with the Code of Professional Conduct for Registered Chinese Medicine Practitioners in Hong Kong and the Code of Conduct for Listed Chinese Medicine Practitioners, in addition to that set out in Chapter 3 of this Code.

Chapter 19 Dental Service

19.1 Staff Requirement and Training

19.1.1 A dentist must be appointed to take overall charge of the service and to review regularly the facilities, equipment and staff training of the service.

19.1.2 Dental hygienist and dental surgery assistant, where applicable, must work under supervision of a dentist.

19.1.3 Dental surgery assistants must have received appropriate training. The training received must be properly documented.

19.1.4 Staffing arrangements for monitoring of patients undergoing procedural sedation must comply with the "Guidelines on Procedural Sedation" published by the Hong Kong Academy of Medicine.

19.1.5 Staff who operate irradiating apparatus must have received appropriate training and abide by the Radiation Ordinance (Cap. 303) and Radiation (Control of Irradiating Apparatus) Regulations (Cap. 303B) in operating the apparatus.

19.2 Physical Conditions

19.2.1 The ceiling, walls and floors must be made from materials that can be easily cleaned and disinfected as needed to meet infection control requirements.

19.2.2 Zoning must be carried out to avoid cross contamination between zones. A one-way dirty to clean traffic flow must be designated in the equipment reprocessing area to prevent contamination.

19.3 Service Delivery and Care Process

19.3.1 There must be written policies and procedures on service delivery and care process which include –

(a) infection control measures;

(b) cleaning, disinfection and sterilisation, and storage of dental equipment and appliances; and

(c) use of single-use devices; and

(d) protection from radiation and / or laser.

19.3.2 All relevant staff must be provided with dosimeter to continuously monitor their radiation exposure level according to the Radiation Ordinance (Cap. 303) while engaging in radiation work or handling of radioactive substances.

Chapter 20 Endoscopy and Day Surgery Services

20.1 Staff Requirement and Training

20.1.1 A specialist in relevant specialty must be appointed to take overall charge of the day surgery or endoscopy services and to review regularly the facilities, equipment and staff training of the services.

20.1.2 A registered nurse who has been trained in operating theatre nursing / perioperative nursing / endoscopy nursing must be available at all times as the duty nurse-in-charge to supervise nursing care of the day surgery / endoscopy services.

20.1.3 Nurses who have received relevant training must be assigned to provide care and support to the patient.

20.1.4 There must be an appropriate number of suitably qualified and experienced staff in attendance during each surgical or endoscopic procedure.

20.1.5 Staffing arrangements for monitoring of patients undergoing procedural sedation, general anaesthesia or major regional anaesthesia must comply with the relevant guidelines published by the Hong Kong Academy of Medicine and its colleges, where applicable.

20.1.6 A medical practitioner or registered nurse trained in post-anaesthetic care must be appointed to take charge of the operation of the recovery area. Staff working in the recovery area must be trained for their respective roles.

20.2 Physical Conditions

20.2.1 The ceiling, walls and floors must be made from materials that can be easily cleaned and disinfected as needed to meet infection control requirements.

20.2.2 The premises must be provided with ventilation system appropriate to the procedure in which it is conducted and to prevent the spread of airborne infectious disease and to minimise surgical site infection. The ventilation systems must be regularly inspected and maintained to ensure effective functioning for patient and staff safety. Documentation of repair and maintenance of the systems must be kept.

20.2.3 Adequate area for scrub and gowning must be provided for operating room.

20.2.4 There must be adequate facilities and space for the collection and storage of specimens.

20.3 Equipment

20.3.1 There must be adequate resuscitation equipment (such as oxygen, suction and monitoring facilities) and drugs to deal with any emergencies or complications arising from the operation / procedure carried out.

20.3.2 Monitoring and recovery of patients who have received sedation or major regional or general anaesthesia must take place in an area that is adequately equipped in accordance with relevant guidelines published by the Hong Kong Academy of Medicine and its colleges.

20.3.3 There must be a proper system of documentation to ensure regular monitoring of the cleanliness / sterility of endoscopes and accessories and surgical instrument.

Reprocessing of Endoscopes

20.3.4 Endoscopes and accessories (including all channels and valves) must be thoroughly cleaned.

20.3.5 Endoscopes, accessories and goggles must be disinfected by a high level disinfectant. Where applicable, endoscopes and accessories must be disinfected or sterilised according to manufacturer's instructions.

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

20.3.7 There must be a system to regularly monitor the effectiveness of disinfection of endoscopes and accessories with documentation.

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

20.3.9 In reprocessing of endoscopes, reference must be taken from occupational safety and health guidelines issued by the Labour Department, including Chemical Safety in the Workplace - Guidance Notes on Safe Use of Chemical Disinfectants.

20.4 Service Delivery and Care Process

20.4.1 There must be written policies and procedures on service delivery and care process which include the following –

(a) patient identification and checking of consent forms;

(b) verification processes to ensure correct patient, surgical site and procedure;

(c) counting of items used during the operations, such as swabs, needles, blades and other operative instruments and supplies, and what to do if items cannot be accounted for;

(d) aseptic practices;

(e) infection control measures;

(f) means of obtaining help in case of emergency;

(g) pre-operative / pre-procedural assessment;

(h) monitoring patient undergoing sedation or general anaesthesia or major regional anaesthesia;

(i) documentation of procedures;

(j) specimen handling;

(k) storage, cleaning, decontamination, disinfection and sterilisation of surgical instrument and equipment;

(l) use of single-use devices;

(m) radiation protection; and

(n) patient discharge, including discharge criteria, and care after discharge.

20.4.2 There must be written pre-operative procedures and guidelines for patients receiving day surgery / endoscopy, including –

(a) provision of appropriate information and advice to a patient on the procedure to be performed before obtaining his / her consent;

(b) fasting;

(c) medication;

(d) post-operative care and discharge (e.g. a responsible adult to escort patient home after deep sedation, major regional anaesthesia or general anaesthesia); and

(e) arrangement for inpatient care on post-operative complications where necessary.

20.4.3 There must be written post-operative policies and procedures, including instructions to the patient on –

(a) pain relief;
(b) bleeding;
(c) care of surgical site;
(d) possible complications;
(e) advice on effects of sedation / anaesthesia; and
(f) a contact telephone number for making enquiry.

20.4.4 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 and 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;
(d) blood and other fluid losses of the patient at the conclusion of the surgery or endoscopic procedure, if applicable; and
(e) any materials which are intentionally retained in the body after procedures or surgery.

20.4.5 The hospital must keep records of anaesthetic care in accordance with the relevant guidelines published by the Hong Kong College of Anaesthesiologists.

Chapter 21 Haemodialysis Service

21.1 Staff Requirement and Training

21.1.1 A specialist in nephrology or relevant specialty must be appointed to take overall charge of the haemodialysis service and to review regularly the facilities, equipment and staff training of the service.

21.1.2 Each patient must be attended to by the specialist in nephrology who is in charge of the patient's dialysis treatment on a regular basis.

21.1.3 The staffing of the service must be appropriate with respect to the patient's condition and with reference to "Clinical Practice Guidelines for the Provision of Renal Services in Hong Kong" published by the Hong Kong College of Physicians and the Central Renal Committee of the Hospital Authority.

21.1.4 A registered nurse who has been trained in the practice of haemodialysis service must be available at all times as the duty nurse-in-charge to supervise nursing care of the service.

21.1.5 Staff must be trained in universal precautions necessary for haemodialysis setting to prevent transmission of infection.

21.2 Physical Conditions

21.2.1 There must be sufficient circulating space around each bed / chair for nursing care to take place.

21.2.2 The clinical areas must have immediate access to hand washing facilities.

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

21.2.4 There must be a utility area (separated from clean area) provided for the handling of dirty linen and materials.

21.3 Equipment

21.3.1 In case of interruption of electricity supply, there must be a supply of backup electricity to allow for the return of blood from dialysis machines. Alternatively, the dialysis machines must be fitted with mechanical devices to allow manual return of blood to the patient.

21.3.2 There must be proper documentation of testing, repair and maintenance of dialysis machines, including back-up machines, and water treatment system to ensure that they are kept in good functional order.

21.3.3 There must be written policies and procedures on regular disinfection of water treatment and distribution systems, haemodialysis machines and equipment. Disinfection of equipment and machines must be carried out in accordance with the recommendations of the manufacturers.

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

21.3.5 Adequate number of unoccupied haemodialysis machine must be available on-site as back-up.

21.4 Service Delivery and Care Process

21.4.1 There must be written policies and procedures in the service by taking reference from the latest relevant guidelines issued by the Infection Control Branch of the Centre for Health Protection of the Department of Health and the Central Renal Committee of the Hospital Authority, including, the "Infection Control Guidelines on Nephrology Services in Hong Kong".

21.4.2 There must be written policies and procedures for safe conduct of haemodialysis procedures which include the following –

(a) admission of patients;
(b) management of patients with blood-borne infections;
(c) immunisation of susceptible patients and staff;
(d) staffing arrangements;
(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;
(j) testing of water quality at haemodialysis machines and at water treatment systems at regular intervals;
(k) the control of infection and cross-infection;
(l) serological testing of blood-borne viruses for patients, with testing conducted prior to commencing haemodialysis, at regular intervals thereafter, and when clinically indicated, with results documented;
(m) management of disinfectant toxicity; and
(n) handling emergencies within the service including sudden cessation of electricity supply, water supply and special arrangement during adverse weather conditions.

21.4.3 There must be safe storage for chemical substances. Such substances must be properly labelled.

21.4.4 No repair and maintenance works by the technician must be undertaken when the haemodialysis procedure is in progress.

Water Quality

21.4.5 Testing of water quality must be performed and documented at regular intervals to ensure that the water quality meets internationally acceptable standards. The testing includes but is 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).

21.4.6 Alarm system must be in place to monitor operation of water treatment system such as water level.

Chapter 22 Intensive Care Service / High Dependency Service

22.1 Overview

Hospitals catering for major operations must have arrangements for intensive care or critical care in place. This must be a unit in which there are specially trained nurses and supportive personnel, and diagnostic, monitoring and therapeutic equipment necessary to provide specialized medical and nursing care to critically ill patients.

22.2 Staff Requirement and Training

22.2.1 A specialist in critical care medicine, intensive care, anaesthesiology or relevant specialty must be appointed to take overall charge of the service and to review regularly the facilities, equipment and staff training of the service.

22.2.2 A resident medical practitioner must be on duty in the hospital at all times and readily available to provide emergency treatment whenever required.

22.2.3 A registered nurse who has been trained in critical care / intensive care nursing must be available at all times as the duty nurse-in-charge to supervise nursing care of the service when the service is in operation.

22.2.4 The nurse to patient ratio must be at least 1:1 at all times for patient requiring intensive care. Only when the condition of a patient receiving intensive care becomes stable or the extent of care required is lowered to high dependent care, the nurse to patient ratio could be stepped down to 1:2. Nurses must be equipped with intensive care nursing knowledge and skills.

22.2.5 In addition to the nurses who are engaged in care of individual patients, there must be nurses on duty at the service to provide backup support. A system must be in place to call for extra staff with critical care training to provide support whenever required.

22.2.6 All staff of intensive care service / high dependency service who provide emergency care to critically ill patients must be familiar with resuscitation. There must be a medical practitioner or nurse who holds a valid certificate in Advanced Cardiac Life Support (ACLS) or equivalent on duty at all times.

22.2.7 Additional requirements for Paediatric Intensive Care Unit (PICU) / Neonatal Intensive Care Unit (NICU) / Special Care Baby Unit (SCBU) include –

(a) A specialist in paediatrics, anaesthesiology or relevant specialty who has experience and competence in providing critical care to paediatric patients must be appointed to take overall charge or as advisor of the service;

(b) A resident medical practitioner who is competent to provide emergency care to critically ill paediatric patients must be on duty in the hospital at all times and readily available to provide emergency treatment whenever required; and

(c) All staff of PICU / NICU / SCBU who provide emergency care to critically ill paediatric patients must be familiar with resuscitation procedures. There must be a medical practitioner or nurse who holds a valid certificate in Paediatric Advanced Life Support (PALS) or equivalent on duty at all times at PICU, and there must be a medical practitioner or nurse who has received training in Neonatal Resuscitation Programme (NRP) or equivalent on duty at all times at NICU / SCBU.

22.3 Physical Conditions

The nurse station must be strategically placed to enable maximum observation of patients. For private wards or where direct observation is not feasible from the nurse station, close-circuit surveillance system must be installed to facilitate monitoring of patients.

22.4 Equipment

22.4.1 The service must be equipped with the following facilities –

(a) cardiac monitoring system;
(b) cardiac support facilities;
(c) ventilation support;
(d) infusion pumps; and
(e) oximetry monitoring system, etc.

22.4.2 There must be equipment including portable ones for advanced life support.

22.4.3 There must be supporting 24-hour pathology service, blood bank, and radiology service.

22.5 Service Delivery and Care Process

22.5.1 Written policies and procedures must be developed for routine procedures, emergency procedures, admission, discharge and transfer.

22.5.2 There must be a call system for the serving staff to call for additional staff in case of emergency.

Chapter 23 Nuclear Medicine Service

23.1 Staff Requirement and Training

23.1.1 A specialist in nuclear medicine or relevant specialty must be appointed to take overall charge of the service and to review regularly the facilities, equipment and staff training of the service.

23.1.2 A Part I radiographer under the Radiographers (Registration and Disciplinary Procedure) Regulation of the Supplementary Medical Professions Ordinance (Cap. 359) must be assigned to take charge of the day to day operation of the service.

23.1.3 A Part I radiographer must be put on duty during the operating hours of the service.

23.1.4 A registered nurse must be available, where necessary, to provide support such as administration of medicine or assisting interventional procedures under the supervision of the specialist in nuclear medicine or relevant specialty.

23.1.5 The staff must use the irradiating apparatuses and radioactive substances under and in accordance with licences issued under the Radiation Ordinance (Cap. 303) and the conditions attached to the licences.

23.2 Physical Conditions

23.2.1 There must be sufficient space for changing rooms, storage for personal belongings of patients, storage space for equipment and records, and toilet facilities located in the vicinity.

23.2.2 There must be a warning (in the form of lights or signs) outside the room that operates irradiating apparatus. Signage on special precautions must be written in both Chinese and English.

23.3 Equipment

23.3.1 All equipment and machines must be properly maintained and calibrated.

23.3.2 An emergency trolley and a defibrillator must be available for resuscitation purpose.

23.3.3 All relevant staff must be provided with dosimeter to continuously monitor their radiation exposure level according to the Radiation Ordinance (Cap. 303) while engaging in radiation work or handling of radioactive substances.

23.4 Service Delivery and Care Process

23.4.1 There must be written policies and procedures on service delivery and care process which include –

(a) obtaining detailed clinical history such as history of allergy;
(b) provision of thorough explanation before written consent is sought from the patient;
(c) steps to be taken during the procedure and preparation;
(d) possible occurrence of allergic reaction(s) after administration of contrast medium;
(e) accurate labelling of all films / imaging records with the patient's name, date of test performed and other identifiers;
(f) safety procedures;
(g) management of accident, emergency, or other adverse event;

(h) incident reporting; and

(i) application of infection control measures.

23.4.2 There must be written policies and procedures on –

(a) safe handling of radionuclides, preparation of patients for imaging and emergency situations;

(b) correct identification of the patient before each imaging; and

(c) ensuring that the correct radiopharmaceutical of the correct radioactivity is administered to the correct patient.

23.4.3 Handling, storage and disposal of radionuclides must comply with the Radiation Ordinance (Cap. 303).

Chapter 24 Obstetrics and Nursery Services

24.1 Staff Requirement and Training

24.1.1 A specialist in obstetrics or relevant specialty must be appointed to take overall charge of the obstetric service and to review regularly the facilities, equipment and staff training of the service. A specialist in paediatrics must also be appointed as advisor of the nursery.

24.1.2 A registered nurse who is also a registered midwife must be available at all times as the duty nurse-in-charge to supervise nursing care of the service.

24.1.3 The healthcare professional who is responsible for caring for pregnant women and assisting at childbirth must be a registered nurse who is also a registered midwife, a registered midwife, an appropriately qualified and experienced medical practitioner, or a specialist in obstetrics.

24.1.4 The hospital must establish and monitor a prearranged roster of specialist in Obstetrics and Gynaecology so that a medical practitioner with qualifications of FHKAM(O&G) or equivalent could respond quickly to emergencies when the medical practitioner-in-charge of the patient is unable to do so. For obstetrics emergencies, the medical practitioner must be available within 30 minutes when required. The on-call roster must be devised in such a manner so as to avoid the same medical practitioner being put on-call for a prolonged period without replacement or backup. A specialist in paediatrics must be available to standby for delivery of high risk foetuses.

24.1.5 There must be emergency arrangements for medical practitioners competent in paediatrics to be on-call for the support of very ill babies. The on-call roster must be devised

in such a manner so as to avoid the same medical practitioner being put on-call for a prolonged period without replacement or backup.

24.1.6 There must be a medical practitioner or nurse who holds a valid certificate in Advanced Life Support in Obstetrics (ALSO) or equivalent on duty in the obstetric service at all times.

24.1.7 Regular drills on the management of emergency maternity situations must be conducted.

24.2 Physical Conditions

24.2.1 An area for hand washing and gowning must be provided for staff and visitors at entrance to the nursery.

24.2.2 Bed screens must be available to ensure privacy of mothers.

24.2.3 Oxygen and suction facilities must be regularly checked.

24.2.4 There must be facilities to provide surgical deliveries where necessary.

24.3 Equipment

24.3.1 Each delivery suite must be equipped with –

(a) cardiotocograph;
(b) delivery table which can be adjusted to the Trendelenburg position;
(c) equipment for administration of analgesia;
(d) anaesthetic machine with emergency oxygen supply;
(e) incubator; and
(f) separate oxygen supply to the incubator.

24.3.2 Emergency trolleys for resuscitation must be available at all times.

24.3.3 The nursery must be equipped with –

(a) sufficient number of cots;
(b) incubators;
(c) phototherapy equipment;
(d) suction equipment; and
(e) oxygen supply.

24.3.4 There must be appropriate equipment or facility for storage of breast milk, which is properly labelled.

24.4 Service Delivery and Care Process

24.4.1 There must be written policies and procedures for –

(a) systematic identification of each newborn baby immediately after delivery and throughout the hospital stay;
(b) management of all common conditions in the antenatal and postnatal wards and the labour room;
(c) supporting breastfeeding, such as rooming-in facilities and breastfeeding support teams where the hospital caters for neonates;
(d) management of common problems of newborn; and
(e) management of foetal compromise including emergency caesarean section, paediatric standby, etc.

24.4.2 There must be prompt supply of blood and blood products at all times.

24.4.3 There must be arrangements for immediate transfer of a patient or her newborn baby to intensive care or special care facilities within the hospital or to nearby hospitals whenever necessary.

24.4.4 The medical record must include the following in addition to those set out in the Chapter 3 of the Code on "Medical Record" –

(a) the labour record;
(b) the date and time of delivery and whether the result was a live-birth, still-birth or abortion;
(c) the sex, weight and length of the newborn, head circumference, physical condition of the newborn at birth (for example, Apgar score) and any physical abnormalities detected;
(d) the names of healthcare professionals attending the patient during delivery;
(e) the condition of mother and newborn on discharge; and
(f) in case of surgical deliveries performed, the pre- and post-anaesthesia record and the operation record.

24.4.5 Where antenatal screening tests are performed, test results must be conveyed to the attending medical practitioners as soon as possible.

24.4.6 Before a decision is made to perform an intervention, for example, labour induction, the patient is assessed on-site by a medical practitioner with appropriate qualifications and experience.

24.4.7 When a decision is made to perform an emergency caesarean section / operation, the person making the decision must indicate clearly the urgency with which it needs to be carried out. The operation must be started as soon as possible and within 30 minutes after the decision to operate is made.

24.4.8 There must be measures to ensure safe custody of babies.

24.4.9 All deaths and births must be reported as required by relevant legislations.

24.4.10 Any preparation of milk for feeding the newborn must be conducted in a hygienic manner.

24.5 Sperm Bank and Reproductive Technology Activities

Where the hospital operates a sperm bank and reproductive technology activities, the procedures must comply with the Human Reproductive Technology Ordinance (Cap. 561), and its Regulations and the relevant Code of Practice.

Chapter 25 Operating Theatre Service

25.1 Staff Requirement and Training

25.1.1 A specialist in anaesthesiology, surgery or relevant specialty must be appointed to take overall charge of the service and to review regularly the facilities, equipment and staff training of the service. Where the surgery relates to a specialty such as gynaecology, obstetrics, ophthalmology and orthopaedics, a specialist of the relevant specialty must be appointed as the advisor.

25.1.2 All surgeries must be carried out by a suitably qualified, skilled and experienced medical practitioner. All general anaesthesia, spinal anaesthesia, epidural anaesthesia, deep sedation, or potent anaesthetic agents with no specific antagonists must be provided only by an anaesthesiologist or a trained medical practitioner under the supervision of an anaesthesiologist.

25.1.3 A registered nurse who has been trained in operating theatre nursing or perioperative nursing must be available at all times as the duty nurse-in-charge to supervise nursing care of the service.

25.1.4 Nurses must receive adequate training before assisting in new operating procedures.

25.1.5 Nurses who have received relevant training must be assigned to assist the medical practitioner, and to provide care and support to the patient.

25.1.6 There must be a medical practitioner or nurse who holds a valid certificate in Advanced Cardiac Life Support (ACLS) or equivalent, on duty in the operating theatre at all times. At times when paediatric patients are undergoing surgery, there must be a medical practitioner or nurse who holds a valid certificate in Paediatric Advanced Life Support (PALS) or equivalent on duty.

25.1.7 A trained nurse must be assigned to carry out circulating duties in the operating theatre where surgery is performed when necessary.

25.1.8 An appropriate number of suitably qualified and experienced staff must be in attendance at all times during each surgical procedure.

25.1.9 A medical practitioner or registered nurse trained in post-anaesthetic care must be appointed to take charge of the operation of the recovery area. Staff working in the recovery area must be trained for their respective roles.

25.1.10 Following anaesthesia, postoperative patients in the recovery area must be closely observed by the anaesthesiologist or a designated registered nurse who holds a valid certificate in ACLS or equivalent until they are discharged from the operating theatre. The progress of patients must be clearly recorded in their medical records. For paediatric patients, the observation must be conducted by the anaesthesiologist or a designated registered nurse who holds a valid certificate in PALS or equivalent.

25.1.11 The anaesthesiologist who administered the anaesthesia for the patient must be responsible for the supervision of the recovery period and the authorization of the patient's discharge from the recovery area.

25.1.12 The hospital must establish and monitor a prearranged roster of medical practitioners who are competent in surgery and anaesthesiology and who could respond quickly to emergencies.

25.1.13 Staffing arrangements for monitoring of patients undergoing procedural sedation, general anaesthesia or major regional anaesthesia must comply with the relevant guidelines published by the Hong Kong Academy of Medicine and its colleges, where applicable.

25.2 Physical Conditions

25.2.1 The ceiling, walls and floors must be made from materials that can be easily cleaned and disinfected as needed to meet infection control requirements.

25.2.2 The operating theatre must be maintained at acceptable levels of sterility by taking reference from the latest "ICB Infection Control Guidelines" promulgated by the Infection Control Branch of the Centre for Health Protection of the Department of Health.

25.2.3 The operating theatre must be provided with specialized ventilation systems of internationally acceptable standards of air quality to prevent the spread of airborne infectious disease and to minimise surgical site infection. The ventilation systems must be regularly inspected and maintained to ensure effective functioning for patient and staff safety. Documentation of repair and maintenance of the systems must be kept.

25.2.4 Adequate area for scrub and gowning must be provided for operating room.

25.2.5 There must be adequate facilities and space for the collection and storage of specimens.

25.3 Equipment

25.3.1 Equipment for general anaesthesia must include at least the following items –

(a) electrocardiograph monitor;
(b) blood pressure measuring device;
(c) pulse oximeter;
(d) life support systems;
(e) continuous oxygen supply;
(f) full range of endotracheal tubes, immediate access to spare apparatus in the event of failure;
(g) laryngoscope and airways;
(h) suction equipment; and
(i) infusion drip sets and fluids.

25.3.2 There must be drugs to deal with any emergencies or complications arising from the operation / procedure.

25.3.3 If the patient is to be revived outside the operating room, monitoring and recovery of patients who have received sedation or major regional or general anaesthesia for an operation must take place in an area that is adequately equipped in accordance with relevant guidelines published by the Hong Kong Academy of Medicine and its colleges. The area must be provided with the following –

(a) monitoring equipment, including ECG;
(b) resuscitation equipment including a defibrillator;
(c) sufficient space to accommodate a patient resting in a recumbent position; and
(d) communication system for staff in the event of an accident or emergency.

25.4 Service Delivery and Care Process

General Requirements

25.4.1 There must be written policies and procedures on service delivery and care process which include the following –

(a) patient identification and checking of consent forms;

(b) verification processes to ensure correct patient, surgical site and procedure;

(c) counting of items used during the operations, such as swabs, needles, blades and other operative instruments and supplies, and what to do if items cannot be accounted for;

(d) aseptic practices;

(e) infection control measures;

(f) pre-operative assessment;

(g) pre-operative instructions (e.g. fasting, medication) and care;

(h) monitoring patient undergoing sedation or general anaesthesia or major regional anaesthesia;

(i) documentation of operations;

(j) specimen handling;

(k) storage, cleaning, decontamination, disinfection and sterilisation of surgical instrument and equipment;

(l) use of single-use devices;

(m) radiation protection;

(n) means of obtaining help in case of emergency; and

(o) patient discharge from operating theatre / recovery area, including discharge criteria, and care after discharge.

25.4.2 There must be supporting services including pathology, with a blood bank and radiology in the hospital.

25.4.3 If treatment under general anaesthesia is to be carried out in the hospital, there must be critical care arrangements in place. Where there are no intensive care facilities in the hospital, major operations must not be performed. Arrangements must be in place for immediate transfer of patients to nearby hospitals with critical care services where necessary.

Medical Records

25.4.4 All operation records must be completed in the patient's record immediately after the operation has been performed including pre-anaesthesia assessment, etc. Furthermore, each patient's post-anaesthesia status must also be monitored and documented at appropriate intervals.

25.4.5 A registry of all surgical operations performed in the hospital must be kept. The registry can be in electronic or written format and must contain the following information –

(a) name of the patient;

(b) number given to identify the medical record of that particular admission, for example, hospital number and patient number;

(c) date and nature of the surgical operation; and

(d) name of the surgeon and surgery assistants.

25.4.6 Operation records include but are not limited to –

(a) name(s) of the medical practitioner(s) performing the operation and the assistant(s), if any;

(b) date, time, operation diagnosis, start time and end time of the operation, anaesthesia and sedation method, name and details of the operation, 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;

(d) blood and other fluid losses of the patient at the conclusion of the surgical operation; and

(e) any materials which are intentionally retained in the body after procedures or surgery.

25.4.7 The hospital must keep records of anaesthetic care in accordance with the relevant guidelines published by the Hong Kong College of Anaesthesiologists.

Chapter 26 Outpatient Service

26.1 Staff Requirement and Training

26.1.1 A medical practitioner, a registered nurse, or a dentist must be appointed to take overall charge of the clinic and to review regularly the facilities, equipment and staff training of the service.

26.1.2 The clinic assistants must work under the supervision of a medical practitioner, dentist or nurse.

26.1.3 The clinic assistants must have received appropriate training. The training received must be properly documented.

26.1.4 Where there is provision of X-ray examination for patient, a radiographer or other qualified healthcare professional must be assigned to take charge of the day to day operation of the irradiating apparatus.

26.2 Physical Conditions

Hand-washing facilities must be available in the clinical areas.

26.3 Equipment

Resuscitation equipment must be easily accessible and checked at regular interval.

26.4 Service Delivery and Care Process

26.4.1 Scales for fees must be displayed in the clinic. Patients must be advised of the fees for proposed treatment in advance.

26.4.2 If minor surgery or investigation procedures are undertaken –

(a) it must take place in a suitably designed and maintained room;

(b) a couch must be provided;

(c) all clinical staff involved must be trained in basic resuscitation; and

(d) resuscitation equipment must be available and checked regularly.

26.4.3 There must be written procedures for –

(a) dealing with emergencies, including arrangements for admission to hospital or transfer to another hospital;

(b) recording, labelling, appropriate storage and transportation of laboratory specimens;

(c) cleansing and sterilisation of equipment; and

(d) storage and disposal of clinical wastes.

26.4.4 There must be a record of drugs stored in the clinic.

26.4.5 The hospital must put in place a triage system so that priority for assessment and treatment is given based on the patient's condition at the time of attendance.

Chapter 27 Pathology Service

27.1 Staff Requirement and Training

27.1.1 A specialist in pathology or relevant specialty must be appointed to take overall charge of the service and to review regularly the facilities, equipment and staff training of the service.

27.1.2 A medical laboratory technologist I must be assigned to take charge of the day to day operation of the laboratory. He must ensure that the procedures and tests performed by technical staff are within the scope of their professional training and experience.

27.1.3 At least one medical laboratory technologist must be put on duty during the operating hours of the service.

27.2 Equipment

There must be appropriate equipment for intended activities and the equipment must be installed, maintained, operated, and calibrated in accordance with manufacturer's recommendations, and maintained at regular intervals with records to ensure proper functioning.

27.3 Service Delivery and Care Process

27.3.1 Hospitals providing acute care must provide an adequate range of pathology services to meet the needs of the patients.

27.3.2 Where special pathology services are not available, appropriate arrangements must be made for the collection and transportation of pathology specimens to be performed in another institution by medical laboratory technologists.

27.3.3 There must be policies and procedures on the following areas –

(a) safety aspect of the laboratory;
(b) maintenance of performance standards including quality control;
(c) recording of all specimens received and processed by the laboratory;
(d) arrangements for notification of urgent test results;
(e) collection, labelling, transportation and storage of pathology specimen, both from other hospital services and within the laboratory;
(f) protection of staff handling pathology specimens;
(g) procurement of reagents;
(h) checking on the expiry dates of reagents;
(i) disposal of specimens and reagents; and
(j) contingency plans for various emergencies including chemical spillage.

27.3.4 There must be a clinical laboratory quality assurance programme.

27.3.5 Records must be kept for calibration and quality control programmes.

27.3.6 Records must be kept for drills on various emergencies.

27.4 Blood Bank

27.4.1 The operation of the blood bank must be in line with the recommendations of the Hong Kong Red Cross Blood Transfusion Service.

27.4.2 Contingency plan must be in place to meet demands for a large amount of blood for transfusion.

27.4.3 There must be proper documentation of use and disposal of all blood products maintained in the bank.

27.5 Organ Bank

27.5.1 Where the hospital operates eye bank and bone bank, the policies and procedures provided must comply with the Human Organ Transplant Ordinance (Cap. 465).

Chapter 28 Pharmacy and Dispensing Service

28.1 Staff Requirement and Training

28.1.1 A pharmacist with relevant qualification / training, and experience must be appointed to take overall charge of the pharmacy service and to review regularly the facilities, equipment and staff training of the service.

28.1.2 Medicines must be dispensed under the supervision of a pharmacist or medical practitioner. Staff responsible for dispensing and administering medicines must receive appropriate training.

28.1.3 Medicines must be administered by a medical practitioner or a nurse.

28.1.4 Staff involved in the preparation of drugs must have received relevant training regularly.

28.2 Physical Conditions

28.2.1 The working surfaces, cupboards and shelves must be clean, smooth, washable and impervious to dirt and moisture.

28.2.2 Storage of medicines must be in accordance with manufacturers' recommendations.

28.2.3 There must be access control to the pharmacy and drug storage areas.

28.2.4 Washing facilities must be available in the dispensing area.

28.3 Equipment

28.3.1 The pharmacy must be provided with distilled or purified water.

28.3.2 All dispensing equipment must be of suitable material, clean and in good working order.

28.3.3 Suitable equipment must be available for storage of medicines requiring special storage conditions (e.g. medicines requiring cold chain) and in good working order. The equipment must be maintained and calibrated as appropriate to ensure the integrity of storage conditions.

28.4 Service Delivery and Care Process

28.4.1 There must be written policy and procedures covering all aspects of management of medicines, other injectable and infusible products including the following –

(a) ordering, procurement, receipt, storage, handling, dispensing, labelling, recording, safe keeping, safe administration, disposal and recall of medicines, other injectable and infusible products;
(b) Patient Safety Incident reporting and management;
(c) management of cold chain breach;
(d) control of access to drug storage; and
(e) cleaning, disinfection, decontamination of the pharmacy and equipment.

28.4.2 The handling and supply of medicines, and other injectable and infusible products at the hospital must comply with the requirements of prevailing legislation, relevant codes of practice and guidelines issued by local authorities in Hong Kong.

28.4.3 Injectable and infusible products may be used only where they qualify under one or more of the following categories or under clause 28.4.4 –

(a) pharmaceutical products registered under the Pharmacy and Poisons Regulations (Cap. 138A), or pharmaceutical products exempted from registration under Cap. 138A, including, where the relevant exemption applies, products imported under a valid import licence issued under the Import and Export Ordinance (Cap. 60) for the treatment of a particular patient by a medical practitioner or a dentist;

(b) medical devices listed under the Medical Device Administrative Control System (MDACS)[2]; or

(c) human organ or human tissue products to which the Human Organ Transplant Ordinance (Cap. 465) applies and which comply with its applicable requirements, or human organ or human tissue products covered by a valid exemption granted under that Ordinance and used in accordance with the conditions of that exemption.

Where more than one regulatory classification referred to in this clause applies, the product must satisfy the corresponding requirements of every applicable subparagraph. Compliance with one subparagraph does not dispense with compliance with another.

28.4.4 Injectable and infusible autografts[3] that are not advanced therapy products[4] may be used where the material is obtained

[2] As a transitional arrangement, the requirement that all injectable and infusible medical devices must be listed under the MDACS will take effect from 1 March 2027.

[3] Autograft means a tissue graft (including cells and organs in this context) taken from one part of the body and transferred to another part of the same individual. For the purpose of clause 28.4.4, the term also includes platelet-rich plasma obtained from and administered to the same individual.

[4] An autograft may be classified as an advanced therapy product, which constitutes a specific class of pharmaceutical products, if its cells or tissues have undergone substantial manipulation or are intended for non-homologous use. Reference should be made to the Pharmacy and Poisons Board of Hong Kong's "Guidance on Classification of Advanced Therapy Products" for guidance on advanced therapy product classification.

from and administered to the same individual for homologous use[5].

28.4.5 The hospital must keep an up-to-date drug formulary at the premises. Where injectable and infusible products that are not pharmaceutical products are supplied at the premises, the hospital must also keep an up-to-date list of those products. The hospital must maintain appropriate drug supply to provide safe and effective patient care by making reference to its size, scale and scope of services. Procurement documents for pharmaceutical and other injectable and infusible products must be kept at the hospital for future reference and inspection. Where applicable, valid import licences for unregistered pharmaceutical products issued under the Import and Export Ordinance (Cap. 60) for the treatment of a particular patient by a medical practitioner or a dentist must also be kept at the hospital for inspection.

28.4.6 All medicines and other injectable and infusible products must be clearly labelled with expiry dates and stored appropriately. Medicines for external and internal use must be kept separately.

28.4.7 The hospital must provide medicines, other injectable and infusible products, and biological products in a safe and effective manner to meet the needs of the patients and to adequately support the clinical services.

28.4.8 Where there is a cold chain requirement for maintaining the efficacy of medicines, there must be a system to monitor and record the temperature of the transport and storage facilities. For example, there must be written policies and procedures on storage and handling of vaccines which are prepared by taking reference from the "Module on Immunisation" under the "Hong Kong Reference Framework for Preventive Care for

[5] Homologous use means using cells or tissues to perform the same essential function in the recipient as in the donor. For the purpose of clause 28.4.4, the donor and the recipient are the same person.

Children in Primary Care Settings" promulgated by the Health Bureau.

28.4.9 There must be a policy setting out whether the patient can bring in medicine for personal use. If this is allowed, the hospital must inform the patient of his / her responsibility to inform the attending medical practitioner. If this is not permitted, this policy must be relayed to the patient before he / she decides to be admitted. Consent form is signed.

28.4.10 In accordance with the Dangerous Drugs Ordinance (Cap. 134) and the Pharmacy and Poisons Ordinance (Cap. 138) and their regulations, there must be in place a regular and documented check of poisons and dangerous drugs by appropriate personnel.

28.4.11 There must be in place a system to check expiry dates of medicines, other injectable and infusible products and disinfectants kept in the store, put on standby for normal use, stored in fridge or wards for emergency use. Expired products must not be used for dispensing or administration and must be properly disposed of.

28.4.12 Pre-packing of medications must be performed under supervision by a pharmacist. There must be a system to keep records in order for identification and tracing. The containers must be clearly labelled.

28.4.13 Compounding of medicines must be supervised by a pharmacist. There must be a system to keep records for compounding to permit identification of raw materials used and to assist in recalling the product if necessary. There must be a written formula drawn up for each preparation which must include the name and quantity of each ingredient with the manufacturing method recorded.

Dispensing and Administration of Medicines

28.4.14 There must be a system to monitor the accuracy of dispensing and administration of medicines. Dispensing records must be kept and available for inspection. Medication errors or near miss incidents must be documented and reported to the responsible medical practitioner through a process and time frame defined by the hospital.

28.4.15 Drugs packed in unit dose containers must be administered immediately after the drug has been removed from the container.

28.4.16 A medication record must be kept for each patient. The entries in the record must be signed by the person who administers showing –

(a) name and identifier of the patient;
(b) name, dose, route of administration of medicine;
(c) frequency and time for administering each dose;
(d) date of prescription; and
(e) any known medicine hypersensitivity or allergies.

28.4.17 The medicine for resuscitation must be easily accessible to staff. The packaging must facilitate the process of resuscitation.

28.4.18 Where medicines are received under a prescription for a named patient, they must be administered to that particular patient and must not be used for other patients. When medicines are no longer required by the named patient, they must be returned to the pharmacy for proper handling and disposal.

28.4.19 Maintenance of the supplies of medicines in ward stock must be performed by pharmacists, dispensers or registered nurses.

28.4.20 Medicines dispensed to patients for use outside the hospital must be clearly labelled with the name of the medicine, directions and precautions for use.

Handling and Disposal of Cytotoxic Pharmaceutical Products

28.4.21 There must be procedures to ensure the safe handling and disposal of cytotoxic pharmaceutical waste.

Chapter 29 Radiology Service

29.1 Staff Requirement and Training

29.1.1 A specialist in radiology or relevant specialty must be appointed to take overall charge of the service and to review regularly the facilities, equipment and staff training of the service.

29.1.2 A Part I diagnostic radiographer registered under the Radiographers (Registration and Disciplinary Procedure) Regulation of the Supplementary Medical Professions Ordinance (Cap. 359) must be assigned to take charge of the day to day operation of the service.

29.1.3 A Part I diagnostic radiographer must be put on duty during the operating hours of the service.

29.1.4 A registered nurse must be available, where necessary, to provide support such as administration of medicine or assisting interventional procedures under the supervision of a radiologist.

29.1.5 The staff must use the irradiating apparatuses and radioactive substances under and in accordance with licences issued under the Radiation Ordinance (Cap. 303) and the conditions attached to the licences.

29.2 Physical Conditions

29.2.1 There must be sufficient space for changing rooms, storage for personal belongings of patients, storage space for equipment and records, and toilet facilities located in the vicinity.

29.2.2 There must be a warning (in the form of lights or signs) outside the room that operates irradiating apparatus. Signage on special precautions must be written in both Chinese and English.

29.3 Equipment

29.3.1 The provision and use of facilities using ionising radiation must be covered by valid licences issued under the Radiation Ordinance (Cap. 303) and comply with Cap. 303 and the conditions attached to the licences. This also applies to the transporting, keeping, storage and disposal of radioactive waste.

29.3.2 Proper radiation safety precautions, including adequate shielding and protective clothing, must be available for staff, patient and accompanying person.

29.3.3 Resuscitation equipment and emergency drugs must be available in the service at all times.

29.3.4 Specific devices for safety and health protection must be provided for specific imaging procedures, for example, hearing protection device must be provided for patient undergoing the magnetic resonance imaging procedure.

29.3.5 All equipment used to conduct radiology and diagnostic imaging studies must be regularly inspected, maintained, and calibrated by qualified persons, and appropriate records must be kept.

29.3.6 There must be written procedures for use of different equipment and its precautions and contraindications.

29.4 Service Delivery and Care Process

29.4.1 Hospitals that provide acute care must provide an adequate range of imaging services to meet the needs of the services therein.

29.4.2 The hospital must comply with the Radiation Ordinance (Cap. 303) in the use of irradiating apparatuses and radioactive substances.

29.4.3 There must be written policies and procedures on service delivery and care process which include –

(a) obtaining detailed clinical history such as history of allergy;
(b) provision of thorough explanation before written consent is sought from the patient;
(c) steps to be taken during the procedure and preparation;
(d) possible occurrence of allergic reaction(s) after administration of contrast medium;
(e) accurate labelling of all films / imaging records with the patient's name, date of test performed and other identifiers;
(f) safety procedures;
(g) management of accident, emergency, or other adverse event;
(h) incident reporting; and
(i) application of infection control measures.

29.4.4 Precautions for accidental release of radiation must be taken if irradiating apparatus is on standby mode. Precautions for, and procedure to deal with, accidental spillage must be taken if unsealed radioactive substance is used.

29.4.5 All relevant staff must be provided with dosimeter to continuously monitor their radiation exposure level according

to the Radiation Ordinance (Cap. 303) while engaging in radiation work or handling of radioactive substances.

29.4.6 There must be written procedures for identifying patients with pacemakers and metallic implants for specific imaging procedures.

29.5 Magnetic Resonance Imaging

29.5.1 The magnetic resonance imaging (MRI) facility must be designed, installed, operated and maintained according to manufacturer's recommendation. There must be defined area to contain the magnetic resonance environment. Access to the defined area must be restricted and suitable warning signs must be displayed at all entrances.

29.5.2 There must be written policies and procedures to control access of patient, personnel and equipment to the defined area, including screening a person for any biomedical implants and ferromagnetic objects before he or she is allowed to enter the controlled access area of the MRI facility.

29.5.3 There must be induction and regular refresher trainings on MRI safety for staff working in the MRI facility and staff who will enter the defined area (e.g. staff responsible for escort / transfer of patients to the MRI service, housekeeping etc.).

29.5.4 All medical equipment or accessory items brought into and used within the defined area must be safe under the magnetic resonance environment.

29.5.5 There must be contingency plan for medical emergency. Drills must be conducted at regular intervals with records.

Chapter 30 Radiotherapy Service

30.1 Staff Requirement and Training

30.1.1 A specialist in clinical oncology or relevant specialty must be appointed to take overall charge of the service and to review regularly the facilities, equipment and staff training of the service.

30.1.2 A Part I therapeutic radiographer registered under the Radiographers (Registration and Disciplinary Procedure) Regulation of the Supplementary Medical Professions Ordinance (Cap. 359) must be on duty during the operating hours of the service.

30.1.3 A registered nurse must be available, where necessary, to provide support such as administration of medicine or assisting interventional procedures under the supervision of the specialist in clinical oncology or other relevant specialities.

30.2 Physical Conditions

30.2.1 There must be sufficient space for changing rooms, storage for personal belongings of patients, storage space for equipment and records, and toilet facilities located in the vicinity.

30.2.2 There must be a warning (in the form of lights or signs) outside the room that operates irradiating apparatus. Signage on special precautions must be written in both Chinese and English.

30.3 Equipment

30.3.1 The provision and use of facilities using ionising radiation must comply with the Radiation Ordinance (Cap. 303). This also applies to the transporting, keeping, storage and disposal of radioactive substances and radioactive waste.

30.3.2 All radiotherapy equipment and machines must be properly maintained and calibrated by qualified persons and appropriate records must be kept.

30.3.3 All relevant staff must be provided with dosimeter to continuously monitor their radiation exposure level according to the Radiation Ordinance (Cap. 303) while engaging in radiation work or handling of radioactive substances.

30.3.4 Proper radiation safety precautions, including adequate shielding and protective clothing, must be available for staff, patient and accompanying person.

30.3.5 An emergency trolley and a defibrillator must be available for resuscitation purpose.

30.4 Service Delivery and Care Process

30.4.1 There must be written policies and procedures for –

(a) patient assessment;
(b) obtaining patient's consent;
(c) prescribing treatment protocol;
(d) setup and treatment delivery;
(e) correct identification of the patient, correct location of his / her treatment site and correct implementation of the radiation treatment plan before each treatment; and
(f) handling emergency situations.

30.4.2 Radiotherapy services must be provided under the direction of a medical practitioner who is a specialist in clinical oncology or other relevant specialities.

30.4.3 The staff must use the irradiating apparatuses under and in accordance with licences issued under the Radiation Ordinance (Cap. 303) and the conditions attached to the licences.

Chapter 31 Sterile Supplies Service

31.1 Staff Requirement and Training

31.1.1 A registered nurse who has been trained in the practice of sterile supplies service must be appointed to take overall charge of the service and to review regularly the facilities, equipment and staff training of the service.

31.1.2 Staff must receive appropriate training in the handling and use of sterile supplies.

31.1.3 Relevant staff must be appropriately trained in the use of the sterilising equipment.

31.2 Physical Conditions

31.2.1 A one-way dirty to clean traffic flow must be designated in the equipment reprocessing area to prevent contamination.

31.2.2 Sterile supplies must be delivered in appropriate carriers and stored in a clean and dry area.

31.3 Equipment

31.3.1 All sterilising equipment must be regularly inspected and maintained. The stock levels of sterile supplies must be checked regularly and correctly rotated.

31.3.2 There must be proper documentation of different batches of sterilised supplies so that recall of sterilised products with problem can be carried out effectively for remedial action.

31.4 Service Delivery

31.4.1 There must be a system for regular checking of expiry of sterile supplies.

31.4.2 There must be written policies and procedures on service delivery which includes –

(a) cleaning, disinfection and sterilisation of reusable equipment;

(b) storage and transportation of sterilised items; and

(c) quality control.

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PART III: SUPPORTING SERVICES

Chapter 32 Requirements on Supporting Services

32.1 Housekeeping Service

32.1.1 Work routines which include schedules of cleansing of the premises and the air-conditioning system must be established.

32.1.2 Patients' rooms including floors, toilets and bathrooms must be cleaned daily and whenever necessary.

32.1.3 Common areas such as lobbies, waiting areas, activity rooms must be kept clean at all times.

32.1.4 Call bells must be kept in good functional order and tested on a regular basis.

32.1.5 All cleaning and disinfecting agents must be correctly labelled with the product names and different purposes of use as specified by the manufacturer.

32.1.6 Pest control must be carried out on a regular interval and where necessary.

32.1.7 The hospital buildings and compound must be kept under proper security control for the safety of patients, visitors and staff and their property. Policies and procedures must be put in place for handling all incidents and other unexpected happening.

32.1.8 When there are renovations or new construction works to be carried out in the hospital, appropriate measures must be taken to contain noise and dust.

32.2 Catering Service

32.2.1 If food is served in the hospital, it must be properly prepared according to the needs of patients.

32.2.2 All staff who handle food must have undertaken regular training in food hygiene.

32.2.3 Food handlers must be supervised by professional staff such as dietitian or registered nurse.

32.2.4 Staff suffering from gastro-enteritis symptoms must refrain from handling of food until symptoms have subsided.

32.2.5 Special diets must be provided on the advice of professional staff or a dietitian. There must be regular monitoring on the quality of food.

32.2.6 Food must be provided in different varieties and menus should be rotated regularly.

32.2.7 The person who is in-charge of the catering service must take reference from the Hazard Analysis Critical Control Point (HACCP) system for ensuring food safety.

32.2.8 The kitchen and place for storage of food must be kept hygienic to avoid pest infestation.

32.2.9 There must be a system to label the expiry date of food that has been prepared and stored for serving later.

32.3 Linen and Laundry Services

32.3.1 An adequate stock of clean linen must be maintained for use.

32.3.2 A schedule for the changing of linen must be set.

32.3.3 There must be written policies and procedures on handling of soiled linen, in particular linen of patients suffering from infectious diseases.

32.3.4 Linen storage rooms must be kept clean and in order.

32.3.5 Where laundry service is provided in house, the washers and dryers must be regularly maintained.

32.3.6 For occupational safety and health, laundry staff must be provided with appropriate personal protective equipment and must receive appropriate training on handling of linen / clothing items, chemical detergents and operation of laundry machines.

32.3.7 The laundry and related machines, and ventilation system of the laundry must be regularly serviced and maintained for effective operation with proper documentation in place.

32.3.8 Mechanism must be in place and documentation must be kept to monitor staff performance and quality of services.

32.4 Clinical and Chemical Waste Management

32.4.1 Clinical and chemical wastes must be handled properly and safely in accordance with relevant legislations and guidelines promulgated by the Environmental Protection Department (EPD).

32.4.2 A clinical and chemical waste management plan must be developed.

32.4.3 Clinical waste must be segregated from domestic waste. It must be properly packaged and labelled, using colour-coded bags with biohazard signs. Similarly, all chemical wastes must be properly stored and labelled before disposal.

32.4.4 Clinical and chemical wastes must be stored securely before collection by specialized waste collectors licensed by the EPD.

32.4.5 A record must be kept to demonstrate that clinical and chemical wastes have been properly disposed.

32.4.6 Staff must be provided with appropriate personal protective equipment and receive appropriate training on handling of clinical and chemical wastes.

32.4.7 Mechanism must be in place and documentation must be kept to monitor staff performance and quality of services.

32.5 Handling of Dead Body and Mortuary Service

32.5.1 There must be written policies and procedures for –

(a) proper identification of a deceased patient or foetus; and

(b) safe transfer of a deceased patient or foetus from the ward or other area in the hospital to the mortuary or temporary storage site and handover of the dead body or foetus to the deceased's family and undertaker.

32.5.2 The mortuary and plant must be regularly inspected and maintained. The temperature of the cold chamber(s) must be monitored and recorded at regular intervals.

32.5.3 Staff must be provided with appropriate personal protective equipment and must receive appropriate training on safe handling of dead body.

PART IV: PRICE TRANSPARENCY

Chapter 33 Price Transparency

33.1 Price Information

33.1.1 Patients must be informed of the charges of service whenever practicable. An up-to-date fee schedule covering all chargeable items must be readily available for reference at the admission / reception office, cashier, nursing station and places wherever appropriate.

33.1.2 If it is not possible to provide a fixed charge for a particular chargeable item, the charge must be presented in the form of a price range or shown with explanation that price information is available upon request.

33.1.3 A schedule of charges must be prepared for all room classes. It includes and is not limited to room charges, operating theatre charges, charges for common nursing procedures, charges for outpatient and specialist clinics consultations, charges for investigative and treatment procedures, charges for applying for medical report and copy of medical records and, if applicable, charges for day and outpatient cases.

33.1.4 The schedule of charges must be updated when there is a change in the charges.

33.1.5 Any change in chargeable items or price must take effect only after the fee schedule has been updated to reflect the changes and published. The licensee must publish notices and make announcements to inform patients of any update of the fee schedule at least 14 calendar days before the new fee schedule takes effect.

33.1.6 The licensee must ensure that patients are kept informed of the updated charges of services provided, including both hospital's charges and doctors' fee, at suitable intervals during hospitalisation.

33.1.7 Patients have the right to examine and be given explanation on their bill, including hospital's charges and doctors' fee.

33.1.8 Feedback on charges of individual patient must be provided to the responsible medical practitioners with admission privileges for their reference.

33.2 Budget Estimate

33.2.1 Patients have the right to know the fees and charges prior to consultation and any procedure.

33.2.2 At admission, staff must respond to / answer patient or his / her family member's enquiry about the expected charges for the use of hospital services or facilities.

33.3 Historical Statistics on Fees and Charges

33.3.1 The licensee must publish historical statistics on the fees and charges for the specified treatments and procedures from time to time in the way specified by the Director of Health.

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PART V: CLOSURE

Chapter 34 Closure of a Hospital

34.1 If the licensee intends to cease operating the hospital 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 fewer than 3 months before the intended date of cessation of operation.

34.2 A closure plan must be submitted to Department of Health where the licensee intends to cease operating the hospital.

34.3 Before the complete cessation of all clinical services, the hospital must provide safe services to patients regardless of the scale of services being provided. The hospital must ensure that the staffing, facilities and equipment relating to its services are adequate and appropriate.

34.4 The hospital must make proper arrangement where necessary for the patients affected to ensure the continuity of care given to them after its closure.

34.5 The hospital must handle records, including medical record, according to the relevant legislation and codes of practice.

34.6 The hospital must arrange proper disposal of the following items–

(a) irradiating apparatus and radioactive substances;
(b) dangerous drugs;
(c) chemical waste (including drugs);
(d) clinical waste and human remains; and
(e) medical equipment.

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

Annex 1

Back-up Power Supply Requirements

1. Medical equipment in critical care areas must be connected to emergency power supply. Critical medical equipment must also be supplied by UPS of suitable type, rating and back-up time.

2. All general lighting installations in critical care areas must be provided with at least two different sources of supply, one of which must be connected to emergency power supply, to provide standby lighting.

3. Operating lamps in operating theatres / rooms must be supplied by UPS and / or batteries with suitable backup time for the clinical services.

4. Emergency power supply, connected to emergency generators in the hospital premises, must be automatically available within 15 seconds upon loss of normal electrical power supply to the hospital. The capacity of the emergency generators and the associated fuel supply systems must be sufficient to support the essential services of the hospital according to its contingency plan.

5. Back-up power supply connected to a UPS system must be automatically available without break upon loss of normal electrical power supply to the supported services of the hospital. A system of UPS and its batteries are sized with suitable back-up time for the services supported by them.

6. A UPS system must comprise 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.

Annex 2

Specialized Ventilation Requirements

1. Specialized ventilation areas must be ventilated according to the following requirements:

	Function of Space	**Pressure Relationship to Adjacent Areas**	**Minimum Outdoor ACH**	**Minimum Total ACH**	**All Room Air Exhausted Directly to Outdoors**	**Air Re-circulated by Means of Room Units**	**Design Relative Humidity %**	**Design Temp. ^{0}C**	**Minimum Filter Efficiency**
1	Operating theatre / room (OT/OR)	Positive	4	20	NR	No	20-60	20-24	MERV-16 or equivalent
2	Airborne Infection Isolation (AII) room	Negative	2	12	Yes	No	Max 60	21-24	MERV-14 or equivalent
3	Protective Environ-ment (PE) room	Positive	2	12	NR	No	Max 60	21-24	HEPA

Note:

(a) 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 in existing facilities to achieve the required room ACH, provided the specified minimum outdoor ACH is supplied.

(c) 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.

(d) NR – no requirement.

2. Airborne Infection Isolation (AII) rooms

2.1 AII rooms must be sealed to provide a minimum differential pressure of -2.5 Pa across the envelope.

2.2 AII rooms must have a permanently installed device and / or mechanism to constantly monitor the differential air pressure between the AII room and the corridor. A local visual means must be provided at the AII room to indicate whenever negative differential pressure is not maintained.

2.3 Exhaust air grilles in the AII room must be located directly above the patient bed, on the ceiling or on the wall near the head of the bed.

3. Protective Environment (PE) rooms

3.1 PE rooms must be sealed to provide a minimum differential pressure of +2.5 Pa across the envelope.

3.2 PE rooms must have a permanently installed device and / or mechanism to constantly monitor the differential air pressure between the room and the corridor. A local visual means must be provided at the PE rooms to indicate whenever positive differential pressure is not maintained.

3.3 Supply air diffusers must be located above the patient bed and return/exhaust grilles must be located near the patient room door.

4. Operating theatres/rooms (OTs/ORs)

4.1 OTs/ORs must be maintained at a positive pressure with respect to all adjoining spaces at all times.

4.2 A pressure differential must be maintained at a value of at least +2.5 Pa.

4.3 Each OT/OR must have individual temperature control.

4.4 OTs/ORs must be provided with a primary supply diffuser array to provide an airflow pattern over the patient and surgical team. The air flow must be unidirectional and downwards.

4.5 OTs/ORs must be provided with at least two low sidewall return or exhaust grilles spaced at opposite corners or as far apart as possible.

Annex 3

Exhaust Discharge Requirements

1. Exhaust discharge outlets that discharge air from Airborne Infection Isolation (AII) rooms, bronchoscopy and sputum collection and pentamidine administration rooms, pharmacy hazardous-drug exhausted enclosures and laboratory work area chemical fume hoods must be designed so that all ductwork within the building is under negative pressure.

2. Exhaust discharge outlets from AII rooms, bronchoscopy and sputum collection exhaust, pharmacy hazardous-drug exhausted enclosures and laboratory work area chemical fume hoods must be arranged to discharge to the atmosphere in a vertical direction (with no device to impede the vertical momentum) and at least 3m above the adjoining roof level.

3. Exhaust discharge outlets from AII rooms, bronchoscopy and sputum collection exhaust, and laboratory work area chemical fume hoods must be located not less than 8m horizontally from outdoor air intakes, openable windows / doors, and areas that are normally accessible to the public.

Annex 4

Back-up Sources Requirements of MGPS

1. All medical gas supplies must comprise three sources of supply identified as “primary”, “secondary” and “reserve” as defined in HTM 02-01, or equivalent.

2. The supply systems must be designed to achieve continuity of supply to the terminal units in normal conditions and in a single fault condition.

3. Types, capacities and locations of primary, secondary and reserve sources of supply must be based on both system design parameters and the need for supply security.

4. The continuity of medical gas supplies must be maintained upon failure of the normal electrical power supply.

5. All medical air systems must be supported by an appropriate, fully-automatic manifold.

Annex 5

Test Requirements of MGPS

1. The following tests and checks must be carried out after installation of the MGPS is completed:

   (a) Tests for leakage on each MGPS;
   (b) 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;
   (c) Tests of line valve assemblies for closure and identification;
   (d) Tests for cross-connection, flow, pressure drop, mechanical function and correct identity of the terminal units: checks for correct labelling and association with AVSUs;
   (e) Tests for mechanical function and identity of non-interchangeable screw thread connectors;
   (f) Performance tests of the pipeline system;
   (g) Functional tests of all supply systems;
   (h) Checks of safety valve certification;
   (i) Tests of warning systems;
   (j) Tests for particulate contamination/odour/taste; and
   (k) Tests for anaesthetic gas scavenging disposal systems (if installed).

2. The following tests must be carried out after purging and filling with the working gas:

   (a) Tests for particulate contamination;
   (b) Tests for gas identity; and
   (c) Tests for gas quality.

Annex 6

Sample 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:_____
Hospital:_____ 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	Pass/Fail	TEST	Pass/Fail

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 ("DMO/DNO").

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_____

Ward/Dept_____

Delete as appropriate