Site visit inspection report on compliance with HTA minimum standards

Guy's and St Thomas' Hospitals, Cellular Pathology

HTA licensing number 12243

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**

18-19 October 2016

Summary of inspection findings

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

Although the HTA found that Guy's and St Thomas' Hospitals, Cellular Pathology (the establishment) had met the majority of the HTA standards, two minor shortfalls were found in relation to the Governance and Quality Systems (GQS) and Premises, Facilities and Equipment (PFE) standards; specifically, the absence of: (i) a documented procedure for identifying and reporting HTA-reportable incidents; and (ii) risk assessments of hub and satellite premises. Advice has been given on matters across the range of standards, including licence management.

Particular examples of strengths and good practice are included in the concluding comments section of the report.

The HTA's regulatory requirements

The HTA must assure itself that the DI, Licence Holder (LH), premises and practices are suitable.

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.

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. The HTA inspects the establishments it licences against four groups of standards:

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

This is an exception-based report: only those standards that have been assessed as not met are included. Where the HTA determines that a standard is not met, 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 given to the DI.

Reports of HTA inspections carried out from 1 November 2010 are published on the HTA's website.

Background to the establishment and description of inspection activities undertaken

This report refers to the activities carried out at Guy's and St Thomas', Cellular Pathology (the establishment), whose licensing arrangements cover St Thomas' Hospital (the hub site) and Guy's Hospital (the satellite site). The DI is a Consultant Histopathologist; the LH is Guy's and St Thomas' NHS Foundation Trust, with the Trust Secretary and Head of Corporate Affairs acting as the named contact (CLHC).

Guy's and St Thomas's NHS Foundation Trust (GSTT) is a large teaching hospital trust with a wide range of specialities providing services from two central London sites. The GSTT department of Cellular Pathology includes the Mortuary & Bereavement Service (MBS) and sits within the Haematology and Oncology Directorate. The pathology laboratory services are operating under Viapath (previously GSTS pathology). Viapath was founded in 2009 and operates pathology services across Guy's and St Thomas' and King's College Hospitals, as well as Bedford Hospital. Cellular pathology consultant staff remain under GSTT management.

St Thomas' Hospital – the hub site

At the hub site, licensable activities take place in the mortuary, Cellular Pathology Department and Maternity Department.

The mortuary has five full time Anatomical Pathology Technologists (APTs), including a Chief APT, two trainees APTs and with the addition of a mortuary assistant, all share their time between the hub and the satellite site. There is a member of mortuary staff on call at all times.

The main mortuary facility is located at St Thomas' Hospital, where around 1,000 PM examinations are undertaken per annum. The majority of these are conducted at the request of the HM Coroner for Southwark (Inner Southern District of Greater London), including a number of Home Office/forensic examinations. However, as the establishment is a specialist referral centre, it also receives cases from a large number of coronial jurisdictions from across the country.

In addition to coronial PM examinations, consented paediatric/perinatal and consented adult PM examinations are undertaken. St Thomas' Hospital is also a specialist referral centre for maternal deaths and chemically contained fatalities. Chemical, biological, radiological and nuclear (CBRN) contained fatalities are conducted in the main PM suite when no other PM is scheduled and specific precautions are taken. St Thomas' Hospital is the only specialist referral centre for specialist CBRN PM examinations in the south east region. Staff have access to personal protective equipment (PPE) when conducting both routine and high risk PM examinations.

The body store consists of 75 refrigerated spaces, which can be increased to 90 spaces by utilising the bottom shelves, which are not routinely used, and 30 paediatric and perinatal spaces, which can be increased to 55 spaces. There are six permanent freezer spaces and five refrigerated spaces suitable for bariatric bodies. In addition, there is a dedicated storage facility for 20 perinatal bodies in a separate freezer. There are visual indicators on the fridges and written on the whiteboard to indicate same/similar names, 'do not release', high risk cases and if tissue is to be returned to a body before release. There are also visual indicators for paediatric and perinatal bodies, highlighting where imprints are to be taken for the family. This is a specialist service offered by the mortuary.

The body store and additional freezer are all temperature monitored, with an alarm linked to the hospital's security. Security staff contact the mortuary and, if needed, the on-call mortuary staff, via a pager if the temperature deviates from the expected range.

The main PM suite consists of six PM tables with adequate space and lighting to work at each table at the same time. The PM tables are not downdraft, however the mortuary ventilation provides 10 air changes per hour and 20 air changes per hour for high risk cases, demonstrated by maintenance records. The pathologist and APT both check and sign the Autopsy Risk Reduction Sheet (ARRS) before evisceration, which details consent and identification details. Tissue taken during the PM examination is cassetted in the PM suite, placed in formalin in a suitable secure container and stays in the secure hatch until collection by histology staff for processing and analysis.

The entrance to the mortuary used by funeral directors is screened from public viewing and CCTV monitors entry and exit points. There are no intruder alarm systems at the main mortuary and the overall premises have not been risk assessed. Despite the mortuary being suitably staffed, lone and out of hours unaccompanied working does occur. However, there are procedures and security arrangements in place to provide protection for staff.

Checks, including condition of the body and identification of the deceased, are carried out on all bodies prior to PM examination, moving a body within the body store, the viewing of a body or release of a body. When a body is received into the mortuary from the hospital, it is brought by the porters and checked in by mortuary staff using the patient's hospital number. When a body is received from the community who was not a previous patient of the hospital, a new hospital number is assigned and a new patient receipt form is completed with all patient details.

On release of bodies, two members of mortuary staff must confirm the identity of the deceased with the funeral director by checking at least three identifiers on the identification tags against the release paperwork before releasing the body. If there are any discrepancies, mortuary staff will not release the body until the correct identification details are confirmed.

Consent for adult hospital PM examinations is sought primarily by the clinician who was treating the deceased before they died. They first discuss the request for a PM examination with a pathologist, who can advise on its scope and answer any questions they may have. When seeking consent from the family of the deceased, the clinician is supported by an APT or a member of the bereavement team, who can both elaborate on the PM process and answer any questions. All those involved in seeking consent are sufficiently trained and are familiar with the forms used to record consent and the patient information leaflets used to support the consent seeking process.

Tissue and organs are occasionally sent offsite for specialist examination. Specimens are taken by a specific courier company, which generates a rider number for each specimen for either King's College Hospital NHS Foundation Trust (brains) or St George's University Hospital NHS Foundation Trust (hearts). Samples sent for toxicological analysis are transported by specific courier companies once a week to Imperial Healthcare NHS Trust (Charing Cross). Forensic samples are sent to a private provider for analysis.

Stillbirths are transferred from the maternity department to the mortuary as soon as possible, but in consideration of the needs and wishes of the parents. Pregnancy remains and still births are stored in a refrigerator in the department pending transfer to the laboratory for histopathological analysis or the mortuary for release (*see advice item 1*). There are two separate fridges; for pregnancy remains of <24 weeks and >24 weeks; the temperatures of these are manually recorded (*see advice item 6*). The bereavement midwives are familiar with the requirements of the Human Tissue Act 2004 (HT 2004) and have a documented consent procedure to follow, which reflects legal requirements. The person giving their consent is allowed the opportunity to change their mind within a 24-hour window and can call the bereavement services on a direct line if they change their mind. Maternity department staff are aware of the HTA's guidance on the disposal of pregnancy remains following pregnancy loss or termination and have implemented this guidance in their practice. The maternity department offers a personalised and extensive service to bereaved mothers, providing a range of support and opportunities for keepsakes.

Guy's Hospital – the satellite site

At the Guy's Hospital satellite premises, the only licensable activity that takes place is storage. The mortuary contains a body store, viewing room and a decommissioned PM room. The body store consists of 65 refrigerated spaces, although one of the units is not operational at present because of corroded pipework, reducing the number of usable spaces to 55 (*see advice item 5*). There are four freezer spaces, eight bariatric spaces and a walk-in fridge for long-stay cases that is kept at 1-2 degrees. Temperature monitoring is similar to the St Thomas' site, with an alarm linked to Guy's hospital security.

The walk in fridge is primarily used for contingency storage but may be required for regular use in the near future. Although in poor repair, it provides adequate storage for bodies but requires upgrade. The satellite site is fitted with an intruder alarm as there are often periods of time where no member of staff is on site. No risk assessment of the satellite premises has been undertaken.

The inspection process

This was the third inspection of the establishment (the previous inspections having taken place in 2009 and 2013). It was a routine inspection, to assess whether the establishment is continuing to meet the HTA's standards and also to provide the HTA with assurance about the suitability of the premises and facilities.

The inspection timetable was developed after consideration of the establishment's previous inspection reports, compliance update information and discussions with the DI. It included a visual inspection of the body store at both sites, the post-mortem (PM) suite, viewing areas, histology department and maternity department. Interviews were held with the DI; Persons Designated (Chief APT, APT and Service Manager); the bereavement midwife; Clinical Lead (Research and Development oversight); Coroner's Officer; Quality Manager, Adult/paediatric pathologist and the CLHc. A thorough review of governance and quality documentation was also undertaken.

During the inspection, the release of two bodies to contracted funeral directors was observed. Processes were checked against SOPs and no discrepancies were found.

The HTA conducted identification audit trails on three bodies stored in the refrigerators at the St Thomas' Hospital site and two bodies stored at the Guy's Hospital site. Body location and identification details on body tags were cross referenced against the information on the fridge doors, whiteboard and electronic mortuary on the CRM database. No discrepancies were found.

Vertical traceability audits were carried out on tissue removed during three PM examinations (one adult hospital, one adult Coronial and one neonatal hospital). Paper records (adult hospital consent form, neonatal consent form, Coroner's form for wishes of the deceased, PM histology request forms, CRM data entries) were compared to the number of blocks and H/E-stained slides held in the Viapath storage area. No discrepancies were found.

A separate audit was carried out on blocks and slides from four PM examinations that had been disposed of (one adult hospital, one adult Coronial, two neonatal hospital). The electronic excel spreadsheet, CRM data entries and PM histology request forms and disposal sheets were compared to the physical location in Viapath. All tissue had been appropriately disposed of and cards in the drawers/boxes confirmed that this tissue had been removed.

Materials held for the police

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

Inspection findings

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

Compliance with HTA standards

Governance and Quality

Standard	Inspection findings	Level of shortfall
GQ7 There are systems to ensure that all adverse events, reactions and / or incidents are investigated promptly.	The current Trust incident reporting policy, although extensive, does not reference the requirement to report mortuary-related incidents to the HTA. The lack of a mortuary-specific procedure on the reporting of incidents means that staff may not be aware of the requirement to report them, the types of incident to report, the process that should be followed, who should report them to the HTA in the absence of the DI and within what timeframe they should be reported (five days). *The establishment provided documentary evidence to address this shortfall prior to the issue of the final report. The HTA has assessed this evidence as satisfactory to address this shortfall.*	**Minor**

Premises, Facilities and Equipment

Standard	Inspection findings	Level of shortfall
PFE1 The premises are fit for purpose.	The walk in fridge at the satellite is 25 years old, in poor repair and requires attention. This would be informed by the addition of a risk assessment of the premises (*See advice item 5).* *The establishment provided documentary evidence to address this shortfall prior to the issue of the final report. The HTA has assessed this evidence as satisfactory to address this shortfall.*	**Minor**

Advice

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

No.	Standard	Advice
1.	N/A	To ensure consistent governance across the Maternity Department, the DI is advised to appoint a PD in this department to oversee licensable activities taking place, to keep staff up to date on HTA-related matters and to report back to the DI on any issues or concerns. The HTA should be notified of these.
2.	GQ1	The DI is advised to set up a forum, attended by all PDs and other relevant staff working under the licence, at which staff can discuss any regulatory issues they may have. In other establishments, governance meetings cover items such as adverse incidents (HTARIs), changes to SOPs, audits and their findings, risk assessments, HTA training, the setting up of agreements with other establishments and updates from the HTA (e.g. e-newsletter items). They should be governed by an agenda and minutes recorded and circulated. The minutes should include timelines for identified actions and there should be a standing agenda item for discussing progress against actions identified at previous meetings.
3.	GQ4	The Cellular Pathology R&D Department has started maintaining a spreadsheet of ongoing research studies in the Department. There are approximately 250 in total. This now needs to be updated to include all NHS REC studies (one so far – brain study), including expiry dates, clinical trials and research studies under local ethics approval (not NHS REC).
4.	GQ8	Although there is a wide range of risk assessments of activities in the mortuary, the DI is advised to review the current suite of risk assessments to ensure they contribute to the prevention of an HTA reportable incident.
5.	PFE1/PFE2/PFE3	In addition to risk assessing the premises at the Guy's Hospital mortuary, the DI is advised to consider steps that could be taken to improve the condition of the walk-in fridge, whilst decisions are made about the future use of the facility. Repairing the broken fridge might also relieve some of their current capacity issues.
6.	PFE3	The temperature of the two fridges in maternity are manually recorded Monday to Friday and checked for trends. The DI is advised that staff on duty should monitor the temperature of the fridges at weekends to mitigate any regulatory risk resulting from temperature fluctuations. In addition, the DI is advised to modify the maternity SOP and to include this in the mortuary quality manual to reflect current practice in the maternity department.

Concluding comments

In the Care Quality Commission's 2015 report of the Trust, they noted the supportive practice of the mortuary and bereavement team as an area of outstanding practice; the HTA agrees with this finding. The mortuary team are both committed and conscientious, taking great pride in their work, and have the interest of the bereaved and care of the deceased as their priority. There were many areas of good practice that were observed throughout the inspection, some examples of which are given below.

- The maternity department is in the process of developing an advice leaflet, "Taking baby home", for bereaved mothers who wish to spend some time with their child at home.

- The department offer an extensive service to bereaved mothers including arranging keepsakes (separate from those provided in the mortuary), sensitive and detailed memory boxes, 'Remember my Baby' books which include carefully edited photographs and clothing from the Cuddles knitting charity.

- The use of CRM as an electronic mortuary register in the mortuary means that information about any deceased person, past or present, can be retrieved instantly and reports on mortuary activity can be produced. The mortuary staff have specifically tailored CRM to reflect their needs; the system includes 'test patients' that can be used in training new staff in procedures such as receipt and release of patients. There is good use of the 'notes' section of CRM to capture all forms to do with the deceased (e.g. consent form, histology request and the Coroner's family's wishes form), and the system aids traceability and prevents errors.

- Extensive porter training is given by mortuary staff and detailed signage is provided in each body store informing them what to do if an incident occurs when they are in the mortuary.

- A red indicator is placed on the fridge and on the body to signify if tissue is to be returned to a body.
- There are extensive monthly audits undertaken on stored tissue to mitigate any risk of misplacement or incorrect disposal of tissue. Good use of 'labels' placed in slide drawer's/block boxes indicates tissue has been removed for disposal in histology.
- The Trust has a very sensitive policy on the disposal of products of conception and non-viable fetuses, which includes cremation or burial.

- There is good paediatric consent training, recording of all training and refresher training that is extended to staff at referring hospitals (KCH, Princess Royal Bexley, Darrent Valley, Brighton, Queen Charlotte's – Hammersmith). This training also incorporates training on the paediatric PM procedure.

There are some of areas of practice that require improvement, including two minor shortfalls. The HTA has given advice to the Designated Individual with respect to Governance and Quality Systems and Premises, Facilities and Equipment standards.

The HTA requires that the Designated Individual addresses the shortfalls by submitting a completed corrective and preventative action (CAPA) plan 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: 16/11/2016

Report returned from DI: 01/12/2016

Final report issued: 12/12/2016

Appendix 1: HTA standards

The HTA standards applicable to this establishment are shown below/. Individual standards which are not applicable to this establishment have been excluded.

Consent standards
C1 Consent is obtained in accordance with the requirements of the Human Tissue Act 2004 (HT Act) and as set out in the code of practice
• There is a documented policy which governs consent for post-mortem examination and the retention of tissue and reflects the requirements of the HT Act and the latest version of the HTA Code of Practice on consent. • 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 written information about the consent process (provided to those giving consent), which reflects the requirements of the HT Act and the latest version of the HTA Code of Practice on consent.
C2 Information about the consent process is provided and in a variety of formats
• Relatives are given an opportunity to ask questions. • Relatives are given an opportunity to change their minds and is it made clear who should be contacted in this event. • Information contains clear guidance on options for how tissue may be handled after the post-mortem examination (repatriated with the body, returned to the family for burial/cremation, disposed of or stored for future use). • Where consent is sought for tissue to be retained for future use, information is provided about the potential uses in order to ensure that informed consent is obtained. • Information on the consent process is available in different languages and formats, or there is access to interpreters/translators.
C3 Staff involved in seeking consent receive training and support in the implications and essential requirements of taking consent
• There is a training programme for taking consent for post-mortem examination and tissue retention which addresses the requirements of the HT Act and HTA code of practice on consent. • Refresher training is available (e.g. annually). • Attendance at consent training is documented. • If untrained staff are involved in consent taking, they are always accompanied by a trained individual.

Governance and quality system standards

GQ1 All aspects of the establishments work are supported by ratified documented policies and procedures as part of the overall governance process

- Documented policies and SOPs cover all mortuary/laboratory procedures relevant to the licensed activity. These may include:
    - post-mortem examination, including the responsibilities of the APTs and Pathologists (e.g. evisceration) and management of high risk cases
    - record keeping
    - receipt and release of bodies, which reflect out of hours arrangements
    - lone working in the mortuary
    - transfer of bodies and tissue (including blocks and slides) to other establishments or off site
    - ensuring that tissue is handled in line with documented wishes of the relatives
    - disposal of tissue (including blocks and slides)

  (Note that individual SOPs for each activity are not required. Some SOPs will cover more than one activity.)
- Policies and procedures are regularly reviewed (for example, every 1-3 years).
- There is a system for recording that staff have read and understood the latest versions of these documents.
- Deviations from documented SOPs are recorded and monitored.

GQ2 There is a documented system of quality management and audit

- There is a quality manual which includes mortuary activities.
- Policies and SOPs are version controlled (and only the latest versions available for use).
- There is a schedule for audits to be carried out (which may include vertical and/or horizontal audits).
- Audits include compliance with documented procedures, records (for completeness) and traceability.
- Audit findings document who is responsible for follow up actions and the timeframe for completing those actions.
- Regular audits of tissue being stored at the establishment ensure that staff are fully aware what material is held and why.
- There is a complaints system in place.

GQ3 Staff are appropriately qualified and trained in techniques relevant to their work and are continuously updating their skills

- Staff are appropriately trained/qualified or supervised.
- Staff have annual appraisals.
- Staff are given opportunities to attend training courses, either internally or externally.
- Attendance by staff at training events is recorded.

- There is a documented training programme for new mortuary staff (e.g. competency checklist).

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

- 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.
- There are documented SOPs for record management.

GQ6 A coding and records system facilitates traceability of bodies, body parts, tissues and cells, ensuring a robust audit trail

- Bodies are tagged/labelled upon arrival at the mortuary.
- There is a system to track each body from admission to the mortuary to release for burial or cremation (e.g. mortuary register, patient file, transport records).
- Organs and tissue samples taken during PM examination are fully traceable.
- Details of organs retained and the number of wax blocks and tissue slides made are recorded.
- The traceability system includes the movement of tissue samples between establishments.
- Details are recorded of tissue that is repatriated or released with the body for burial or cremation.
- Regular audits of tissue storage and traceability are undertaken to ensure compliance with operational procedures; tissue samples found which are not being stored with consent are disposed of with reference to the family's wishes.
- Multiple identifiers used, including at least one unique identifier (e.g. post mortem number, name, dates of birth/death, etc) to identify bodies and tissue.

GQ7 There are systems to ensure that all adverse events, reactions and / or incidents are investigated promptly

- Staff are trained in how to use the incident reporting system.
- Staff know how to identify incidents and near-misses which must be reported, including those that must be reported to the HTA
- The incident reporting system clearly outline responsibilities for reporting, investigating and follow up for incidents.
- The incident reporting system ensures that follow up actions are identified (i.e. corrective and preventative actions) and completed.
- Information about incidents is shared with all staff (including the reporter) to avoid repeat errors.

GQ8 Risk assessments of the establishment's practices and processes are completed regularly and are recorded and monitored appropriately

- All procedures related to the licensed activities (as outlined in standard GQ1) are risk assessed.
- Risk assessments include risks associated with non-compliance with HTA standards as well as health and safety risks.
- Risk assessments are reviewed regularly (along with SOPs), for example every 1-3 years.
- 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.

Premises, facilities and equipment standards

PFE1 The premises are fit for purpose

- There is sufficient space for the activities to be carried out.
- Refrigerated storage units are in good working condition and well maintained.
- Surfaces are made of non-porous materials.
- The premises are in reasonable condition (structure and cleanliness of floors, walls, entranceways).
- The premises are secure (e.g. there is controlled access to bodies, tissue, equipment and records).

PFE 2 Environmental controls are in place to avoid potential contamination

- There is clear separation of clean, transitional and dirty zones (e.g. doors, floor markings, signs).
- There is appropriate PPE available and routinely worn by staff.
- There is adequate critical equipment and/or PPE available for high risk post mortems.
- There are documented cleaning and decontamination procedures.
- There are documented cleaning schedule and records of cleaning and decontamination.

PFE3 There are appropriate facilities for the storage of bodies, body parts, tissues and cells, consumables and records.

- There is sufficient capacity for storage of bodies, organs and tissues.
- Temperatures of fridges and freezers are monitored on a regular basis.
- There are documented contingency plans in place should there be a power failure, or overflow.
- Bodies are shrouded whilst in storage.
- There is separate storage for infants and babies. If not, special measures are taken for the bodies of infants and babies.

PFE 4 Systems are in place to protect the quality and integrity of bodies, body parts, tissues and cells during transport and delivery to a destination

- There are documented procedures for transportation of bodies and tissue anywhere outside the mortuary (e.g. lab, other establishment), including record-keeping requirements.
- There are written agreements in place with any external parties (e.g. undertaker, or courier) who transport bodies and/or tissue behalf of the establishment (laboratory or mortuary).

  (Note that coroners usually have their own agreements with external parties for transportation bodies and tissue; however, documentation for traceability purposes must still be maintained by the establishment for these cases.)

PFE5 Equipment is appropriate for use, maintained, quality assured, validated and where appropriate monitored

- Items of equipment in the mortuary are in a good condition and appropriate for use:
  - fridges / Freezers
  - hydraulic trolleys
  - post mortem tables
  - hoists
  - saws (manual and/or oscillating)
  - PPE for high risk cases (e.g. respirators)
- The use of porous materials is kept to a minimum and has been risk assessed
- Maintenance/service records are kept for equipment, including fridges/freezers, trolleys, post mortem tables (if downdraught) and post mortem suite ventilation.

(Note: These records may be held by the mortuary or centrally by the Trust, e.g. Estates Department.)

Disposal Standards

D1 There is a clear and sensitive policy for disposing of human organs and tissue

- There is a documented Trust or mortuary/laboratory policy for the disposal of human tissue, which reflects the requirements of the HTA code of practice on disposal.
- The policy states the position with regard to the retention and use of microscope slides, and in particular that tissue slides must be disposed of or returned to the family in accordance with their wishes if consent is not obtained for their continued storage and future use once the PM has concluded.

D2 PM tissue is disposed of if consent is not given for its storage and use for scheduled purposes

- There are documented procedures for disposal of human tissue, which include methods of disposal for whole organs, wet tissue, wax blocks and microscope slides.
- Tissue is disposed of in accordance with the documented wishes of the deceased person's

family.

- Disposal details of organs and tissue blocks are recorded, including the date and method of disposal.
- There is a rolling programme of tissue disposal that ensures that tissue, including microscope slides, is disposed of in a timely fashion when it is no longer needed for the purposes of the Coroner or to determine the cause of death.

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.