

Site visit inspection report on compliance with HTA licensing standards

Southampton General Hospital

HTA licensing number 12214

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**

27th April 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 Southampton General Hospital had met the majority of the HTA's standards, three shortfalls were found against the Premises, Facilities and Equipment standards and one against the Governance and Quality Systems standards. These relate to the condition and security of the funeral directors' access area and the completion of audits, 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

Southampton General Hospital (the establishment) is a large teaching hospital and part of the University Hospital Southampton NHS Foundation Trust. The Corporate Licence Holder contact is the Chief Financial Officer for the Trust; the Designated Individual is an experienced Consultant Histopathologist. The mortuary is managed by the Trust's pathology services.

The establishment receives approximately 3,000 bodies each year from the hospital and the community and performs around 1,100 adult, perinatal and paediatric post mortem (PM) examinations annually, an increase on previous years. This figure includes high risk (up to category 3) cases, forensic paediatric cases and a small number of adult hospital (consented) cases. Most routine adult PM examinations are performed under the authority of HM Coroner for Hampshire. Forensic adult cases are transferred to another licenced establishment. There are currently nine consultant histopathologists who conduct adult post mortem examinations and one paediatric pathologist. The mortuary is staffed by seven APT staff, including a mortuary manager.

The establishment is a referral centre for perinatal, paediatric and neuropathology cases. Perinatal and paediatric cases are predominantly hospital (consented) examinations with a small number being performed under coronial authority.

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 (see advice item 2). Consent is sought by the bereavement care team for adult hospital PM examinations; consultant clinicians and bereavement midwives seek consent for perinatal and paediatric PM examinations (see advice item 3).

Porters transfer and admit all hospital bodies to the mortuary. Mortuary staff oversee this process within normal working hours and undertake patient identification checks of all bodies. Coroner's cases are only admitted by mortuary staff, including out of hours, during which staff provide an on-call service. Training for porters in mortuary practices is provided by mortuary staff; this has recently stopped due to staffing levels (see advice item 7).

The establishment has a range of refrigerated storage for standard, bariatric and paediatric/perinatal bodies; this includes dedicated spaces for high-risk cases. There are currently two Nutwell refrigeration units on site; one within the body store area (on hire since autumn 2016) and another purchased by the Trust and located outside the body store in a partially-covered area used by funeral directors bringing bodies to the mortuary. This area is in urgent need of attention and currently presents a risk to the dignity and security of the deceased (see shortfall PFE2 (a) and advice item 12).

Freezer storage is available for both adult and perinatal/paediatric bodies. The dedicated freezer storage space available for perinatal/paediatric cases has reduced due to the decommissioning of a freezer unit.

The majority of the fridge and freezer units are monitored remotely and alarmed. In addition, the estates department and switchboard are alerted in the event of an alarm, and contact the on-call mortuary staff. These fridges and freezers are also and linked to the Trust's back-up generators in case of power failure (see advice item 15).

The Princess Anne Maternity Hospital, located adjacent to the establishment, has two fridges within a 'holding room' for storage of fetuses and neonatal bodies prior to transfer to the mortuary at Southampton General Hospital. All information, including the logging in and out of bodies and transfer details, is contained in a register for that purpose. Transfers to the mortuary are carried out by a nominated funeral director. Fridge temperatures are monitored and recorded by the maternity unit porters at set times, three times per day. The fridges are not remotely monitored or connected to the alarm system (see advice item 14).

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 include the accident and emergency department (A&E) and the neonatal intensive care unit (NICU) at Princess Anne Hospital (see advice item 5).

The post mortem suite at Southampton General Hospital contains six post-mortem tables, each with a dedicated dissection bench. There is a separate paediatric suite with two dissection tables and a high-risk suite with one post mortem table and dissection bench. Identification and external examinations of bodies for PM examination are carried out by pathologists prior to any evisceration by APTs. A 'one-at-a-time' system and the dedicated dissection benches are used to avoid mix-up of tissue samples and organs removed during PM examinations.

Description of inspection activities undertaken

The establishment has been licensed by the HTA since June 2007. Previous routine site visit inspections took place in July 2007, July 2011 and February 2014. This report describes the fourth routine site visit inspection in April 2017. The inspectors interviewed staff involved with licensable activities and reviewed documentation. They also carried out a visual inspection of the mortuary, pathology laboratory, holding area and body storage area at Princess Anne Hospital. An audit of body identifiers, storage locations, mortuary register details and associated documentation for three adult bodies and one paediatric body in the mortuary found no anomalies. In addition, records relating to two adult bodies (one consented and one coronial case) and one paediatric body (consented case), which had been subject to a PM examination and where tissues or organs were retained for analysis, were also audited. The

audit included records from admission of the body to the mortuary through to the wishes of the family and storage of tissue following PM examination. No anomalies were found.

Material held for the police

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

Inspection findings

The HTA found the Licence Holder, 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
PFE1 The premises are secure and well maintained and safeguard the dignity of the deceased and the integrity of human tissue.		
a) The premises are clean and well maintained.	The floor within the main post-mortem suite is showing significant signs of wear, including cracking and crumbling at the drain edges. This compromises mortuary staff's ability to clean and decontaminate the post mortem suite sufficiently and is a potential risk to their health and safety. <i>The Trust has identified this as a problem and there is a plan in place to address this in 2017.</i>	Major
e) Security arrangements protect against unauthorized access and ensure oversight of visitors and contractors who have a legitimate right of access.	Access to the outside area body store from the hospital road is via padlocked metal doors and there is no CCTV coverage. These arrangements do not provide for the safety of any bodies stored within the Nutwell unit located there.	Major

PFE2 There are appropriate facilities for the storage of bodies and human tissue		
a) Storage arrangements ensure the dignity of the deceased.	The contained area outside the body store, where a Nutwell body storage unit is located, is only partially roofed; as a result, it is exposed to the elements and there is evidence of the presence of pigeons and rats, as well as other detritus. In its current condition, this area is not suitable for the dignified storage of bodies of the deceased.	Major

GQ2 There is a documented system of audit		
a) There is a documented schedule of audits	The documented audit schedule on Q-Pulse does not include audits relating to body or tissue traceability, or procedural audits relating to documentation and mortuary practice.	Minor

Advice

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

No.	Standard	Advice
1.	C1 (d)	In the 'Guide to a Post Mortem Examination (Adult)', the section headed 'What happens next?' does not make it clear that family's wishes for retained organs to be returned to the body will delay the release of the body for a funeral. The DI is advised to include this information to ensure relatives are aware of the potential delay if they select this option.
2.	C1 (g)	Although the consent form used by the Bereavement Care Team (Version 4, 2014) is compliant with HTA standards and is available for them to print via the hospital intranet, the adult PM consent form available on the Q-Pulse system is not the current version, nor is it compliant with HTA's consent requirements; it should therefore be removed or updated to the correct version.
3.	C2 (a)	Staff who seek consent for adult and perinatal/paediatric PM examinations have undertaken initial training in the consent process but do not receive regular refresher training. In light of the publication of the HTA's revised codes and standards, the DI is advised to review the content of consent training and provide opportunities for refresher training.

4.	GQ1 (a)	<p>Mortuary standard operating procedures (SOPs) include inaccuracies, inconsistencies and duplication. For example:</p> <ul style="list-style-type: none"> • The 'Clerking procedure for adult deaths from community repatriation' and 'Clerking procedure for adult deaths from UHSFT referral sites' are both numbered MP300 002. • The 'Release of adult patients' LP300 007 SOP states what additional identifiers should be checked for same/similar name bodies but not which routine identifiers should be checked. In addition, the 'stepwise' guide for staff in this SOP does not follow a sequential order: step 6.6.23 should be after 6.6.28. <p>The DI is advised to review all SOPs, amend accordingly and update them in line with the HTA's new codes and standards. To prevent repetitive information and assist with accuracy, the DI may wish to streamline SOPs and make them more 'user friendly' for staff. For example, one SOP for admission of adult bodies in to the mortuary could contain relevant information for all types of admission. The use of flowcharts may also aid understanding.</p>
5.	GQ1 (g)	<p>The DI is advised to appoint Persons Designated (PD) within the A&E department and NICU at Princess Anne Hospital. This will provide the DI with assurance that licensed activities carried out in these areas are subject to regular oversight. In addition, the mortuary manager should re-register as a PD for the portal on the HTA website to enable them to report HTA reportable incidents. This is especially important in the absence of the DI, as all HTARIs must be reported within five working days of discovery.</p>
6.	GQ1 (h)	<p>Staff meetings have not taken place regularly due to staffing levels. The DI is advised to ensure that meetings to discuss HTA-related matters are scheduled where possible and minuted, the minutes being made available to all relevant staff. While staffing levels are low, these could be in the form of short team briefings at regular intervals.</p>
7.	GQ3 (a)	<p>Although porter training in mortuary procedures has been carried out regularly by mortuary staff, this has recently ceased due to staffing levels within the mortuary. The DI is advised to reinstate the training as soon as possible to ensure portering staff continue to remain competent in these tasks.</p>
8.	GQ3 (e)	<p>Staff should be given the opportunity to attend training courses relevant to their work, to ensure they remain proficient and up to date in mortuary practice. This training should also be recorded.</p>

9.	T1(c)	The DI is advised to ensure bodies are released from the mortuary using documented identifiable information that can be cross-referenced with the funeral director on release of a body. Three identifiers should be used, including at least one unique identifier. Written documentation from funeral directors is not a legal requirement but is a mitigating step in reducing the risk of releasing a wrong body.
10.	PFE1 (d)	The DI is advised to ensure that the double doors between the main PM suite and the body store are closed during post mortem sessions. This will mitigate the risk of unauthorised or unintentional access from the body store area and ensure the ventilation system can work efficiently, maintaining the required air changes per hour.
11.	PFE1 (e)	The access door to the viewing room from the body store is not lockable. Although the door is concealed by a curtain, there is potential for unauthorised access by visitors. The mortuary staff are advised to secure this door during viewings.
12.	PFE2 (b)	The Trust is advised to proceed with the commissioning of the new integral fridges, which has been delayed for some time. These will increase capacity within the permanent body store and reduce the need for the use of temporary Nutwell storage units and associated risks. Staff currently transfer bodies from the permanent fridges in to the Nutwell units to increase capacity for overnight hospital deaths and at weekends, which may lead to traceability issues.
13.	PFE2 (e)	The mortuary staff are advised to challenge the fridge alarms on a regular basis to assure themselves that the system will alert staff when temperatures deviate from normal ranges. These tests should be recorded.
14.	PFE2 (e)	The DI is advised to risk assess the absence of remote monitoring and alarming of the fridges within the maternity unit and consider whether they should be connected to the Trust's back-up generators. Although the fridges are regularly monitored manually, an incident has been highlighted where power was turned off to these fridges and this wasn't discovered until sometime later. Fortunately, the fridges were empty at the time.
15.	PFE2 (f)	Mortuary staff are advised to regularly monitor and record fridge and freezer temperatures to identify any significant temperature deviations at the earliest opportunity. This is especially important for the temporary Nutwell unit within the body store area, which is not subject to automatic temperature monitoring and is not connected to the fridge alarm system. Mortuary staff should also be aware of the upper and lower alarm trigger points for the fridges and freezers.

Concluding comments

The DI, laboratory and mortuary staff work well together as a team. There have been some changes in staffing, which the Trust is seeking to address through the use of rotational Biomedical Support Workers assigned routine non-technical duties, such as body receipt and some administrative tasks.

Despite increased workloads and staffing pressures, the mortuary team are very motivated and innovative in their approach to mortuary practice. There were several examples of good practice:

- The management of paediatric and perinatal cases including:
 - documentation specifically designed for these cases, which helps ensure accuracy and completeness;
 - the use of a 'traffic light' system as a visual queue to indicate case progress;
 - review dates to ensure PM examinations are chased up and carried out as soon as possible.
- The design and implementation of special 'carriers' for paediatric bodies, that can be used in the fridge or freezer and provide for a separation between adult and paediatric cases.
- The head rest designed by the mortuary manager to help prevent post mortem lividity to the face and purging of body fluids.
- A colour coding system for the fridges and freezers to help identify and allocate the correct and most appropriate space.
- Warning magnets placed on the body store doors to highlight bodies with implant devices, tissues retained, same/similar names and bodies not to be released. In addition, patients with same/similar names are given an orange wrist band and highlighted in the mortuary register.
- The use of a dedicated white board within the paediatric PM suite to record and update the progress of specimens taken at PM examination.
- A dedicated Biomedical Scientist (BMS) to deal with the traceability and disposal of PM specimens in line with relatives wishes for all consent and coronial cases.
- The use of spreadsheets in the mortuary and laboratory for PM tissue traceability. Traceability systems for specimens and bodies are particularly robust.

There are a number of areas of practice that require improvement, including three major shortfalls and one minor shortfall.

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: 22/05/2017

Report returned from DI: 08/06/2017

Final report issued: 26/06/17

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: 15 October 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>

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 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.