Site visit inspection report on compliance with HTA licensing standards

St George's Hospital

HTA licensing number 12387

Licensed under the Human Tissue Act 2004 for the

- **making of a post mortem examination;**
- **removal from the body of a deceased person (otherwise than in the course of an anatomical examination or post-mortem examination) of relevant material of which the body consists or which it contains, for use for a scheduled purpose other than transplantation; and**
- **storage of the body of a deceased person or relevant material which has come from a human body for use for a scheduled purpose**

11 & 12 December 2018

Summary of inspection findings

The HTA found the Designated Individual (DI) and the Licence Holder (LH) to be suitable in accordance with the requirements of the legislation.

Although the HTA found that St George's Hospital had met the majority of the HTA's standards, two major and fourteen minor shortfalls were found against standards for Governance and Quality, Traceability and Premises, Facilities and Equipment.

The shortfalls relate to standard operating procedures (SOPs); risks assessments for licensable activities; audits; traceability and maintenance of premises.

Particular examples of strengths and good practice are included in the concluding comments section of the report.

The HTA's regulatory requirements

Prior to the grant of a licence, the HTA must assure itself that the Designated Individual is a suitable person to supervise the activity authorised by the licence and that the premises are suitable for the activity.

The statutory duties of the Designated Individual are set down in Section 18 of the Human Tissue Act 2004. They are to secure that:

- the other persons to whom the licence applies are suitable persons to participate in the carrying-on of the licensed activity;
- suitable practices are used in the course of carrying on that activity; and
- the conditions of the licence are complied with.

Its programme of site visit inspections to assess compliance with HTA licensing standards is one of the assurance mechanisms used by the HTA.

The HTA developed its licensing standards with input from its stakeholders. They are designed to ensure the safe and ethical use of human tissue and the dignified and respectful treatment of the deceased. They are grouped under four headings:

- consent
- governance and quality systems
- traceability
- premises facilities and equipment.

This is an exception-based report: only those standards that have been assessed as not met are included. Where the HTA determines that there has been a shortfall against a standard, the level of the shortfall is classified as 'Critical', 'Major' or 'Minor' (see Appendix 2: Classification of the level of shortfall). Where HTA standards are fully met, but the HTA has identified an area of practice that could be further improved, advice is provided.

HTA inspection reports are published on the HTA's website.

Background to the establishment

St George's Hospital (the establishment) has been licensed by the HTA since March 2010. The establishment is licensed for the making of a post-mortem (PM) examination, removal of relevant material from the deceased and storage of bodies of the deceased and relevant material for use for scheduled purposes. The Designated Individual (DI) is Divisional Director of Nursing and the Corporate Licence Holder contact is the Medical Director for St George's Hospital NHS Trust.The mortuary at St George's Hospital is currently staffed by a senior Anatomical Pathology Technologist (APT) and Mortuary Manager, two locums APTs and one bank administrator who all work full-time. Two full time APTs have recently been appointed. The bank administrator was introduced due to the number of APTs available to provide cover for administration duties.

The establishment performs around 1,100 PM examinations annually, the total figure includes: adult coronial, forensic, adult and paediatric/perinatal hospital consented and high risk PM examinations. Consultant obstetricians and bereavement midwives seek consent for paediatric/perinatal PM cases, which is recorded using consent forms based on the Stillbirth and Neonatal Death (Sands) charity documentation. The Lead Consultant Pathologist seeks consent for all adult consented cases. PM consent is recorded using a form based on the HTA's model form. Only clinicians who complete the PM consent training are permitted to seek consent for paediatric/perinatal PM examination. The paediatric/perinatal training is conducted twice a year for clinicians and three times a year for bereavement midwives.

Removal of tissue from deceased children in cases of sudden unexpected death in infancy (SUDI) is carried out in the Accident & Emergency (A&E) department, with authorisation from the Coroner on a case-by-case basis. Staff will notify the trained clinicans who will invoke the SUDI protocol.

The mortuary has 198 refrigerated body storage spaces, including 143 bariatric spaces, 15 of which are super-bariatric and 40 freezer spaces for long-term storage of bodies. In addition, the mortuary has two temporary refrigerated body storage units, which provide 24 additional spaces as contingency; these were not in use at the time of inspection. There are two separate fridges for the storage of perinatal/paediatric cases, one for storage of cases from the establishment wards, the other for cases that have been transferred to the establishment for PM examination. All fridges and freezers are connected to a remote monitoring system and have audible alarms, which are connected to the mortuary office, notifying mortuary staff of temperature fluctuations during working hours. Outside of working hours a message is sent to a pager carried by the on-call APT. The mortuary staff review the fridge temperature records for trends and carry out fridge alarm testing, however, this is not documented (see shortfall against PFE2(e)). The fridge on the maternity ward is used for the temporary storage of fetuses before transfer to the mortuary. The temperature is checked and documented twice daily, however, is not alarmed (see shortfall against PFE2(e)).

The entrance to the mortuary from the hospital is secured by swipe card access, which is limited to mortuary and trained portering staff. The hospital and funeral directors entrances to the mortuary have an intercom system and are covered by CCTV, which can be viewed from the mortuary office. The funeral directors entrance can be seen from the viewing area entrance and can also be used for disabled visitor parking (see *Advice* item 10).

Portering staff are responsible for the transfer of bodies from hospital wards to the mortuary. On arrival, porters place bodies in an available refrigerated body space in body store room one, and update the mortuary 'log book' with information of bodies brought into the mortuary. In addition, the name of deceased and their arrival date is written on the fridge door white board. The Coroner's contracted funeral directors transfer all community bodies to the mortuary and complete the same mortuary log book. All community bodies arrive with two wristbands, which are attached to the body by the funeral directors or police before arrival at the mortuary. An additional wristband with the mortuary unique number is added to bodies for consented post mortems and Coroner's post mortems.

Mortuary staff perform body checks of all bodies the next working day, verifying the identification band details on the bodies against the logbook and make sure all bodies are appropriately shrouded. Mortuary staff complete the electronic mortuary register for each body, and are assigned a unique mortuary number; an additional wristband is added to the body with this unique number. A white board in the mortuary office is updated with different coloured pens to indicate which month a body arrived. Mortuary staff add a colured magnet to fridge spaces and the mortuary office whiteboard containing bodies with same and/or similar names to alert staff to the presence of these bodies.

The mortuary only release bodies during normal working hours and have a 'Hospital Release Form', which undertakers must present to mortuary staff before a hospital body can be released. For community bodies that have not had a PM examination the funeral director will bring a copy of the 'green form'. For Coroner's bodies, the funeral directors will state the details of the deceased verbally (see shortfall against T1(c)).

Fetuses and babies are transferred to the mortuary by a member of the portering staff and are always released from the mortuary.

The mortuary operates an appointment system for viewings, which generally takes place during working hours. Although viewings are discouraged outside of working hours, the bed manager along with two members of the portering staff will accommodate viewings out-of-hours if there is a particular requirement (see shortfall against T1(c)).

The main PM suite has three downdraft PM tables and three additional movable trolleys that can be used if required. There are three dissection units for the preparation of tissue samples. PM examinations take place one at a time to help minimise the risk of organ and tissue mix-up between cases. The external examination and identification of bodies is

always checked by the pathologist and an APT prior to evisceration. There is a separate high risk/forensic PM suite with one downdraft table that can also be used as a contingency PM room, as well as a separate paediatric/perinatal PM room (see shortfall against PFE1(a)). There is also a storage room containing material stored under Police and Criminal Evidence Act 1984 (PACE).

Mortuary staff have access to PPE within the PM room and body store area and there is demarcation of clean and dirty areas within the mortuary. Material retained at PM examination for histological examination is placed into formalin-filled containers and the identifying information is handwritten on the container label by mortuary staff. The mortuary use a 'PM Tissue' form to record the number and type of tissue taken at PM examination .

Tissue samples may be kept, if appropriate consent has been given for retention or for use for scheduled purposes. Relatives' wishes with regards to the fate of any tissue retained following PM examination are managed by the mortuary staff, who enter details onto the electronic patient record that is accessible to mortuary staff and pathologists. A new process is to be implemented in the New Year to assist in improving communication between the establishment and Coroner's Office (see shortfall against T2(b)).

Description of inspection activities undertaken

This was the fifth site visit inspection of the establishment; the previous inspection took place in 2016. The inspection team reviewed governance and quality system documentation, carried out interviews with key members of staff, a visual inspection of the mortuary body store areas, PM rooms and viewing area.

An audit of body identifiers, storage locations, mortuary register details, mortuary database details and associated documentation was carried out for eight bodies (two adult community deaths, five adult hospital deaths and one baby); no discrepancies were identified.

In addition, tissue removed during PM examinations for four cases between 2015 and 2018 were audited for traceability (three Coroner's cases and one hospital consented case). The audit included details of tissue type, number of tissue blocks and slides retained, consent forms, and other associated paperwork and electronic database records; no discrepancies were identified.

Material held for the police

Home Office PM examinations are conducted at the establishment. Under section 39 of HT Act, relevant material held for criminal justice purposes is outside the scope of HTA regulation and is not subject to the licensing requirements for storage. However, the 2012 report of the Association of Chief Police Officers' (ACPO) audit of tissue held under police authority contained a recommendation that police exhibits held on HTA-licensed premises should be included within the regular HTA inspection process. Therefore, procedures for

Home Office PM examinations and management of tissues and organs taken for criminal justice purposes were reviewed by the HTA at this site visit inspection

Inspection findings

The HTA found the Licence Holder and the Designated Individual to be suitable in accordance with the requirements of the legislation.

Compliance with HTA standards

Standard	Inspection findings	Level of shortfall
GQ1 All aspects of the establishment's work are governed by documented policies and procedures		
d) Policies and SOP's are reviewed regularly by someone other than the author, ratified and version controlled. Only the latest versions are available for use	Although the establishment have a range of SOPs covering licensable activiites, these documents have not been reviewed regularly e.g. MOR-GEN-006, Receipt of deceased adults and MOR-GEN-009, Processing adult post mortem cases. The most recent versions of some SOPs submitted to the HTA for review prior to the inspection have not been uploaded to the Quality Management System.	**Minor**
h) Matters relating to HTA-licensed activities are discussed at regular governance meetings involving establishment staff	The DI does not meet with Persons Designated (PDs) in maternity, A&E or in the mortuary, therefore does not have a formal way of ensuring relevant information is disseminated, or be assured of HTA related activities in these areas for which she is responsible	**Minor**

GQ2 There is a documented system of audit		
a) There is a documented schedule of audits	The establishment does not have a documented schedule of audits and no audits have been performed since 2016. (*as a result, standards GQ2(b) and (c) cannot be met*)	**Major**

GQ3 Staff are appropriately qualified and trained in techniques relevant to their work and demonstrate competence in key tasks		
c) Staff are assessed as competent for the tasks they perform	Competency reassessment is not undertaken for mortuary staff and porters on a regular basis.	**Minor**

GQ5 There are systems to ensure that all untoward incidents are investigated promptly		
a) Staff know how to identify and report incidents, including those that must be reported to the HTA	The porters are not aware of incidents that should be reported to the HTA, meaning they may not report such incidents to the mortuary staff for action.	**Minor**
d) Information about incidents is shared with all staff to avoid repeat errors	Actions raised from relevant incidents are not shared with porters to mitigate the risk of similar incidents re-occurring.	**Minor**

GQ6 Risk assessments of the establishment's practices and processes are completed regularly, recorded and monitored		
a) All procedures related to the licensed activities (as outlined in standard GQ1) are risk assessed on a regular basis	Although the establishment has a comprehensive risk assessment identifying all potential hazards, which are appropriately assessed and include what control measures have been implemented, the risk assessment is past its review date.	**Minor**

T1 A coding and records system facilitates traceability of bodies and human tissue, ensuring a robust audit trail		
c) Three identifiers are used to identify bodies and tissue, (for example post mortem number, name, date of birth/death), including at least one unique identifier	i) Although the Coroner's office send an email directly to the mortuary containing three identifiers that can be checked against those bodies that have undergone a PM examination, the funeral directors do not bring documentation with them that states the required three identifiers. For those bodies admitted from the community that do not require a PM examination, funeral directors bring a copy of the 'green form', which only contains two identifiers that can be checked against the body (name and date of death). (see *Advice* item 4). ii) Families are not being asked to provide three identifiers when attending the establishment to undertake viewings and often, only the name of the deceased is requested. (see *Advice* item 5). The use of less than three separate identifiers when identifying bodies, presents a risk of releasing and viewing the wrong body.	**Major**

T2 Disposal of tissue is carried out in an appropriate manner and in line with the HTA's codes of practice		
b) There are effective systems for communicating with the Coroner's Office, which ensure tissue is not kept for longer than necessary.	The establishment has issues with consistently obtaining relatvies wishes for tissues and when the Coroner's authority has ended, to be able to act on those wishes, despite the establishment following-up on these cases. However, without obtaining this information in a timely manner, the DI cannot be assured that tissues being stored by the establishment are being held with authority from the Corooner or with appropriate consent from the relatives. The Lead Pathologist has already collated information on all historic cases being stored by the establishment and recently re-requested the relatives' wishes for tissues and/or confirmation that the Coroner's authority has ended. The DI is required to ensure that the requested information for the historic cases is obtained and acted on, and there is a robust system in place to obtain this information for cases in the future.	**Minor**
d) The method and date of disposal are recorded.	When instructions for disposal of tissues is received, the method and date of disposal is not recorded either on the mortuary register or Laboratory Information Management System.	**Minor**

PFE1 The premises are secure and well maintained and safeguard the dignity of the deceased and the integrity of human tissue.		
a) The premises are clean and well maintained	i) The cork boards used within the paediatric/perinatal PM room are porous, meaning they cannot be adequately cleaned or disinfected, posing a potential infection risk. All cork boards should be disposed of and replaced with non-porous replacements. ii) Some areas of cracking were noted on the floor in the paediatric/perinatal PM room that require repair. (see *Advice* item 7).	**Minor**
c) There are documented cleaning and decontamination procedures and a schedule of cleaning	Although mortuary staff stated that the fridges and freezers are cleaned, there is no documented cleaning schedule or records to help mortuary staff keep track of which fridge or freezer banks were cleaned and when.	**Minor**

PFE2 There are appropriate facilities for the storage of bodies and human tissue.		
a) Storage arrangements ensure the dignity of the deceased.	The alarm trigger points for the main fridges in the body stores (0°C and 10°C) will not ensure the alarms are triggered at appropriate temperatures to optimally maintain bodies stored in there. (see *Advice* item 8)	**Minor**
e) Fridge and freezer units are alarmed and the alarms are tested regularly to ensure that they trigger when temperatures go out of upper and lower set range	i) The mortuary staff do not test the body store alarms on a regular basis. This does not provide assurance that the alarms will trigger when temperatures deviate from the expected range ii) Although the fridge on maternity is monitored twice a day, it is not alarmed, meaning staff will not be alerted if temperatures deviate from expected range (see *Advice* item 9)	**Minor**

PFE3 Equipment is appropriate for use, maintained, validated and where appropriate monitored		
c) The ventilation system provides the necessary ten air changes per hour and is checked and maintained at least annually	The establishment was unable to provide the ventilation service records during the inspection to provide assurance the ventilation system is working to the required standard and is regularly maintained. The mortuary should have copies of these records.	**Minor**
f) Key items of equipment, including fridges/freezers, trolleys and post mortem tables (if downdraught) are subject to regular maintenance and records are kept	Equipment is overseen by the estates department and mortuary staff were unable to locate maintenance reports for mortuary equipment during the inspection. The mortuary should have copies to provide assurances the equipment is functioning to the required standard. This would allow mortuary staff to identify when servicing, maintenance and equipment issues need to be escalated to senior staff.	**Minor**

Advice

The HTA advises the DI to consider the following to further improve practice:

No.	Standard	Advice
1.	GQ1(a)	The DI is advised to ensure up to date cross references to other relevant documents are included in SOPs e.g. HSE Guidance – 'Safe Working and the prevention of infection in the mortuary and post mortem room' has now been superseded by 'Managing infection risks when handling the deceased'.
2.	GQ3(g)	The DI is advised to ensure that locum staff have access to copies of SOPs and risk assessments to refer to while they are working in the mortuary, in addition to reading and signing for them during their induction.
3.	GQ5(a)	The DI is advised to review the Trust Incident Policy to ensure the HTA are listed as an organisation to be notified of relevant incidents.
4.	T1(c)	The DI may wish to consider the introduction of a form, which can be used by funeral directors for the release of all bodies. This form could include relevant identification information so that three identifiers can be checked on the body before being released to the funeral director and could be used in conjunction with other documentation, e.g. the 'green form' and Coroner's release form.
5.	T1(c)	The DI may wish to consider the introduction of a form to be completed by relatives when they attend for viewings. This form could include relevant identification information so that three identifiers can be checked on the body before the viewing takes place. Guidance is also available on the HTA website: updated guidance for Traceability Standard T1c.
6.	T1(g)	The DI is advised to ensure that the mortuary have a record of tissue sent to the histopathology laboratory, such as access to the DART system to review scanned tissue forms to ensure any discrepancies can be traced. In addition, this will provide assistance when undertaking regular traceability audits.
7.	PFE1(a)	The DI is advised to monitor areas in the PM rooms for wear and tear e.g. breakdown of the grouting between tiles on the floors and seals at the base of PM tables. The DI is advised to ensure there is a programme of planned preventative maintenance to keep equipment and premises fit for purpose.
8.	PFE2(a)	The DI is advised to ensure fridge temperatures in all areas are maintained between 4-6°C, with lower and upper triggers points of around 2°C and 8°C, respectively, with an appropriate time period before the alarm triggers. It is also important that all staff are aware of what the fridge and freezer temperatures should be to recognise any potential equipment failures before they occur.
9.	PFE2(e)	The DI may wish to consider linking the maternity fridge to the existing remote alarm system to ensure staff are alerted to any temperature deviations.
10.	N/A	The DI is advised to explore options to better conceal the funeral directors' entrance from the mortuary viewing room access door, to help prevent members of the public seeing into this area. In addition, the DI is advised to consider how the use of the disabled parking space can be managed to help ensure visitors do not see the admission and release of bodies.

Concluding comments

The establishment have been short staffed for a lengthy period of time, with a number of staff leaving in quick succession and recruitment has proved difficult. Despite these pressures, staff have continued to demonstrate a sensitive and dedicated approach to their work and maintain the running of the mortuary service. The recent appointment of two qualified APTs will help alleviate workload pressures and support the out-of-hours call-out rota.

The permanent mortuary staff are a cohesive, long-standing and experienced team, communicate well with each other and are open to accepting advice and guidance.

The HTA observed some areas of strength and good practice during the inspection:

- mortuary staff are open to sharing learning particularly with regards to HTA reportable incidents and work together to improve practices to prevent further incidents;

- using different coloured marker pens for different months as a visual indicator of long-term bodies;

- staff hold daily minuted morning meetings to discuss mortuary workload and issues, which is especially useful as the department currently has locum APTs covering staff vacancies.

There are a number of areas of practice that require improvement, including two major and fourteen minor shortfalls.

The HTA requires the Designated Individual to submit a completed corrective and preventative action (CAPA) plan setting out how the shortfalls will be addressed, within 14 days of receipt of the final report (refer to Appendix 2 for recommended timeframes within which to complete actions). The HTA will then inform the establishment of the evidence required to demonstrate that the actions agreed in the plan have been completed.

The HTA has assessed the establishment as suitable to be licensed for the activities specified subject to corrective and preventative actions being implemented to meet the shortfalls identified during the inspection. The HTA has assessed the establishment as suitable to be licensed for the activities specified.

Report sent to DI for factual accuracy: 07.01.2019

Report returned from DI: 21.01.2019

Final report issued: 28.01.2019

Completion of corrective and preventative actions (CAPA) plan

Based on information provided, the HTA is satisfied that the establishment has completed the agreed actions in the CAPA plan and in doing so has taken sufficient action to correct all shortfalls addressed in the Inspection Report.

Date: 09.01.2020

Appendix 1: HTA licensing standards

The HTA standards applicable to this establishment are shown below; those not assessed during the inspection are shown in grey text. Standards that are not applicable have been excluded.

Consent
C1 Consent is obtained in accordance with the requirements of the Human Tissue Act 2004 (HT Act) and as set out in the HTA's codes of practice
a) There is a documented policy which governs consent for post-mortem examination and the retention of tissue and which reflects the requirements of the HT Act and the HTA's Codes of Practice. b) There is a documented standard operating procedure (SOP) detailing the consent process. *Guidance* *This should include who is able to seek consent, what training they should receive, and what information should be provided to those giving consent for post-mortem examination. It should make reference to the use of scanning as an alternative or adjunct to post-mortem examination.* c) There is written information for those giving consent, which reflects the requirements of the HT Act and the HTA's codes of practice. *Guidance* *Information on consent should be available in different languages and formats, or there is access to interpreters/translators. Family members should be given the opportunity to ask questions.* d) Information contains clear guidance on options for how tissue may be handled after the post-mortem examination (for example, repatriated with the body, returned to the family for burial/cremation, disposed of or stored for future use), and what steps will be taken if no decision is made by the relatives.

e) Where consent is sought for tissue to be retained for future use, information is provided about the potential uses to ensure that informed consent is obtained.

f) The deceased's family are given an opportunity to change their minds and it is made clear who should be contacted in this event and the timeframe in which they are able to change their minds.

g) The establishment uses an agreed and ratified consent form to document that consent was given and the information provided.

Guidance

This may be based on the HTA's model consent form for adult post-mortem examinations available on the HTA website, or in relation to infants, the resources pack developed by the Stillbirth and neonatal death charity, Sands. The consent forms should record the consent given for the post-mortem examination and for the retention and future use of tissue samples.

C2 Staff involved in seeking consent receive training and support in the essential requirements of taking consent

a) There is training for those responsible for seeking consent for post-mortem examination and tissue retention, which addresses the requirements of the HT Act and the HTA's codes of practice.

Guidance

Refresher training should be available (for example annually).

b) Records demonstrate up-to-date staff training.

c) If untrained staff are involved in seeking consent, they are always accompanied by a trained individual.

d) Competency is assessed and maintained.

Governance and quality systems

GQ1 All aspects of the establishment's work are governed by documented policies and procedures

a) Documented policies and SOPs cover all mortuary/laboratory procedures relevant to the licensed activity, take account of relevant Health and Safety legislation and guidance and, where applicable, reflect guidance from RCPath. These include:

i. post-mortem examination, including the responsibilities of Anatomical Pathology Technologists (APTs) and Pathologists and the management of cases where there is increased risk;

ii. practices relating to the storage of bodies, including long term storage and when bodies should be moved into frozen storage;

iii. practices relating to evisceration and reconstruction of bodies;

iv. systems of traceability of bodies and tissue samples;

v. record keeping;

vi. receipt and release of bodies, which reflect out of hours arrangements;

vii. lone working in the mortuary;

viii. viewing of bodies, including those in long-term storage, by family members and others such as the police;

ix. transfer of bodies internally, for example, for MRI scanning;

x. transfer of bodies and tissue (including blocks and slides) off site or to other establishments;

xi. movement of multiple bodies from the mortuary to other premises, for example, in the event that capacity is reached;

xii. disposal of tissue (including blocks and slides), which ensures disposal in line with the wishes of the deceased person's family;

xiii. access to the mortuary by non-mortuary staff, contractors and visitors;

xiv. contingency storage arrangements.

Guidance

SOPs should reflect guidance contained in the HSE's document: Managing the risks of infection in the mortuary, post mortem room, funeral premises and exhumation.

Individual SOPs for each activity are not required. Some SOPs will cover more than one activity.

b) Procedures on evisceration ensure that this is not undertaken by an APT unless the body has first been examined by the pathologist who has instructed the APT to proceed.

c) Procedures on body storage prevent practices that disregard the dignity of the deceased.

Guidance

For example, placing more than one body on a tray, placing bodies unshrouded on trays, or storing bodies in unrefrigerated storage should not take place.

The family's permission should be obtained for any 'cosmetic' adjustments or other invasive procedures prior to release of bodies, for example, sewing the deceased's mouth to close it or the removal of a pacemaker. It is also good practice to discuss with the family any condition that may cause them distress, for example when viewing or preparing the body for burial, such as oedema, skin slippage of signs of decomposition.

If identification of the body is to take place before a post-mortem examination, if available, a Police Family Liaison or Coroner's Officer should have a discussion with the family about the injures and let them know that reconstruction may be required.

However, the Pathologist should see the body without any changes being made, so if there is a need to reconstruct or clean a body before the post-mortem examination, it should be with the agreement of both the Pathologist and the Coroner. In Home Office cases, a viewing cannot normally take place until after the post-mortem examination.

d) Policies and SOPs are reviewed regularly by someone other than the author, ratified and version controlled. Only the latest versions are available for use.

e) There is a system for recording that staff have read and understood the latest versions of these documents.

f) Deviations from documented SOPs are recorded and monitored via scheduled audit activity.

g) All areas where activities are carried out under an HTA licence are incorporated within the establishment's governance framework.

Guidance

These areas include maternity wards where storage of fetuses and still born babies takes place, areas where material is stored for research, the Accident and Emergency Department where removal of samples may take place in cases of sudden unexpected death in infancy. There should be an identified Person Designated in areas of the establishment remote from the main premises.

h) Matters relating to HTA-licensed activities are discussed at regular governance meetings involving establishment staff.

Guidance

Meeting minutes should be recorded and made available to staff.

GQ2 There is a documented system of audit

a) There is a documented schedule of audits.

Guidance

As a minimum, the schedule should include a range of vertical and horizontal audits

checking compliance with documented procedures, the completion of records and traceability.

b) Audit findings document who is responsible for follow-up actions and the timeframe for completing these.

Guidance

Staff should be made aware of the outcomes of audits and where improvements have been identified.

c) Regular audits are carried out of tissue being stored so that staff are fully aware of what is held and why and to enable timely disposal of tissue where consent has not been given for continued retention.

Guidance

Audits of stored tissue should include samples held under the authority of the police, where applicable.

GQ3 Staff are appropriately qualified and trained in techniques relevant to their work and demonstrate competence in key tasks

a) All staff who are involved in mortuary duties are appropriately trained/qualified or supervised.

Guidance

This includes portering staff, who have responsibility for bringing bodies to the mortuary out of hours and who may not be aware of the potential risks to the deceased during transfer into refrigerated storage, and unqualified mortuary 'assistant' staff.

APTs should be trained in reconstruction techniques to ensure that the appearance of the deceased is as natural as possible. APTs should be encouraged to work towards the achievement of the RSPH Level 3 Diploma in Anatomical Pathology Technology.

b) There are clear reporting lines and accountability.

c) Staff are assessed as competent for the tasks they perform.

Guidance

Assessment of competence should include the standard of APTs' reconstruction work.

d) Staff have annual appraisals and personal development plans.

e) Staff are given opportunities to attend training courses, either internally or externally.

Guidance: attendance by staff at training events should be recorded.

f) There is a documented induction and training programme for new mortuary staff.

g) Visiting / external staff are appropriately trained and receive an induction which includes the establishment's policies and procedures.

Guidance

The qualifications of locum staff should be checked prior to them commencing work in the mortuary and their competency to undertake each task should be assessed.

Contractors, visiting and temporary staff and funeral service staff bringing bodies out of hours should be required to read relevant standard operating procedures and sign to confirm their understanding.

GQ4 There is a systematic and planned approach to the management of records

a) There is a system for managing records which includes which records must be maintained, how they are backed up, where records are kept, how long each type of record is retained and who has access to each type of record.

Guidance

Records include mortuary registers, PM examination records, tissue retention forms and records of transfer and return of organs/tissue sent elsewhere for examination.

b) There are documented SOPs for record management which include how errors in written records should be corrected.

c) Systems ensure data protection, confidentiality and public disclosure (whistle-blowing).

GQ5 There are systems to ensure that all untoward incidents are investigated promptly

a) Staff know how to identify and report incidents, including those that must be reported to the HTA.

Guidance

HTA-reportable incidents must be reported within five days of the date of the incident or date of discovery.

Incidents that relate to a failure of hospital staff to carry out end of life care adequately should be reported internally and the incidence of these monitored.

b) The incident reporting system clearly outlines responsibilities for reporting, investigating and follow up for incidents.

c) The incident reporting system ensures that follow up actions are identified (i.e. corrective and preventative actions) and completed.

d) Information about incidents is shared with all staff to avoid repeat errors.

e) The establishment adopts a policy of candour when dealing with serious incidents.

GQ6 Risk assessments of the establishment's practices and processes are completed regularly, recorded and monitored

a) All procedures related to the licensed activities (as outlined in standard GQ1) are risk assessed on a regular basis.

Guidance

Risks to the dignity and integrity of bodies and stored tissue should be covered. The HTA's reportable incident categories provide a good basis for risk assessments. Risk assessments should be reviewed at regular intervals, for example every 1-3 years or when circumstances

change. Staff should be involved in the risk assessment process.

b) Risk assessments include how to mitigate the identified risks. This includes actions that need to be taken, who is responsible for each action, deadlines for completing actions and confirmation that actions have been completed.

Guidance

Relevant staff should have knowledge of risks and the control measures that have been taken to mitigate them.

c) Significant risks, for example to the establishment's ability to deliver post-mortem services, are incorporated into the Trust's organisational risk register.

Traceability

T1 A coding and records system facilitates traceability of bodies and human tissue, ensuring a robust audit trail

a) Bodies are tagged/labelled upon arrival at the mortuary.

Guidance

The condition and labelling of bodies received in body bags should always be checked and their identity confirmed. They should be labelled on the wrist and/or toe. Body bags should not be labelled in place of the body.

b) There is a system to track each body from admission to the mortuary to release for burial or cremation (for example mortuary register, patient file, transport records).

Guidance

Body receipt and release details should be logged in the mortuary register, including the date and name of the person who received/released the body and, in the case of release, to whom it was released. This includes bodies sent to another establishment for PM examination or bodies which are sent off site for short-term storage which are subsequently returned before release to funeral service staff.

c) Three identifiers are used to identify bodies and tissue, (for example post mortem number, name, date of birth/death), including at least one unique identifier.

Guidance

Identification details should not be written on bodies. Where bodies are moved off site for contingency storage the DI should ensure that suitable systems are in place to identify same or similar names.

d) There is system for flagging up same or similar names of the deceased.

e) Identity checks take place each time a body is moved whether inside the mortuary or from the mortuary to other premises.

Guidance

Mortuary white boards containing the names of the deceased give potential for error if wiped clean (such as when visitors attend for reasons of confidentiality), and should not be relied upon as the sole source of information about the locations of bodies.

Fridge/freezer failures that require bodies to be moved temporarily whilst repairs take place present a risk to traceability. Full identification checks should be made when theyare placed back into normal storage.

f) There are procedures for releasing a body that has been in long term storage and is therefore not in the current register.

g) Organs or tissue taken during post-mortem examination are fully traceable, including blocks and slides (including police holdings). The traceability system ensures that the following details are recorded:

i. material sent for analysis on or off-site, including confirmation of arrival

ii. receipt upon return to the laboratory or mortuary

iii. the number of blocks and slides made

iv. repatriation with the body

v. return for burial or cremation

vi. disposal or retention for future use.

Guidance

Consent information which covers retention/disposal of tissues should be made available to the other site, as appropriate.

h) There are documented procedures for transportation of bodies and tissue anywhere outside the mortuary, (such as to the lab or another establishment), including record-keeping requirements.

Guidance

Formal written agreements with funeral services are recommended. Coroners usually have their own agreements for transportation of bodies and tissue; however, documentation for traceability purposes must still be maintained by the establishment forthese cases.

T2 Disposal of tissue is carried out in an appropriate manner and in line with the HTA's codes of practice.

a) Tissue is disposed of as soon as reasonably possible once it is no longer needed, such as when the coroner's or police authority over its retention ends or the consented post-mortem examination process is complete.

b) There are effective systems for communicating with the Coroner's Office, which ensure tissue is not kept for longer than necessary.

c) Disposal is in line with the wishes of the deceased's family.

Guidance

Organs and tissue returned to the body prior to its release should be contained in clear viscera bags, which prevent leakage, are biodegradable and pose no issues for crematoria in relation to emissions and pollution. Clinical waste bags or household bin bags should not be used for this purpose.

Tissue blocks and glass slides should not be placed inside the body for the purpose of reuniting tissues with the deceased. Blocks and slides should be placed in a suitable container and transported with the body should the family wish to delay the funeral until the slides are returned.

d) The method and date of disposal are recorded.

Premises, facilities and equipment

PFE1 The premises are secure and well maintained and safeguard the dignity of the deceased and the integrity of human tissue

a) The premises are clean and well maintained.

Guidance

Floors, walls and work surfaces should be of non-porous construction and free of cracks and chips. The premises should be subject to a programme of planned preventative maintenance, which ensures that the premises, facilities and equipment remain fit for purpose.

b) There is demarcation of clear, dirty and transitional areas of the mortuary, which is observed by staff and visitors.

c) There are documented cleaning and decontamination procedures and a schedule of cleaning.

d) The premises are secure (for example there is controlled access to the body storage area(s) and PM room and the use of CCTV to monitor access).

Guidance

Relatives who visit for a viewing should not be able to access the body store area. Security systems and lone working arrangements should take into account viewings which take place out of hours.

e) Security arrangements protect against unauthorized access and ensure oversight of visitors and contractors who have a legitimate right of access.

PFE2 There are appropriate facilities for the storage of bodies and human tissue

a) Storage arrangements ensure the dignity of the deceased.

Guidance

Refrigeration of bodies should be at a temperature of approximately 4 degrees Celsius. The optimal operating temperature for freezer storage is around -20 Celsius, +/- 4 degrees.

b) There is sufficient capacity for storage of bodies, organs and tissue samples, which takes into account predicated peaks of activity.

Guidance

Capacity should be regularly reviewed, particularly if contingency arrangements are used for an extended period.

c) Storage for long-term storage of bodies and bariatric bodies is sufficient to meet needs.

Guidance

There should be sufficient frozen storage for the long-term storage of bodies; the HTA advises that bodies should be moved into frozen storage after 30-days in refrigerated storage if there is no indication they are soon to be released or further examined, or before, depending on the condition of the body. Where there is insufficient freezer storage to meet needs, there should be arrangements with other establishments, or other contingency steps, to ensure that bodies can be stored appropriately.

Bodies in long-term storage should be checked regularly; this should include confirmation of their identity and the reason for their continued storage.

Where new fridges are installed, these should measure 24"-26" in width and consideration should be given to the proportion that should be larger to accommodate bariatric bodies.

d) Fridge and freezer units are in good working condition and well maintained.

e) Fridge and freezer units are alarmed and the alarms are tested regularly to ensure that they trigger when temperatures go out of upper or lower set range.

f) Temperatures of fridges and freezers are monitored on a regular basis.

Guidance

Temperature monitoring should enable the establishment to identify trends and may mitigate the risk of a possible fridge failure.

g) Bodies are shrouded or in body bags whilst in storage.

h) There is separate storage for infants and babies. If not, special measures are taken for the bodies of infants and babies.

i) There are documented contingency plans in place should there be a power failure or insufficient numbers of refrigerated storage spaces during peak periods.

Guidance

Where contingency arrangements involve the transfer of bodies to other premises, these should be assessed to ensure that they are suitable and that traceability systems are of the required standard. Stacking bodies on the same fridge tray is not considered suitable practice.

Establishments should have documented agreements with any funeral services that they may use for contingency storage. Consideration should be given to whether the funeral service provides contingency storage for other mortuaries. SOPs should address issues such as risk assessments and same/similar name systems.

The hire of temporary storage units should not be the sole contingency arrangement for an establishment. Establishments should put in place other formally agreed arrangements for contingency storage. Where the hire of temporary storage facilities

forms part of establishments' contingency arrangements, consideration should be given well in advance and steps taken to ensure availability of funds, and of units for hire.

Establishments should consider entering in to Mutual Aid Agreements

with neighbouring organisations in order that they can provide and obtain support during periods of capacity shortages.

PFE3 Equipment is appropriate for use, maintained, validated and where appropriate monitored

a) Items of equipment in the mortuary are in a good condition and appropriate for use:

   i. fridges / freezers

   ii. hydraulic trolleys

   iii. post mortem tables

   iv. hoists

   v. saws (manual and/or oscillating)

Guidance

Equipment should be made of material that is easy to clean, impervious, non-rusting, non-decaying and non-staining.

b) Equipment is appropriate for the management of bariatric bodies.

c) The ventilation system provides the necessary ten air changes per hour and is checked and maintained at least annually.

Guidance

COSHH requires a thorough examination of the ventilation system at 14-month intervals, and sets out what the examination should cover.

d) Staff have access to necessary PPE.

Guidance

Where face masks should be worn, they should be face fitted.

e) Where chemicals are used for preservation of tissue samples, there is adequate ventilation.

f) Key items of equipment, including fridges/freezers, trolleys and post mortem tables (if downdraught) are subject to regular maintenance and records are kept.

Guidance

This includes fridges in Maternity where fetuses or still born babies are stored prior to examination. Maintenance records may be held by the mortuary or centrally by the Trust, such as the Estates Department. They should be available for review during inspection by the HTA.

Appendix 2: Classification of the level of shortfall

Where the HTA determines that a licensing standard is not met, the improvements required will be stated and the level of the shortfall will be classified as 'Critical', 'Major' or 'Minor'. Where the HTA is not presented with evidence that an establishment meets the requirements of an expected standard, it works on the premise that a lack of evidence indicates a shortfall.

The action an establishment will be required to make following the identification of a shortfall is based on the HTA's assessment of risk of harm and/or a breach of the HT Act or associated Directions.

1. Critical shortfall:

A shortfall which poses a significant risk to human safety and/or dignity or is a breach of the Human Tissue Act 2004 (HT Act) or associated Directions

or

A combination of several major shortfalls, none of which is critical on its own, but which together could constitute a critical shortfall and should be explained and reported as such.

A critical shortfall may result in one or more of the following:

(1) A notice of proposal being issued to revoke the licence

(2) Some or all of the licensable activity at the establishment ceasing with immediate effect until a corrective action plan is developed, agreed by the HTA and implemented.

(3) A notice of suspension of licensable activities

(4) Additional conditions being proposed

(5) Directions being issued requiring specific action to be taken straightaway

2. Major shortfall:

A non-critical shortfall that:

- poses a risk to human safety and/or dignity, or
- indicates a failure to carry out satisfactory procedures, or
- indicates a breach of the relevant CoPs, the HT Act and other relevant professional and statutory guidelines, or
- has the potential to become a critical shortfall unless addressed

or

A combination of several minor shortfalls, none of which is major on its own, but which, together, could constitute a major shortfall and should be explained and reported as such.

In response to a major shortfall, an establishment is expected to implement corrective and preventative actions within 1-2 months of the issue of the final inspection report. Major shortfalls pose a higher level of risk and therefore a shorter deadline is given, compared to minor shortfalls, to ensure the level of risk is reduced in an appropriate timeframe.

3. Minor shortfall:

A shortfall which cannot be classified as either critical or major, but which indicates a

departure from expected standards.

This category of shortfall requires the development of a corrective action plan, the results of which will usually be assessed by the HTA either by desk based or site visit.

In response to a minor shortfall, an establishment is expected to implement corrective and preventative actions within 3-4 months of the issue of the final inspection report.

Follow up actions

A template corrective and preventative action plan will be sent as a separate Word document with both the draft and final inspection report. You must complete this template and return it to the HTA within 14 days of the issue of the final report.

Based on the level of the shortfall, the HTA will consider the most suitable type of follow-up of the completion of the corrective and preventative action plan. This may include a combination of

- a follow-up site-visit inspection
- a request for information that shows completion of actions
- monitoring of the action plan completion
- follow up at next desk-based or site-visit inspection.

After an assessment of your proposed action plan you will be notified of the follow-up approach the HTA will take.