Site visit inspection report on compliance with HTA licensing standards

Peterborough City Hospital

HTA licensing number 30032

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**

20th June 2017

Summary of inspection findings

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 Peterborough City Hospital had met the majority of the HTA's standards, seven shortfalls were found against the Governance and Quality and the Premises, Facilities and Equipment standards. These relate primarily to governance, audits and the fridge on the maternity unit, respectively.

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

Peterborough City Hospital (the establishment) is part of the North West Anglia Foundation Trust and is licensed under the HT Act 2004 for post mortem (PM) examination, removal from the body of a deceased person of relevant material and storage of the body of a deceased person or relevant material which has come from a human body for use for scheduled purposes. The Corporate Licence Holder contact is the Chief Executive Officer for the Trust; the Designated Individual (DI) is an experienced Consultant Histopathologist,

who is relatively new to the Trust and the role of DI. The mortuary operates as a combined service with the Trust's bereavement service; both are managed by the Trust's pathology services.

The establishment receives approximately 2000 bodies each year from the hospital and community and performs around 450 adult post mortem (PM) examinations annually. This figure includes high-risk (up to category 3) cases, forensic adult cases and a few adult hospital (consented) cases. The majority of routine adult cases are performed under the authority of HM Coroner for Peterborough and Cambridgeshire. Routine and forensic paediatric/perinatal cases are transferred to another licenced establishment; however, consent for these cases is obtained on site.

There are currently two full-time Consultant Histopathologists based at Peterborough City Hospital; in addition, a third Consultant from another Trust attends to undertake PM examinations. Four Anatomical Pathology Technologists (APTs), including two locum APTs, and the Mortuary and Bereavement Services Manager, staff the mortuary.

Consent forms for both paediatric and adult PM examinations are based on the HTA's model consent forms, therefore fully compliant with statutory and regulatory requirements. Consent is sought by two APTs trained to undertake this task for adult hospital PM examinations (see advice item 2); consultant clinicians who have undertaken training for post mortem consent, seek consent for perinatal and paediatric PM examinations. This training is recorded and refreshed annually.

Porters transfer and admit all hospital bodies to the mortuary. Mortuary staff oversee this process within normal working hours. Porters are also responsible for admitting Coroner's cases out of hours and mortuary staff are available on-call for advice and assistance. Mortuary staff complete patient identification checks and the admission process the next working day. Training for the porters in mortuary practice is provided by mortuary staff to the portering supervisors, who cascade this training (see advice item 8).

Perinatal cases, pregnancy remains and their associated documentation are organised and transferred to the mortuary by the maternity unit staff. There are some inconsistencies in the use of the documentation and information provided to the mortuary by the maternity unit (see shortfall GQ1(a,i)).

Bodies from the community are brought in to the mortuary via a service road, leading to the mortuary external shutter door and pedestrian access door. Staff inside the mortuary can see and speak to visitors and funeral directors via a camera and intercom system, and control the opening and closing of these doors which provide access to a contained area outside the body store. Staff from the Trust's estates department sometimes require access to a service stairwell in this area. Although access is well controlled and monitored when

bodies are being moved, there are further steps the establishment could consider to further ensure the dignity of the deceased (see advice item 13).

The mortuary contains 96 ‘double ended’ fridges, eight of which can accommodate bariatric bodies; this number includes five dedicated spaces for high-risk cases and five spaces for paediatric bodies. In addition, there is currently a Flexmort refrigeration unit in a room adjacent to the body store, which has been purchased by the Trust. Although the unit has been in use during busy periods, it was not in operation at the time of inspection. Freezer storage is available by converting nine fridge spaces (five standard and four bariatric) into freezers (see advice item 14).

All fridges and freezers within the mortuary are monitored remotely and alarmed, including the Flexmort refrigerated storage when in operation. In the event of an alarm, switchboard staff are alerted and contact the on-call mortuary staff. These fridges and freezers are also linked to the Trust’s back-up generators in case of power failure.

The establishment has a maternity unit where there is a fridge for the storage of fetuses and neonatal bodies prior to transfer to the mortuary. This fridge is serviced regularly and is located in a secure room. Staff check the temperature daily and make a record. However, the fridge is not remotely monitored or connected to an alarm system (see shortfall PFE2(e)).

In addition to the storage activities described above, there are areas outside the mortuary where the removal of tissue samples from the body of a deceased child occasionally takes place. These areas were visited as part of the inspection and include the Accident and Emergency Department (A&E) and the maternity unit. There are Persons Designated (PDs) in both these areas.

The mortuary’s post mortem suite contains four post mortem tables, each with a dedicated dissection bench. There is a separate suite with a single table and dissection unit for high-risk cases. The pathologists and APTs carry out identification and external examinations of bodies for PM examination prior to any evisceration. Once these checks have been completed, a green wristband is placed on the body next to the identification wristband. On occasion, these checks are carried out the day before the PM examination or early on the same day, before being placed back into refrigerated storage. When removed again for the PM examination, identification is checked again by two APTs prior to any evisceration occurring (see shortfall GQ1 (a,ii)). A ‘one at a time system’ is used to avoid mix-up of organs and tissue samples removed during PM examination.

Description of inspection activities undertaken

The establishment has been licensed by the HTA since October 2010. Previous routine site visit inspections took place in September 2011 and March 2014. This report describes the

third routine site inspection visit in June 2017. The inspectors interviewed staff involved with licensable activities and reviewed documentation. They also carried out a visual inspection of the mortuary, histopathology laboratory and the body store area in the maternity unit. An audit of body identifiers, storage locations, mortuary register details and associated documentation for three adult bodies in the mortuary, including two with same/similar names was carried out. A minor anomaly was found in relation to the documentation for one body, in that the mortuary register number was not written on the mortuary admission form. In addition, records relating to three adult bodies that had been subject to a PM examination (one consented and two coronial cases), where tissues or organs were retained for analysis, were also audited. The audit included sample records from the PM examination through to the wishes of the family and storage/disposal of tissue following PM examination. A minor anomaly was found in relation to one case, where three more slides had been retained (as per the family's wishes) than the number stated in the electronic laboratory record.

Material held for the police

Although the establishment conducts Home Office PM examinations, at the time of the inspection there were no PACE specimens held on site.

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

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 the relevant Health and Safety legislation and guidance, where applicable, reflect guidance from RCPath.	i) Although there are SOPs for the management and traceability of fetuses in the maternity unit, they do not extend to the mortuary and the role of staff there. Paperwork from the maternity unit is not always completed accurately and on occasion has not been sent with the body. In addition, the mortuary does not consistently receive parents' wishes regarding the disposal of fetuses or pregnancy remains from the maternity unit. The Trust's 'Notification of Death Form' for adults, currently in use, does not lend itself well to recording relevant information for these cases (see advice item 4). ii) Some SOPs do not reflect current practice. For example, SOP CPM-LP 'Post Mortem Examination Preparation', does not state that a green ID band is placed on the body after the identification has been checked by the pathologist and APT prior to the post mortem examination, or that identification checks are carried out by two APTs if the body is replaced and removed from the fridge at a later time.	**Minor**

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	i) SOPs are not always written and authorised by different people. The person authorising SOPs should have sufficient understanding of the process to be able to assess if the content of the SOP is relevant and reflects current practice. ii) The version number and the review date of SOPs stated in the electronic record on the Q-pulse system do not always match the version or review date on the SOP attached to that record. For example, SOP CP-M-011 'Cleaning the body store and mortuary', (revision eight); the revision date on the document doesn't match the revision date on the Q-Pulse record.	**Minor**
e) There is a system for recording that staff have read and understood the latest versions of these documents	The distribution lists for SOPs in the Q-pulse system do not always include all the relevant staff; therefore, there is no record that they have read and understood SOPs that govern their work. In addition, locum staff, who do not have access to the Q-pulse system, should sign a signatory sheet to indicate they have read and understood SOPs.	**Minor**
g) All areas where activities are carried out under the licence are incorporated within the establishments governance framework	Activities carried out under the licence in other areas require incorporating in to the establishment's governance framework (see advice item 5).	**Minor**
h) Matters relating to HTA-licensed activities are discussed at regular governance meetings involving establishment staff	There are no formal meetings involving mortuary staff or those working in other areas at which issues relating to HTA-licensed activities are discussed (see advice item 6).	**Minor**

GQ2 There is a documented system of audit		
a) There is a documented schedule of audits	Although audits have been scheduled, they have not always been completed (see advice item 7).	**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.	The fridge in the maternity unit is not alarmed. Staff are therefore not aware of any significant temperature deviation or power failure and are depended on the daily manual checks.	**Minor**

Advice

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

No.	Standard	Advice
1.	C1 (a)	The DI is advised to update the Trust's policy 6.15, 'Guidelines for Perinatal Post Mortem Consent, Peterborough City Hospital', reviewed in June, which refers to the HTA's old codes of practice. Revised codes of practice and licensing standards were published by the HTA on 1 April this year.
2.	C2 (a)	The only member of staff to attend post mortem consent training is a locum APT, who has cascaded this training to another APT. The DI is advised to ensure that permanent mortuary staff attend training on post mortem consent, including refresher training, to ensure an adequate level of knowledge.
3.	C2 (d)	The DI is advised to ensure consent seekers are competency assessed at regular intervals and to maintain a record of competency assessments.
4.	GQ1(a)	• The mortuary manager is advised to review all mortuary SOPs and update them to refer to the HTA's new codes of practice were necessary. • Relevant SOPs, for example, those on admission and release of bodies, should be updated to include the use of the mortuary spreadsheet: how this is completed and monitored to maintain oversight of long stayers and the trigger for placing bodies into long-term storage. • The DI is advised to review mortuary and histopathology SOPs for disposal of post mortem tissue to provide assurance that tissue is: o fully traceable (including records) o dealt with as efficiently as possible and in line with relatives' wishes. • SOP CP- PM Tissue Retention and Disposal (currently under review) identifies the senior pathology secretary as being responsible for communicating relatives' wishes to the laboratory and mortuary staff. The DI is advised to train other staff in this process to ensure tissue is dealt with as efficiently as possible, in the pathology secretary's absence. • SOP CP-M-025 'Specimen Transport' does not include the requirement to send the CP-F-121 'Confirmation of Specimen Receipt' form with samples when they are sent off site. The mortuary manager is advised to amend the SOP accordingly to prevent this important document being omitted. • The DI and mortuary manager are advised to liaise and work with the PD and staff in the maternity unit to develop robust procedures and documentation for perinatal cases and pregnancy remains (see shortfall GQ1 (g)).
5.	GQ1 (g)	To maintain sufficient oversight in A&E and the maternity unit, the DI should establish good working relationships with staff in these areas (including existing PDs) and other staff groups, e.g. the chaplaincy. This will ensure there is a mutual understanding and development of streamlined processes to

		comply with the HTA's codes of practice and licensing requirements (see shortfall GQ1 (g).
6.	GQ1 (h)	i) In addition to the daily informal 'huddle' meetings, the mortuary manager is advised to introduce regular minuted meetings for mortuary and bereavement staff as they work closely together. ii) The DI is advised to implement regular scheduled governance meetings with PD's in A&E and the maternity unit and other relevant staff. These meetings should be minuted, include HTA related activities/issues and information, and made available to staff. iii) The DI is advised to establish regular contact with the CLHc to ensure he is aware of any pertinent HTA related activities or issues that may require escalation.
7.	GQ2 (a)	Mortuary staff regularly carry out daily body audits. However, these are not recorded and should include checks of body identification and associated paperwork. The DI should consider further help from the Pathology Quality Manager to monitor and assist in this as staffing levels have had an impact on the mortuary team's ability to complete scheduled audits. There should be a range of vertical and horizontal audits checking compliance with documented procedures, the completion of records and traceability of bodies and tissues.
8.	GQ3 (a) & (c)	The training for portering supervisors should be documented, including what is covered, especially if changes in practice occur. Training should be refreshed regularly to ensure competency in mortuary procedures. This is particularly important as the supervisors cascade this training to the portering staff.
9.	GQ6 (a)	The DI is advised to expand the range of risk assessments to ensure the licenced activities (outlined in GQ1) and all the HTARI categories are included.
10.	T1 (b)	The DI is advised to continue with the implementation of the mortuary IT system. This will alleviate some pressure on staff and assist in numerous areas of mortuary practice. For example, body and tissue traceability and identification of bodies with same/similar names.
11.	T1 (c)	The DI is advised to consider removing identification bands that state 'unknown' once a body has been formally identified; leaving these ID bands insitu, in addition to the ID bands correctly identifying a body, could lead to confusion.
12.	PFE1 (e)	Access to the mortuary from the bereavement suite is via a single door immediately adjacent to the main post mortem room viewing gallery. This door is secured by a thumb lock by staff when the post mortem room is in use. There are large modesty screens placed to prevent unauthorised viewing of the post mortem session when entering through this door. However, the locking of this door relies on staff to remember. The DI is advised to install a more robust lock on this door.
13.	PFE1 (e)	To maintain the dignity of the deceased and prevent them being visible to hospital staff during admission and release from the mortuary, the DI may wish to consider if steps could be taken to shield from view the contained area outside the body store visible from the service stairwell in that area.

14.	PFE2(a)	When the freezers are in operation, signs should be used to indicate this (in addition to them being locked). This will clearly indicate when these units are operating as freezers and prevent bodies being placed in them in error on admission.

Concluding comments

The mortuary staff and the DI are all relatively new to the Trust. There have been significant changes in staffing within the mortuary and recruitment has proved difficult but is on-going. A risk assessment of staffing has been carried out and subsequently escalated to the Trust's risk register. The planned introduction of support staff to undertake non-technical duties, such as body receipt and some administrative tasks, will help with current staffing pressures, ensuring that qualified staff can focus on the skilled and technical duties associated with PM examination.

Despite these pressures and being a new team, the mortuary staff are enthusiastic and dedicated, and should be commended for their efforts and achievements in the last 15 months. There were several examples of good practice:

- Additional security measures have been implemented to better control and monitor access to the mortuary, for example, coded door locks preventing access to restricted areas in the mortuary;
- Traceability systems for body identification, including the documentation used for admission of bodies, are particularly robust;
- After checking the identity of the deceased, mortuary staff place an additional identification band on a body to include the unique mortuary register number and additional address, if applicable;
- Both community and hospital admission forms include sections to communicate any pertinent information to the mortuary staff;
- In addition to warning magnets placed on the fridge doors, bodies with same/similar names are given a yellow wristband and their name is highlighted on the door label and mortuary register;
- The use of a green wrist band acts as a visual cue that a body has been identified by the pathologist prior to any evisceration taking place;
- There is a robust risk assessment process for all bodies prior to post mortem examination to identify high-risk cases;
- The use of the mortuary spreadsheet to identify and appropriately manage long-term bodies in the mortuary. The planned implementation of a mortuary IT system will assist in this and other areas of audit;
- The use of a laboratory spreadsheet for the recording of post mortem tissue and subsequent instructions;
- The premises are exceptionally clean, tidy and well organised.

There are a number of areas of practice that require improvement, including seven 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: 17/07/2017

Report returned from DI: 01/08/17

Final report issued: 22/08/17

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: 31/10/18

Appendix 1: HTA licensing standards

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

Consent

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

a) There is a documented policy which governs consent for post-mortem examination and the retention of tissue and which reflects the requirements of the HT Act and the HTA's Codes of Practice.

b) There is a documented standard operating procedure (SOP) detailing the consent process.

Guidance

This should include who is able to seek consent, what training they should receive, and what information should be provided to those giving consent for post-mortem examination. It should make reference to the use of scanning as an alternative or adjunct to post-mortem examination.

c) There is written information for those giving consent, which reflects the requirements of the HT Act and the HTA's codes of practice.

Guidance

Information on consent should be available in different languages and formats, or there is access to interpreters/translators. Family members should be given the opportunity to ask questions.

d) Information contains clear guidance on options for how tissue may be handled after the post-mortem examination (for example, repatriated with the body, returned to the family for burial/cremation, disposed of or stored for future use), and what steps will be taken if no decision is made by the relatives.

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

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

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

Guidance

This may be based on the HTA's model consent form for adult post-mortem examinations available on the HTA website, or in relation to infants, the resources pack developed by the

Stillbirth and neonatal death charity, Sands. The consent forms should record the consent given for the post-mortem examination and for the retention and future use of tissue samples.

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

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

Guidance

Refresher training should be available (for example annually).

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

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

d) Competency is assessed and maintained.

Governance and quality systems

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

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

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

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

iii. practices relating to evisceration and reconstruction of bodies;

iv. systems of traceability of bodies and tissue samples;

v. record keeping;

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

vii. lone working in the mortuary;

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

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

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

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

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

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

xiv. contingency storage arrangements.

Guidance

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

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

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

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

Guidance

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

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

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

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

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

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

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

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

Guidance

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

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

Guidance

Meeting minutes should be recorded and made available to staff.

GQ2 There is a documented system of audit

a) There is a documented schedule of audits.

Guidance

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

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

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

Guidance

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

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

Guidance

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

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

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

Guidance

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

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

b) There are clear reporting lines and accountability.

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

Guidance

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

d) Staff have annual appraisals and personal development plans.

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

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

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

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

Guidance

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

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

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

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

Guidance

Records include mortuary registers, PM examination records, tissue retention forms and

records of transfer and return of organs/tissue sent elsewhere for examination.

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

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

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

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

Guidance

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

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

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

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

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

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

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

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

Guidance

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

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

Guidance

Relevant staff should have knowledge of risks and the control measures that have been taken

to mitigate them.

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

Traceability

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

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

Guidance

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

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

Guidance

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

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

Guidance

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

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

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

Guidance

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

Fridge/freezer failures that require bodies to be moved temporarily whilst repairs take place

present a risk to traceability. Full identification checks should be made when theyare placed back into normal storage.

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

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

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

ii. receipt upon return to the laboratory or mortuary

iii. the number of blocks and slides made

iv. repatriation with the body

v. return for burial or cremation

vi. disposal or retention for future use.

Guidance

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

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

Guidance

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

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

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

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

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

Guidance

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

this purpose.

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

d) The method and date of disposal are recorded.

Premises, facilities and equipment

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

a) The premises are clean and well maintained.

Guidance

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

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

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

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

Guidance

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

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

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

a) Storage arrangements ensure the dignity of the deceased.

Guidance

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

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

Guidance

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

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

Guidance

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

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

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

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

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

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

Guidance

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

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

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

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

Guidance

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

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

assessments and same/similar name systems.

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

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

Establishments should consider entering in to Mutual Aid Agreements

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

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

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

   i. fridges / freezers

   ii. hydraulic trolleys

   iii. post mortem tables

   iv. hoists

   v. saws (manual and/or oscillating)

Guidance

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

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

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

Guidance

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

d) Staff have access to necessary PPE.

Guidance

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

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

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

Guidance

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

Appendix 2: Classification of the level of shortfall

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

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

1. **Critical shortfall:**

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

   or

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

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

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

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

   (3) A notice of suspension of licensable activities

   (4) Additional conditions being proposed

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

2. **Major shortfall:**

   A non-critical shortfall that:

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

   or

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

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

3. **Minor shortfall:**

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

departure from expected standards.

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

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

Follow up actions

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

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

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

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