



中華人民共和國香港特別行政區政府總部食物及衛生局
Food and Health Bureau, Government Secretariat
The Government of the Hong Kong Special Administrative Region
The People's Republic of China

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4 December 2012

Ms Elyssa WONG
Chief Council Secretary
Panel on Health Services
Legislative Council Complex
1, Legislative Council Road
Central, Hong Kong

Dear Ms WONG,

Regulation of Medical and Clinical Laboratories

As requested at the Panel on Health Services Special Meeting on 26 October 2012, we have prepared supplementary information on the captioned subject at **Annex**.

Yours sincerely,

A handwritten signature in black ink, appearing to read 'Sheung-yuen LEE'.

(Sheung-yuen LEE)

for Secretary for Food and Health

**Administration's Response to
Follow-up to the Special Meeting of the
Panel on Health Services on 26 October 2012**

Item (7)(b) -

The existing regulatory control on medical and clinical laboratories, as well as any other premises, which undertook aseptic work.

Administration's response

2. Laboratories within private hospitals are subject to regulation under the Hospitals, Nursing Homes and Maternity Homes Registration Ordinance (Cap. 165) and the Code of Practice for Private Hospitals, Nursing Homes and Maternity Homes issued by the Department of Health. Pathology services of private hospitals are required to have a pathology specialist appointed to be in charge of the laboratory services and a Part I Medical laboratory technologist (MLT) (please see paragraph 4 below) assigned to take charge of the day-to-day operation. Compliance with this requirement is a condition for the registration and re-registration of private hospitals under the Cap. 165.

3. Laboratories in public hospitals under the aegis of Hospital Authority (HA) are administrated in accordance with the Safety Manual (Manual) and Code of Practice issued by HA. The Manual and Code of Practice provides a reference guideline to HA laboratories to ensure laboratory safety through appropriate operation, handling and disposal of equipment, organic solvents, chemicals, clinical wastes and other related materials.

4. As for laboratories operating outside hospital setting, they are subject to the relevant provisions under the Supplementary Medical Professions Ordinance (Cap. 359) and its subsidiary legislation. MLTs are required to register with the MLT Board established under Cap. 359 and observe requirements on ethical and professional standard prescribed by the MLT Board. The register of MLTs is divided into three parts. Persons registered in Part I can practise without supervision, whereas those registered in Part II or III can only practise under the supervision of a person registered in Part I.

5. Cap. 359 stipulates that MLTs shall practise his profession in premises which are considered to be suitable for practice by the MLT board. It also stipulates that a corporation carrying on the business of practising the MLT profession should have at least one professionally qualified director and all employees practising the MLT profession shall be registered in respect of the profession.

6. The Prevention and Control of Disease Ordinance (Cap. 599) aims to provide for the prevention and control of infectious diseases and to enable our compliance with the requirement of the International Health Regulations promulgated by the World Health Organization. For ensuring laboratory safety, the Director of Health may require a laboratory to surrender a scheduled infectious agent listed under Cap. 599 (at **Enclosure**) for disposal if the Director of Health has reasons to believe that (a) the laboratory does not have sufficient facilities and equipment to handle the scheduled infectious agent; (b) the person handling the agent in the laboratory does not have the necessary competency to do so; or (c) the agent is handled by the laboratory in a manner that may pose a public health risk. In case there is a leakage of a scheduled infectious agent in the laboratory that may pose a public health risk, the owner of the laboratory concerned is required to notify the Director of Health immediately and shall provide necessary information to facilitate the investigation of the leakage.

Food and Health Bureau
December 2012

List of Scheduled Infectious Agent under Cap. 599

1. *Bacillus anthracis* (炭疽芽胞桿菌)
2. *Clostridium botulinum* (肉毒桿菌)
3. Crimean-Congo haemorrhagic fever virus
(克里米亞 — 剛果出血熱病毒)
4. Dengue virus (登革病毒)
5. Ebola virus (埃博拉病毒)
6. *Francisella tularensis* (土拉桿菌)
7. Guanarito virus (瓜納瑞托病毒)
8. Hantavirus (漢坦病毒)
9. Hendra virus (亨德拉病毒)
10. Herpes simiae virus (B virus) (猴疱疹病毒(B 病毒))
11. Influenza virus type A (subtype H2, H5 and H7)
(甲型流行性感冒病毒(H2、H5 及 H7 亞型))
12. Japanese encephalitis virus (日本腦炎病毒)
13. Junin virus (鳩寧病毒)
14. Kyasanur Forest disease virus (基薩諾爾森林病病毒)
15. Lassa virus (拉沙病毒)
16. Machupo virus (馬秋波病毒)
17. Marburg virus (馬爾堡病毒)
18. Monkeypox virus (猴痘病毒)
19. *Mycobacterium tuberculosis* (multidrug-resistant)
(結核分枝桿菌(耐多藥))
20. Nipah virus (尼巴病毒)
- 20A. Novel Coronavirus associated with Severe Respiratory Disease
(致嚴重呼吸系統病新型冠狀病毒)
21. Omsk haemorrhagic fever virus (鄂木斯克出血熱病毒)
22. Polio virus (wild) (脊髓灰質炎病毒(野毒株))
23. Rabies or rabies-related virus (狂犬病毒或類狂犬病毒)
24. Rift Valley fever virus (立夫特谷熱病毒)
25. Sabia virus (薩比亞病毒)
26. Severe Acute Respiratory Syndrome—coronavirus
(嚴重急性呼吸系統綜合症 — 冠狀病毒)
27. Tick-borne encephalitis virus (蜱傳腦炎病毒)
28. Variola virus (天花病毒)
29. West Nile virus (西尼羅河病毒)
30. Yellow fever virus (黃熱病毒)
31. *Yersinia pestis* (鼠疫耶爾森菌)