**Site visit inspection report on compliance with HTA licensing standards**

**Tunbridge Wells Hospital at Pembury**

**HTA licensing number 12616**

**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**

**27 - 29 November 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 Tunbridge Wells Hospital had met the majority of the HTA's standards, three major and eleven minor shortfalls were found against standards for Consent, Governance and Quality, Traceability and Premises, Facilities and Equipment.

The shortfalls relate to the post-mortem (PM) examination consent policy and training procedures; standard operating procedures (SOPs); storage of bodies; risk assessments for licensable activities; audits; traceability; maintenance of premises and security of premises.

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

## The HTA's regulatory requirements

Prior to the grant of a licence, the HTA must assure itself that the Designated Individual is a suitable person to supervise the activity authorised by the licence and that the premises are suitable for the activity.

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

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

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

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

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

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

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

**Background to the establishment**

Tunbridge Wells Hospital (TWH), the establishment) has been licensed by the HTA since March 2014. The establishment is licensed for the making of a post-mortem (PM) examination, removal of relevant material from the deceased and storage of bodies of the deceased and relevant material for use for scheduled purposes. Maidstone Hospital (MH) is licensed as a satellite of TWH and is licensed for storage and removal only. The Designated Individual (DI) is a Consultant Histopathologist and the Corporate Licence Holder contact is the Chief Executive for Maidstone and Tunbridge Wells NHS Trust. The Mortuary Manager is a Lead Biomedical Scientist/Molecular Pathology Manager, who works cross-site and is based at MH. The mortuary at TWH is staffed by a Lead Anatomical Pathology Technologist (APT) and two APTs who all work full-time. MH mortuary is staffed by one full time Mortuary Technician who works alone.

The establishment performs around 556 PM examinations annually, the total figure includes: adult coronial, forensic and hospital consented cases. Paediatric/perinatal cases are transferred to another HTA licensed establishment. However, consultant obstetricians and bereavement midwives seek consent for these cases, which is recorded using consent forms based on the Stillbirth and Neonatal Death (Sands) charity documentation. Only staff who complete the online consent training are permitted to seek consent for adult and paediatric/perinatal PM examination (see shortfall against C2(b)).

Removal of tissue from deceased children in cases of sudden unexpected death in infancy (SUDI) is not performed in the Accident & Emergency (A&E) department. Staff will notify the police who will invoke the SUDI protocol and refer such cases to another licensed establishment, where all samples will be taken at PM examination.

The mortuary has 65 refrigerated body storage spaces, including 11 bariatric, 3 of which are super-bariatric and 10 spaces that can be converted to freezers for long-term storage of bodies. The mortuary has temporary external cold room storage, which provides 25 additional body storage spaces as contingency and a refrigerated temporary unit (see shortfall against PFE2(e)) which provides 15 spaces; these were not in use at the time of inspection. There is a separate fridge for the storage of perinatal and paediatric cases. The permanent fridges including the cold room, are connected to a remote temperature monitoring system and have audible alarms, which are connected to the hospital estates department who notify mortuary staff of temperature fluctuations during and outside of working hours. The estates department review the fridge temperature records for trends and carry out fridge alarm testing which is documented. There is no fridge on the maternity ward for the temporary storage of fetuses as cold-cots are used before transfer to the mortuary.

The entrance to the TWH mortuary from the hospital is secured by swipe card access, which is limited to mortuary and trained portering staff and there is a video intercom system in place. Funeral directors have their own entrance, which is under cover and discreetly

located. This entrance has swipe card access and a video intercom system to allow staff to see who is requesting access.

Portering staff are responsible for the transfer of bodies from hospital wards to the mortuary. On arrival at the mortuary, porters place bodies in an available refrigerated body space and update the mortuary log book with information of bodies brought into the mortuary. In addition, they bring the 'Last Offices Form' for each body from the ward and leave this in a designated tray in the mortuary. The Coroner's contracted funeral directors transfer all community bodies to the mortuary and porters assist with admitting these bodies out-of-hours. All community bodies arrive with a wristband, which is attached to the body by the police before arrival at the mortuary and placed into an available refrigerated body space by the funeral directors; bodies are logged into the mortuary log book by the funeral directors.

Mortuary staff perform checks of all bodies the next working day, verifying the identification (ID) band details on the bodies against the log book and 'Last Offices Form' for hospital bodies and make sure all bodies are appropriately shrouded. Mortuary staff complete an 'Adult Mortuary Pathway Body Checklist' for each body and assign a unique mortuary 'T number'; an additional wristband is placed on the body with this unique number. Mortuary staff note details of any bodies with same and/or similar names and place a sign on the fridge door to alert staff to the presence of these bodies.

The mortuary only release bodies during normal working hours and have devised a 'Funeral Director Release Form', which funeral directors must present to mortuary staff before a hospital body can be released. For Coroner's cases, the Coroner will email authorisation to the mortuary for release (see shortfall against T1(c)).

Babies over 24 week's gestation are transferred to the mortuary by a member of the portering staff and are always released from the mortuary. Babies under 24 weeks gestation for hospital cremation are transferred to the histopathology laboratory or, if the family are making their own funeral arrangements, the laboratory liaise with the mortuary and maternity unit regarding release of these bodies.

The mortuary operates an appointment system for viewings, which generally takes place during working hours. Although viewings are discouraged outside of working hours, the site practitioner along with a member of the portering staff will accommodate viewings out-of-hours if there is a particular requirement (see shortfall against T1(c)).

The PM suite at the establishment has two downdraft PM tables and there is a dissection bench for the preparation of tissue samples. There is also a storage cupboard containing material stored under Police and Criminal Evidence Act 1984 (PACE). PM examinations take place one at a time to help minimise the risk of organ and tissue mix-up between cases. The external examination and identification of bodies is always checked by the pathologist and an APT prior to evisceration.

Mortuary staff have access to PPE within the PM room and body store area and there is demarcation of clean and dirty areas within the mortuary. Material retained at PM examination for histological examination is placed into formalin-filled containers and the identifying information is handwritten on the container label by mortuary staff. The mortuary have devised a 'PM Tissue Pathway Checklist' to record the number and type of tissue taken at PM examination.

Tissue samples may be kept, if appropriate consent has been given for retention or for use for scheduled purposes, but the establishment does not routinely store samples for use for research. Relatives' wishes with regards to the fate of any tissue retained following PM examination are managed by the Mortuary Manager, who enters details onto the electronic patient record that is accessible to mortuary and histology laboratory staff.

*Maidstone Hospital (MH)*

The mortuary at MH is located in the main hospital building. This site also functions as a contingency storage site for TWH. Portering staff are responsible for the transfer of bodies from hospital wards to the mortuary. The mortuary is accessed via key locks at both the hospital entrance and funeral director entrance; there is no hospital CCTV or audio-visual intercom system to confirm who is requesting access to the mortuary (see shortfall against PFE1(d)). The body store has 40 refrigerated spaces and 8 bariatric spaces. The fridges are connected to a remote monitoring alarm system, which contacts the switchboard and alerts on-call staff if the temperatures deviate outside the normal temperature ranges. No community bodies are received into this mortuary. Viewings are rarely undertaken but when they are, the APT is left alone with relatives (see shortfall against PFE1(d)). There is no maternity ward at this hospital and the removal of tissue from deceased children in cases of sudden unexpected death in infancy (SUDI) is not performed in the A&E department.

**Description of inspection activities undertaken**

This was the second site visit inspection of the establishment; the previous inspection took place in 2015. The inspection team reviewed governance and quality system documentation, carried out interviews with key members of staff, a visual inspection of the mortuary body store areas, PM room, viewing area and conducted traceability audits of bodies and tissue blocks and slides in storage.

An audit trail was undertaken at each of the sites:

• TWH - five bodies in refrigerated storage were audited; two from the community and three from the hospital, including one baby. Body location and identification details on identification bands were cross-checked against the information recorded in the mortuary logbook and relevant documentation. No discrepancies were identified;

• MH - four bodies in refrigerated storage were audited; all adult hospital bodies. Body location and identification details on identification bands were cross-checked against the information recorded in the mortuary logbook and relevant documentation. No discrepancies were identified.

In addition, tissue retained during PM examinations at TWH for four cases between 2014 and 2017 were audited for traceability; three Coroner's cases, including one case where tissue was disposed of and one hospital consented case where tissue was retained. The audits included details of tissue type, number of tissue blocks and slides retained, consent forms, and other associated paperwork and electronic database records, no discrepancies were identified.

**Material held for the police**

Home Office PM examinations are conducted at the establishment. Under section 39 of HT Act, 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, the 2012 report of the Association of Chief Police Officers' (ACPO) audit of tissue held under police authority contained a recommendation that police exhibits held on HTA-licensed premises should be included within the regular HTA inspection process. Police holdings stored at the establishment were reviewed by the HTA during the inspection. Any findings in relation to police holdings have been shared with the Home Office, but do not appear in this report as they are outside the scope of the HT Act.

## Inspection findings

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

## Compliance with HTA standards

| Standard | Inspection findings | Level of shortfall |
|---|---|---|
| **C1 Consent is obtained in accordance with the requirements of the Human Tissue Act 2004 (HT Act) and as set out in the HTA's codes of practice** | | |
| a) There is a documented policy which governs consent for post-mortem examination and the retention of tissue and which reflects the requirements of the HT Act and the HTA's Codes of Practice | The Trust consent policy 'Policy and Procedure for Consent to Examination or Treatment' has a section on the process for seeking consent for adult PM examination and the term 'family' is referenced throughout. For PM consent, this could imply that a person not ranked highest in the hierarchy of qualifying relationships could give consent to a PM examination or retention and future use of tissues.<br>The policy also references out of date HTA Codes of Practice. | **Minor** |
| b) There is a documented standard operating procedure (SOP) detailing the consent process | In the SOP 'Obtaining Consent Forms for a Hospital Post Mortem', the term 'family' is used throughout, which could imply that a person not ranked highest in the hierarchy of qualifying relationships could give consent to a PM examination or retention and future use of tissues.<br>This SOP also only refers to the process of obtaining consent for adult PM examinations. There is no SOP that details the process or references the procedure that should be followed by staff involved in seeking consent for perinatal/paediatric consented PM examinations. This presents a risk that there may be an inconsistent or incorrect approach taken when seeking consent. | **Minor** |

| **C2 Staff involved in seeking consent receive training and support in the essential requirements of taking consent** | | |
|---|---|---|
| b) Records demonstrate up-to-date staff training | Staff involved in seeking consent for adult and perinatal/paediatric PM examinations have received some training in PM consent and demonstrate a good knowledge of the consent process and the HTA Codes of Practice. However, there are no records to demonstrate that staff are suitably trained or undertake regular refresher training to seek consent for paediatric/perinatal and adult PM examination.<br><br>As a result, the consent standard C2(d) cannot be met. | **Minor** |

| **GQ1 All aspects of the establishment's work are governed by documented policies and procedures** | | |
|---|---|---|
| a) Documented policies and SOPs cover all mortuary/laboratory procedures relevant to the licensed activity, take account of relevant Health and Safety legislation and guidance and, where applicable, reflect guidance from RCPath. | Some of the SOPs do not accurately reflect current practice or contain sufficient detail regarding the procedures that must be followed. Examples include but are not limited to:<br>- RWF-CP-MOR-L1120 'Mortuary discharge of bodies at TWH' does not mention checking three points of ID against the pink release form for funeral directors and does not mention the process for checking ID for community cases and what documentation the ID will be checked against;<br>- RWF-CP-MOR-SOP37 'Mortuary discharge Maidstone' does not clearly state that the process for transferring bodies to TWH for PM examination and does not reference the checking of three points of ID for release and the documentation to check against;<br>- RWF-CP-MOR-SOP18 'Mortuary viewing procedure' references procedures that are no longer carried out, such as Midwives preparing babies for viewings. There is no reference to checking three points of ID and the documentation families need to bring with them for viewings. In addition, there is no reference to the process for conducting viewings out–of- hours.<br>- RWF-CP-MOR-SOP32 'Admission of bodies to TWH' does not state the same and/or similar name procedure and when to add cards to the fridges to indicate this. In addition, it does not state the process of receiving bodies from MH for PM examination and the process of assigning a new mortuary number.<br>In addition, there is no documented SOP for lone working at MH; however, lone working is a frequent occurrence at this mortuary.<br>To address this shortfall, the establishment should review all SOPs relating to mortuary activities to ensure that they reflect practice. In addition, the mortuary have many SOPs some of which are extremely long and could be separated for clarity. If procedures are not clear, this could lead to issues with staff not reading SOPs or following correct practice. | **Minor** |

| GQ2 There is a documented system of audit | | |
|---|---|---|
| a) There is a documented schedule of audits | Although the establishment has a documented schedule of audits, they do not cover horizontal or vertical audits of all mortuary activities, for example, bodies in storage, admission and release of bodies and PM procedures. This does not provide assurance that the procedures in place are robust or being followed. | **Minor** |
| b) Audit findings document who is responsible for follow-up actions and the timeframe for completing these | 'Completed' audits reviewed by the inspection team on Q-Pulse, showed that they were incomplete. The findings from the audits have not been documented and actions have not been completed, meaning there is no evidence that any actions arising from the audits have been followed up appropriately. | **Minor** |

| 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 | Although the establishment has a range of risk assessments in place, most do not consider all the risks relating to the activity being assessed. For example, the risk assessment for release of the wrong body only considers hospital body releases and does not fully consider all of the risks involved.<br><br>In addition, some risk assessments are past their review date and many of the risk assessments are cross-site and apply to MH and TWH; however, there are different risks and control measures at each site.<br><br>The risk assessments require review to ensure that all potential hazards are identified, appropriately assessed and measures to mitigate them are identified and implemented. | **Minor** |

| | | |
|---|---|---|
| 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 | Where risk assessments have been documented, many of the identified risks and current control measures do not accurately reflect procedures and practices. The residual risk ratings do not therefore provide an accurate representation of the risks involved with undertaking licensed activities.<br><br>The distribution lists for risk assessments in the Q-pulse system do not always include all the relevant staff or do not have a distribution list at all; therefore, there is no record that staff have read and understood risk assessments associated with their work, for example:<br><br>RWF-H&S-RA-CP-MOR69 – 'Mortuary risk assessment for lone worker at Maidstone', states that the lone worker should have regular contact with the TWH mortuary staff, and staff should contact the lone worker at the start and end of shift, however, this does not happen consistently and the distribution list for this risk assessment does not include the APT based at MH.<br><br>(see *Advice,* item 4) | **Minor** |

| **T1 A coding and records system facilitates traceability of bodies and human tissue, ensuring a robust audit trail** | | |
|---|---|---|
| c) Three identifiers are used to identify bodies and tissue, (for example post mortem number, name, date of birth/death), including at least one unique identifier | i) Community bodies are identified with three identifiers when admitted to the mortuary. Although the Coroner's release email usually contains three points of identification , this is currently being emailed directly to the mortuary. The funeral directors do not bring paperwork with them for release, so the mortuary are releasing on a verbal request of name only from them and are not checking the identifiers on the body against any paperwork.<br><br>ii) Families are not being asked to provide three identifiers when attending the establishment to undertake viewings and often, only the name of the deceased is requested.<br><br>The use of less than three separate identifiers (one being unique) when identifying bodies, presents a risk of releasing and viewing of the wrong body. | **Major** |
| 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 | When perinatal/paediatric cases are sent off-site for PM examination, there is no documentation which states the process involved and when mortuary staff should follow these cases up, to see if a body is going to be returned to the mortuary for release to funeral directors, or released directly from the referring establishment.<br><br>Having no documented procedure may lead to loss of traceability of bodies sent off-site for PM examination. | **Minor** |

| PFE1 The premises are secure and well maintained and safeguard the dignity of the deceased and the integrity of human tissue. | | |
|---|---|---|
| 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) | There is no mortuary or hospital CCTV within, or at access points to the mortuary and there is no audio-visual intercom system at MH. Staff are only able to verify who is requesting access by opening the entrance doors to the mortuary. This could pose a potential risk to the security of staff and premises, especially as there is only one member of staff lone working at this site.<br><br>The APT at MH routinely undertakes viewings at the mortuary and is left alone with families. There are no panic alarms installed within the mortuary (personal or fixed), for the APT to alert security.<br><br>At MH, the APT stated that they do not routinely lock the door from the viewing area to the body store. This could allow relatives to access the bodystore area, unintentionally, or otherwise. The DI is required to ensure that this door is locked during viewings and this information is included in the viewing SOP for staff to follow. | **Major** |

| PFE2 There are appropriate facilities for the storage of bodies and human tissue. | | |
|---|---|---|
| b) There is sufficient capacity for storage of bodies, organs and tissue samples, which takes into account predicated peaks of activity | The inspection team were told that the establishment does not have sufficient capacity for refrigerated storage of bodies for extended periods during the winter months, including when the temporary refrigerated storage unit is in use. Last winter, the mortuary staff had to 'double-up' bodies in refrigerated storage due to insufficient capacity. This is not considered suitable practice and disregards the dignity of the deceased.<br><br>The inspection team were made aware that funds may be available in the future for the establishment to increase permanent refrigerated storage capacity. However, this is not guaranteed and there isn't a time frame on this.<br><br>(see *Advice,* item 6) | **Major** |
| e) Fridge and freezer units are alarmed and the alarms are tested regularly to ensure that they trigger when temperatures go out of upper or lower set range | The temporary refrigeration unit in the mortuary at TWH is not connected to the remote monitoring system when in use. The likelihood is that this unit will be used over the winter; an alarm that sounds locally provides no assurance that if the fridges were to fail, the mortuary staff would be made aware in time, which poses a risk to the bodies in storage. | **Minor** |

| PFE3 Equipment is appropriate for use, maintained, validated and where appropriate monitored | | |
|---|---|---|
| f) Key items of equipment, including fridges/freezers, trolleys and post mortem tables (if downdraught) are subject to regular maintenance and records are kept | While the majority of equipment does undergo regular maintenance, this is overseen by the estates department and mortuary staff were unable to locate maintenance reports for the body hoists at MH during the inspection. The mortuary should have copies to provide assurance the equipment is functioning to the required standard. In addition, this would allow mortuary staff to identify when servicing, maintenance and equipment issues need to be escalated to senior staff. | **Minor** |

## Advice

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

| No. | Standard | Advice |
|---|---|---|
| 1. | GQ1(h) | Although the DI has contact with staff within the maternity unit, he is advised to identify a suitable person for the role as Person Designated (PD) within the department and hold regular meetings with them. This would help the DI maintain oversight of relevant activities in that area, for example, staff are regularly undertaking appropriate PM consent training and refresher training. |
| 2. | GQ5(a) | The DI is advised to place signage in the mortuary to raise awareness amongst all staff working there of the importance of reporting any incidents, including a list of all the HTA Reportable Incident (HTARI) categories. In addition, the DI is advised to liaise with the maternity department to raise awareness of incidents that need to be reported to him. |
| 3. | GQ6(a) | In addressing the shortfall that was identified against standard GQ6(a) the DI is advised to consider reviewing the HTA's publication 'Regulation of the Post Mortem Sector: What we have learned' (October 2016) which provides guidance and information in relation to risk assessments. This is available on the HTA's website. |
| 4. | GQ6(b) | The DI is advised to re-assess the risk to the APT who works alone at MH to ensure that the current lone working risk assessment is sufficient to cover their needs and prevent risk to them and the bodies they are handling. |
| 5. | T1(c) | In addressing the shortfall identified under this standard the DI is advised to consider ways to strengthen the procedure for undertaking viewings. The DI may wish to consider the introduction of a form to be completed by relatives when they attend for viewings. This form could include relevant identification information so that three identifiers can be checked on the body before the viewing takes place. |
| 6. | PFE2(b) | To address the shortfall identified against PFE2(b), the DI is advised to continue with the plans to increase refrigerated body storage and obtain assurance that funds will be available for this. Increasing body storage capacity will help prevent unsuitable body storage practices being adopted during times of peak activity. |

## Concluding comments

The HTA observed some areas of strength and good practice during the inspection.

All staff involved in the inspection demonstrated a sensitive and dedicated approach to their work. The mortuary staff are a cohesive, long-standing and experienced team, communicate well with each other and are open to accepting advice and guidance. A range of positive feedback cards given to the mortuary staff from families of the deceased were seen.

The establishment are very open to sharing learning particularly with regards to HTA reportable incidents and work together to improve practices to prevent further incidents.

The establishment have developed their own body pathway forms, which provide a way of checking the identification of bodies at every stage of the process from admission, PM examination, through to release.

The establishment have already submitted a business case for increasing storage capacity at both the Tunbridge and Maidstone mortuaries. They are taking a proactive approach to try and address some of the issues identified during the inspection.

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

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

The HTA has assessed the establishment as suitable to be licensed for the activities specified subject to corrective and preventative actions being implemented to meet the shortfalls identified during the inspection. The HTA has assessed the establishment as suitable to be licensed for the activities specified.

**Report sent to DI for factual accuracy: 21 December 2018**

**Report returned from DI: 21 January 2019**

**Final report issued: 30 January 2019**

**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: 20 May 2020**

## 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.<br>b) There is a documented standard operating procedure (SOP) detailing the consent process.<br>*Guidance*<br>*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.*<br>c) There is written information for those giving consent, which reflects the requirements of the HT Act and the HTA's codes of practice.<br>*Guidance*<br>*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.*<br>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.