



## **Site visit inspection report on compliance with HTA licensing standards**

### **East Ham Public Mortuary**

**HTA licensing number 12032**

**Licensed under the Human Tissue Act 2004 for the**

- **making of a post mortem examination; 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**

**2 April 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.

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

Although the HTA found that East Ham Public Mortuary had met the majority of the HTA's standards, four major and sixteen minor shortfalls were found against standards for Governance and Quality, Traceability and Premises, Facilities and Equipment.

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**

East Ham Public Mortuary (the establishment) has been licenced by the HTA since July 2007, this report describes the third routine inspection. The current DI has been in post since March 2015 and this is their second HTA site visit inspection as DI.

The mortuary admits bodies from the local community via two local Coroner's contracted funeral director (FD) companies. Access to the mortuary by FDs is via a rear entrance to the building directly into the mortuary and body store area. This entrance is overlooked by high-

rise housing developments in all directions. However, the doors open into a canopied and fenced area in the grounds of the mortuary (see shortfall against PFE1(d)).

Out-of-hours FDs admitting bodies from the community are responsible for identifying a fridge location and transferring the body into refrigerated storage. A body admission sheet is completed and placed into a designated tray. During working hours, the mortuary staff review the mortuary occupancy checklist and complete body identity checks of all bodies admitted to the mortuary.

Release of bodies is only conducted by the mortuary staff in normal working hours. The establishment is contracted to facilitate a PM examination service for one Coronial district. There are two visiting pathologists who attend the establishment to conduct PM examinations authorised by the Coroner. There are two full-time Anatomical Pathology Technologists (APTs) who staff the mortuary, one of whom is also the Mortuary Manager.

The establishment receives approximately 400 bodies per year from the community, all of which are for PM examination, including blood-borne high-risk (up to biological hazard group 3) and defence (second PM examination) cases. Forensic PM examinations are also performed and material is held under the Police And Criminal Evidence Act 1984 (PACE) at the establishment. No perinatal or paediatric cases are received into this establishment.

The body store consists of 39 refrigerated spaces, four of which are suitable for bariatric cases. In addition, there are ten dedicated freezer spaces all of which were full at the time of inspection (see shortfall against PFE2(c)).

All fridges and freezers are alarmed with upper and lower trigger points, which when triggered sound in the mortuary and calls the mobile phone of the DI or on-call APT in her absence (see shortfall against PFE2(e)).

The mortuary has one PM suite with three sets of metal stands, onto which fridge trays are secured for PM examination. High-risk and forensic PM examinations are conducted at the end of each PM session, if required. The pathologist completes each PM examination prior to commencing the next to help mitigate the risk of mixing-up organs and tissue samples (see *Advice* item 5). The Coroner's Office email authorisation for a PM examination to the mortuary. The pathologist and APT check the identity of the body before the external examination and evisceration of the body (see shortfall against T1(c)).

Material retained at PM examination for histological analysis is labelled, documented, packaged and sent to other HTA-licensed establishments. Relatives' wishes with regards to the fate of any tissue retained following PM examination is managed by the Coroner's office. The pathologist informs the Coroner of what material has been retained which is then communicated to the family. Consent for the fate of any tissues retained at PM examination is initially taken verbally and then confirmed in writing by the Coroner's office. Where

appropriate consent has been given, blocks and slides are stored for use for scheduled purposes at the HTA-licenced establishments where analysis is completed. Whole organs for repatriation to a body are returned to the mortuary. If the body has already been authorised for release by the Coroner, the organ will be collected by the relevant FD and repatriated with the body or disposed of according to the relatives' wishes.

### **Description of inspection activities undertaken**

Traceability audits of body identifiers, storage locations and mortuary checklist details were conducted for five adult bodies, including two bodies from the freezer. The mortuary wipe board details, admission paper work and Coroner's PM examination authorisation paperwork for each case was checked. Discrepancies in the address for one body audited was found between the wrist band attached to the body and the documentation. This body also had only two identifiers on the wrist band (see shortfall against T1(c)).

In addition, whole organs removed during PM examination for two cases in 2018 were audited for traceability. The records for relatives' consent wishes for any other year were not held by the establishment as these have recently been requested from the Coroner's office.

Material removed following PM examination is recorded and a record sheet is retained by the establishment, however no record of receipt is obtained from the receiving establishment. The Coroner's office send relative's wishes regarding the fate of whole organs retained at PM examination to the establishment when they are to be repatriated to the body. Repatriation of whole organs to a body undertaken by the mortuary staff is not recorded by the establishment (see shortfall against T1(g)). Organs for repatriation to bodies that have already been released from the mortuary to FDs, are signed for on collection by the FD (see *Advice*, item 7).

Interviews were conducted on the day of the site visit inspection with the the DI; Mortuary Manager; an APT and the Coroner's Officer's Manager. No pathologist was available for interview.

### **Material held for the police**

Under s39 of the Human Tissue Act 2004, 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, in response to a recommendation resulting from the 2012 report of the Association of Chief Police Officers' audit of tissue held under police authority, police exhibits held on HTA licensed premises are included within the regular HTA inspection process. Police holdings stored at the establishment were reviewed by the HTA during the inspection. Any findings in relation to police holdings have been shared with the Home Office, but do not appear in this report as they are outside the scope of the HT Act.

## 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

<b>GQ1 All aspects of the establishment's work are governed by documented policies and procedures</b>		
<p>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.</p>	<p>While the establishment has a single document in place that includes many of the processes, it lacks sufficient detail or attention to wording. The processes for which there are insufficient details includes, but are not limited to:</p> <ul style="list-style-type: none"> <li>• Preparation of bodies for PM examination section - Does not state what three identifiers on the body should be checked and cross referenced against the Coroner's instruction for PM examination;</li> <li>• Body viewing section - Does not state that three identifiers should be obtained from those wishing to view a body and that this information should be cross referenced with the information on the wristband of the body prior to viewing;</li> <li>• Release of bodies section – Does not state that three identifiers provided by the FD should be cross referenced with information on the wristband of the body prior to release;</li> <li>• Contingency section – Does not detail the contingency arrangements in place and how staff can activate the contingency plan;</li> <li>• References at the end of this document are out of date or obsolete and should be updated or removed.</li> </ul> <p>All sections of the document require review to ensure all processes are robust and reflective of current practice.</p>	<p><b>Minor</b></p>
<p>e) There is a system for recording that staff have read and understood the latest versions of these documents</p>	<p>There is currently no method in place for recording staff have read and understood the latest version of the processes document. Therefore the DI cannot be assured that staff are aware and following the procedures that govern their work.</p>	<p><b>Minor</b></p>
<p>h) Matters relating to HTA-licensed activities are discussed at regular governance meetings involving establishment staff</p>	<p>There is currently no regular meetings between the DI and staff at the mortuary to discuss HTA-licensed activities.</p>	<p><b>Minor</b></p>

<b>GQ2 There is a documented system of audit</b>		
a) There is a documented schedule of audits	There is currently no schedule of audits of licensable activities conducted at the mortuary.  <i>Standard GQ2(b) and (c) can therefore not be assessed</i>	<b>Major</b>

<b>GQ3 Staff are appropriately qualified and trained in techniques relevant to their work and demonstrate competence in key tasks</b>		
c) Staff are assessed as competent for the tasks they perform	While staff are trained for the tasks they perform, staff are not regularly competency assessed to ensure they are following procedures correctly.	<b>Minor</b>
d) Staff have annual appraisals and personal development plans	Staff do not have annual appraisals or documented personal development plans.	<b>Minor</b>

<b>GQ4 There is a systematic and planned approach to the management of records</b>		
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	There is no system in place for managing retention of records. There is no documented system for how long records need to be kept or which records should be maintained.	<b>Minor</b>
b) There are documented SOPs for record management which include how errors in written records should be corrected.	No SOP was available at the time of inspection that details how records should be maintained or how written records should be corrected.	<b>Minor</b>

<b>GQ5 There are systems to ensure that all untoward incidents are investigated promptly</b>		
b) The incident reporting system clearly outlines responsibilities for reporting, investigating and follow up for incidents	There is no incident reporting system employed by the establishment. Incidents are shared verbally with the DI at informal staff meetings. This increases the risk of incidents reoccurring as root causes are not investigated or followed up sufficiently.  <i>Standards GQ5(b), GQ5(c), GQ5(d) and GQ5(e) could not be assessed</i>	<b>Major</b>

**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	While risk assessments are conducted for a number of procedures, risk assessments have not been reviewed since the last HTA site visit inspection.	<b>Minor</b>
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**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	<p>A body audited from the freezer was found to have had a PM examination using effectively a single identifier. While the wrist band attached to the body stated the name and address, discrepancies between the address on the wrist band and the Coroner's authorisation documentation meant this identifier could not be used.</p> <p>The release of a body was witnessed by the inspection team. The details provided by the FD was not used to cross reference the details found on the wrist band attached to the body.</p> <p>On two separate occasions during the inspection FDs arrived without any paperwork to collect a body; it is usual practice to release a body on a verbal communication of one or two identifiers.</p> <p>In addition, bodies are viewed after staff are provided with only verbal communication of the identity of the deceased from those visiting the mortuary. No further identification check of the body is performed prior to the viewing.</p> <p>These practices increase the risk of conducting a PM examination, releasing or viewing of a wrong body. The establishment is required to review its current systems to ensure three identifiers are available to identify a body that can be checked when conducting any relevant process or procedure.</p>	<b>Major</b>
g) Organs or tissue taken during post-mortem examination are fully traceable, including blocks and slides (including police holdings).	While the establishment retains records for tissue retained at PM examination, no receipt of material sent for analysis is obtained from the receiving establishment.	<b>Minor</b>

<b>T2 Disposal of tissue is carried out in an appropriate manner and in line with the HTA's codes of practice.</b>		
c) Disposal is in line with the wishes of the deceased's family	The establishment do not receive confirmation of disposal of relevant material retained at PM examination following completion of the Coroner's authority from the referral centre. Therefore the DI cannot be assured tissue is disposed of in line with the wishes of the relatives.	<b>Minor</b>

<b>PFE1 The premises are secure and well maintained and safeguard the dignity of the deceased and the integrity of human tissue.</b>		
a) The premises are clean and well maintained	<p>While the mortuary is clean, there are areas that require maintenance and attention. These include, but are not limited to:</p> <ul style="list-style-type: none"> <li>• Large areas of exposed plaster in both the PM suite and body store area;</li> <li>• Wooden door frames and exposed wood in the PM suite;</li> <li>• Damage to the floor around drain covers and a large access panel in the floor of the body store area;</li> </ul> <p>The damage makes these areas porous, meaning staff cannot clean and decontaminate these surfaces effectively.</p> <p>In addition there is no drain/barrier present between the PM suite and the body store area, meaning contaminated water may enter the body store during cleaning following a PM examination.</p>	<b>Major</b>
b) There is demarcation of clean, dirty and transitional areas of the mortuary, which is observed by staff and visitors	<p>Bodies are transported from the PM suite following a PM examination through the body store area. This area is accessed at the same time by FD's collecting and bringing bodies in from the community. While signs are in place to distinguish between dirty, transitional and clean areas, no PPE is used by visitors or staff.</p> <p><i>Refer to shortfall against standard PFE3(d)</i></p>	<b>Minor</b>
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)	<p>The mortuary is located in a built-up residential area with a number of high rise buildings overlooking the building and its grounds. There is main road with high pedestrian footfall directly outside the grounds of the establishment.</p> <p>The inspection team witnessed a FD arrive to collect a body. They parked at the side of the building and had not reversed up to the rear entrance doors. This would have allowed oversight of movement of bodies from the mortuary to their vehicle.</p>	<b>Minor</b>

<b>PFE2 There are appropriate facilities for the storage of bodies and human tissue.</b>		
a) Storage arrangements ensure the dignity of the deceased	Bodies stored for more than 28 days are moved to the freezer storage facilities. However, these freezer units are currently set to -12°C. This temperature is not sufficient to help prevent the deterioration of bodies and therefore should be lowered to the recommended -20°C (+/- 4°C).	<b>Minor</b>
c) Storage for long-term storage and bariatric bodies is sufficient to meet needs	The freezers were full at the time of inspection despite normal levels of activity. As the establishment provides a forensic PM examination service it often relies on its freezer storage. There were no freezer facilities available for bariatric cases.	<b>Minor</b>
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	The fridge/freezer alarm system is not regularly challenged by the establishment staff. The system is only challenged once annually as part of the routine maintenance testing and may not necessarily provide the DI with sufficient assurance that the alarm will trigger when required. In addition, all alarm challenges should be recorded and staff should be aware of the upper and lower alarm trigger temperatures for the alarm system.	<b>Minor</b>

<b>PFE3 Equipment is appropriate for use, maintained, validated and where appropriate monitored</b>		
d) Staff have access to necessary PPE	Bodies are transported on trolleys directly from the PM suite in dirty footwear to the body store area, making the body store area a dirty area.  FDs are not provided with appropriate PPE, for example, disposable over-shoes on entry to the body store area. PM examinations and access to the body store by FDs often coincide.	<b>Minor</b>

### Advice

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

No.	Standard	Advice
1.	GQ1(a)	While currently there is one large document in place containing relevant procedures, the DI may wish to consider splitting this document into individual procedures, making them easier to refer to and update when required.
2.	GQ1(a)	The DI is advised to add the procedure for the thawing of frozen bodies into the mortuary procedures document.
3.	GQ3(e)	While staff are offered the opportunity to apply for funding to attend training courses, staff have not attended any training courses as staff stated there was a lack of available time or staff to cover in their absence. The DI is therefore

		advised to look at staffing levels to allow the development and training requirements of staff to be met.
4.	T1(a)	A collection of human bones were being held by the establishment at the time of inspection wrapped in a sheet inside a body bag. The DI is advised to determine the number of bones present, record this on the mortuary checking in sheet to ensure traceability.
5.	T1(c)	While an identification check of bodies of prior to PM examination is conducted by two APTs and the pathologist, only the pathologist signs to record this identification check has been undertaken. The DI is advised that APTs should also sign to confirm they have performed an identification check of the body against the Coroners instruction documentation using three identifiers. This will strengthen this process and help mitigate against the risk of performing a PM examination on the wrong body.
6.	T1(g)	A number of bodies are eviscerated at one time prior to PM examination and trolleys are used in addition to fix stands to hold eviscerated bodies and organs. The DI may wish to consider using a labelling system for bowls used to collect organs during the PM examination procedure to further mitigate the risk of organ mix-up during PM examination.
7.	T1(g)	The DI is advised to liaise with the Coroner's Office to seek assurance that relatives are informed when a body is authorised for release without an organ(s) being returned and that they will be returned to the FD at a later date for their wishes to be carried out.
8.	PFE1(d)	The DI may wish to consider extending the current CCTV coverage to include all the grounds of the establishment to discourage unauthorised persons accessing the grounds of the mortuary.
9.	PFE1(d)	There are very low walls and gates to the grounds in which the mortuary is located. The gates are manually operated and therefore are left open during working hours, allowing unauthorised persons to enter the grounds of the building unchallenged. There was evidence of fires and broken glass at the rear of the building where there was no CCTV coverage. The staff reported unauthorised persons were regularly found on the grounds.  The DI may wish to consider the introduction of electronic gates restricting access to the grounds of the mortuary to those who have been given authorisation. This could help to mitigate the risk of unauthorised access to the mortuary and increase the safety of staff.
10.	PFE2(a)	The DI is advised to transfer the collection of bones to a suitable storage container to mitigate the risk of loss of any of the bones and preserve the dignity of the deceased.
11.	PFE2(b)	Staff stated they felt the capacity for the storage of bodies was often not sufficient to meet needs. They have needed to rely on local FDs or the SLA they have in place with other establishments to store bodies during times of peak activity. The DI is therefore advised to risk assess the capacity to help ensure that the contingency they have in place is sufficient.

## Concluding comments

Despite the number of shortfalls identified, areas of good practice were observed during the inspection. The establishment demonstrated a commitment to the continual improvement of

practices and compliance with the HT Act.

There are a number of areas of practice that require improvement, four major shortfalls and sixteen 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.

**Report sent to DI for factual accuracy: 29 April 2019**

**Report returned from DI:**

**Final report issued: 04 June 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.

<b>Consent</b>
<b>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</b>
<p>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.</p> <p>b) There is a documented standard operating procedure (SOP) detailing the consent process.</p> <p><i>Guidance</i></p> <p><i>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.</i></p> <p>c) There is written information for those giving consent, which reflects the requirements of the HT Act and the HTA's codes of practice.</p> <p><i>Guidance</i></p> <p><i>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.</i></p> <p>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.</p> <p>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.</p> <p>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.</p> <p>g) The establishment uses an agreed and ratified consent form to document that consent was given and the information provided.</p> <p><i>Guidance</i></p> <p><i>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</i></p>

*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 or 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 injuries 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 they are 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 for these 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.