Site visit inspection report on compliance with HTA licensing standards

Central Mortuary Birmingham

HTA licensing number 12194

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**

16 January 2019

Summary of inspection findings

This is the first inspection of this establishment against the HTA's revised licensing standards, which came into force on 3 April 2017.

Although the HTA found that Central Mortuary Birmnigham had met the majority of the HTA's standards, nine major and fifteen 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

Central Mortuary Birmingham (the establishment) has been licensed by the HTA since September 2007. The Designated Individual (DI) is Head of Environmental Health and the Corporate Licence Holder contact is the Interim Head of Birmingham City Council. The mortuary is currently staffed by a Mortuary Manager, a senior Anatomical Pathology Technologist (APT) and three APTs who all work full-time.

The establishment performs around 1,700 adult coronial post-mortem (PM) examinations annually.

The mortuary has 74 refrigerated body storage spaces, including eight bariatric spaces and 27 freezer spaces for long-term storage of bodies, of these six are suitable for the storage of bariatric bodies (see shortfall against PFE2(c)). In addition, the mortuary has a second PM room which can be chilled and used as a temporary refrigerated body storage area as contingency; this room was not fit for use at the time of the inspection. A service level agreement (SLA) is in place with a funeral directors for contingency storage for up to 50 refrigerated spaces (see shortfall against PFE2(i)).

All fridges and freezers are connected to a remote monitoring system and have audible alarms, which are connected to the provider, notifying mortuary staff of temperature fluctuations during working hours. Outside of working hours, an email message is sent to the phone carried by the on-call APT (see *Advice,* item 8). The mortuary staff do not review the fridge temperature records for trends (see shortfall against PFE2(f)). The mortuary staff carry out fridge alarm testing biannually, however, this is not documented (see shortfall against PFE2(e)).

The mortuary is located in the same building as the Birmingham Coroner's Court. The mortuary facility has a separate entrance which is secured by a gate and CCTV. Access to the mortuary is by swipe card which opens the door to the mortuary office. The funeral director appointed by the Coroner transfers bodies to the mortuary in and out of normal working hours. Staff from the mortuary are contacted directly out-of-hours by the funeral directors to gain admittance to the mortuary.

Mortuary staff are responsible for checking all bodies that have been admitted, verifying identification details from the identification tags attached to the bodies against the information provided by the police or Coroner. If any information is missing the mortuary staff contact the police or Coroner to verify the details. Bodies with same and/or similar names are indicated on the body store white board by using a different colour marker, a sticker in the mortuary register and highlighted in the computer records (see *Advice,* item 5).

When bodies are released to funeral directors they confirm the identify of the body with the funeral director by checking identification details on the identification tags against the information brought by the funeral director and cross reference the information with the

computer record to confirm the Coroner has confirmed release of body (see shortfall against T1(e)).

The mortuary operates an appointment system for viewings, which are generally for identification purposes. Mortuary staff do not interact with the families directly for viewings, this is done by Coroner's Officer during work hours and the police out-of-hours. However, they are responsible for the preparation and identification of the body prior to viewings (see shortfall against T1(c)).

The PM suite has four tables. There is a dedicated dissection bench 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. Ventilation service records for the air changes in the PM suite and maintenance records for the fridges and freezers were not available during the inspection (see shortfalls against PFE3(c) and (f)).

Mortuary staff have access to PPE within the PM room and body store area. There is demarcation of clean and dirty areas within the PM room, but not in the transitional area from the PM room to the body store (see shortfall against PFE1(b)). 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 staff use a 'PM Tissue' form to record the number, weight and type of tissue taken at PM examination. This information is also stored electronically in the deceased's mortuary record.

Tissue or toxicology samples are stored and couriered to the approved Coroner's testing laboratory or the pathologist's hospital histopathology department, respectively, for examination. There is a system in place to ensure that when relatives request that tissue or organs are repatriated to a body, this is carried out before the body is released.

Description of inspection activities undertaken

This was the third site visit inspection of the establishment; the previous inspection took place in 2015. 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 four adult bodies (three in refrigerated and one in frozen storage); no discrepancies were identified.

In addition, tissue removed during PM examinations for four cases between 2017 and 2019 were audited for traceability. The audit included details of tissue type, number and weight of tissue retained, coronial tissue forms, and other associated paperwork and electronic database records; no discrepancies were identified.

Inspection findings

Although the HTA found the Licence Holder and the Designated Individual to be suitable in accordance with the requirements of the legislation, the number and severity of shortfalls identified is of concern. Advice and guidance was given to the DI to further improve practices following the last inspection in 2015. During the current inspection similar areas for improvement were identified, and are captured in the shortfalls below.
Although the DI has been deemed to a be a suitable person to hold the role, the shortfalls identified demonstrate that the he has not ensured that there are suitable practices in place for the conduct of the licensed activities.

The HTA will monitor progress of these shortfalls through the Corrective and Preventative Action (CAPA) plan to be completed by the establishment and keep the suitability of the DI under review.

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		
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:	While the establishment has a number of the required SOPs in place, they lack sufficient detail and do not reflect practice. These include but are not limited to: i) SOP 4.1 'Body receipt and handling', does not state that a minimum of three identifiers should be attached to the body, or detail what is acceptable information to receive on the Removal Body form. The SOP states the mortuary identification number is written on the body and blood is removed to determine infectious status. Neither of these practices take place, therefore, these steps need to be removed. In addition, the SOP does not clearly outline the requirement to fully shroud all bodies upon receipt and prior to storage; ii) SOP 4.2 'Viewing of bodies', there is insufficient detail of the viewing procedure. The SOP does not describe the process for removing or replacing a body following a viewing. In addition, there is no mention of checking the identification of the body at any stage of the process; iii) There is no documented SOP for lone working, however, lone working is a frequent occurrence in the mortuary, especially out-of-hours; iv) There is no documented SOP for HTA Reportable Incidents (HTARIs). All SOPs that are in place require review to ensure they reflect current practice and contain sufficient detail. Additional SOPs are also required to ensure all activities under the licence are included. (see *Advice,* item 1)	**Major**
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 activities, these documents are not version controlled or indicate they are reviewed regularly. For example, SOP 4.1 Body Receipt and Handling and SOP 4.4 Processing Post Mortems. (see *Advice,* item 2)	**Minor**

GQ2 There is a documented system of audit		
a) There is a documented schedule of audits	The establishment does not have a suitable documented schedule of audits for HTA licensable activities, or a system to record any deviations from SOPs. (*as a result, standards GQ2(b) and (c) cannot be met*) (see *Advice,* item 3)	**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	Although staff have been initially 'signed off' on completion of training, there is no on-going competency assessments for staff. Competency (and training) assessments should be regularly completed for all staff.	**Minor**
f) There is a documented induction and training programme for new mortuary staff	There is no documented local induction programme for new mortuary staff.	**Minor**
g) Visiting/external staff are appropriately trained and receive an induction which includes the establishments policies and procedures.	There is no documented induction programme for visiting Pathologists who attend the mortuary to undertake post mortem examinations for the Coroner.	**Minor**

GQ4 There is a systematic and planned approach to the management of records		
b) There are documented SOPs for record management which include how errors in written records should be corrected.	There is no documented SOP in place for how errors in records should be corrected. It was noted in the visual inspection that correction fluid had been used in the mortuary register and histology book.	**Minor**

GQ5 There are systems to ensure that all untoward incidents are investigated promptly		
c) The incident reporting system ensures that follow-up actions are identified (i.e. corrective and preventative actions) are completed	The establishment does not have a documented incident reporting system in place. Therefore the DI cannot be assured that staff are aware and know how to report incidents and be assured that when incidents occur, follow-up actions are completed.	**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 comprehensive risk assessments identifying all potential hazards, which are appropriately assessed and include what control measures have been implemented, the risk assessments do not have 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	Three identifiers are not obtained from those wishing to view the deceased. The mortuary are contacted verbally by the Coroner's office or police to arrange viewings; only the name is recorded on a white board located in the mortuary. Further checks of the identity of the body are not performed when preparing the body for viewing, or prior to a viewing being undertaken. (see *Advice,* item 4). The use of less than three separate identifiers when identifying bodies, presents a risk of viewing the wrong body.	**Major**
e) Identity checks take place each time a body is moved whether inside the mortuary or from the mortuary to other premises.	Although the procedure in the SOP states that paperwork brought by the funeral director should be used for identification of a body prior to release, a release of a body was observed by the inspection team and the paperwork was not used directly to identify the body. There is a reliance by the APTs to remember the three required identifiers on the paperwork when undertaking their initial two-person identity check. There is no direct check of the three identifiers documented on the paperwork against the body identification tags by either the mortuary staff or funeral director prior to release.	**Major**
g) Organs and 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.	A record of the quantity of tissue blocks retained at PM examination is recorded on the histology request form that is sent with the tissue to the laboratory. The tissue form is scanned into the computer record and a book is signed by the mortuary staff and courier when collecting the tissue. However, the establishment do not receive confirmation that PM specimens are received at the relevant histopathology or toxicology laboratories. The DI cannot be fully assured of PM specimen traceability; (see *Advice,* item 6)	**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	The inspection team identified issues with the cleanliness and maintenance of the body store and PM room including but not limited to: i) there was large amount of accumulated hair and debris in the drains of the PM room; ii) the floor of the body store was cracked, rust-stained and pitted; iii) there is a large area of damage to the lower wall in the transitional area, leaving porous surfaces exposed; iv) The doors to the PM room are damaged, with small areas of wood exposed and the door paint is peeling off. In addition, the PM room doors do not close properly. Porous surfaces make it difficult to clean and decontaminate effectively and inadequate cleaning routines pose a potential infection risk to staff. (see *Advice,* item 7)	**Major**
b) There is demarcation of clean, dirty and transitional areas of the mortuary, which is observed by staff and visitors.	There is no demarcation of transitional areas between the PM room (dirty area) and the body store (clean area). Making it difficult for visitors and staff to determine clean areas from dirty contaminated areas.	**Minor**
c) There are documented cleaning and decontamination procedures and a schedule of cleaning	There is no documented cleaning schedule for the PM suite, body store area or fridges and freezers.	**Minor**

PFE2 There are appropriate facilities for the storage of bodies and human tissue.		
a) Storage arrangements ensure the dignity of the deceased	During the site visit, the inspection team observed the doors to the PM suite from the body store being propped open whilst a PM examination was being undertaken. The doors to the PM suite should be kept closed whilst bodies are on the PM tables and/or a PM examination is being conducted. This will help prevent unauthorised or unintentional access or viewing of PM room activities and maintains the dignity of the deceased. In addition, closing these doors will help ensure the ventilation system can work efficiently, maintaining the required 10 air changes per hour (see shortfall against PFE3(c)).	**Major**

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 record the body store alarm tests; ii) There is no lower alarm trigger point for the fridge units to mitigate the risk of unintentionally freezing bodies.	**Minor**
f) Temperature of fridges and freezers are monitored on a regular basis.	Mortuary staff do not consistently monitor and record fridge and freezer temperatures or review them for trends to help identify and mitigate the risk of potential equipment failure.	**Minor**
g) Bodies are shrouded or in body bags whilst in storage.	Heads were not shrouded of bodies in storage. This may impact the dignity of the deceased.	**Minor**
i) There are documented contingency plans in place should there be a power failure or insufficient numbers of refridgerated storage spaces during peak periods.	While a SLA exists for refrigerated bodies to be sent to funeral directors for storage. There is no contingency arrangements for bodies in long-term freezer storage. At the time of inspection, the majority of the freezer spaces were full. In addition, there is no generator back-up in case of electrical breakdown.	**Major**

PFE3 Equipment is appropriate for use, maintained, validated and where appropriate monitored		
a) Items of equipment in the mortuary are in good condition and appropriate for use.	i) Body trolleys and hoists in the mortuary were found to be in poor condition, with multiple areas of rust and metal exposed, making the equipment difficult to clean and decontaminate. ii) The body store freezer units had large amounts of ice around the doors due to the door seals having deteriorated. This increases the risk of failure of these units.	**Major**

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 commissioning records for the temporary units during the inspection to provide assurance the ventilation system is working to the required ten air changes per hour. Emails seen at the time of the inspection, state that the air changes of the temporary ventilation units are calculated based on room dimensions. There is no evidence or verbal assurance from the establishment staff that physical measurements to check the effectiveness of the ventilation system, have occurred. In August 2018, the establishment had provided assurance to the HTA that the temporary ventilation system would be checked to ensure that it would work effectively . In addition, during the inspection, the doors to the PM room were propped open while a PM examination was being undertaken. This therefore increases the area for which the ventilation system would be required to work; an area far in excess of the size of the PM room for which the calculations for air handling are based.	**Major**
f) Key items of equipment, including fridges/freezers, trolleys and post mortem tables (if downdraught) are subject to regular maintenance and records are kept	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 also 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. HTA Code of Practice 3 has now been superseded by HTA Code B: Post-mortem.
2.	GQ1(d)	It is unknown if the author and authoriser of the Central Mortuary SOPs are different. Mortuary staff should be involved in writing SOPs and the SOPs then verified by someone who is familiar with mortuary practice and procedures.
3.	GQ2(a)	The DI is advised to develop an audit schedule to include horizontal and vertical audits of all licensable activites for example, receipt of a body, release of a body and relevant material going off site. The DI is advised to use these procedural audits as an opportunity to review SOPs to see if practice reflects what is written in the SOP for each activity.
4.	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 by mortuary staff on the body before the viewing/police identification takes place. Guidance is also available on the HTA website: updated guidance for Traceability Standard T1c.
5.	T1(d)	The DI may wish to consider using coloured wrist tags on bodies and/or a sign on the fridge door to strengthen the current procedure for flagging same and/or similar names.
6.	T1(g)	The DI may wish to consider requesting an email acknowledgment as confirmation that specimens have been received at the relevant laboratory. This will help ensure any discrepancies can be traced and will provide assistance when undertaking regular traceability audits.
7.	PFE1(a)	The DI is advised to ensure there is a programme of planned preventative maintenance to keep equipment and premises fit for purpose.
8.	PFE2(c)	The DI is advised to consider risk assessing the storage capabilities of storing larger bariatric bodies at the establishment.
9.	PFE2(e)	The DI is advised to consider an audible alert for fridge temp deviations for out-of-hours notifications as an email alert is unlikely to receive attention during the night.

Concluding comments

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;

- the electronic record system in place for admitting and releasing bodies is robust and also helps with traceability of tissues, as the number and weight of the tissue taken for histopathology can be recorded.

There are a number of areas of practice that require improvement, including nine major and fifteen 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: 11.02.2019

Report returned from DI: 15.02.2019

Final report issued: 05.03.2019

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: 03.07.2019

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.