HOKLAS SC-23
Issue No. 6
Issue Date: 1 November 2018
Implementation Date: 1 November 2018
Page 1 of 6

HOKLAS Supplementary Criteria No. 23

'Medical Testing' Test Category – Hospital Autopsy

1. Introduction

- 1.1 This document is an application document for the requirements of HKAS 002 and HOKLAS 015 accrediting examinations in hospital autopsy within the test category of 'Medical Testing'. This document only details those requirements that require further elaboration but does not include all the accreditation requirements. Therefore, it has to be read in conjunction with HKAS 002, HOKLAS 015, HOKLAS SC-33 and relevant HOKLAS supplementary criteria.
- 1.2 The checklist given in the Annex serves as guidance for laboratories to self-assess their management system and operation procedures against the requirements given in HOKLAS 015 and this document.

2. Personnel

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- 2.1 A qualified anatomical pathologist shall be a pathologist who has obtained postgraduate qualification in anatomical pathology, such as the Fellowship of the Hong Kong College of Pathologists, or equivalent as advised by the College.
- 2.2 Pathologist trainee shall be a registered medical practitioner who is enrolled and is undergoing active training in a training programme recognised by the Hong Kong College of Pathologists, or equivalent as advised by the College.
- 2.3 Medically qualified individuals in specialties other than anatomical pathology shall have adequate autopsy training equivalent to the level as advised by the Hong Kong College of Pathologists and similar to that of a fellow under the specialty of anatomical pathology.
- 2.4 Pathologists shall fulfil the 3-year cycle of CME/CPD requirement of the Hong Kong Academy of Medicine or Hong Kong Medical Council or equivalent bodies.
- All medical personnel shall have continuous working experience after completion 2.5 of training. Proof of proficiency is required if there is a break of service for more than 2 years. Evidence of participation in continuing medical education is expected.

HOKLAS SC-23
Issue No. 6
Issue Date: 1 November 2018
Implementation Date: 1 November 2018
Page 2 of 6

3. Accommodation and environmental conditions

- 3.1 Autopsy tables, dissection areas, instruments, and reusable aprons shall be adequately disinfected after use.
- 3.2 The administrative area shall be outside of the autopsy rooms and adequately separated from the body receiving area.

4. Examination processes

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- 4.1 Procedures for proper handling and examination of highly infectious cases should be documented.
- 4.2 All autopsies shall be performed by a qualified anatomical pathologist or pathologist trainee under the direct supervision of a qualified anatomical pathologist.

5. Post-examination processes

5.1 The minimum retention period for request forms, copies of reports, slides and blocks shall be as follows:

Request forms	3 years							
Slides	20 years							
Blocks	20 years							
Copies of reports	20 years, permanent if possible							
Wet tissue	3 months after final report							

- 5.2 The retained specimens, whether for disposal or further investigation, shall be stored in a secure manner that access to the specimens is controlled. The retained specimens shall be labelled and unequivocally traceable to the identified dead body.
- 5.3 Records of disposal of retained specimens shall be maintained.

HOKLAS SC-23
Issue No. 6
Issue Date: 1 November 2018
Implementation Date: 1 November 2018
Page 3 of 6

6. Reporting of results

- 6.1 The autopsy shall be reported by a qualified anatomical pathologist (or qualified pathologist as advised by the Hong Kong College of Pathologists) or pathologist trainee under the direct supervision of a qualified anatomical pathologist.
- 6.2 The final autopsy report shall contain sufficient information in an appropriate format to ascertain the patient's major disease processes and probable cause of death.
- 6.3 Where relevant, photographs (in hardcopy or electronic format) should be taken and kept as part of the autopsy records.

- End -

HOKLAS SC-23 Annex: Checklist on compliance with HOKLAS requirements - Hospital Autopsy

Page 4 of 6 Issue No. 6

HOKLAS Requirement	Clause (HOKLAS 015, 5 th edition and relevant SC)	*1	Y	N	NA	Lab's Document Reference or Remarks ²	Assessment Team's remarks / questions to be asked at the laboratory
Discipline Specific Technical Requirements							
Accommodation and environmental conditions	5.2						
Are there adequate spaces allotted to:							
- refrigerated storage of bodies?	5.2.3	•					
- lockers, changing area and shower facilities?	5.2.4	•					
- facilities for authorised viewing?	5.2.5	•					
Is ventilation adequate to eliminate noxious fumes and biological odors?	5.2.2	•					
Are autopsy tables, dissection areas, instruments and aprons adequately disinfected after use?	SC-23 3.1	•					
Is the administrative area separate from the autopsy rooms and body receiving area?	SC-23 3.2	•					
Laboratory equipment, reagents, and consumables	5.3						
Bone saw							
Are the safety measures checked according to the manufacturer's recommendations and documented?	5.3.1.3	•					
Autopsy Downdraft Table							

Note: 1. The assessor should concentrate on items marked with a •; other items will be checked by the team leader.

2. Please put down the laboratory's document reference(s) where there are descriptions or procedures related to the requirement.

-	HOKLAS Requirement	Clause (HOKLAS 015, 5 th edition and relevant SC)	*1	Y	N	NA	Lab's Document Reference or Remarks ²	Assessment Team's remarks / questions to be asked at the laboratory
	Is the downdraft table under regular maintenance with its flow rate regularly checked?	5.3.1.3	•					
	Pre-examination processes	5.4						
	Are available clinical records reviewed and/or clinical information discussed with the attending doctor before conducting the autopsy?	5.4.3	•					
	Are there written instructions covering items such as receipt, storage and release of bodies?	5.4.4.3	•					
	Does the request form include:	5.4.3						
	- date and approximate time of death?		•					
	- test requested? (limited or full autopsy)		•					
	Examination processes	5.5						
	Are there documented procedures for handling and examination of highly infectious cases?	SC-23 4.1	•					
	Are the autopsies performed by a qualified pathologist?	SC-23 4.2	•					
	When autopsies are performed by a pathologist trainee, is he/she under the direct supervision of a qualified pathologist?	SC-23 4.2	•					

Note: 1. The assessor should concentrate on items marked with a •; other items will be checked by the team leader.

2. Please put down the laboratory's document reference(s) where there are descriptions or procedures related to the requirement.

HOKLAS SC-23 Annex: Checklist on compliance with HOKLAS requirements - Hospital Autopsy

Page 6 of 6 Issue No. 6

HOKLAS Requirement	Clause (HOKLAS 015, 5 th edition and relevant SC)	*1	Y	N	NA	Lab's Document Reference or Remarks ²	Assessment Team's remarks / questions to be asked at the laboratory
Post-examination processes	5.7						
Are minimum retention periods of the following met:							
- request forms – 3 years?	SC-23 5.1	•					
- slides – 20 years?	SC-23 5.1	•					
- blocks – 20 years?	SC-23 5.1	•					
- copies of reports – 20 years (permanent if possible)?	SC-23 5.1	•					
- wet tissue – 3 months after final report	SC-23 5.1	•					
Are the retained specimens stored in a secure manner that access to the specimens is controlled?	SC-23 5.2	•					
Are the retained specimens labelled and unequivocally traceable to the identified dead body?	SC-23 5.2	•					
Are disposal records of specimens maintained?	SC-23 5.3	•					
Reporting of results	5.8						
Does the final autopsy report contain sufficient information in an appropriate format to ascertain the patient's major disease processes and probable cause of death?	SC-23 6.2	•					
Are photos taken for documentation, where appropriate?	SC-23 6.3	•					

Note: 1. The assessor should concentrate on items marked with a •; other items will be checked by the team leader.

2. Please put down the laboratory's document reference(s) where there are descriptions or procedures related to the requirement.