



Site visit inspection report on compliance with HTA licensing standards

Tameside General Hospital

HTA licensing number 12067

Licensed under the Human Tissue Act 2004 for the

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

10 October 2017

Summary of inspection findings

This is the first inspection of this establishment against the revised HTA licensing standards, which came into force on 3 April 2017. The previous inspection took place in April 2014. The HTA found the Designated Individual (DI), the Licence Holder (LH), the premises and the practices to be suitable in accordance with the requirements of the legislation.

Although the HTA found that Tameside General Hospital had met the majority of the HTA's standards, three major and four minor shortfalls were found against standards relating to governance & quality systems, 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

Tameside General Hospital (the establishment) has been licensed by the HTA since 2010, for the making of a post mortem (PM) examination; removal of relevant material from the deceased; and, storage of bodies of the deceased and relevant material for use for scheduled purposes.

Since October 2016, the establishment has taken on additional storage and PM cases (both hospital and community deaths) from the Trafford area of the Manchester South Coronial district (268 cases), via a service level agreement (SLA) with the Coroner. This is in addition to the pre-existing Tameside workload (557 cases). Additionally, the establishment has a new SLA with the Coroner (in place since October 2017) to receive bodies for storage from the Stockport area (622 cases). These changes have required a new staffing structure in the mortuary via a business plan to include a new banding structure, an additional Anatomical Pathology Technologist (APT) and a change to the provision of the on-call service by the portering team, with cover by mortuary staff as required. The Bereavement Office function is now directly managed by the mortuary.

The establishment has five members of permanent mortuary staff: a mortuary manager, two permanent APTs, a locum APT and a Mortuary Assistant. The establishment has plans to restructure the management role in the mortuary due to the increase in PM workload.

The mortuary and PM facilities are secured by swipe card access and there is an intercom system for staff to allow entry of funeral directors to the rear of the mortuary. The main visitor entrance is through the Bereavement Office, which leads to the viewing areas and main mortuary. Out of hours viewings are conducted only by mortuary staff, with access to a wall-mounted alarm for security. There is closed-circuit television (CCTV) monitoring both within the mortuary and of the building entrances, and there is a security alarm.

The mortuary has 92 fridge spaces for adult bodies, including eight spaces for bariatric cases. There are 13 freezer spaces for bodies requiring long-term storage. Perinatal/ paediatric cases are stored in a separate fridge in the mortuary, which has four spaces. The establishment also has a refrigerated 'chill' room with a four-tier racking system that acts as a contingency store and for storage of super-bariatric bodies. The establishment also has a cross-site contingency storage agreement with a number of HTA-licensed establishments.

There is a storage temperature monitoring and alarm system for the mortuary fridges and freezers (except the perinatal/paediatric fridge), which alerts switchboard when the temperatures deviate from their expected ranges. On-call mortuary staff are then contacted. A member of mortuary staff is on call at all times. The establishment's procedure is for staff to check and record storage temperatures of the mortuary fridges and freezers daily, including

on weekends and Bank Holidays if they attend the mortuary. However, the HTA observed gaps in the temperature records for the perinatal/paediatric fridge. Temperature monitoring of the paediatric storage unit is done manually when mortuary staff are on site; however, there is no external monitoring or alarm for this fridge (see shortfall against PFE2(e)).

The PM suite has four downdraft tables and four dedicated downdraft cut-up benches for the preparation of tissue samples. The equipment in the PM suite is fit for purpose; however, repairs are required to several of the PM tables (see shortfall against PFE3(a)). When admitting bodies from the hospital, the porters access the mortuary through a link corridor, which has a side door to the PM suite that is not routinely locked during PM examination (see advice against PFE1(d)).

The establishment conducted approximately 900 adult coronial PM examinations in the last year, including high-risk PM examinations. This is due to increase to approximately 1500 cases in the coming year. All PM examinations are performed under Coronial authority; adult consented PM examinations are not offered at the establishment. Perinatal, paediatric and Home Office cases are transferred to other HTA-licensed establishments. Consent for paediatric and perinatal PM cases is sought on-site.

Consent for perinatal hospital PM examinations is sought by clinical staff using the consent form and information leaflet provided by the Stillbirth and Neonatal Death (Sands) charity. Clinical staff receive training in seeking consent for PM examination as part of their clinical training and the establishment has a programme for competency assessment.

Material removed during a PM examination is cassetted in the PM suite and then transferred to the University Hospital of South Manchester (UHSM). UHSM processes, stores and manages all PM histology specimens under a separate HTA licence with appropriate governance arrangements to ensure correct management through the Tameside Partnership Board. Tissue is rarely ever returned to Tameside mortuary, unless there is a family request. The majority of tissue samples from PM examinations previously undertaken at the establishment have been moved to UHSM. Samples from PM examinations prior to August 2014 (before the South Manchester agreement was in place) are stored at Tameside Hospital and this storage area was visited as part of this inspection.

Whole organs may also be stored temporarily in the mortuary, 'incidental to transportation'. The mortuary uses paper and electronic registers to record sample details, including details of storage location, details of transport where samples are sent to other organisations for analysis, and the family's wishes for the fate of the samples.

Description of inspection activities undertaken

This report describes the second, routine site visit inspection of the establishment. The inspection team interviewed staff involved with licensable activities, reviewed documentation and conducted visual inspections of the mortuary, PM suite and tissue transport area. The inspection team also conducted a visual inspection of the site where archived PM tissue blocks and slides are being stored.

Procedural audits were done on the release of two bodies from the mortuary to funeral directors. The establishment's procedure is that a hospital case is not released without the funeral director providing relevant paperwork; however, their procedure allows a coronial case to be released with verbal confirmation of the name of the deceased by the funeral director (see shortfall against T1(c)). A mortuary bier trolley is used to transport the deceased from the mortuary to funeral directors' vehicles; however, when used in combination with funeral directors' folding stretchers placed on top, this poses a risk of accidental damage to the deceased (see shortfall against PFE3(a)).

A traceability audit was conducted on four adult bodies in the mortuary, including confirmation of storage locations and identifiers recorded in the paper and electronic mortuary records. The storage locations recorded in the paper and electronic mortuary records for these cases showed no discrepancies and resulted in full traceability. At the time of the inspection, a brain was being stored for a fixation period before it was transported to the University of Manchester. All relevant documentation and records were checked in relation to this organ and no discrepancies were found.

Inspection findings

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

Compliance with HTA standards

GQ1 All aspects of the establishment's work are governed by documented policies and procedures		
<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>Many mortuary standard operating procedures (SOPs) are inadequate and do not provide sufficient details of the licensed activities undertaken at the establishment.</p> <p>The mortuary SOPs have poor version control and many have not been regularly reviewed and are out of date.</p> <p>A number of these SOPs relate to identification checks outlined in viewing and transfer SOPs referenced in the shortfall against T1(c).</p> <p><i>Refer to shortfall against standard T1(c) and Advice, item 1.</i></p>	<p>Minor</p>
<p>e) There is a system for recording that staff have read and understood the latest versions of these documents</p>	<p>Whilst there is a system for recording that staff have read and understood documented policies and procedures, Pathologists have not recorded that they have read and understood relevant SOPs (for example MORT.SOP.0028 for PM examination)</p>	<p>Minor</p>

GQ2 There is a documented system of audit		
<p>a) There is a documented schedule of audits</p>	<p>There is no documented schedule of audits and no audits have been undertaken for a significant period of time.</p> <p>There were records of audit templates but no audit reports of any previous audits undertaken could be evidenced.</p> <p>Audit templates are not sufficient and do not cover all licensed activities.</p> <p><i>Refer to Advice, item 2.</i></p>	<p>Major</p>

GQ4 There is a systematic and planned approach to the management of records		
<p>b) There are documented SOPs for record management which include how errors in written records should be corrected</p>	<p>The establishment does not have a documented policy or SOP for the management of mortuary records or a sufficient quality management system in place.</p> <p>There are no documented SOPs for record management, which describe how records are maintained and backed up, where records are kept, how long each record is retained and how errors in written records should be written records should be corrected.</p>	<p>Minor</p>

T1 A coding and records system facilitates traceability of bodies and human tissue, ensuring a robust audit trail		
<p>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>	<p>Identification checks for release and viewings of a body do not routinely use three identifiers, as a minimum. Documented procedures for identification checks do not describe in sufficient detail what identifiers should be checked and against what they should be checked.</p> <ul style="list-style-type: none"> - MORT.SOP.026 Viewing of babies, stillbirths & foetuses references only two identifiers and does not detail how these identifiers are obtained from the family. Staff described the procedure for obtaining the identifiers from the family upon arrival at the mortuary as being based on name only. - MORT.SOP.021 Transfer of deceased patients for scanning out of normal working hours contains no details of identification checks. - For release of bodies (coronial cases), the establishment staff check identifiers from the funeral director, which may be full name of the deceased given verbally only, and this is used to identify the release paperwork and mortuary records held by the mortuary. 	<p>Major</p>

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	<p>The bases and connections of several of the PM tables are not sealed with the floor, leading to difficulties cleaning these areas effectively. Failure of the seals was particularly severe on the connection of PM table 1, which is the most frequently used PM table.</p> <p>Additionally, part of the wall covering behind PM table 4 has started to deteriorate, meaning that there is exposed plaster which results in difficulties cleaning this area effectively.</p>	Minor

PFE2 There are appropriate facilities for the storage of bodies and human tissue.		
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	<p>The paediatric fridge is not alarmed and temperature monitoring relies on manual checking.</p> <p>The establishment's procedure is for the fridge temperature to be checked and recorded by staff daily during the working week and on weekends, if staff attend the mortuary. However, the HTA observed several gaps in the temperature records for this fridge over a three week period with no temperature logs during the weekend.</p> <p>There is a risk that failure of this fridge unit could go unnoticed for a period of time. The impact of this failure could have a significant impact on the integrity of bodies stored in this fridge.</p> <p><i>Refer to Advice, item 8.</i></p>	Major

Advice

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

No.	Standard	Advice
1.	GQ1(a)	In addressing the shortfall against standard GQ1(a), the DI should review all mortuary SOPs to ensure that they are accurate and contain sufficient details of procedures.
2.	GQ2(a)	The DI is advised to develop a documented schedule of audits to cover mortuary procedures, which are currently not subject to audit. This should include auditing stored tissue in the mortuary, PM suite and the archive store. Audit findings should document who is responsible for undertaking the audit, any follow-up actions and the timeframes for completing these. Audit findings should also be shared with staff to enable learning.
3.	GQ5(a)	The DI is advised to ensure that reference to the establishment's procedure for reporting HTA Reportable Incidents (HTARIs) to the HTA is included in relevant procedures and policies. For example, the HTARI SOP should be referenced in the establishment's Mortuary Operational Policy (MORT.QM.001) section on incidents in the mortuary.
4.	T1(c)	The DI is advised to ensure that transcription of identification information between documents and whiteboards is done with reference to the documented information available and not from memory. This will help to ensure that the information recorded is correct which will strengthen the establishment's procedures for identification of the deceased.
5.	T1(d)	The DI is advised to add identifiable wrist tags to the deceased who have the same or similar name. This will help to strengthen the system for flagging bodies with same or similar names, strengthening traceability procedures.
6.	T1(h)	The DI is advised to ensure that traceability procedures for transfer of samples include confirmation that the samples have been received at the destination and that this is recorded.
7.	PFE1(e)	The DI is advised to ensure that the mortuary security procedures are followed by all staff. At the time of the inspection, the door between the viewing room and the body store was not locked. Although the establishment's procedure for viewings includes checking that the doors are secured, this door should be kept locked when not in use.
8.	PFE2(f)	The temperature alarm trigger point for the fridge is currently 10°C and, for the freezer, minus 20°C; however, it is not clear whether there are upper and lower limits and what the tolerance timeframes are for the trigger points. The DI is advised to document these details in the procedure for temperature monitoring.
9.	N/A	The DI is advised to consider displaying the HTA licence/s in all areas where licensed activities are taking place, including the store of historical PM tissue.

Concluding comments

The mortuary team appear committed and hard-working, particularly during times of increased workload and staffing issues, and have the interest of the bereaved - and care of the deceased - as their priority.

Areas of good practice observed during the inspection included:

- Mortuary staff read out the spelling of the name of the deceased during identification procedures;
- There is a system that highlights bodies stored for more than 14 days, ensuring that appropriate actions are taken so that storage conditions protect the dignity of the deceased;
- There is a system for families to authorise or restrict viewings of their relatives; and
- There are a selected team of porters who undertake mortuary activities. Mortuary staff are directly involved in training porters in the mortuary procedures.

There are a number of areas of practice that require improvement, including three major shortfalls and four 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: 14/11/2017

Report returned from DI: No comments received

Final report issued: 12/12/2017

Completion of corrective and preventative actions (CAPA) plan

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

Date: 03 July 2018

Appendix 1: HTA licensing standards

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

Consent
C1 Consent is obtained in accordance with the requirements of the Human Tissue Act 2004 (HT Act) and as set out in the HTA's codes of practice
<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</i></p>

available on the HTA website, or in relation to infants, the resources pack developed by the Stillbirth and neonatal death charity, Sands. The consent forms should record the consent given for the post-mortem examination and for the retention and future use of tissue samples.

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

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

Guidance

Refresher training should be available (for example annually).

- b) Records demonstrate up-to-date staff training.
- c) If untrained staff are involved in seeking consent, they are always accompanied by a trained individual.
- d) Competency is assessed and maintained.

Governance and quality systems

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

- a) Documented policies and SOPs cover all mortuary/laboratory procedures relevant to the licensed activity, take account of relevant Health and Safety legislation and guidance and, where applicable, reflect guidance from RCPATH. These include:
- i. post-mortem examination, including the responsibilities of Anatomical Pathology Technologists (APT's) 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.