Briefing on the Private Healthcare Facilities Ordinance

DEPARTMENT OF HEALTH

2019

Agenda

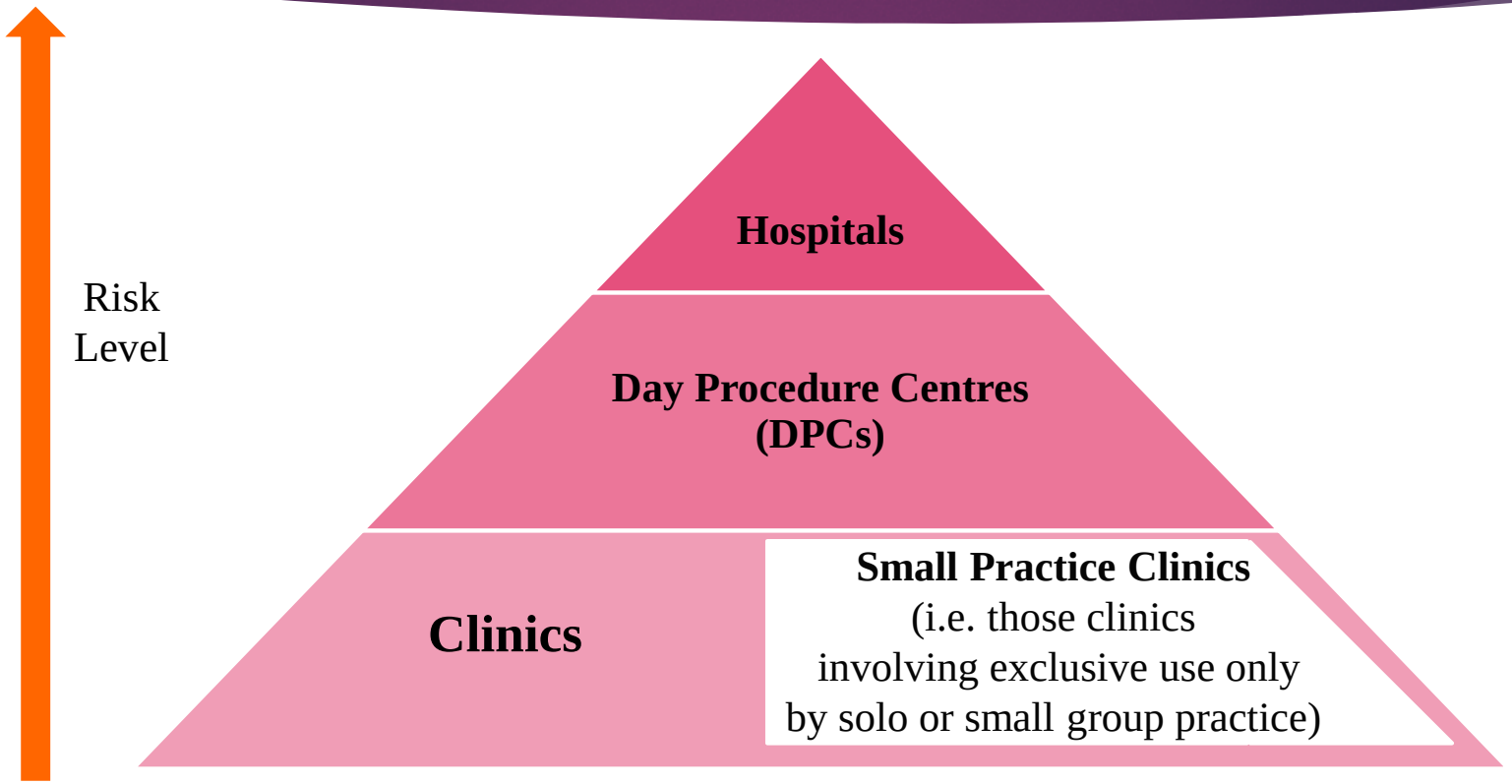
- Introduction to the Private Healthcare Facilities Ordinance
  - ✓ Differentiation between hospitals, day procedure centre (DPC) and clinics
  - ✓ Transitional arrangements
  - ✓ Small practice clinics
  - ✓ Licensee, Chief Medical Executive, Medical Advisory Committee
  - ✓ Requirements on premises and separate entrance
- Code of Practice and Highlights on Infection Control Measures
- Questions & Answers session

Introduction to the Private Healthcare Facilities Ordinance

Private Healthcare Facilities Ordinance (Cap 633)

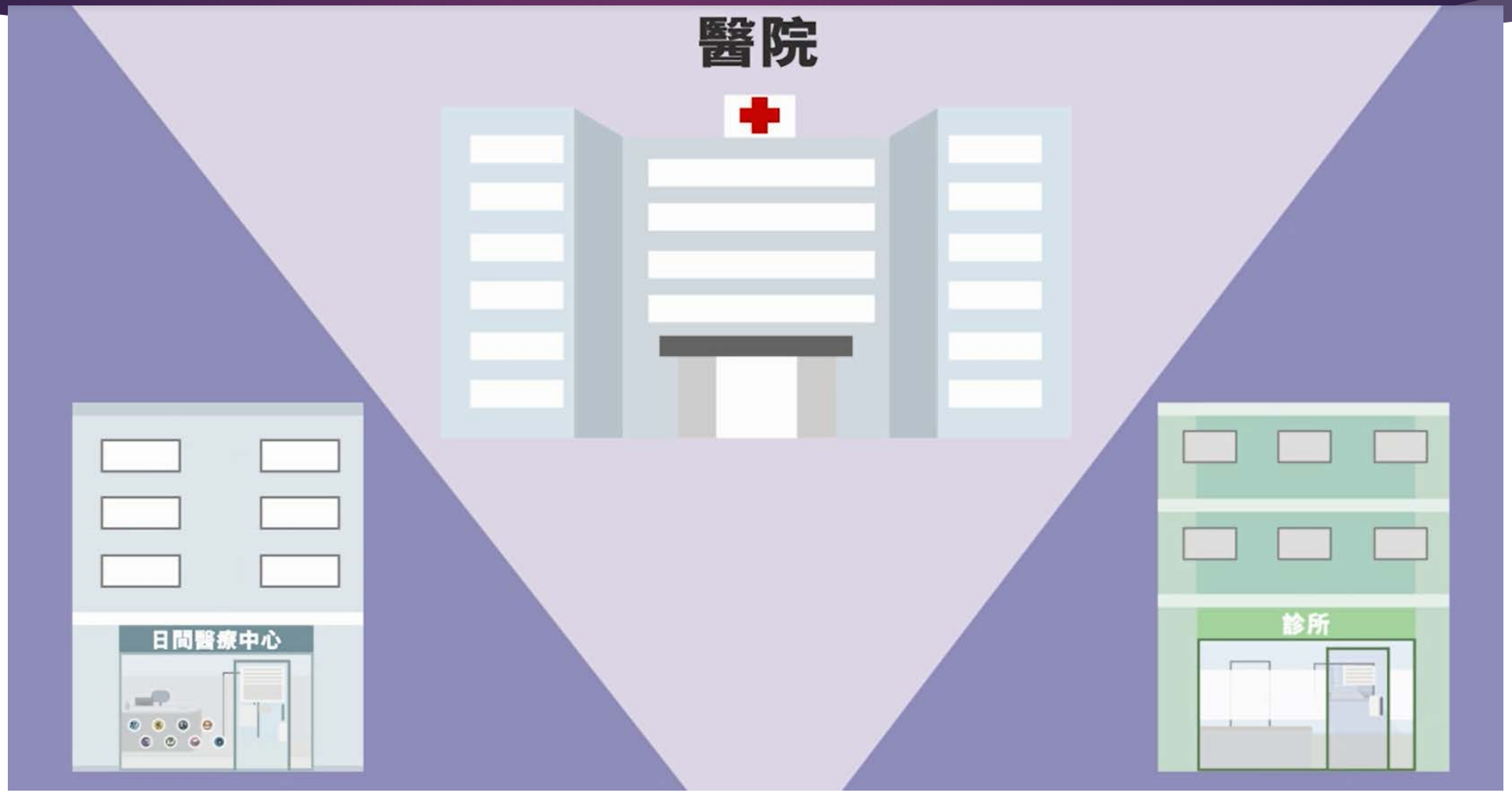
- Passed in November 2018
- Provides for a new regulatory regime for private healthcare facilities (PHFs), for premises where registered medical practitioners and/or dentist practise
- Key licensing requirements:
  - Appointment of Chief Medical Executive
  - Complying with the requirements of the Ordinance, Conditions of Licence and Code of Practice issued by the Director of Health
  - Putting in place a Complaints Management System
  - Price Transparency measures

Q1: What are the types of PHFs to be regulated?



- Health services establishments: Schedule 9 to the Ordinance

(Animation – Overview on the PHFO)



Q2: How to differentiate between a hospital, a DPC and a clinic?

	Hospitals	Day Procedure Centres	Clinics
Medical procedure requiring lodging	✓	×	×
Medical procedures which require continuous confinement of the patient within the facility for more than 12 hours	✓	×	×
Services to pregnant women for and immediately after childbirth	✓	×	×
Medical procedures specified in the "Code of Practice for Day Procedure Centres" to be conducted only in hospitals	✓	×	×
"Scheduled Medical Procedures" specified in Column 2 of Schedule 3 to the Ordinance	✓	✓	×
Consultation services and "Minor Medical Procedures" (Such as procedures specified in Section 2 and Column 3 of Schedule 3 to the Ordinance	✓	✓	✓

Scheduled medical procedures

- Procedures specified in Schedule 3 to the Ordinance that are carried out in ambulatory settings
- Include the following **eight classes of specialized services** –
  - Endoscopic procedure
  - Chemotherapy
  - Haemodialysis
  - Interventional radiology and lithotripsy
  - Radiotherapy
  - Surgical procedure
  - Anaesthetic procedure (such as general anaesthesia and deep sedation)
  - Dental procedure
- Refer to Section 2 of the Ordinance on the interpretation of "Scheduled Medical Procedure" and Column 2 of Schedule 3 "Classes of Specialized Services" on the particular medical procedures

Performance of scheduled medical procedures?

Yes

Day procedure centre
LICENCE
* In operation on 30 Nov 2018 may apply for a **provisional licence**

No

Eligible for exemption as small practice clinic?

Yes

Small practice clinic
LETTER OF EXEMPTION

Sole proprietor/ ≤ 5 partners or directors who are **ALL** medical practitioner with full registration/ dentist

No other doctor/ dentist practise in the clinic

Limits on locum days

No

Clinic
LICENCE
* In operation on 30 Nov 2018 may apply for a **provisional licence**

Licence vs Letter of Exemption

	Licence	Letter of exemption
Applicable PHF	DPC and Clinic	Small Practice Clinic
Renewal	DPC – 3 years Clinic – 5 years Scheduled Clinic – 1 year	Not required
Fee	Licence fee depends on scale of DPC / Clinic	No application fee
Operation standards	Licensing requirements and the Code of Practice	Exemption condition, requirements promulgated by MCHK/DCHK
Premises	Distinct and separate premises with separate entrance (exception: clinic with provisional licence)	

Q3: Am I eligible for transitional arrangements (provisional licence)?

Eligible PHFs

- ✓ **Day procedure centres (section 135) and clinics (section 136)**
  - ✓ in operation on specified date (30 November 2018)
  - ✓ application for licence made within specified period
    - DPC: 2 January 2020 – 30 April 2020
    - Clinic: To be announced
- ✓ Documentary proof of operation of the relevant services at the premises on the specified date. E.g. business registration records, records of procurement / maintenance of equipment / drugs

Provisional licence vs full licence

Provisional licence

Applicable to DPC/clinic in operation on 30 Nov 2018 only

Documentary proof of operation of the relevant services at the premises on 30 Nov 2018

Will be followed by processing of full licence application

Valid until 1) a full licence is issued, 2) the application of full licence is refused or withdrawn or 3) a date specified by SFH

Full licence

Applicable to **ALL** DPC and clinic

Proof of compliance of all licensing requirements and the Code of Practice

Renewal every 3-5 years

*Licences of scheduled clinics valid for one year

Q4: Is my clinic eligible for exemption (i.e. as a small practice clinic)? (Animation – small practice clinics)

Scenario 1

- My clinic is operated through a company which has 5 directors including myself
- Amongst the directors of our company, 2 are medical practitioners under full registration, 3 are registered dentist
- All directors, and no one else, practise in this clinic

✓ **No. of company directors <=5**

Scenario 2

- I am the sole proprietor operating a clinic
- I take 4 months of annual leave in a year
- When I am on leave, my clinic is closed

✓ **Locum time not exceeding 60 days**

Scenario 3

- My clinic is operated through a company which has 4 directors including myself (all are medical practitioners under full registration)
- Each of us takes 6 weeks (42 days) of annual leave in a year, and our duties are taken up by locums

✓ **Cumulative locum time not exceeding 180 days**

Scenario 4

- My clinic is operated through a partnership which has 5 partners including myself
- Amongst the partners of our clinic, 3 are medical practitioners under full registration, 1 is a registered dentist, and 1 is a physiotherapist

Not all partners are medical practitioners under full registration or registered dentists

Scenario 5

- My clinic is operated through a company of 5 directors, all of which are medical practitioners under full registration
- We are planning to re-structure the company, with the replacement of 2 directors in the directors board
- To facilitate a smooth transition, we are contemplating to expand the directors board by including the two new directors briefly for 3 months, and then exit of 2 directors afterwards

✖ **No. of company directors > 5**

Scenario 6

- My clinic is operated through a partnership of 5 partners including myself
- We all practice in the clinic
- 4 of our partners are registered medical practitioners under full registration, and the other is a registered dentist
- We also regularly engage two friends to serve in the clinic, one is a doctor under full registration and the other is a registered dentist

✖ **Not permissible to engage other doctors/dentists to practice**

Scenario 7

- I am the only registered doctor having full registration working full time in my clinic as a sole proprietor
- I normally take 2 months off during the summer and 2 months off during winter, and hire a locum who works 6 days a week for the entire period while I am on leave

✖ **Locum time exceeding 60 days**

Scenario 8

- My clinic is operated through a partnership of 5 partners who are all medical practitioners under full registration, including myself
- Each of us plan to take 2 months off in a year, and plan to hire locums for the entire periods which we are on leave

✖ **Cumulative locum time exceeding 180 days**

Scenario 9

- I have 5 clinics, each of them fulfills the criteria of a small practice clinic
- Can I apply letters of exemptions for all 5 clinics?

✖ **In the capacity of more than 3 small practice clinics**

(Animation – Requirements on Governance and Premises)

Q5: What are the roles for Licensee, and Chief Medical Executive (CME)?

- Applicable to licensed PHFs

  (i.e. not for small practice clinics being exempted)

- ✓ Wholly responsible for the operation of the PHF
  - Ensuring the facility's compliance with the condition of licence, code of practice
  - Setting up and enforcing relevant rules, policies and procedures
- ✓ Appointing the CME

- ✓ Taking charge of the PHF's day to day administration
- ✓ Different requirements on CME for different types of PHFs

Requirements on CME

	Hospital	DPC	Clinic	Group of ≥ 4 clinics operated by the same licensee
General	• Must possess the necessary qualifications and experience • Must be physically and mentally fit to administer a PHF • Must be of integrity and good character			
Qualifications	Registered medical practitioner	• Medical practice: Registered medical practitioner • Dental practice: Registered dentist • Combined medical and dental practices: Registered medical practitioner (with a registered dentist appointed to assist CME)		
Experience (Registered in HK)	≥ 15 years	≥ 6 years	≥ 4 years	≥ 8 years

Requirements on CME (cont'd)

	Hospital	DPC	Clinic	Group of ≥ 4 clinics operated by the same licensee
Others	Must not serve as CME of another PHF at the same time	Must **not** serve as CME of – ➢ More than two DPCs; ➢ More than three clinics; or ➢ More than one DPC and one clinic, except for the case at the column on the right		A person may serve as CME of ≥ 4 clinics of the same licensee at the same time, provided that – ➢ A Medical Advisory Committee is established for the clinics; ➢ For each clinic, a registered medical practitioner / registered dentist serving the clinic is appointed to assist CME; and ➢ The person does not serve as CME of another PHF at the same time

Q6: When do I need to set up a Medical Advisory Committee (MAC)?

Both licensee and CME are responsible for ensuring that MAC's advice is properly implemented

MAC to be established by the licensee –

- hospital, or
- A group of clinics (≥ 4 clinics) and appoint the same CME

Q7: When should I apply for a licence / letter of exemption?

Types of PHFs	Commencement of Licence Application	First batch of Licences Taking Effect	All Facilities Operating with Licence
Hospital	2 July 2019	Early 2021 (Full only)	Early 2021
Day Procedure Centre	2 January 2020	Early 2021 (Full/provisional)	To be determined
Clinics	2021 (at the earliest)#	To be determined	To be determined

Timeline equally applies to request for exemption of Small Practice Clinics

Q8: What should I do to get ready for applying a licence?

- Set up distinct and separate premises for your facility
  - Ensure the entrance is separate and not shared with any premises that serve a purpose not reasonably incidental to the type of your facility
- Appoint a CME with qualifications commensurate with the type of your facility
- Set up an MAC if you are going to operate a group of 4 or more clinics and appoints 1 CME
- Comply with requirements in the Code of Practice issued by the Director of Health
- Put into practice a suitable complaints management system, and price transparency measures

Complaints Management System

- A two-tier complaints handling system is proposed

First Tier

- PHF to manage complaints at source
- Licensee to put in place a complaints handling procedure

Second Tier

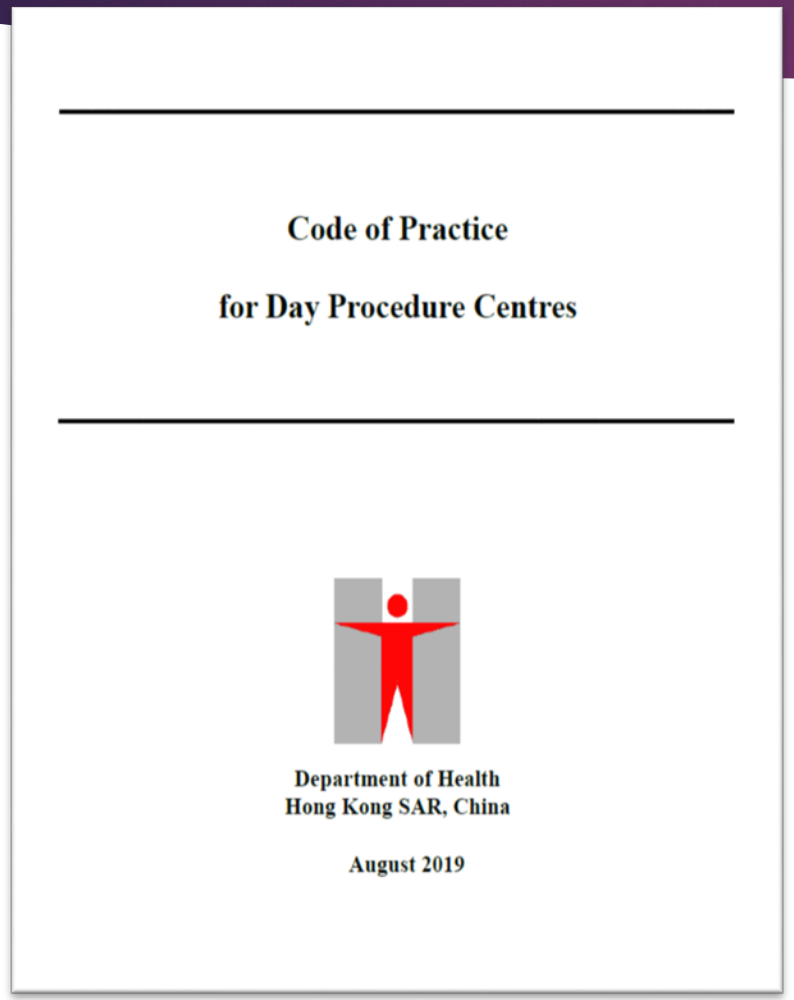
- Unresolved complaints to be handled according to a centralized mechanism *(Committee on Complaints against Private Healthcare Facilities)*

Price Transparency

	Hospital	Day Procedure Centre (DPC)	Clinic
Provision of Fee Schedules / Price Information	✓	✓	✓
Provision of Budget Estimates	✓	-	-
Disclosure of Historical Bill Sizes Statistics	✓	-	-

Code of Practice and Highlights on Infection Control Measures

Code of Practice for Day Procedure Centres


Code of Practice

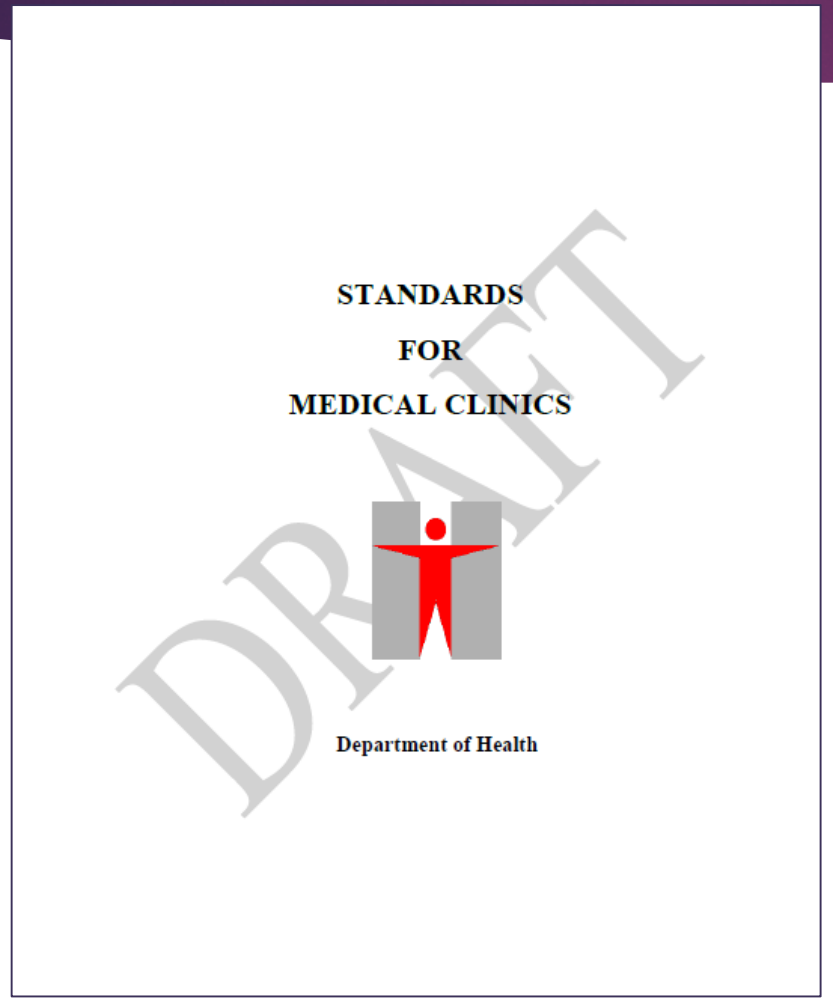
for Day Procedure Centres

Department of Health
Hong Kong SAR, China

August 2019

- Gazetted on 9 August 2019
- Applicable to all DPCs – may carry out scheduled medical procedures on patients without lodging
- Compliance is a condition for issuance and renewal of licences

Draft Standards for Medical Clinics



- Will be updated and adopted as Code of Practice for Clinics

Code of practice – Framework for DPCs and Clinics

- Management / governance
- Physical conditions
- Service delivery and care process
- Infection control
- Resuscitation and contingency

- Staffing
- Equipment
- Accommodation
- Policies and Procedures

Code of practice – Framework for DPCs and Clinics

- Management / governance
- Physical conditions
- Service delivery and care process
- **Infection control**
- Resuscitation and contingency

Requirements in
Code of Practice for DPCs

General (Core Standards)
- Infection control policies and procedures
- Cleaning, disinfection and sterilisation of medical equipment

Specific examples
- Surgical procedures
- Operating rooms

Infection Control Policies and Procedures

- Written policies and procedures with reference to guidelines promulgated by relevant health and professional authorities, for example:
  - *Guide to Infection Control in Clinic Setting* (Centre for Health Protection, DH)
  - *Recommendations on Prevention of Surgical Site Infection* (Centre for Health Protection, DH)
  - *Guidelines on Infection Control in Anaesthesia* (Hong Kong College of Anaesthesiologists)
- Active infection control programme to prevent, identify and control infections
- Appropriate and adequate stocks of personal protective equipment
- Report of statutorily notifiable infectious diseases

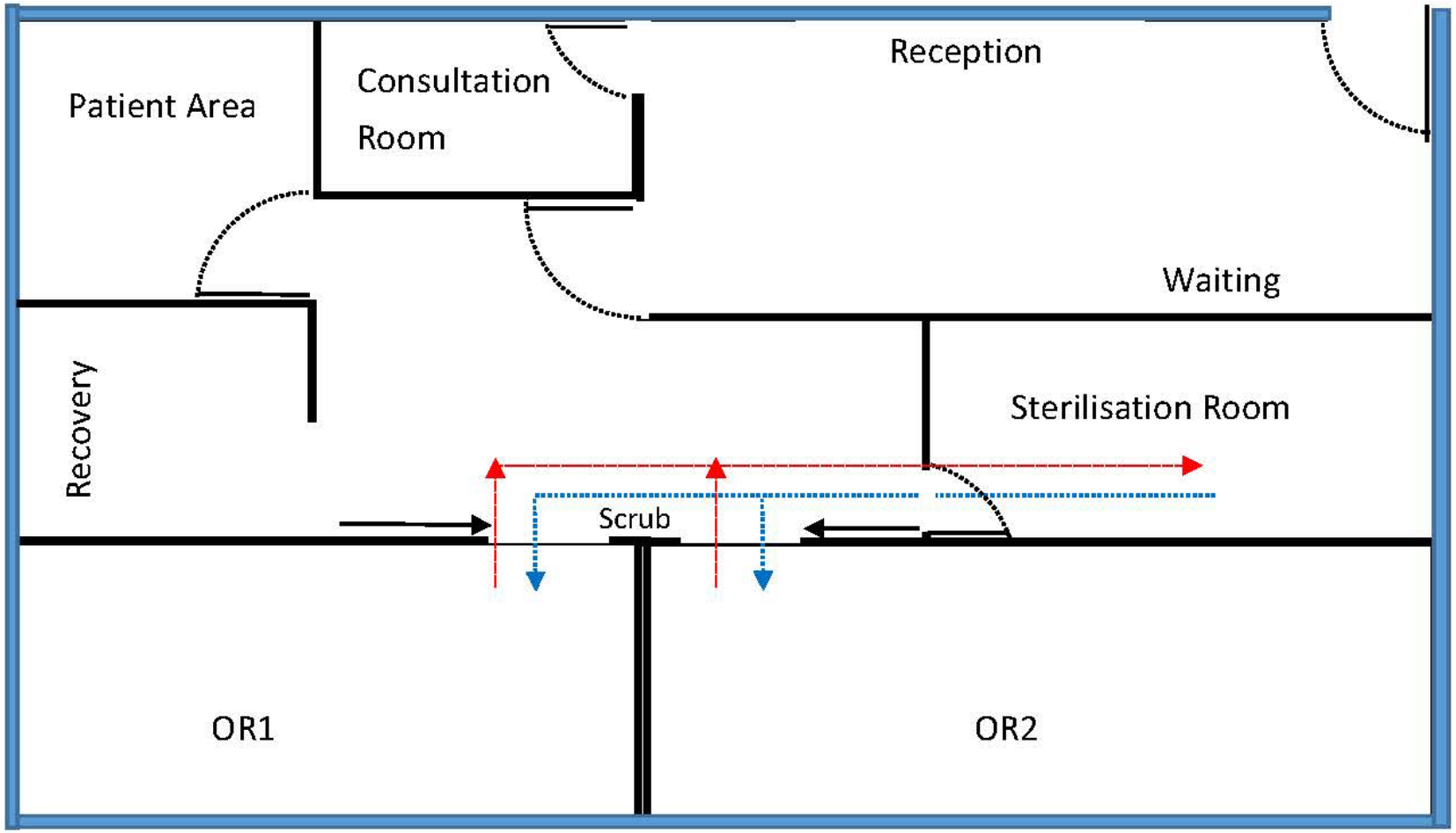
Cleaning, Disinfection and Sterilisation of Medical Equipment

Items	Requirements
Disposable equipment	• Policies and procedures on use
Reusable equipment and supplies	• Proper process and sterilization as appropriate • Method of control to assure cleaning, disinfection and sterilisation
Sterile equipment and supplies	• Stored in clean and dry area • System for regular checking of expiry
Sterilising equipment	• Regularly inspected and maintained with proper documentation • Relevant staff are appropriately trained in the use of sterilising equipment

Infection Control Requirements for Surgical Procedures

- **Equipment reprocessing area and sterile stores**
  - One-way dirty to clean traffic flow
- **Infection control policies and procedures**
  - Standard precautions
  - Use of aseptic techniques
  - Environmental cleansing and disinfection
  - Cleaning, disinfection and sterilization, and storage of surgical and/or anaesthetic equipment
  - Monitoring of effectiveness of infection control measures

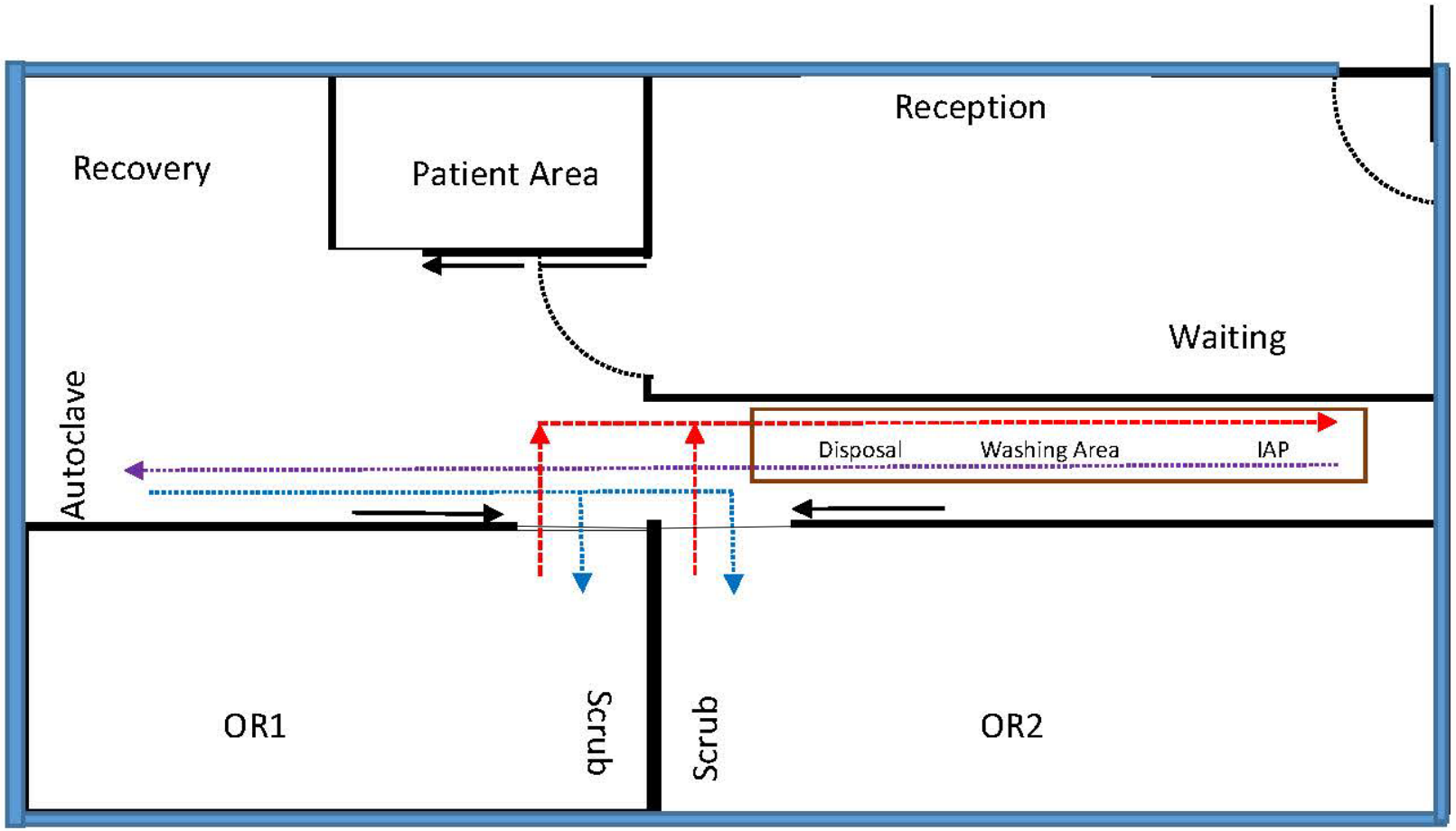
Day Procedure Centre – Common layout



Notes:

1. After Autoclave and cooling, equipment are put in a disinfected and sealed box for transportation
2. Used instrument and sterile instrument transportation should be segregated by time slot
3. Arrows ⟶ are sliding doors
4. Used instrument path
5. Sterile instrument path
6. Carts/ Trolleys are washed (disinfected) at Disposal and Washing Area of the Sterilisation Room

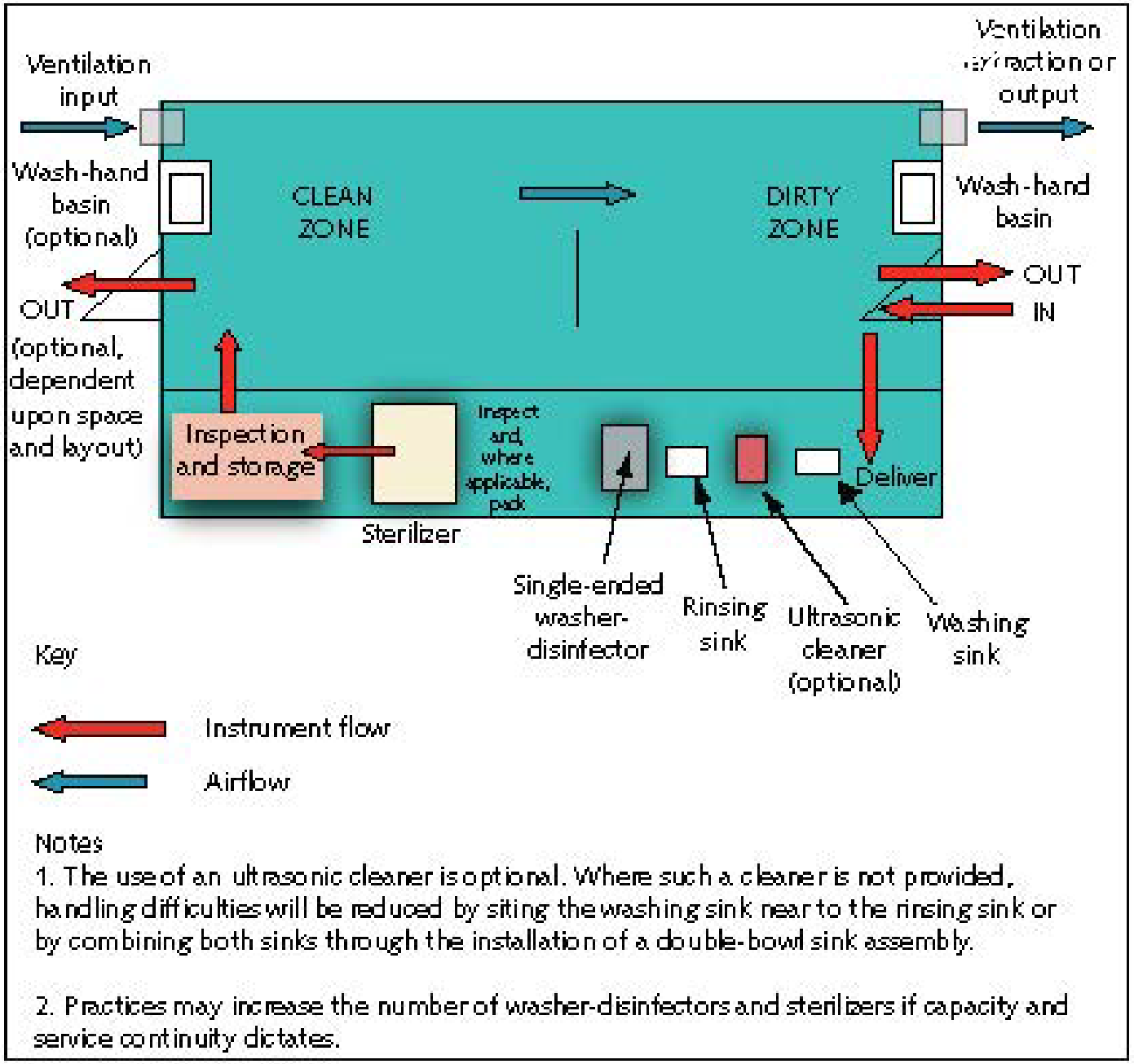
Day Procedure Centre- Not Preferred



Notes:

1. Arrows → are sliding doors
2. Used instrument path
3. Clean instrument path
4. Sterile instrument path

Principles of one-way direction and example layout for single decontamination room



Notes

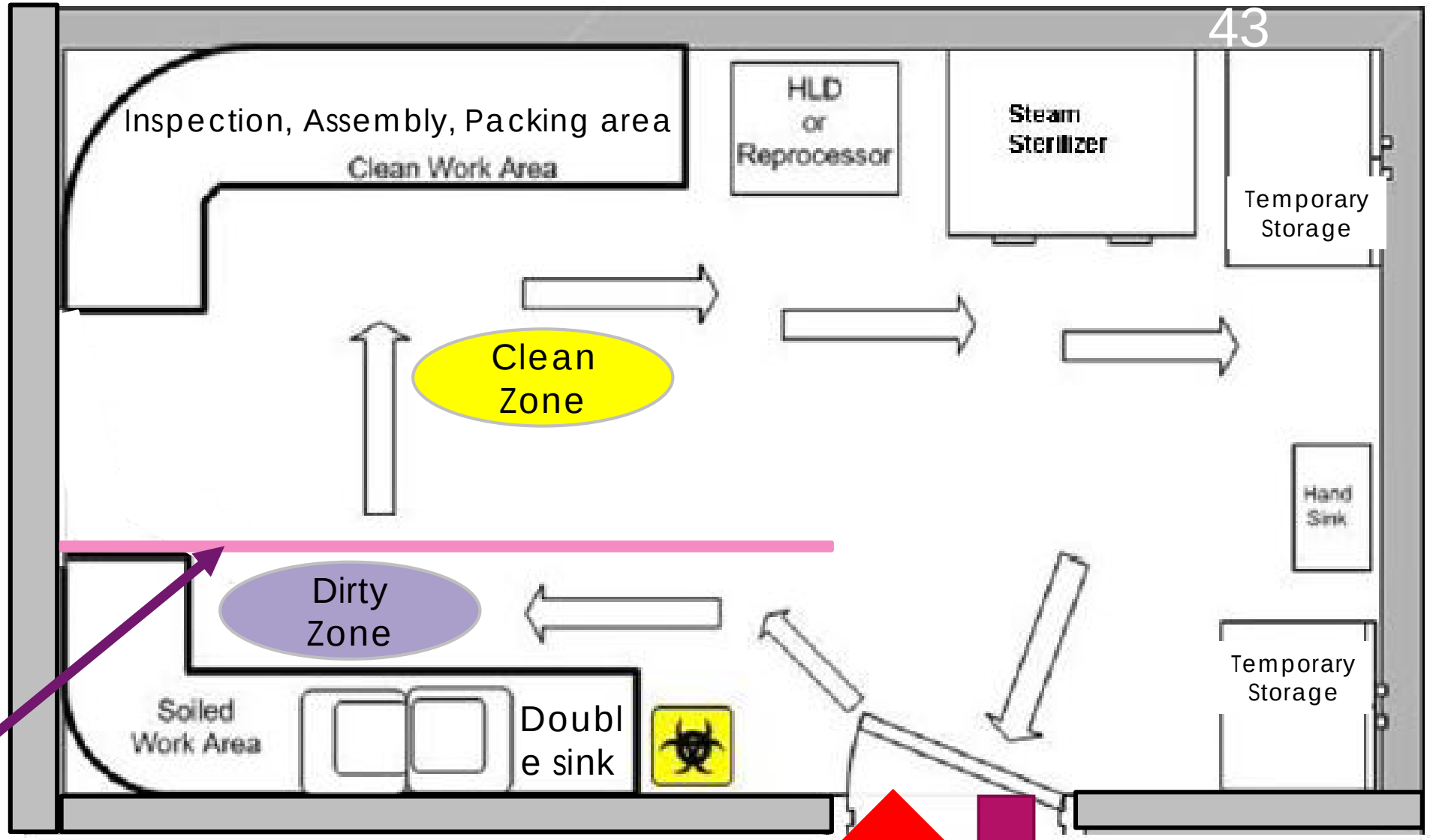
1. The use of an ultrasonic cleaner is optional. Where such a cleaner is not provided, handling difficulties will be reduced by siting the washing sink near to the rinsing sink or by combining both sinks through the installation of a double-bowl sink assembly.

2. Practices may increase the number of washer-disinfectors and sterilizers if capacity and service continuity dictates.

Source from: HTM 01-05, 2013

Workflow for decontamination process

- One way direction
- Dirty to clean workflow
- Segregation
  - Physical (preferred)
  - Time slot



Clear delineation of dirty and clean zones

Soiled instrument entrance
(Segregated by time slot)

Sterile instrument outlet
(Segregated by time slot)

Infection Control Requirements for Operating Rooms

- Maintained at acceptable level of sterility
- The ceiling, walls and floors are made from materials that can be easily cleaned and disinfected
- Equipped with specialized ventilation system of internationally acceptable standards of air quality
- Ventilation system is regularly inspected and maintained with documentation
- Adequate area for scrub and gowning

More information

Website of the Office for Regulation of Private Healthcare Facilities:

www.orphf.gov.hk

Q&A Session