

# Practice Management Package

(Version 2011 September)

## Appendixes

<b><i>Appendix A</i></b>	- <b>Details of Permitted Sizes and Measurement of Signboards .....</b>	<b>P. 1</b>
<b><i>Appendix B</i></b>	- <b>Routine Environmental Cleaning.....</b>	<b>P. 3</b>
<b><i>Appendix C</i></b>	- <b>“Spills” Protocol.....</b>	<b>P. 4</b>
<b><i>Appendix D</i></b>	- <b>Disinfection.....</b>	<b>P. 5</b>
<b><i>Appendix E</i></b>	- <b>Sterilization .....</b>	<b>P. 8</b>
<b><i>Appendix F</i></b>	- <b>Waste Management .....</b>	<b>P. 13</b>
<b><i>Appendix G</i></b>	- <b>Needle Stick Injury and Blood/Body Substance Occupational Exposure Management Protocol.....</b>	<b>P. 14</b>
<b><i>Appendix H</i></b>	- <b>Handling and Disposal of Sharps .....</b>	<b>P. 17</b>
<b><i>Appendix I</i></b>	- <b>Procedures of Proper Dispensing.....</b>	<b>P. 18</b>
<b><i>Appendix J</i></b>	- <b>Vaccine Storage .....</b>	<b>P. 19</b>
<b><i>Appendix K</i></b>	- <b>Expired Medication Disposal .....</b>	<b>P. 21</b>
<b><i>Appendix L</i></b>	- <b>Dangerous Drugs Ordinance .....</b>	<b>P. 22</b>

## **Details of Permitted Sizes and Measurements of Signboards**

### **I. Signboard**

The area of a signboard is taken to be the length multiplied by the breadth of its face, or faces, including all borders.

The areas of any number of visible faces (i.e. can be read from different directions) on the signboards must not in aggregate exceed the permitted maximum size of signboards in that precise location.

*Generally permitted.* Every registered medical practitioner is permitted to exhibit not more than two signboards on or beside that door which gives immediate and direct access to his surgery. The size of the signboards beside that door must not exceed ten square feet.

### **Additional signboards permitted**

#### **A. For Ground Floor offices with direct access from the pavement**

*One signboard:* The wording of which is visible from the street, exhibited below first floor level.

*N.B. For offices in this category, no more than three signboards in total may be exhibited.*

#### **B. For offices situated within a building having one public entrance**

*One signboard:* The wording of which is visible from the street, exhibited at the floor level where the practice is conducted.

*One signboard:* The wording of which is visible from the street, exhibited adjacent to the public entrance to the building.

*N.B. For offices in this category no more than four signboards in total may be exhibited.*

#### **C. For offices situated within a building having more than one public entrance**

*One signboard:* The wording of which is visible from the street, exhibited at the floor level where the practice is conducted.

*Two signboards:* The wording of which is visible from the street, exhibited adjacent to a maximum of two public entrances to the building.

*N.B. For offices in this category no more than five signboards in total may be exhibited*

*NOTE:*

1. The maximum number of signboards permitted in total includes the number “Generally permitted” plus the number shown under “Additional signboards permitted”.
- 2.1.No additional signboard exhibited below First Floor level may exceed ten square feet.
- 2.2.No additional signboard exhibited at Mezzanine Floor or First Floor level may exceed thirteen square feet.
- 2.3.No additional signboard exhibited at a level above First Floor level may exceed twenty square feet.

## ***II. Directory Boards***

Where directory boards are provided in buildings having a number of entrances and lobbies there will be no objection to the use of whatever number of boards are provided. The particulars which may appear on directory boards are those which may appear on signboards. Each entry must conform to the standard size for every other entry on the board.

## ***III. Directional Notices***

Directional notices must contain only the name of the registered medical practitioner, the permitted prefix and the room number of his premises. They can be exhibited only inside a building. The numbers which may be exhibited will be left to the discretion of the practitioner but the guidance given at section 4.2.3.1 of the Code (Professional Code and Conduct for Guidance of Registered Medical Practitioners by Medical Council of Hong Kong November 2000 issue) must be given due consideration.

Directional notices must not exceed one square foot in area and all borders must be included in the calculation.

## ***IV. Notices of Consulting Hours***

Every registered medical practitioner is permitted to exhibit one separate notice containing his name and details of his surgery hours provided that this information is not already shown on some other sign. The placement of such a notice is left entirely to the practitioner. However, it is emphasized that only one such notice is permitted and its maximum size, including borders, is limited to two square feet.

## **Routine Environmental Cleaning**

*Definition: Routine cleaning refers to regular and conscientious general cleaning and aims to achieve a clean environment.*

**Notes:**

- Extraordinary measures do not need to be taken in a general practice environment. Routine cleaning with detergent and water is sufficient for almost all surfaces.
- Damp wiping of surfaces and damp mopping of smooth floors is the preferred method as dry dusting and sweeping will cause airborne bacteria levels to rise.
- Cleaning is best accomplished with water, detergents and mechanical action.
- There should be a documented routine cleaning schedule for use by practice staff and cleaners and if outside contractors are employed, such a schedule should be included in the cleaning contract.
- A daily cleaning routine should include all bench tops and trolleys, examination and treatment couches, protective eyewear, reusable aprons, sinks, floors, toilets/bathroom, food handling and eating areas.
- Weekly cleaning should include waiting room and office furniture and waiting room toys. When making up a detergent solution for surface cleaning, strictly adhere to the recommended dilution. All cleaning agents mixed should be discarded at the end of the day. Spray bottles should be emptied at the end of the day, rinsed and left upside down to dry overnight.
- Buckets, cleaning cloths and mop heads should be stored clean and dry between uses. Sponges do not dry out easily and should not be used.
- General purpose gloves should be worn when cleaning (protective eye wear and gown as well if there is a risk of splashing).
- Review the cleaning products (read the labels) available in the practice and try to rationalize them as it is far more cost effective to use one good detergent for all cleaning processes than to spend a lot of money on many similar products. Mild alkaline detergents are preferred over neutral pH detergents in most applications because alkalinity improves the detergent's cleaning efficacy. The product should be in the pH range of 8–10.8.
- Surfaces should not be left wet as this encourages the growth of microorganisms.

## **“Spills” Protocol**

A *standard precautions* policy under which all blood and body fluids are considered potentially infectious should be implemented in all health-care settings.

Personal protective equipment should be used, heavy duty gloves are essential and the use of an apron and protective eyewear may also be indicated.

Any blood or body fluid that is split should be dealt with immediately. The area needs to be assessed and a decision made as to how the spill is to be removed.

### **Spills of blood product**

- In the general practice setting blood spills are infrequent and usually quite small – less than a few millimeters.
- Spills of this type are best first contained using a blotting action with paper towels to remove all visible contaminants and then cleaned by wiping over with detergent and cool water.
- Spills of larger volumes can be contained by the use of paper towels or granular ‘swimming pool’ chlorine or absorbent granules. The spill, paper towels/absorbent granules should be placed into a *labeled biohazard bag* supported in a rigid container. This is followed by cleaning the spill site with *10,000ppm hypochlorite solutions*.

### **Spills of vomitus**

- If vomitus is involved, the bulky portion can be picked up between two sheets of cardboard before the use of paper towels or absorbent granules.
- The spill, cardboard sheets, paper towels/absorbent granules is placed into a usual waste bag. This is followed by cleaning the spill site with *1,000ppm hypochlorite solutions*.

*The area in all instances should be dried before it is used again. This becomes more complex if the spill is on carpet or soft furnishings in the waiting area of the practice in which case the area should be quarantined until dry.*

## DISINFECTION

*Definition: The removal or inactivation of pathogenic microorganisms from inanimate objects or surfaces. Note: The degree of reduction does not meet the requirements of a sterilization process.*

Disinfection (not a sterilizing process) can be achieved by thermal (hot water) systems and chemical disinfectants.

The margin of safety and efficacy of chemical disinfectants able to be used in general practice is very small and so their use should be limited, as detailed below, wherever possible.

### **Notes:**

1. Sterilization is the preferred process for all reusable instruments and equipment (non-critical, semi-critical, and critical) that can withstand this process regardless of their intended reuse.
2. Pre-cleaning and cleaning **MUST** be performed prior to both thermal and chemical disinfection to reduce the bio-burden in order to achieve a effective disinfection process. The cleaning process can be achieved either manually or ultrasonically.
3. If an item cannot be cleaned it cannot be disinfected.

### **Thermal (Hot water) disinfection**

- Thermal disinfection uses heat and water at temperatures that destroy pathogenic vegetative organisms. When suitable, this is the most efficient and cost effective method of disinfection. It does not kill all bacterial spores and therefore cannot sterilize instruments.
- **Given that thermal disinfection does not achieve sterilization, thermal disinfection can only be used for instruments not intended to penetrate skin, mucous membrane and/or other tissue i.e. low risk (*non-critical*), and medium risk (*semi-critical*) items only.**
- Thermal disinfection (hot water/pasteurizers) should be used in preference to chemical disinfection.
- For items that are unlikely to contain high numbers of heat-resistant organisms, the following minimum surface temperature–time relationship for thermal disinfection is recommended.

Surface temperature (°C)	Minimum disinfection time (min)
90	1
80	10
70	100

**Notes:**

- Instruments should be removed aseptically and placed on a clean or disinfected surface to cool down. At all times avoid any contact between contaminated instruments and the disinfected instruments. (This can be difficult as clean instrument looks the same as one that has been disinfected – sterilization in a package serves to reduce this risk.)
- Careful maintenance and attention to the quality of the water is essential for proper disinfection. Water should be changed daily with clean, distilled, pre-boiled or deionized water.

**Chemical disinfection**

- Chemical disinfection should only be used when effective thermal disinfection is inappropriate. Sterilization for high-risk (*critical*) items and thorough, routine cleaning for surfaces and low risk (*non-critical*) items have largely replaced routine chemical disinfection.
- Chemical disinfection is primarily suitable for medium-risk (*semi-critical*) items such as thermometers or flexible endoscopes that can be damaged by heat or steam. Chemical disinfectants should not be used for instruments categorized as high-risk (*critical*).
- Use of disinfectants should be limited to *semi-critical* items and environmental surfaces.
- For many *non-critical* items it has been found that thorough cleaning is at least equally reliable for appropriate infection control compared to soaking in a disinfectant. The use of chemical disinfectants for soaking is problematic because of the risks of contaminating the solution and relying on the chemical rather than thorough cleaning. However, chemical disinfectants do have a place and their correct use will result in lowering of the bio-burden of a surface or item, thus aiding good infection control practices.

## SUMMARY OF CHEMICAL DISINFECTANTS

Disinfectants	Properties	Disadvantages
<i>Alcohols</i>	<ul style="list-style-type: none"> <li>● A concentration of 70-90% v/v of alcohol, but not more than 90%, is recommended for use as chemical disinfectant</li> <li>● Reusable ear pieces &amp; thermometers that have been thoroughly washed in detergent and dried can be wiped with 70% alcohol and stored dry</li> </ul>	<ul style="list-style-type: none"> <li>● Evaporation may diminish its concentration</li> <li>● No residual action</li> <li>● Inactivated by organic material</li> <li>● May harden rubber and cause deterioration of glues</li> </ul>
<i>Glutaraldehyde (Cidex)</i>	<ul style="list-style-type: none"> <li>● Can destroy viruses and bacteria within 4 minutes</li> <li>● Most advisory authorities recommend a 20 – minute soak time for standard situation</li> </ul>	<ul style="list-style-type: none"> <li>● Can cause damage to patient, user, instruments and the environment if proper precautions not instituted</li> </ul>
<i>Chlorhexidine</i>	<ul style="list-style-type: none"> <li>● No place in instrument disinfection or storage</li> <li>● Useful as a skin antiseptic</li> </ul>	<ul style="list-style-type: none"> <li>● Contamination by <i>Pseudomonas</i> &amp; other gram –ve organisms is not unusual</li> <li>● Seriously inactivated by many materials including many soaps and detergents</li> </ul>
<i>Hypochlorite</i>	<ul style="list-style-type: none"> <li>● Not suitable for instrument disinfection</li> <li>● Useful for cleaning environmental surfaces</li> </ul>	

## **Sterilization**

*Definition: A validated process used to render a product free from all forms of viable microorganisms. The nature of microbial death is described by an exponential function and although the probability can be reduced to a very low number, it can never be reduced to zero.*

Sterility can be achieved by steam sterilization under pressure at 121–134°C and by dry heat at 150–160°C, or by large scale systems of ionizing radiation, ethylene-oxide or chemical treatment that are not applicable in office practice.

A comprehensive sterility assurance program incorporates every aspect of processing including cleaning, packaging, loading the sterilizer, monitoring the sterilization cycle, unloading the sterilizer, storage, distribution and handling to the point of use.

### **Steam under pressure (Autoclaves)**

Steam under pressure is the most reliable way of sterilizing cleaned instruments and it is recommended for use in general practice. In general practice, the self-contained bench-top sterilizer is most frequently used.

Sterilizers work by transferring the latent heat of condensation to the microbes on the surfaces of the instruments. This results in coagulation of the microbe's protein structures.

#### **A. Types of steam sterilizers**

1. ***Portable.*** Air removal in this type of sterilizer is by a relatively slow process relying partly on displacement of the air by steam, and partly on mixing of chamber air with steam generated by water boiling within the chamber. Air is gradually removed as the air/steam mixture is continually being released via the chamber drain line back to the sterilizer's internal water reservoir during the air removal phase of operation.
2. ***Assisted air removal, portable.*** Air removal in this type of sterilizer is like that described in 1 above, but is greatly assisted by several positive steam pressure excursions followed by release of pressure nearly to atmospheric pressure during the air removal phase of operation of the sterilizer.
3. ***Pre-vacuum, portable.*** Air removal in this type of sterilizer utilizes one or more vacuum stages together with positive excursion(s) of steam under pressure. The utilization of chamber pressures below atmospheric pressure, 'vacuum', defines this type of sterilizer as a pre-vacuum steam sterilizer and different approaches to sterilizer design, testing and routine monitoring of machine function become necessary. Currently these include leak rate test, Bowie Dick type air removal test, and air detector function and performance tests.

## **B. Procedures**

- Thorough cleaning of instruments → packing of instruments → loading of instruments into the autoclave → sterilisation → unloading → storage of sterilised items

## **C. Packaging of instruments prior to sterilization**

- Aim to provide an effective barrier against sources of potential contamination in order to maintain sterility and to permit aseptic removal of the contents of the pack
- Packages and/or wrapped items must be completely dry prior to opening the door, otherwise sterility is compromised (If a wrapped item emerges from the sterilizer wet, it cannot be considered sterile)
- Unpackaged items do not remain sterile and therefore cannot be stored for later use in sterile procedures (even if stored inside the sterilizer) but can be used immediately

### **Notes:**

1. Sharp instruments may perforate the material. Tip protectors which allow exposure to steam are available.
2. Instruments should be open and unlocked.
3. Mixed packs containing instruments, gauze and a small amount of material for a sterile field are acceptable provided they are validated.
4. Hollow items such as bowls and kidney dishes should be packed with the open side against the paper if laminated packaging is used so that steam is not later trapped by the plastic.
5. No not use pins, staples, string or non-adhesive tape to seal packages.
6. If using laminated rolls or pouches which require heat sealing the plastic side should be closest to the heat source when being sealed.

## **D. Loading**

- Bench top portable sterilizers that are typically used in general practice eliminate the air inside the chamber by displacing it with steam. The air inside the sterilizer chamber and the load must be removed by the incoming steam so that the pressure inside the chamber is entirely due to steam. Any residual air will contribute to the total pressure, making the 'steam' pressure registered by the gauges inaccurate and thereby compromising the sterilization process. This means that cylinders or boxes with lids that will trap air cannot be sterilized in these sterilizers.
- In sterilizers with a drying cycle, items sealed in laminate (paper/plastic) packaging or pouches must be positioned on their edge to enable air removal and steam penetration. Care needs to be taken when loading the sterilizer that the steam can circulate effectively and that all surfaces are accessible and exposed to the steam. Suitable racks to separate packaging work very well.
- Care must be taken not to overload trays. Ensure adequate space to allow steam circulation. Items should be placed on perforated or mesh trays. 'Toast' racks can be used to evenly separate small instrument packs. Items to be sterilized in a sterilizer without a drying cycle must not be wrapped. Bowls, kidney dishes, jugs etc. should be tilted on their edge to allow the steam to displace the air and also to allow drainage of condensate. If drapes are being sterilized, position them on their edge to provide the least resistance for the passage of steam.

- General rules to follow when loading the sterilizer:
  - All items should be neatly packed ensuring adequate space between each item to allow air removal and steam penetration. Items should not be crushed together.
  - The sterilizer should be loaded in a manner that prevents items touching the floor, top or walls of the chamber.
  - Hollow items should be positioned on the edge.

### **E. Unloading**

- ***Sterilizers with a drying cycle*** – Once the cycle is completed, the contents of the chamber should be removed and visually inspected to ascertain that the load is dry, the packaging is intact and the indicator(s) have changed color. Directly after the sterilizing process, items are vulnerable to recontamination by moisture or improper handling. Hot or warm items must not be placed on a solid surface as this may cause condensate to form. Allow items to cool inside the chamber or on a cooling rack; a mesh cake rack can be used for this purpose. Any items that are dropped, torn, wet, have broken seals or the chemical indicator on the packaging has not changed color, should be considered as contaminated and reprocessed – that is, they must be re-packaged before sterilization.
  
- ***Sterilizers without a drying cycle*** – On completion of the cycle, the door of the sterilizer should be opened, color change of the chemical indicator noted and items allowed to cool. Items should be used as soon as they are cool enough to be handled to reduce the possibility of recontamination. Items sterilized in this way cannot be stored either dry or in the sterilizer or left soaking in an antiseptic ‘bath’ and used later as ‘sterile’.

### **G. Sterilisation time**

- Whenever the sterilizer is used, the operator should ensure that the recommended time at temperature and pressure is maintained.
- The ‘holding time’ does not include the time taken for heating the load to the desired temperature (penetration time). Wrapped items will have a longer penetration time than unwrapped loads and hence a longer sterilization time.
- The penetration time is often preset by manufacturer
  
- ***Total processing time = Penetration time + Holding time + Safety factor***

Temp (°C)	Pressure			Holding Time( Min) Plus safety factor
	KPa	Psi	bar	
121	103	15	1	15
126	138	20	1.4	10
132	186	27	1.8	4
134	206	30	2	3

(Modified from Australian Standard AS4187)

## **H. Monitoring of the Sterilisation Cycle**

- Monitoring of sterilization cycles can be best accomplished by a combination of several distinct methods and recorded in a log.
  
- Methods of monitoring:
  - (1) ***Mechanical/physical:***
    - Time and temperature monitoring, either manually or by automatic printout or computerised data logger
  
  - (2) ***Chemical indicators:***
    - Often incorporated on the ready made pouches and packages for wrapping instruments
    - In the form of stripes and shapes that changes colour. Chemical indicators merely provide a visible indicator that the conditions required to achieve sterilisation, such as time temperature and pressure, have been met.

**Class 1 – process indicators**  
**Class 4 – multi-parameter indicators**  
**Class 5 – integrating indicators**  
**Class 6 – emulating indicators (cycle verification indicators)**

### **(3) *Biological/enzymatic indicators***

- Monitor the actual effectiveness of the sterilisation process, which is intended to kill all microbes, including spores. The spores chosen for biologic monitoring must be appropriate for the method of sterilisation being monitored. *Bacillus stearothermophilus* spores are preferred for autoclaves
- The biological/ enzymatic indicators are placed together with the instruments to be sterilised inside the pack. After the cycle is complete, the spores are then incubated along with an un-sterilized control. Traditionally, commercially prepared biologic indicators require an incubation time of 24 to 48 hours prior to reading. Nowadays, the use of enzymatic indicator of a spore-bound enzyme offer much quicker reading.

## **I. Frequency of monitoring**

- Mechanical and Chemical monitoring are recommended for each cycle of sterilisation
- Biologic monitoring is recommended for at least once per week according to the Canadian Guideline.

## **J. Maintenance of the autoclave**

- Routine servicing by practice staff according to manufacturer's instructions,
- Cleaning of the autoclave's trays and racks and regular calibration is needed
- Twelve monthly servicing and calibration by a qualified technician is necessary and evidence of this maintenance should be retained.

## **Dry Heat Ovens**

Seldom used in Hong Kong

### Sterilisation Time:

<b>Temp(°C)</b>	<b>Holding time (Min)</b>
160	60
170	40
180	20

Monitoring and maintenance is similar to autoclaves.

## Waste Management

2 main types: Clinical waste and General waste

### Clinical waste:

- The clinical waste control scheme is effective in Hong Kong, as under the Waste Disposal Ordinance and the Waste Disposal (Clinical Waste) (General) Regulation, since 1 August 2011.
  - <http://www.epd.gov.hk/epd/clinicalwaste/nonflash/eindex.html>
- Clinical Waste: from medical premises or laboratory; has the potential to cause disease/ cuts and needle-stick injuries to, people at the work place, cleaners, waste handlers, and the general public. Examples: discarded sharps, laboratory waste, animal and human tissue, blood, swabs and dressing.
- Examples of major clinical waste producers:
  - Hospitals, government clinics, nursing homes (including dialysis center)
- Examples of small clinical waste producers:
  - Private medical and dental clinics, medical laboratories, residential care homes/ elderly homes, universities with medical teaching or research
- Code of practice for major/ small clinical waste producers available:
  - <http://www.epd.gov.hk/epd/clinicalwaste/nonflash/english/best/practices.html>
    - Segregation, packaging, labeling:
      - Leak-proof, yellow/ red containers/ bags for respective types of clinical wastes, label with clinical waste symbol, tag showing the waste producer's name /address/ date of sealing.
    - Storage:
      - Well partitioned area or cupboard, warning sign
    - Collection and transportation:
      - By waste producers themselves, or through licensed waste collectors. Record keeping: for 12 months from the date of consignment/delivery.
    - Staff training:
      - Planning, supervision and training: to prevent danger or injury to staff and public; prevent nuisance to neighborhood.

### General waste:

- Other than clinical waste defined as above.
- Include: office waste, kitchen waste, urine, feces, teeth, hair, nails, sanitary napkins, tampons, disposable nappies, used tongue depressors, disposable vaginal speculae, cervical cytology spatulas and non-hazardous pharmacological waste.

## **Needle Stick Injury & Blood/Body Substance Occupational Exposure Management Protocol**

The blood and body substances of all people are potential sources of infection regardless of diagnosis or perceived risk.

<i>Types of Accidents</i>
<ul style="list-style-type: none"> <li>• Injury from a needle or sharp that has been in contact with blood or other body substances</li> <li>• Blood or body substance in eyes/nose/mouth</li> <li>• Blood or body substance on non-intact skin.</li> </ul>

<i>Classification of Exposures</i>	
<b>Percutaneous exposure to blood</b>	<p><i>High risk:</i></p> <ul style="list-style-type: none"> <li>• BOTH exposure to a large volume of blood (eg. deep injury with a large diameter hollow needle previously in the source patient's vein or artery) AND</li> <li>• Exposure to blood containing high titer of HIV, hepatitis B or hepatitis C.</li> </ul> <p><i>Low increased risk:</i></p> <ul style="list-style-type: none"> <li>• NEITHER exposure to a large volume of blood NOR exposure to blood with a high titre of HIV, HBV, HCV.</li> </ul>
<b>Mucous membrane exposure</b>	Exposures to eyes or mouth involving blood, fluid containing visible blood or other potentially infectious fluids
<b>Significant skin exposure</b>	Exposures of non-infectious skin involving blood, fluid containing visible blood or other potentially infectious fluids
<b>Other exposure</b>	Percutaneous, mucous membrane or cutaneous exposures to non-blood stained urine or saliva

Following a needle stick injury or other exposure to a body substance:

**1 Clean/Decontaminate:**

- Skin: wash with soap and water
- Mouth, nose, eyes: rinse well with water or saline.
- The wound should then be disinfected and appropriately dressed

**2 Report the incident to a medical practitioner or infection control nurse about:**

- The nature of the incident/substance exposure
- The time of the incident
- How the incident happened
- Exactly what the staff was injured with (specify the gauge of the needle)
- How much source patient blood/body fluid was on the sharp or splashed on the staff, and what personal protective equipment (if any) the staff was using.

\* *If the source of the sharp/blood/body fluid is not known, document 'source patient not known'.*

\* *If the incident occurred during a procedure, you must document whether or not, after the injury, any of your blood went into the patient or onto instruments that were then used. If the patient has been exposed to your blood from the injury, then you also have a duty of care for the patient.*

**3 Obtain informed written consent from the source patient for testing for hepatitis B, hepatitis C and HIV.**

- The source patient's confidentiality must be maintained.
- Reassure the patient that he/she is not responsible for the accident and that he/she has not been exposed.
- Explain to the source patient that you want to do the tests because:
  - Every health care facility follows this protocol after an exposure of a health care worker to blood or body fluids
  - All source patients are asked to be tested, there is, no discrimination, and you have a duty of care to the exposed person.

\* *Most patients will agree to a blood test if they are approached in a sensitive manner.*

*Ask the source patient if they are prepared for possible psychological and social consequences if their blood test is positive for HIV or hepatitis B or hepatitis C.*

***The injured staff and the source patient can be diverted to Accident & Emergency Department for procedures 4 to 11.***

**4 Ask the source patient about at-risk activities, especially in the past 6 months:**

- Unprotected sexual intercourse
- Sharing needles, or tattoos, or body piercing
- Sharing razor blades, or sharing toothbrushes
- Another person's blood on their mucous membranes (eyes or mouth or nose)
- Another person's blood on their non-intact skin (cuts, abrasions, dermatitis, eczema, acne, tinea)
- Previous transfusion, especially before 1990 (for hepatitis C)

- 5** *Ask the source patient has he/she ever been told that he/she has HIV or hepatitis B or hepatitis C? Inform the source patient that, if he/she has had at-risk activities, a blood test might not show it until 3-6 months after the at-risk activity.*
- 6** *Obtain informed written consent from the exposed practice worker for testing for hepatitis B, hepatitis C and HIV.*
- These ‘baseline’ tests establish whether the health care worker has previously acquired an infection from other exposures or at-risk activities.
  - The health care worker’s confidentiality must be maintained, and staff may choose to have these tests performed at a different general practice or at a hospital emergency room or at an STD clinic.
  - Advise the health care worker to practice ‘safer sex’ (use condoms) until their results, the patient’s results and the patient’s risk history have been reviewed.
- 7** *Have the source patient’s blood tested as soon as possible.*
- 8** *If the source patient’s HIV results will not be available within 24 hours and if either:*
- The source patient is likely to be positive or in the window period, or
  - It was a high-risk injury from an unknown source then chemoprophylaxis should be commenced, and then reassessed when test results become available.
- 9** *If the health care worker does not know their hepatitis B status, request urgent results for hepatitis B on the health care worker and the source patient.*
- Remind the injured health care worker that they MUST return within 48 hours of the incident (or sooner) to find out their hepatitis B immune status (unless immunity is already documented).
  - If the source patient’s hepatitis B result will not be available within 24–48 hours, and if the health care worker’s hepatitis B status is not documented, then give:
    - Hepatitis B immunoglobulin, and
    - Hepatitis B vaccine (first dose).
- 10** *If the needle had been in rubbish or on the floor, also consider the health care worker’s tetanus status. Administer ATT if necessary.*
- 11** *The exposed practice worker must be referred for immediate consultation with an infectious diseases specialist:*
- If the injury is classified as high risk, or
  - If the source patient has had at-risk activities, or
  - If the source patient has a positive blood test.

## **Handling and Disposal of Sharps**

- Safe use and disposal of sharp articles and instruments is necessary to prevent injury and the possible transmission of disease to those who handle discarded materials.
- Sharps includes needles, scalpel blades, ampoules, broken glass, sharp, plastic items and single use punch biopsy equipment.
- Scalpels and needles should be passed in a rigid container or kidney dish if required during procedures if an assistant is used.
- Needles must not be recapped (unless this can be carried out by a safe method with specifically designed equipment), removed from disposable syringes, or broken or bent by hand after use because these maneuvers can cause skin puncture.

### **Sharps Container**

- All disposable sharp articles and instruments must be placed into an approved disposable sharps container immediately after use or at the end of each procedure.
- Sharp containers are yellow, made from puncture resistant material and show a bio-hazard sign. They should be placed in all areas where sharps are generated.
- Care should be taken in the placement of sharp containers so that children cannot reach them under any circumstances. They must not be located on the floor as children can be injured by putting their hands inside.
- Items must not be forcefully inserted. Otherwise, they may puncture the container.
- Containers should not be filled past the three-quarter level (the red line). Once this level is reached they should be sealed and stored securely prior to disposal.
- Items inadvertently dropped in sharps container should not be retrieved.

### **Note:**

If practice staff finds a sharp that has not been discarded into a sharps container, e.g., a needle or blade on the floor or in a rubbish bag, they must:

- use appropriate care to pick up and correctly dispose of the sharp
- report the incident to the practice manager or principal doctor, describing the type of sharp and the place it was found. Incidents of incorrect disposal of sharps should be investigated, with the aim of *preventing such incidents from recurring*.

## **Procedures of Proper Dispensing**

Pharmacist or dispenser is advised to follow the “*3checks 5rights principles*” before any drug is going to be dispensed:

**1<sup>st</sup> Check:** *Checking **BEFORE** taking the medication out from the container*

**2<sup>nd</sup> Check:** *Checking **AFTER** removing the medication from the container*

**3<sup>rd</sup> Check:** *Checking of the medication **against the container** before dispensing*

**1<sup>st</sup> Right:** *Right **PATIENT**—Patient’s name and Drug allergy*

**2<sup>nd</sup> Right:** *Right **DRUG***

**3<sup>rd</sup> Right:** *Right **DOSE***

**4<sup>th</sup> Right:** *Right **ROUTE***

**5<sup>th</sup> Right:** *Right **TIME** —time of administration*

**Note:**

*Should pharmacist/dispensers have any doubt during the course of the dispensing procedure, they should withhold drug dispensing until verified by the doctor who writes the prescription.*

## **Vaccine Storage**

### **The Cold Chain**

- The cold chain is the system of transporting and storing vaccines within the safe temperature range of +2° C to +8° C
- The cold chain begins from the time the vaccine is manufactured, moves through to the state or territory vaccine distribution centers and ends when the vaccine is administered
- Vaccines must be stored and transported at all times within the recommended temperature range of +2° C to +8° C

### **Use of Domestic Refrigerator for Vaccine Storage**

Domestic refrigerators are not recommended for vaccine storage because:

- Temperature varies significantly every time the door is opened
- Cabinet temperature is easily affected by ambient temperature
- Temperature setting is crude and inaccurate

But it is possible to manage domestic refrigerators to reduce the risks to vaccines if the following steps are followed:

1. The refrigerator is used exclusively for the storage of vaccines
2. The refrigerator maintains temperature without fluctuating into the danger zones (< +2° C, > +8° C)
3. The refrigerator is reliable and has not required repairs over the last 2 years
4. The refrigerator is free of any water or coolant leaks
5. The seals are in good condition and are sealing tightly
6. The door of the refrigerator closes properly

*If the above criteria are not met, a purpose-built vaccine refrigerator should be considered*

### **Using domestic refrigerator for vaccine storage**

1. Ensure the refrigerator is placed out of direct sunlight and the manufacturer's instructions for air circulation around the back and sides are followed
2. Ensure the power source is marked clearly in way to prevent the refrigerator from being accidentally unplugged or turned off
3. Place water bottles or ice-packs in the freezer to stabilize the temperature
4. Fill the lower drawers and the door with plastic bottles/containers filled with water. Leave a small space between the bottles/containers
5. Modify and stabilize the temperature of the refrigerator before stocking with vaccine
6. Recording temperature throughout the refrigerator. The key areas to monitor are on each shelf from top to bottom, front to back and side to side.
7. Store the vaccines in enclosed plastic containers, in their original packaging. Do not crowd the vaccines by overfilling the shelves. Ensure a gap of at least 4cm from all refrigerator walls, including the back.
8. Vaccines must never be stored in the door of the refrigerator.
9. Place freeze-tolerant vaccines (e.g. MMR, Oral Polio, BCG vaccines) in the shelves identified as being the coldest and freeze-sensitive vaccines (e.g. DPT, Hib, Pneumococcal, Influenza, Hepatitis, Inactivated Polio, some Varicella vaccines) are better placed on the

shelves where the temperature is more stable.

10. Ensure that each domestic refrigerator storing vaccine has a maximum/minimum thermometer and a temperature recording chart.
11. Check the record maximum/minimum temperatures at least daily, before the vaccine is used.
12. Keep the door closed as much as possible. The refrigerator should have a sticker to remind staff to keep door opening to a minimum.
13. Establish and document protocols for response to cold chain breaches.

## **Management of Cold Chain Problems**

### **A. Power failure**

#### ***Domestic refrigerator***

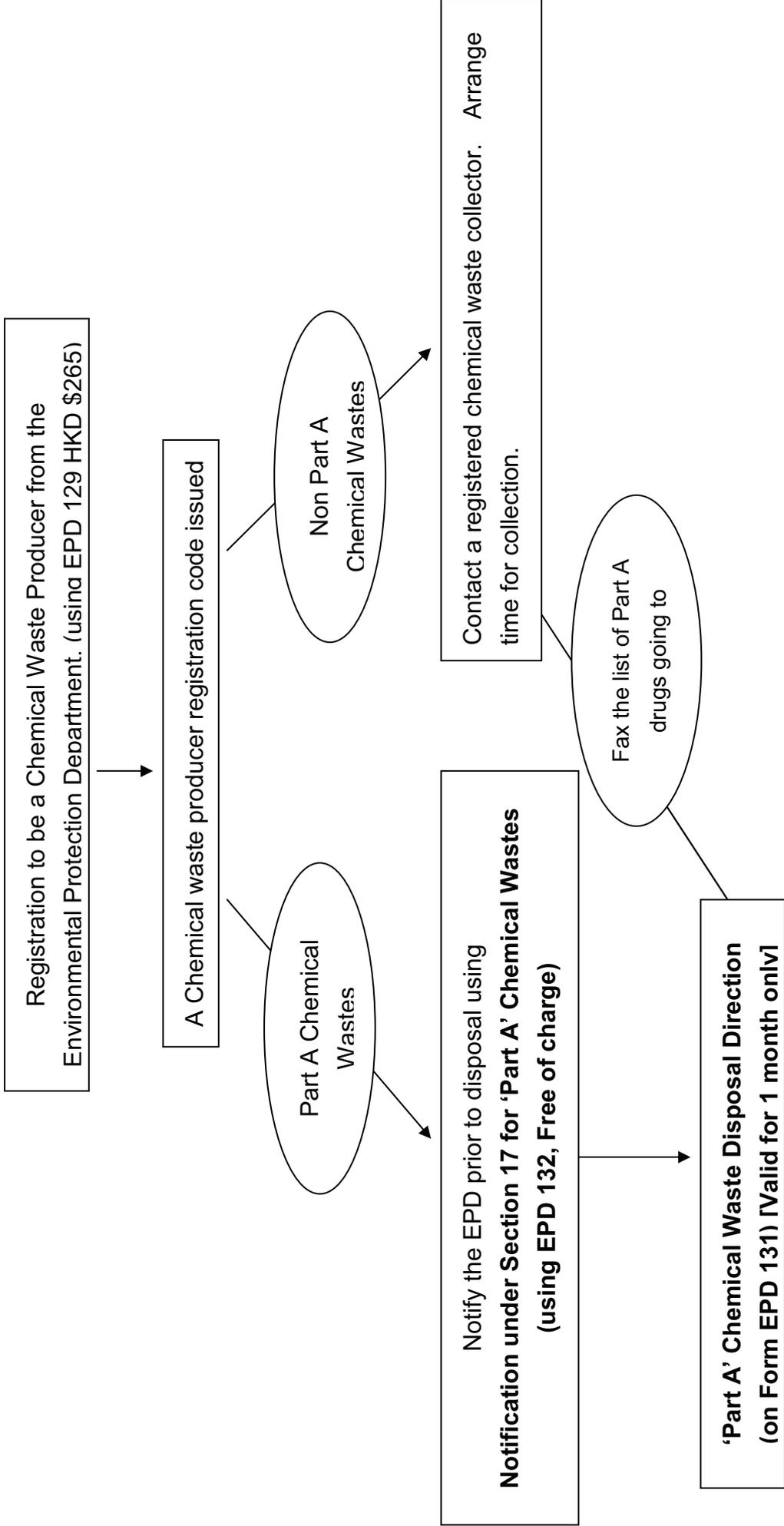
- During a power failure of  $\leq 4$  hours, the refrigerator door should be kept closed
- For power failure  $> 4$  hours, store the vaccines in a cooler with conditioned ice packs/gel packs. Continue to monitor the temperature of the vaccines by placing the thermometer probe inside a vaccine box inside the cooler.

#### ***Purpose-built vaccine refrigerator***

- Monitor the temperature of the refrigerator. If vaccines are at risk, use alternative storage arrangements.

### **B. Cold Chain Breach**

1. Immediately isolate the vaccines until you have been in touch with the relevant vaccine manufacturer /drug company
2. Keep vaccines refrigerated between  $+2^{\circ}$  C &  $+8^{\circ}$  C and label "DO NOT USE"
3. Do not discard any vaccine until advice has been sought from the vaccine manufacturer or drug company
4. Take active steps to correct and prevent the problem recurring



## Chapter 134 DANGEROUS DRUGS ORDINANCE

### CAP 134A DANGEROUS DRUGS ORDINANCE

Chapter:	134A	Title:	DANGEROUS DRUGS REGULATIONS	Gazette Number:	L.N. 556 of 1997; L.N. 3 of 1999
Regulation:	3	Heading:	<b>Requirements with respect to prescriptions</b>	Version Date:	15/01/1999

(1) A person by whom a prescription prescribing a dangerous drug is given shall comply with the following requirement that is to say, the prescription shall-

- (a) be in writing and signed by the person giving it with his usual signature, and be dated by him;
- (b) be in ink or otherwise so as to be indelible;
- (c) specify the address of the person giving it;
- (d) specify the name, identity card number and address of the person for whose treatment it is given or, if it is given by a registered veterinary surgeon, of the person to whom the article prescribed is to be delivered; (L.N. 191 of 1996; L.N. 556 of 1997)
- (e) have written thereon-
  - (i) if given by a registered dentist, the words "For local dental treatment only" (僅供本地牙治療之用); and
  - (ii) if given by a registered veterinary surgeon, the words "For animal treatment only" (僅供動物治療之用); (L.N. 556 of 1997)
- (f) if the dangerous drug prescribed is a preparation, or if all the dangerous drugs prescribed are preparations,- (L.N. 191 of 1996)
  - (i) specify the total amount of the preparation or of each preparation, as the case may be; or
  - (ii) when the preparation is packed in ampoules, either specify as aforesaid or specify the total amount of the preparation or of each preparation, as the case may be, intended to be administered or injected; and
- (g) if the dangerous drug is not a preparation, specify the total amount of the drug to be supplied. (L.N. 191 of 1996)

(2) In the case of a prescription given for the treatment of a patient in a prescribed hospital or a health centre maintained by the Crown, sub-paragraph (d) of paragraph (1) shall be deemed to have been complied with if the prescription is written on the patient's bed card or case sheet, and in such a case the initials of the person giving the prescription shall be a sufficient signature for the purposes of sub-paragraph (a) of paragraph (1).

(3) For the purpose of paragraph (1)(d), in the case of a person who is not resident in Hong Kong, the reference number of any proof of identity other than an identity card shall be specified in the prescription. (L.N. 191 of 1996)

[cf. S.I. 1964/1811 reg. 14 U.K.]

Chapter: 134A	Title:	DANGEROUS DRUGS REGULATIONS	Gazette Number:
Regulation: 4	Heading:	<b>Marking of packages and bottles</b>	Version Date: 30/06/1997

(1) Save as provided in paragraph (2), no person shall-

(a) supply a dangerous drug, other than a preparation, unless the package or bottle in which it is contained is plainly marked with the amount of the dangerous drug contained therein; or

(b) supply a preparation, unless the package or bottle in which it is contained is plainly marked-

(i) in the case of a powder, solution or ointment, with the total amount thereof in the package or bottle and the percentage of the dangerous drug contained in the powder, solution or ointment; or

(ii) in the case of cachets, single dose injections, lozenges, suppositories, pills, tablets or similar articles, with the amount of the dangerous drug in each article and the number of articles in the package or bottle.

(2) Paragraph (1) does not apply-

(a) in a case where a preparation is lawfully supplied by a registered medical practitioner;

(b) in a case where a preparation is lawfully supplied on a prescription lawfully given by a registered medical practitioner; or

(c) in relation to the supply of a dangerous drug specified in Part III of the First Schedule to the Ordinance.

(3) Any person who contravenes paragraph (1) shall be guilty of an offence and shall be liable on conviction to a fine of ten thousand dollars and to imprisonment for twelve months.

[cf. S.I. 1964/1811 reg. 16 U.K.]

Chapter:	134A	Title:	DANGEROUS DRUGS REGULATIONS	Gazette Number:	L.N. 556 of 1997; L.N. 3 of 1999
Regulation:	5	Heading:	<b>Keeping of register or other records</b>	Version Date:	15/01/1999

(1) Every person authorized by or licensed under the Ordinance to supply a dangerous drug, except a sister authorized by section 22 of the Ordinance, shall comply with the following provisions, that is to say-

(a) he shall, in accordance with this regulation and regulation 6, keep a register and enter therein in chronological sequence in the form specified in the First Schedule true particulars with respect to every quantity of a dangerous drug, other than a preparation specified in Part II of the First Schedule to the Ordinance, obtained by him and with respect to every quantity of a dangerous drug, other than a preparation specified in Part II of the First Schedule to the Ordinance, supplied by him, whether to persons within or outside Hong Kong;

(b) he shall use a separate register or separate part of the register for entries made with respect to each of the dangerous drugs specified in paragraph 1 of Part I of the First Schedule to the Ordinance or in paragraph 2, 3, 4, 5, 6 or 7 thereof and for this purpose-

(i) each such drug shall be deemed to comprise its salts and any preparation, admixture, extract or other substance containing any proportion of it or its salts; and

(ii) any isomer of a dangerous drug the existence of which is possible within its specific chemical designation shall be deemed to be identical with that drug;

(c) he shall use a separate page within the register or separate part of the register for entries made with respect to different dangerous drugs and different strengths of preparations comprised within the class of dangerous drugs to which that register or separate part relates. (L.N. 191

of 1996)

(2) (Repealed L.N. 191 of 1996)

(3) Where a registered medical practitioner, a registered dentist, a registered veterinary surgeon or a specified person obtains or supplies any dangerous drug (which, in the case of the specified person, means a specified dangerous drug) packed in ampoules, he shall be deemed to have complied with the requirements- (2 of 1992 s. 13; L.N. 556 of 1997)

(a) of paragraph (1) in regard to entry in the register required to be kept under that paragraph of true particulars with respect to every quantity of every dangerous drug obtained or supplied; or

(b) (Repealed L.N. 191 of 1996)

if he enters as the amount which he has obtained or supplied, as the case may be, true particulars as to either the total quantity of the dangerous drug or the total quantity thereof intended to be administered or injected.

(4)-(5) (Repealed L.N. 191 of 1996)

(6) (a) Subject to sub-paragraph (c), a manufacturer of any preparation specified in Part II of the First Schedule to the Ordinance and a wholesale dealer in any such preparation shall keep every invoice or other like record issued in respect of each quantity of any such preparation obtained by him and in respect of each quantity of any such preparation supplied by him.

(b) A retail dealer in any such preparation shall keep every invoice or other like record issued in respect of each quantity of any such preparation obtained by him.

(c) Sub-paragraph (a) does not apply in the case of a preparation manufactured by a registered medical practitioner, or by a person referred to in subsection (5) of section 22 of the Ordinance, under the authority conferred by sub-section (4) or (5) of the said section 22, as the case may be.

(7) Any person who contravenes any of the provisions of paragraph (1) or (6) shall be guilty of an offence and shall be liable on conviction to a fine of \$450000 and to imprisonment for 3 years. (L.N. 191 of 1996; L.N. 201 of 1996)

(8) It is a defence for a person charged with committing an offence under paragraph (7) in relation to paragraph (1) to show that he took all reasonable steps and exercised all due diligence to avoid committing the offence. (L.N. 288 of 1996)

[cf. S.I. 1964/1811 reg. 17 U.K.]

Chapter:	134A	Title:	DANGEROUS DRUGS REGULATIONS	Gazette Number:
----------	------	--------	--------------------------------	--------------------

The following requirements shall be complied with by any person required to keep a register under regulation 5, that is to say-

- (a) there shall be specified at the head of any page of such register-
  - (i) the class of dangerous drugs; and
  - (ii) where applicable, the particular dangerous drug and the particular strength of the preparation comprised within such class, to which the entries on that page relate; (L.N. 191 of 1996)
- (b) every entry required to be made under regulation 5 in such register shall be made on the day on which the dangerous drug is received or, as the case may be, on which the transaction with respect to the supply of the dangerous drug by the person required to make the entry takes place, or, if that is not reasonably practicable, on the day next following the said day;
- (c) no cancellation, obliteration or alteration of any such entry shall be made, and every correction of such an entry shall be made only by way of a marginal note or footnote which shall specify the date on which the correction is made;
- (d) every entry required to be made under regulation 5 in such register, and every correction of such an entry, shall be made in ink or otherwise so as to be indelible;
- (e) such a register shall not be used for any purpose other than the purposes of the Ordinance;
- (f) such person shall if so required by the Director or any public officer authorized in writing by the Director in that behalf-
  - (i) furnish such particulars as may be required with respect to the obtaining or supplying by him of any dangerous drug, or with respect to any stock of dangerous drugs in his possession;
  - (ii) for the purpose of confirming any such particulars, produce any stock of dangerous drugs in his possession; and
  - (iii) produce such register and such other books or documents in his possession relating to any dealings in dangerous drugs as may be required;
- (g) a separate register shall be kept in respect of each set of premises at which the person required to keep the register carries on business, but

save as aforesaid not more than one register shall be kept at one time in respect of each class of dangerous drug in respect of which he is required to keep a separate register or part of a register, so, however, that a separate register may, with the approval of the Director, be kept in respect of each department of the business carried on by him;  
 (h) every such register shall be kept at the premises to which it relates and so as to be at all times available for inspection.

[cf. S.I. 1964/1811 reg. 25 U.K.]

Chapter:	134A	Title:	DANGEROUS DRUGS REGULATIONS	Gazette Number:
Regulation:	7	Heading:	<b>Preservation of documents</b>	Version Date:
				30/06/1997

- (1) All registers, records, books, prescriptions and other documents which are kept, issued or made pursuant to the requirements, or for the purposes, of the Ordinance shall be preserved-
- (a) in the case of a register, book or other like record, for a period of two years from the date on which the last entry therein is made; and
  - (b) in the case of any other document, for a period of two years from the date on which it is issued or made.
- (2) In the case of any document kept pursuant to paragraph (6) of regulation 5, the keeping of a copy thereof made at any time during the said period of two years shall be treated for the purposes of paragraph (1) as if it were the keeping of the original document.
- (3) Any person who contravenes any of the provisions of paragraph (1) shall be guilty of an offence and shall be liable on conviction to a fine of ten thousand dollars and to imprisonment for twelve months.

[cf. S.I. 1964/1811 reg. 26 U.K.]

Chapter:	134A	Title:	DANGEROUS DRUGS REGULATIONS	Gazette Number:
Schedule:	1	Heading:	<b>FORM OF REGISTER</b>	Version Date:
				30/06/1997

[regulation 5]

Date of	Name and address of	Patient's identity	Amount	Invoice	Balance
---------	---------------------	--------------------	--------	---------	---------

receipt/ supply	person* or firm from whom received/to whom supplied	card number+	received	supplied	No.	

\* Cross reference of the person to whom supplied may be made in which case only the reference number of the person's treatment record needs to be given.

+ For a patient who is not resident in Hong Kong, the reference number of any proof of identity, other than an identity card, specified in section 17B(1) of the Immigration Ordinance (Cap 115) shall be inserted.

(L.N. 191 of 1966)