Site visit inspection report on compliance with HTA licensing standards

St Mary's Hospital

HTA licensing number 12553

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**

26-28 June 2018

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 St Mary's Hospital had met the majority of the HTA's standards, three minor shortfalls were found. They were in relation to: (i) consent training (C2(c)); (ii) governance meetings (GQ1(h)); and (iii) the testing and monitoring of the refrigerator and freezer alarm system (PFE2(e)).

Advice has been given relating to the Governance and Quality systems, and Premises, Facilities and Equipment standards, as well as advice on licence management.

Particular examples of strength 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 (DI) is a suitable person to supervise the activity authorised by the licence and that the premises are suitable for the activity.

The statutory duties of the DI are set down in Section 18 of the Human Tissue Act 2004. They are to secure that:

- the other persons to whom the licence applies are suitable persons to participate in the carrying-on of the licensed activity;
- suitable practices are used in the course of carrying on that activity; and
- the conditions of the licence are complied with.

Its programme of site visit inspections to assess compliance with HTA licensing standards is one of the assurance mechanisms used by the HTA.

The HTA developed its licensing standards with input from its stakeholders. They are designed to ensure the safe and ethical use of human tissue and the dignified and respectful treatment of the deceased. They are grouped under four headings:

- consent
- governance and quality systems
- traceability
- premises facilities and equipment.

This is an exception-based report: only those standards that have been assessed as not met are included. Where the HTA determines that there has been a shortfall against a standard, the level of the shortfall is classified as 'Critical', 'Major' or 'Minor' (see Appendix 2: Classification of the level of shortfall). Where HTA standards are fully met, but the HTA has identified an area of practice that could be further improved, advice is provided.

HTA inspection reports are published on the HTA's website.

Background to the establishment

This report refers to the activities carried out at St Mary's Hospital (the establishment), whose HTA licensing arrangements cover St Mary's Hospital (SMH; the hub site) and two satellite sites (Hammersmith Hospital, HH; Charing Cross Hospital, CXH). The establishment was issued an HTA licence in February 2010. This was the third HTA site visit inspection of the establishment (the last inspection was in May 2014). This inspection was a routine one to assess whether the establishment is continuing to meet the HTA's standards.

The hub site is licensed under the Human Tissue Act 2004 for the making of a post-mortem (PM) examination, the removal of relevant material from the deceased for use for a scheduled purpose and the storage of a body and relevant material for use for a scheduled purpose. Both satellite sites are only licensed for the storage of a body and relevant material

for use for a scheduled purpose. Although only consisting of a body store and viewing facility, both satellite mortuaries fall under the licence as bodies can be stored for longer than seven days pending PM examination at another licensed site.

The DI supervising activities taking place under the licence is a the Lead Clinician in Cellular Pathology, the Corporate Licence Holder (CLH) is Imperial College Healthcare NHS Trust with the Chief Executive as the named contact. There are currently seven Persons Designated (PDs) named under the licence (see *Advice*, item 1).

St Mary's Hospital (SMH) – Hub Site

At the hub site, licensed activities occur within Cellular Pathology, which includes the mortuary and Histopathology Department. The Division of Cellular Pathology is awaiting accreditation by the United Kingdom Accreditation Service (UKAS) to International Organization for Standardization (ISO) standard 15189 (2012). This will include the Histopathology Department.

Although SMH has an Accident and Emergency (A&E) Department, which includes paediatric A&E, it is the policy of local Coroners for specimens not to be removed from cases of sudden or unexpected death in infants and children (SUDIC). The A&E Department does not therefore fall under the licence.

Although SMH has a Maternity Unit, storage of stillbirths and perinatal deaths are not stored but are transferred directly to the SMH mortuary. The Maternity Unit does not therefore fall under the licence.

Cellular Pathology (mortuary)

The SMH mortuary receives approximately 900 bodies each year and carries out approximately 120 adult PM examinations annually. Paediatric, perinatal and stillbirth PM cases are carried out at a separate HTA-licensed establishment.

There are no Home Office PM examinations and the establishment does not store any tissue specimens held under the Police and Criminal Evidence Act 1984 (PACE).

Approximately 50% of PM cases are under Coronial authority (predominantly HM Coroner - London Inner West, but also HM Coroner - London West and HM Coroner - London North). The remainder are 'hospital' (consented) PM cases.

There is one consultant pathologist who carries out PM examinations at SMH. He is assisted by two qualified senior Anatomical Pathology Technologists (APTs). The APTs also assist tissue retrieval teams in procuring multiple tissue types for human application; tissue 'procurement' is under a separate licence held by another organisation under the Human Tissue (Quality and Safety for Human Application) Regulations 2007.

Consent for PM examination at each of the sites is sought by members of a core consent team, who have attended a consent training programme organised by one of the consultant

pathologists [see shortfall against standard C2(c)]. If the patient's attending clinician is not a member of this core team, a team member takes the lead in the consent process. For adult PM examinations, a consent form and information leaflet developed from the HTA template are used to record consent. For stillbirth and perinatal cases , the Stillbirth and Neonatal Deaths (Sands) consent form and information leaflet are used.

Each of the three mortuaries is purpose built. SMH's mortuary is located separately from the main hospital buildings and has been recently refurbished. The mortuaries at HH and CXH are located within the main hospital buildings. Entry and exit points to each mortuary are monitored by closed-circuit television (CCTV) and there is electronic access control (key code or video phone and swipe card). There are standard operating procedures (SOPs) to cover lone working both during and out of hours.

Adjacent to each mortuary is a viewing facility, which is well lit, spacious and discreetly decorated. Viewings at each site are managed by patient services or bereavement staff, who may also attend viewings to support relatives. Bodies for viewing are prepared by mortuary staff in office hours and by porters out of office hours. Viewings out of office hours are arranged by site operation managers (see *Advice*, items 4 and 6).

Body Store and PM Room

The SMH body store contains 60 refrigerated spaces, including five which can be used for frozen storage and five for bariatric storage. There is a separate refrigerator for perinatal deaths, stillbirths and foetuses. Labels are available to mark spaces storing bodies where a risk of infection has been identified. The establishment has detailed SOPs governing the management and sensitive disposal of products of conception, non-viable foetuses and foetuses, according to parents' wishes.

Refrigerator (and freezer) temperatures are recorded manually on a daily basis by mortuary staff and monitored externally via a wired system linked to the hospital switchboard. If temperatures exceed the set limits, a local audible alarm is sounded and an electronic signal is sent to the hospital switchboard for action. There is an on-call rota of staff in the Estates Department and mortuary staff are available to manage callouts and the movement of bodies, when required.

Refrigerators and freezers on all sites are subject to regular servicing and planned preventative maintenance (see *Advice*, item 13). In addition, the establishment has a contingency plan for disaster recovery and individual plans for additional body storage demand.

Clean, transitional and dirty areas are clearly delineated within the establishment and there are wall notices and diagrams clarifying when and how personal protective equipment should be worn.

There are clear policies and SOPs for cleaning and decontamination and records of cleaning and decontamination are maintained.

The PM room contains three PM tables, each with an accompanying dissection bench, and has adequate working space and good lighting. Ventilation levels were above the required 10 air changes per hour (see *Advice*, item 12) .

Receipt, Storage and Release of Bodies

The process followed for receipt, storage and release of bodies is largely uniform across all three sites. Bodies arriving from the community are brought into the mortuary by a dedicated funeral director under a formal agreement with the Coroner. Those arriving from one of the other two sites within the Trust are brought in by a different funeral director under agreement with the Trust. All bodies from within the hospital are transported by trained porters (see *Advice*, item 4).

Upon arrival, information is entered into the mortuary register and the body is given a unique, sequential number. Where the deceased requires a PM examination, a separate PM number is also allocated and a record is kept in the PM register. Records from both registers are entered into the Cellular Pathology database, which can be accessed by all Cellular Pathology staff, including mortuary staff, at each site.

If porters bring a body to the mortuary out of hours, they place the body in the most appropriate vacant space and place a copy of the relevant notification of death form on a clipboard or wall mounted folder in the mortuary office. The mortuary team reviews all new bodies the next day and transfer the details into the mortuary register and the Cellular Pathology database. Bodies that have surnames which are the same or similar to those of other bodies that are in storage are highlighted, both on the refrigerator door labels, on the mortuary location whiteboard and in the mortuary register.

The details of tissue specimens and organs taken for analysis during PM examination are recorded on the histopathology request card and in the Cellular Pathology database. Bodies which require repatriation of tissue specimens are highlighted in the PM register, on the refrigerator door labels and on the location whiteboard.

Wet tissue specimens removed as part of Coronial or hospital PM examinations are delivered the next day by mortuary staff to the Histopathology Department for histological analysis.

Body fluid specimens removed as part of Coronial or hospital PM examinations are delivered to the Biochemistry Department for toxicological analysis or are sent externally for toxicological and asbestos fibre analysis. External transportation is by a dedicated courier under an agreement with the establishment.

Brain tissue/whole brains, cardiac tissue/whole hearts, and occasionally whole lungs, are transported offsite to separate HTA-licensed establishments for specialist examination. External transportation is by a dedicated courier operating under an agreement with the establishment.

Funeral directors collect bodies and bring their own documents (either release forms, signed

by families, or the relevant disposal paperwork). Bodies under Coronial authority are only released when Coronial release documents have been received directly by the mortuary. Release of bodies during office hours is carried out by a member of the mortuary staff in conjunction with the attending funeral director, following a defined SOP with both signing the register to confirm a dual check of identity. Out of hours release, which occurs rarely, is by site operation managers acting in conjunction with funeral directors.

Cellular Pathology (Histopathology)

The Histopathology Department has dedicated storage areas for wet tissue, tissue blocks and tissue slides. The department uses the same electronic database as the mortuary to record sample details, including consent for the continued retention and use of samples after determining the cause of death. The specimens may be stored with appropriate consent for use for various scheduled purposes including research.

Archival blocks and slides are stored offsite at a separate HTA-licensed establishment.

Hammersmith Hospital (HH) – Satellite Site

At the HH site, licensed activities occur within the body store, which receives approximately 500 bodies each year. Although there is a Maternity Unit at the adjacent hospital (Queen Charlotte's and Chelsea Hospital), storage of stillbirths and perinatal deaths are not stored and are transferred directly to the HH mortuary. The Queen Charlotte's and Chelsea Hospital Maternity Unit does not therefore fall under the licence.

The HH body store contains 40 refrigerated spaces, including dedicated spaces for bariatric and infectious cases. There are separate spaces reserved for the storage of perinatal deaths, stillbirths and foetuses.

Adult bodies requiring PM examination are transported to SMH by funeral director under agreement with the Trust. Stillbirths requiring PM examination are transported to a separate HTA-licensed establishment by funeral director under agreement with the Trust. Foetuses are transported to SMH by funeral director under an agreement with the Trust.

Refrigerator temperatures are recorded manually on a daily basis by mortuary staff and monitored externally via a wireless system linked to the hospital helpdesk. The system monitors temperatures every five minutes and temperature archives are stored on an external server, although the temperature data is not reviewed for trends (see *Advice*, item 11). If temperatures exceed the set limits, a local audible alarm is sounded and an electronic signal is sent to the hospital helpdesk for action. There is an on-call rota of staff in the Estates Department and mortuary staff available to manage callouts and the movement of bodies, when required.

Charing Cross Hospital (CXH) – Satellite Site

At the CXH site, licensed activities occur within the body store, which receives approximately 800 bodies each year. There is an A&E Department at CXH but removal of specimens from SUDIC cases does not take place. The A&E Department does not therefore fall under the licence.

The CXH body store contains 44 refrigerated spaces, including dedicated spaces for bariatric and infectious bodies. There is also a decommissioned PM room on site that is now used for storage of documents.

Adult bodies requiring PM examination are transported to SMH by funeral director under an agreement with the Trust.

Refrigerator temperatures are recorded manually on a daily basis by mortuary staff and monitored externally via a wireless system linked to the security callout system. The system monitors temperatures every five minutes and temperature archives are stored on an external server, although the temperature data is not reviewed for trends (see *Advice*, item 11). If temperatures exceed the set limits, a local audible alarm is sounded and an electronic signal is sent to the hospital helpdesk for action. There is an on-call rota of staff in the Estates Department and mortuary staff available to manage callouts and the movement of bodies, when required. The alarm and callout system is not regularly tested [see shortfall against standard PFE2(e)].

Description of inspection activities undertaken

The timetable for the site visit inspection was developed after consideration of the establishment's previous inspection reports, compliance update information and communications with the HTA. The inspection included a visual inspection of the hub site (Cellular Pathology – Mortuary and Histopathology Department) and satellite sites (HH Mortuary, CXH Mortuary), discussions and interviews with key staff, and a review of documentation. Interviews were held with: the DI, CLHC, one PD from each site, two APTs, one trainee APT, the Cellular Pathology Quality and Governance Manager, a Lead Biomedical Scientist for Histopathology, a Senior Bereavement Midwife, the Lead Clinician for Cellular Pathology and the Deputy Heads of Portering Services at SMH and HH.

A documentation review and horizontal and vertical audits were carried out.

- At SMH, a horizontal traceability audit was conducted on three randomly selected adult bodies in the refrigerators. Body location and identification details on wrist and ankle tags were checked against the labels on the refrigerator doors, mortuary location whiteboard, mortuary register and Cellular Pathology database. No discrepancies were identifed.
- A reverse horizontal audit was conducted on three randomly selected adult bodies in the mortuary register. The recorded details in the register were checked against the physical body location and identification details on wrist and ankle tags, labels on the refrigerator doors and mortuary location whiteboard. Again, no discrepancies were

identifed.

- A vertical audit was conducted on tissue removed and retained following PM examination from three randomly selected cases (two Coronial and one hospital case). The specimens had been processed into blocks and slides. Specimen details were checked against the PM register, the histopathology request card, the Cellular Pathology database and the families' wishes on the completed Coroner's 'Next of kin statement' or Hospital 'Consent form for adult PM examination', as appropriate. The physical blocks and slides were sought where applicable and the numbers checked against the records. There was full traceability, with no discrepancies noted.
- At the HH satellite, a horizontal traceability audit was conducted on three randomly selected bodies (two adults, one stillbirth). There was full traceability in two of the cases and one minor discrepancy in the third, stillbirth case [see shortfall against standard C2(c)].
- At the CXH satellite, a horizontal traceability audit was conducted on two randomly selected adult bodies. No discrepancies were identifed.

Inspection findings

The HTA found the DI and the CLH to be suitable in accordance with the requirements of the legislation.

Compliance with HTA standards

Consent

Standard	Inspection findings	Level of shortfall
C2 Staff involved in seeking consent receive training and support in the essential requirements of taking consent		
c) If untrained staff are involved in seeking consent, they are always accompanied by a trained individual	Consent for PM cases is sought by members of a core consent team, who have attended a consent training programme organised by a consultant pathologist. During the inspection, a horizontal traceability audit was carried out at the HH site. It was found that, in one case, the person seeking consent for a stillbirth PM examination had not yet attended the consent training programme.	**Minor**

Governance and Quality Systems

Standard	Inspection findings	Level of shortfall
GQ1 All aspects of the establishment's work are governed by documented policies and procedures		
h) Matters relating to HTA-licensed activities are discussed at regular governance meetings involving establishment staff	Governance meetings relating to HTA-licensed activities took place regularly until the end of 2017. Their re-introduction is especially important in the light of: (i) a new CLHC being in place (July 2017); (ii) new HTA Codes of Practice having been introduced; and (iii) the fact that the Pathology Directorate has moved from the Trust into a separate joint pathology services organisation, although each mortuary will remain separately within the Trust (Division of Medicine). All PDs involved in licensed activities should be invited to attend the meetings, as well as the CLHC. The DI may also wish to consider whether to include representatives from other departments (e.g. Clinical Governance, Information Technology, Estates, Portering Staff) to continually develop the establishment's working practices.	**Minor**

Premises, facilities and equipment

Standard	Inspection findings	Level of shortfall
PFE2 There are appropriate facilities for the storage of bodies and human tissue.		
e) Fridge and freezer units are alarmed and the alarms are tested regularly to ensure that they trigger when temperatures go out of upper or lower set range.	During the inspection, it was noted that: • The testing of the callout system for body store refrigerators and freezers at one site (CXH) was not carried out. • There were no documented upper and lower temperature limits for the various storage locations and staff were not aware of these limits should be. • There were discrepancies in the readouts between the refrigerator digital display and the remote temperature monitoring charts.	**Minor**

Advice

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

No.	Standard	Advice
1.	N/A	The DI is advised to rationalise the number of PDs in relation to the different licensed activities taking place across the Trust as there is duplication and some of the registered PDs are no longer involved in such activities.
2.	GQ1(a)	The DI is advised to consider adding the maximum length of time a body is stored in the body freezer to the freezer storage SOP.
3.	GQ1(h)	Joint governance meetings, involving DIs across the different sectors, are a feature in several other organisations that hold multiple HTA licences. The Trust is the CLH on four HTA licences and the University (Imperial College London) is CLH on two additional HTA licences within the Trust. Although there are frequent local meetings of the Quality Management Team, there are currently no meetings between DIs and individuals named on the licences described above. The DI and CLHCs are advised to consider setting up joint governance meetings involving staff on all of these licences as an opportunity for shared learning.

4.	GQ3(a), (c)	Porters have received detailed training in mortuary procedures and have detailed knowledge of procedures associated with handling bodies and placing them in storage, or knowledge of the factors that may prevent risk of damage to a body. Although there has been an intense effort to train porters on all three sites, 30% of porters still need to be trained in mortuary activities, including out of hours activities. The DI is advised to undertake this training in a timely manner to help assure themselves that all porters are appropriately trained.
5.	GQ3(a), (c)	The DI is advised to consider adding training in the different categories of HTA reportable incidents for porters and site operation managers.
6.	GQ3(a), (c)	The DI is avised to ensure that there is regular refresher training for staff who deal with bodies out of hours, most notably, porters and site operation managers.
7.	GQ6(a)	The DI is advised to risk assess the use of the electric truck used to transport bodies from the hospital building to the SMT mortuary.
8.	PFE1(c)	During the inspection, it was noted that the cleaning records at the HH mortuary had not been completed. The DI is advised to ensure that all cleaning events are appropriately recorded.
9.	PFE1(d)	The DI is advised to introduce panic buttions in each viewing room or to provide staff with personal alarms that are linked to other areas of the hospital such as security so that they are avaialable to use when staff are conducting out of hours viewings.
10.	PFE1(e)	The DI is advised to consider creating a visitor book for each mortuary to be completed by estates staff and other visitors, so that they may review details of the staff requesting access to the mortuary,.
11.	PFE2(f)	The DI is advised to consider initiating a programme by which, at suitable timeframes, the temperature plots from the fridge and freezer temperature monitoring system are reviewed. This may help to identify a potential failure of the systems before they occur.
12.	PFE3(c)	The DI is advised to consider keeping records of service visits for the ventilation system locally in the SMH mortuary so that they are available for staff to review and so that the next maintenance visit can be organised when due.
13.	PFE3(f)	The DI is advised to consider keeping records of refrigerator and freezer service visits locally in each mortuary so that they are available for staff to review and so that the next maintenance visit can be organised when due.

Concluding comments

During the inspection areas of strength and good practice were noted:

- The enthusiasm and dedication of the teams in all the Departments inspected. There is a weekly newsletter covering all Cellular Pathology activities distributed to all relevant staff.
- There are well lit, spacious and discreetly decorated viewing rooms on all sites.
- The detailed consent training process for adult and paediatric consent. Staff involved in paediatric consent have organized an annual and national Bereavement Midwife Forum.
- As part of the establishment's audit activity, a full audit against the HTA standards is carried out every six months to help assure the DI that the standards are being met.
- When cases are received into the mortuary on each site from the community the body is logged onto the hospital system to generate an identification band.
- The system of daily checks of identification of deceased also includes a check on condition. Staff grade the condition of the deceased on receipt to inform decisions on allowing viewing of bodies. As the daily check includes a further grading of body condition, any deterioration is noted. Similarly, the daily checks prompt actions to deal with any deceased who have remained in store pending decisions on burial or cremation.
- The detailed competence training for APTs on all sites.
- The incident reporting SOP is particularly comprehensive, providing guidance to staff on the types of incidents which fall into the classification of HTA reportable incidents. Examples are provided, having been selected from documentation published by the HTA and an example incident is worked through in the SOP itself, to guide staff on the practical aspects of reporting.
- The establishment has captured all incidents relating to mortuary activities by creating different categories on the Trust DATIX system.
- Risk assessments are reviewed annually, on process change or following incidents, and evidence was seen of risk assessment being carried out as part of a change control process and in relation to the drafting of new documentation.
- The establishment has a well developed contingency plan, particularly in relation to capacity for frozen storage or bariatric cases, both of which it has risk assessed and incorporated on the Trust risk register.

There are a number of areas of practice that require improvement, including three minor shortfalls. The HTA has given advice to the DI with respect to the Governance and Quality systems, and Premises, Facilities and Equipment standards, as well as advice on licence management.

The HTA requires the DI to submit a completed corrective and preventative action (CAPA) plan setting out how the shortfalls will be addressed, within 14 days of receipt of the final report (refer to Appendix 2 for recommended timeframes within which to complete actions). The HTA will then inform the establishment of the evidence required to demonstrate that the actions agreed in the plan have been completed.

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: 26 July 2018

Report returned from DI: 8 August 2018

Final report issued: 29 August 2018

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: 30 November 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

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.