Site visit inspection report on compliance with HTA licensing standards

King's Mill Hospital

HTA licensing number 12451

Licensed under the Human Tissue Act 2004 for the

- **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**

15 and 16 November 2017

Summary of inspection findings

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

Although the HTA found that King's Mill Hospital (the establishment) had met the majority of the HTA's standards, five minor shortfalls and two major shortfalls were found against the Consent, Governance and quality systems, Traceability and Premises, facilities and equipment standards.

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

King's Mill Hospital (the establishment) is part of Sherwood Forest Hospitals NHS Foundation Trust. The establishment has been licensed by the HTA since May 2007. The establishment is licensed for the removal of relevant material from the deceased and storage of bodies of the deceased, and relevant material, for use for scheduled purposes. The DI is a Consultant Histopathologist, the Corporate Licence Holder (CLH) is Sherwood Forest Hospitals NHS Foundation Trust and the CLH contact is the Chief Executive of the Trust.

Since April 2013, the establishment does not carry out any PM examinations. The establishment was licensed previously for the making of a PM examination and regularly conducted between 600 and 700 coronial PM examinations per year. Whilst on-site clinicians remain responsible for obtaining consent for adult, paediatric and perinatal hospital (consented) PM examinations, these are carried out, under formal agreements, at other HTA-licensed establishments.

Mortuary

The mortuary has three members of staff, including one Anatomical Pathology Technologist (APT) who is also the mortuary supervisor, and two assistants. A laboratory technician, who is responsible for the retrieval of samples for a Research Tissue Bank (RTB), is also trained in mortuary procedures and, on occasion, undertakes mortuary activities. Porters transfer the bodies from hospital wards to the mortuary. During working hours, the Bereavement Services team are involved in organising viewings and accompanying families. Mortuary staff undertake viewings out of working hours.

The mortuary admits approximately 1600 bodies per year from the hospital and Mansfield area from the ambulance service. The majority of bodies are admitted from the hospital. The establishment does not receive forensic cases. High-risk bodies (up to hazard group 3 biological agents) are admitted to the mortuary.

The mortuary is located within the main hospital building. There is closed-circuit television (CCTV) monitoring of the mortuary areas and out of hours, the mortuary is alarmed. The entrances to the mortuary from the hospital and at the rear are secured by swipe card access and there is an intercom system to allow entry to visitors. There are number code locks on some of the other entrances to the mortuary. There is a shared access corridor between the mortuary and the Cellular Pathology Department; access to the mortuary, including the body store and former PM suite, from this corridor is not restricted. The corridor between the family waiting area and the mortuary is not secured (see Shortfall, against standard PFE1(e)).

The mortuary has 89 spaces for refrigerated storage of bodies, including 10 spaces for semi-bariatric bodies. There are two additional spaces in the cold room that can be used to store

bodies which do not fit into the designated spaces. There are four spaces designated for perinatal/paediatric cases (see *Advice,* item 24). There is a temporary storage unit which can store an additional 12 bodies located in the former PM suite. Contingency arrangements for the refrigerated storage of bodies are provided by an unlicensed body store and a local funeral service under formal agreements. Although one of the storage units can be switched to freezer mode, it is permanently set to refrigeration mode and there is no dedicated freezer storage (see shortfall against standard PFE2(c)). The establishment informed the HTA that a Service Level Agreement (SLA) is currently being finalised with another HTA-licensed premises as a contingency for freezer storage (see *Advice,* item 22).

The mortuary fridges are alarmed locally and there is an external alarm system linked to the hospital security room. In the event of a deviation from the set limits, out of hours, porters are alerted to check the fridges and, if the problem continues, a member of mortuary staff will be contacted. The alarm system for the temporary storage unit is connected to an external company that automatically alerts the on-call mortuary staff member in the event of the alarm being triggered. Mortuary staff conduct regular testing of the call-out systems for the alarm and manually record the fridge temperatures daily. The mortuary fridges are on the hospital emergency power supply system and are maintained under service contracts.

Consent for hospital PM examinations takes place very occasionally, with approximately five adult cases undertaken in 2016. In adult cases, consent is sought by clinical staff who are accompanied by a trained facilitator from the Bereavement Services using a Sherwood Forest Hospitals NHS Foundation Trust consent form (see shortfall against standard C1(a)). Consent for perinatal and paediatric hospital PM examinations is sought by clinical staff using a consent form provided by the establishment to which the cases are referred and information leaflet provided by the Stillbirth and Neonatal Death (Sands) charity or Sheffield Children's NHS Trust. All clinical staff receive training in seeking consent as part of their clinical training; however, this training is not specific for PM consent, it is not refreshed and competency is not assessed (see shortfall against standard C2(a)).

Bodies are transferred from hospital wards to the mortuary by portering staff. The mortuary supervisor trains porters annually. Perinatal and paediatric cases are transferred from the Maternity Department to the mortuary by clinical staff or porters. There is no storage of relevant material on the Maternity Ward. Bodies are released from the mortuary by mortuary staff. The mortuary use paper records to record details of bodies, including admission and release (see *Advice,* item 9).

Accident and Emergency Department

Removal of relevant material from the deceased takes place in the Accident and Emergency (A&E) Department in cases of sudden unexpected death in infancy (SUDI) under pre-emptive coronial authority. The A&E Department manages approximately six SUDI cases each year. In such cases, body fluids and swabs are removed by paediatric consultants in a

specified paediatric bay within the Department. There are documented procedures that are available in the Department. Samples removed are packaged with pre-printed identification labels and transferred immediately to the Cellular Pathology Department.

Cellular Pathology Department

All PM histology samples are stored as part of a closed collection from when the establishment carried out PM examinations. All samples are stored with consent. Samples are stored in the Cellular Pathology Department and in a separate archive building on the hospital site. Both premises are secured by swipe card access. The establishment uses paper records and electronic databases to record sample details.

Removal and storage of samples for research

The establishment is involved in the removal and storage of relevant material for the scheduled purpose of research. The establishment are a collecting site for a RTB of spine and joint tissues for research into human disease. Tissue is removed from approximately 40-50 deceased patients per year. Tissue removed during standard surgical procedures is also stored from approximately 100-200 patients per year. All consent is obtained on site using consent forms and information sheets specific to the study (see shortfall against standard C1(b)). Samples from deceased donors are removed in the former PM suite of the mortuary by the research technician and mortuary staff and then processed. Mortuary staff are responsible for the identification of the deceased and all staff involved check the consent documentation prior to starting the procedure. All samples are deidentified, given a unique number and stored in a designated -80°C freezer in the mortuary. The freezer temperature is checked and recorded daily and it has an audible alarm for alerting staff of temperature deviations (see *Advice,* item 23). Monthly, samples are transferred to the RTB in Nottingham where they are stored under another HTA licence. Tracking forms and dispatch sheets maintain traceability.

Description of inspection activities undertaken

This report describes the HTA's third, routine site visit inspection of King's Mill Hospital. The inspection team interviewed staff involved with licensable activities, reviewed documentation and conducted visual inspections of the mortuary, area where relevant material is removed in the A&E Department and the Cellular Pathology Department storage areas.

A traceability audit was conducted for four adult bodies and two non-viable fetus (NVF) cases. These audits included checks of storage locations and identifiers recorded in the mortuary records. For one adult case, one minor discrepancy was found in the mortuary register, where the month of birth was different to the patient's wristband. For the NVF cases, the mothers name is the only identification used which is handwritten on the storage box. In one of the cases, the mother's name was spelt differently on the box compared with the entry in the register (see shortfall against standard T1(c)).

Audits of traceability were conducted for archived tissue blocks from four PM cases, including checks of the consent documentation for storage of the samples. There were no discrepancies in traceability or consent records for these samples.

Audits of traceability were conducted on samples being stored for the RTB, including one from a deceased patient and one from a living patient, including checks of the consent documentation for storage of the samples. There were no discrepancies in traceability or consent records for these samples.

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
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.	The documented consent policy, standard operating procedure (SOP), adult hospital PM consent form and information leaflet used for paediatric hospital PMs do not accurately reflect the consent requirements of the HT Act. The procedure for requesting a PM examination and gaining informed consent all refer to the next of kin. *Refer to Advice, item 1.* *The HTA did not find evidence that the establishment have removed, used or stored relevant material with consent from a person who is not the appropriate person under the HT Act; however, these procedures, if followed, have the potential to result in a statutory breach of the HT Act.*	**Minor**
b) There is a documented SOP detailing the consent process (including who is able to take consent, what training they must receive, and what information must be provided to those giving consent) for post-mortem examination.	There is no SOP for consent for removal of samples from the deceased for research The SOP for seeking consent for hospital PM examinations does not contain sufficient details of the consent procedure, including the withdrawal procedures and the consent training requirements for staff seeking consent. This poses the risk that staff may not follow the required procedure for seeking consent in accordance with the requirements of the HT Act and HTA Codes of Practice.	**Minor**

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.	Staff who seek consent for hospital PM examinations have undertaken general training in the consent process but do not receive training specific for the taking of consent for PM examination or the requirements of the HT Act and HTA Codes of Practice. *Refer to Advice, items 3 and 4.*	**Minor**

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.	There is no SOP describing the practices relating to long-term storage of bodies and when bodies should be moved into frozen storage. The following SOPs need to include more detail: • Retrieval of tissue for research. • Viewing of a deceased patient. *Refer to Advice, item 5.*	**Minor**

T1 A coding and records system facilitates traceability of bodies and human tissue, ensuring a robust audit trail		
c) Three identifiers are used to identify bodies and tissue, (for example post mortem number, name, date of birth/death), including at least one unique identifier.	The establishment's procedures for identification of bodies do not always use three identifiers. Bodies may be released from the mortuary using only one or two or three identifiers depending on the form used. Identification of the deceased for viewings may be based on only one identifier (the deceased's name) provided by the family. NVF boxes are stored on one tray in the body store. The boxes are labelled with only one identifier (the mother's name) and the contents of the boxes are unlabelled. This presents a significant risk of misidentification of the deceased. *Refer to Advice, items 13, 14 and 15.*	**Major**

PFE1 The premises are secure and well maintained and safeguard the dignity of the deceased and the integrity of human tissue.		
e) Security arrangements protect against unauthorised access and ensure oversight of visitors and contractors who have a legitimate right of access.	Staff from the Cellular Pathology Department have unrestricted access to the mortuary, including the body store and former PM suite, through a shared corridor area. This poses a risk of unauthorised access by staff to the mortuary. The door between the family waiting area and the body store area is not secured. Whilst visitors to the mortuary are accompanied at all times, there remains a risk of unauthorised access by visitors to the mortuary from the family waiting area.	**Minor**

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

c) Storage for long-term storage of bodies and bariatric bodies is sufficient to meet needs.	The establishment does not have appropriate arrangements in place for the long-term storage of bodies, specifically: • The establishment does not use its freezer storage unit and does not have formalised contingency arrangement for frozen storage of bodies at other premises. • Checks on the condition of bodies are not undertaken frequently enough. • At the time of the inspection, one body had been stored in refrigerated storage for in excess of five weeks, resulting in deterioration in the condition of the body. These arrangements pose a significant risk to the integrity and dignity of the deceased requiring long-term storage. *Refer to Advice, items 5 and 21.*	**Major**

Advice

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

No.	Standard	Advice
1.	C1(a)	The establishment must ensure that appropriate consent under the HT Act is given for the removal, storage and use of samples for scheduled purposes. The 'next of kin' may not be the person highest in the list of qualifying relationships under the Section 27(4) of the HT Act. Policies, SOPs, consent forms and information leaflets should be updated to reflect this. Information on the consent requirements of the HT Act can be found in HTA Code of Practice A – Guiding Principles and Fundamental Principle of Consent, which is available on the HTA's website.
2.	C1(b)	To address the shortfall against standard C1(b), the DI should review the SOP for seeking consent for hospital PM examinations to ensure that it contains sufficient details of the consent seeking process, including the consent withdrawal procedures and the consent training requirements for staff seeking consent. This will help to ensure that staff follow the expected procedure and the required standards are met.
3.	C2(b)	Training should be undertaken with those seeking consent. Refresher training should be provided on a regular basis. The DI should ensure that training is recorded and documented as this provides evidence that staff have up-to-date training in undertaking this procedure.
4.	C2(d)	A schedule of competency assessment should be implemented where staff involved in seeking consent are observed seeking consent. This will provide the DI with assurance that staff seeking consent are doing so appropriately and confidently.

5.	GQ1(a)	All aspects of the establishment's work should be governed by documented policies and SOPs to include; • Practices relating to the long-term storage of bodies including when bodies should be moved in to frozen storage. • Practices relating to the identification checks that take place prior to tissue retrieval for the RTB. • Practices relating to the roles of the Bereavement Services, the roles of the mortuary staff and the identification checks that take place before a viewing.
6.	GQ1(a)	The DI is advised to ensure that references in the establishment's documents are up-to-date, including references to the HTA Codes of Practice.
7.	GQ1(d)	Policies and SOP's should be reviewed regularly by someone other than the author (e.g. Quality Manual SFHPAT-QM-GEN001).
8.	GQ2(a)	The DI is advised to strengthen audits of mortuary activities by ensuring that they cover all mortuary procedures in sufficient detail, including that the required standards are being met. For example, process audits of identification procedures should include checking that three identifiers are used for identification of the deceased. Audits can help to ensure that procedures are performed in-line with SOPs and identify areas where additional training may be required or where a process may need to be amended.
9.	GQ4(b)	An entry in the mortuary register was seen where the original entry had been crossed out but not initialled by the person making the amendment. The DI is advised to ensure that staff are aware of the control of records procedure when making written amendments to records, including that all written amendments are initialled and dated to allow full traceability.
10.	GQ5(a)	The DI should improve awareness of the HTARI reporting requirements and the establishment's procedures for reporting incidents. The DI is advised include signs in the mortuary to remind staff of the requirements and procedures for reporting incidents, including near-miss incidents.
11.	GQ6(a)	The establishment has a good range of risk assessments that include how to mitigate the risks identified. The DI is advised to distribute risk assessments to all relevant staff and include an acknowledgement section to ensure that staff have read and understood them.
12.	T1(b)	The DI is advised to label the body store fridge doors with the individual space letters to match the mortuary whiteboard. This will reduce the risk of misidentifying the location of the deceased for both porters and mortuary staff.
13.	T1(c)	The DI must ensure that three identifiers (including at least one unique identifier) are used to identify bodies throughout all procedures in the mortuary including: • When bodies are released from the mortuary, including three identifiers that can be cross-referenced with the funeral director. • When there is a viewing of a body, including three identifiers that can be cross-referenced with the family. • Before tissue retrieval takes place, including three identifiers that can be cross-referenced with the consent forms.

14.	T1(c)	The DI may wish to consider strengthening the procedure for viewings by introducing a form to record the information from the visitor used to identify the deceased. By recording this information, these identifiers can be checked when preparing the body for the viewing and immediately prior to the viewing taking place to help to ensure that the required standards are met.
15.	T1(c)	The DI must strengthen the identification procedures for NVFs. This includes ensuring that: • boxes are labelled with three identifiers; and • within the boxes, NVFs are labelled with three identifiers.
16.	T1(f)	There are procedures for flagging bodies that have been in longer-term storage that include adding a pink tab to the mortuary register. The DI is advised to include this procedure in the relevant mortuary SOP.
17.	PFE1(a)	The floor within the former PM suite is showing some signs of wear. The DI is advised to keep the suitability of the mortuary premises under review.
18.	PFE1(d)	The DI is advised to ensure that when the former PM suite is being used for removal of tissue for research, the doors to this area are closed and the demarcation of clean and dirty areas is adhered to. This will reduce the risk of unauthorised or unintentional access from the body store area, ensure the ventilation system can work efficiently and reduce the risk of contamination of clean areas of the mortuary.
19.	PFE1(d)	There is a broken glass panel on the rear door to the mortuary. The glass is broken from the inside and it is wired. The mortuary staff have identified the problem and reported it to management. The DI is advised to ensure this is fixed in a timely manner.
20.	PFE2(a)	Bodies are transferred to the highest and lowest refrigerated storage spaces to allow the porters easy access to the middle spaces. At the time of the inspection, storage capacity was not an issue; however, all the top and bottom spaces were occupied. Furthermore, six NVF boxes at the top of the fridge were not secure when the tray was pulled out. There are a number of risks associated with this practice and the DI is advised to consider the risks including: • The general risks of moving bodies in the fridge (e.g. risk of damage, risk of storage location misidentification). • The possible impacts on impeding air flow by bodies being in such close proximity to the fan units. • The risk of NVF boxes falling from the top shelf.
21.	PFE2(c)	The HTA advises that bodies should be moved into frozen storage after 30 days in refrigerated storage if there is no indication that they are soon to be released or further examined, or before, depending on the condition of the body. As part of the corrective and preventative actions to address the shortfall against standard PFE2(c), the DI is advised to conduct more frequent checks on the condition of bodies and consider the introduction of a documented checklist to record checks performed. This will provide assurance that the establishment's storage arrangements ensure the dignity of the deceased is maintained.

22.	PFE2(c)	The HTA were informed that an SLA is currently being prepared with another HTA-licensed establishment for freezer storage. The DI is advised to finalise this SLA. Further advice on contingency storage arrangements can be found in the HTA's guidance document 'Storage capacity and contingency arrangements in mortuaries: Guidance for DIs in HTA-licensed establishments', which is available on the HTA's website.
23.	PFE2(e)	Although the research tissue freezer is monitored daily it has an alarm that sounds only locally. This means that an alarm could sound for a period of time, for instance overnight or at the weekend, without staff hearing it. The DI is advised to undertake a risk assessment of the current arrangement. The DI is also advised to ask security or mortuary staff to regularly check the area when the unit is in use; and to provide clear guidance for them on what steps to take if the alarm does sound.
24.	PFE2(h)	There is a designated fridge for paediatric/perinatal cases however, at the time of the inspection, an adult body was stored in the lower space despite capacity available elsewhere (refer to Advice, item 21). The DI is advised to keep the storage of adult and paediatric/perinatal cases separate wherever possible.
25.	PFE3(a)	The trolley in the mortuary has extensive areas that are rusting. The DI should keep the suitability of the mortuary equipment under regular review.

Concluding comments

The HTA observed some areas of strength and good practice throughout the inspection. Staff involved in the inspection demonstrated a sensitive approach to their work and dedication to providing a good service. Staff also demonstrated a willingness for continuous improvement and compliance with the regulatory requirements, and were open to the advice given by the HTA.

There are a number of areas of practice that require improvement, including two major shortfalls and five 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: 11 December 2017

Report returned from DI: 20 December 2017

Final report issued: 20 December 2017

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.