Site visit inspection report on compliance with HTA licensing standards
Inspection date: **26 November 2019**

Haringey Public Mortuary

HTA licensing number 12263

Licensed under the Human Tissue Act 2004

Licensed activities

The table below denotes whether the site is licensed to carry out an activity and whether or not the activity is currently carried out in that area.

Area	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	Storage of the body of a deceased person or relevant material which has come from a human body for use for a scheduled purpose
Haringey Public Mortuary	Licensed	Not licensed	Licensed
Mortuary	*Carried out*	-	*Carried out*

Summary of inspection findings

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

Although the HTA found that Haringey Public Mortuary (the establishment) had met the majority of the HTA's standards, eight major and five minor shortfalls were found against standards for Governance and Quality, Traceability and Premises, Facilities and Equipment.

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.

Compliance with HTA standards

Major shortfalls

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.	Standard operating procedures (SOPs) do not include sufficient details of procedures. • The SOPs for viewings, release of bodies from the mortuary and post-mortem (PM) examination do not include sufficient details of what identifiers could be used to identify the deceased and how identification checks should be performed. • The SOP for disposal of tissue following PM examination states that consent for the fate of tissue taken at PM examination can be sought from the next of kin/family/relatives. This does not reflect the requirements of the HT Act or HTA Codes of Practice. No reference is made to obtaining consent from the person themselves in life, their nominated representative or those in a qualifying relationship. • The SOP for movement of bodies into freezer storage does not describe the procedure or timeframe for checking the condition of bodies. The SOP does not detail the criteria used to determine if a body should be transferred to freezer storage. • There is no documented policy or procedure describing the practices for shrouding bodies.	**Major**

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	Anatomical Pathology Technologists (APT) undertake evisceration before external examination of the body by the pathologist. The SOP for PM examination describes that evisceration can be undertaken by an APT without the body first being examined by a pathologist.	**Major**
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	Staff are not following the establishment's procedure for labelling bodies received from other establishments. An additional identification band is not added to the body on arrival. This means that bodies are not consistently labelled with information that can be used by the establishment for identification purposes.	**Major**
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	Procedures for identification of bodies and tissue do not always use a minimum of three identifiers of the deceased. • Bodies received from other establishments are not always labelled with a minimum of three identifiers upon arrival at the mortuary. The inspection team's audit identified one body that had been received from another establishment and had only two identifiers on the wristband. Tissue stored with this body was labelled with only two identifiers, one of which was not linked to the establishment's traceability records. • Bodies may be released from the mortuary using only two identifiers to check the identification of the deceased. • Identification of bodies for viewings may be based on only one identifier of the deceased (full name) provided verbally by the family upon arrival at the mortuary.	**Major**

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 floor of the PM room is showing signs of wear. • The seals around the drains in the floor are eroded. • There are cracks in the joins of the floor. • Some areas of the floor are corroded. This means that the floor surface is difficult to clean and disinfect adequately. The inspection team's visual inspection of the PM room found a small blood spot on the dissection sink and some residue of cleaning product on the PM tables.	**Major**
b) There is demarcation of clean, dirty and transitional areas of the mortuary, which is observed by staff and visitors	The premises and procedures do not adequately control the contamination risk at the rear entrance to the PM room. • The procedure for transferring bodies between the PM room and the body store area could contaminate the body store area, which is currently considered to be a clean area of the premises. • There is no demarcation between the PM room, storage room and corridor to the body store area. There are no signs to alert staff or visitors to the contamination risk within these areas or what personal and protective equipment is required. • There are no barriers between the PM room and storage room leading to the corridor outside. This means that contaminated fluid on the floor of the PM room could enter the storage room and corridor.	**Major**

PFE2 There are appropriate facilities for the storage of bodies and human tissue.		
c) Storage for long-term storage of bodies and bariatric bodies is sufficient to meet needs	The mortuary does not have sufficient freezer storage capacity to meet the need for long-term storage of bodies. At the time of the inspection, mortuary staff had identified that a number of bodies in refrigerated storage had deteriorated in condition and required freezer storage.	**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 or lower set range	There is no temperature alarm system for the temporary body storage unit. The temperature alarm system for the permanent fridges and freezers is not manually challenged to ensure that it will trigger as expected.	**Major**

Minor Shortfalls

Standard	Inspection findings	Level of shortfall
GQ2 There is a documented system of audit		
a) There is a documented schedule of audits	There is no documented audit schedule for licensed activities. Some SOPs state that audits are to be conducted monthly; however, these SOPs do not describe the type or scope of audits.	**Minor**

GQ3 Staff are appropriately qualified and trained in techniques relevant to their work and demonstrate competence in key tasks		
g) Visiting / external staff are appropriately trained and receive an induction which includes the establishment's policies and procedures	A pathologist who performs PM examinations at the establishment had not read or acknowledged the local SOPs for the activities they undertake.	**Minor**
GQ6 Risk assessments of the establishment's practices and processes are completed regularly, recorded and monitored		
c) Significant risks, for example to the establishment's ability to deliver post-mortem services, are incorporated into the Trust's organisational risk register	The establishment has identified the risk of low staffing levels on the delivery of PM services. However, a risk assessment has not been performed to consider the risks this presents to business continuity.	**Minor**
T1 A coding and records system facilitates traceability of bodies and human tissue, ensuring a robust audit trail		
g) Organs or tissue taken during post-mortem examination are fully traceable, including blocks and slides (including police holdings).	The inspection team's audit identified discrepancies in the records relating to the number of tissue blocks retained at PM examination.	**Minor**
PFE2 There are appropriate facilities for the storage of bodies and human tissue.		
a) Storage arrangements ensure the dignity of the deceased	The temperature alarm trigger points for the mortuary fridge and freezers are not set appropriately. This means that the establishment cannot provide assurance that alarms will trigger when storage temperatures deviate from ranges that will optimally maintain the condition of bodies.	**Minor**

The HTA requires the DI 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.

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

Number	Standard	Advice
1.	C1(d)	The DI may wish to discuss with the Coroner's office the clarity of the form used to record the consent wishes for tissue retained at PM examination. This may help to improve the clarity of the records of the family's consent wishes for both whole organs and tissues taken at PM examination.
2.	GQ1(g)	The DI may wish to consider identifying Persons Designated for the licence. This may help the DI to oversee licensed activities and ensure that incidents can be reported to the HTA in the DI's absence.
3.	GQ6(b)	The current severity ratings descriptions in the risk assessment for licensable activities consider health and safety risks only. The DI is advised to broaden the scope of the severity rating definitions for this risk assessment to include other risks (for example, risks to the dignity of the deceased and of regulatory non-compliance).
4.	T1(d)	The DI is advised to review the procedure for identifying bodies with same or similar names. The current procedure relies on using magnets on the fridge/freezer storage units. The DI is advised to strengthen the procedure by implementing additional strategies to identify bodies with same or similar names.
5.	PFE1(a)	The inspection team's visual inspection of the PM room found that there was a residue of cleaning product on the PM tables. The DI is advised to review the procedures for cleaning the PM room.

6.	PFE3(d)	At the time of the inspection, all staff who perform high-risk PM examinations had been face-fit tested for the use of FFP3 masks. The DI may wish to consider also providing alternative personal protective equipment for staff who cannot be or have not been face-fit tested for these face masks.

Background

Haringey Public Mortuary has been licensed by the HTA since October 2009. This was the fourth routine site visit inspection of the establishment; the most recent previous inspection took place in May 2015

Since the previous inspection, there has been a change in the DI in August 2016. No other significant changes to the licence arrangements or the activities carried out under the licence have occurred.

Description of inspection activities undertaken

The HTA's regulatory requirements are set out in Appendix 1. The inspection team covered the following areas during the inspection:

Standards assessed against during inspection

60 out of the total 72 HTA licensing standards were covered during the inspection (standards published 3 April 2017). Standards covered at this inspection are listed in appendix 3. Any standards that were not applicable to the establishment have been deleted from this table.

Review of governance documentation

The inspection team reviewed policies and procedural documents relating to licensed activities, cleaning records for the mortuary and PM room, contracts for servicing of equipment and records of servicing, ventilation reports, audits, risk assessments, meeting minutes, temperature monitoring for the storage units, reported incidents, and staff training records.

Visual inspection

The inspection team carried out a visual inspection of the body storage areas, PM room, viewing rooms and tissue storage area.

Audit of records

The inspection team performed traceability audits of five bodies in storage, including one in long-term freezer storage. Identification details were crosschecked between the identification band on the body, information on the door of the storage unit and the mortuary register. For one body, there was a discrepancy in the forename and date of birth on the identification band compared to the mortuary register and database records. For one body, which had been transferred to the establishment for storage only, there were only two identifiers on the identification bands attached to the body. Tissue stored with this body was labelled with only the date of birth of the deceased and a number that was not linked with the establishment's traceability records.

Audits were conducted of tissue taken at PM examination for four cases. Information was crosschecked between the mortuary documentation, Coroner's paperwork, family wishes forms and the mortuary database. All four cases reviewed confirmed that disposal of tissue had been completed in line with the wishes of the family. However, discrepancies were found for three cases. For two cases, there were discrepancies between the number of tissue blocks taken at PM examination and the number of tissue blocks detailed on the consent forms. For a third case, whilst there was information about the consent wishes for whole organs retained at PM examination, there was no information about consent for tissue blocks.

Meetings with establishment staff

The inspection team met with staff carrying out processes under the licence, including mortuary staff and the DI. A telephone interview was conducted with one of the visiting pathologists who performs PM examinations at the establishment.

Materials held for the police

Under section 39 of the HT Act, relevant material held for criminal justice purposes is outside the scope of HTA regulation and is not subject to the licensing requirements for storage. However, in response to a recommendation resulting from the 2012 report of the Association of Chief Police Officers' audit of tissue held under police authority, that police exhibits held on HTA licensed premises should be included within the regular HTA inspection process, police holdings stored in a designated area in 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.

Report sent to DI for factual accuracy: 13 December 2019

Report returned from DI: 16 December 2019

Final report issued: 17 December 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: 11 December 2020

Appendix 1: The HTA's regulatory requirements

Prior to the grant of a licence, the HTA must assure itself that the DI 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 DI 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.

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 Human Tissue Act 2004 (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 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:

   - A notice of proposal being issued to revoke the licence
   - 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.
   - A notice of suspension of licensable activities
   - Additional conditions being proposed
   - 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 Codes of Practice, 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 review or at the time of the next 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. Establishments 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 routine site visit inspection.

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

Appendix 3: Standards assessed during site visit inspection

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) Identification 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 a deceased give potential for error if wipes 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.*

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.

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.*