



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

**Milton Keynes University Hospital**

**HTA licensing number 12201**

**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**

**23<sup>rd</sup> August 2017**

### **Summary of inspection findings**

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

Although the HTA found that Milton Keynes University Hospital had met the majority of the HTA's licensing standards, a total of five minor shortfalls were found against the Consent (C), Governance and quality (GQ) systems and Premises, facilities and equipment (PFE) standards. These related to the information used to support the seeking of consent, risk assessments, ventilation system maintenance and the monitoring of the fridge on the maternity unit.

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

2017-08-23 Milton Keynes University Hospital – FINAL

## **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**

This report refers to activities carried out in the mortuary located at Milton Keynes University Hospital (the establishment), which is incorporated into, and managed by, the department responsible for cellular pathology. In summary, the establishment is licensed under the Human Tissue Act 2004 (HT Act) for: carrying out post-mortem (PM) examinations; removal from the body of a deceased person of relevant material (for scheduled purposes), and; storage of the body of a deceased person or relevant material which has come from a human body for use for scheduled purposes. The Corporate Licence Holder contact is the Pathology Services Manager for the Trust; the Designated Individual (DI) is an experienced Consultant Histopathologist.

The establishment undertakes approximately 260 PM examinations per year, the majority of which are conducted for HM Coroner for Milton Keynes. These include some high-risk cases, a small number of forensic PM examinations and a few hospital ('consented') PM examinations. Consent for adult hospital PM examinations is sought by clinicians with the help and support of the DI and specially trained Anatomical Pathology Technologists (APTs) or bereavement staff. Consent for perinatal and paediatric cases is undertaken on site by clinicians supported by specially trained midwives; these cases are routinely sent to another HTA-licensed establishment for PM examination. Training is recorded and refreshed annually. Consent forms for adult PM examinations are based on the HTA's model consent forms, and the SANDs consent form is used for paediatric/perinatal cases, therefore fully compliant with statutory and regulatory requirements.

The establishment has 104 refrigerated body spaces and four freezers for the storage of bodies. This includes spaces for bariatric bodies. There are two body store areas in the mortuary. The smaller body store has 16 'double-ended' fridge spaces, with direct access in to the PM room. These are used for bodies requiring PM examination from the community or from the hospital. Super-bariatric bodies can be accommodated in these fridges as they have removable racking but this reduces the fridge capacity in this area to eight spaces. The larger body store is used for hospital bodies and has a separate fridge for paediatric/perinatal cases and pregnancy remains.

Swipe card access is required for all doors in the mortuary, including restricted access to certain areas within the mortuary itself. For example, support services staff (porters) cannot access the body store area for community bodies. All external access doors are monitored by CCTV.

A private company, that employs independent Consultant Histopathologists from other Trusts, and the DI at the establishment fulfil the PM service. There are currently four consultants who conduct PM examinations, two or three days per week, on a rotational

basis. The histopathology laboratory at the establishment processes all histological tissue taken at PM examination. Slides are sent to, or collected by, the relevant Histopathologist for examination, and blocks remain in the mortuary. All slides are returned to the mortuary to be dealt with in accordance to the family's wishes.

The mortuary has three full time APTs, including a mortuary manager, senior APT and trainee APT.

Support services staff transfer and admit all hospital bodies to the mortuary. Bodies are transferred from the wards using a concealment trolley or 'XC-cube' system via lifts to the staff corridor leading to the mortuary. The support services staff complete the 'Deceased Movement Record' form for each body admitted to the mortuary. Mortuary staff complete patient identification checks and the admission process as soon as possible on the day, or the next working day if the body was admitted out of hours, using the 'Notification of Death' sheet transferred with each body. Training in mortuary practice is provided by mortuary staff to the senior support services staff. This training is then cascaded to the wider support services team. This is recorded, competency assessed and refreshed annually (see *Advice*, item 8). Perinatal cases, pregnancy remains and their associated documentation are transferred to the mortuary by support services staff using a dedicated remains carrier.

Community bodies are brought into the mortuary via a secluded service road, leading to the mortuary external doors. Mortuary staff can see and speak to funeral directors via a camera and intercom system. Mortuary staff work on-call and are responsible for admitting Coroner's cases out of hours, and carrying out all viewings and formal identifications. All bodies are entered into the mortuary register and allocated a mortuary register ('M') number and entered on to the electronic mortuary system (see *Advice*, item 12 (i)).

The establishment has a maternity unit, where there is a fridge for the storage of fetuses and neonatal bodies prior to transfer to the mortuary (see shortfall against PFE2(e)). The fridge is located in a secure room, with only certain staff allowed access. Details of all bodies within the fridge, including transfer information, is recorded on the 'Baby room fridge tracker' (see *Advice*, item 12 (ii)). The DI has appointed a Person Designated (PD) to help maintain oversight of activities in this area.

In addition to the storage activities described above, the removal of tissue samples from the body of a deceased child occasionally takes place in the Accident and Emergency Department (see *Advice*, item 6). The process and documentation for these cases was reviewed as part of the inspection and found to be compliant with current guidelines.

The mortuary's PM suite contains four PM tables, each with a dedicated dissection bench. The pathologists and APTs carry out identification checks of bodies prior to PM examination.

Both the APT and pathologist will sign the 'ID book' in the PM room to confirm this has been done prior to the external examination and evisceration taking place. A 'one-at-a-time' system is used to avoid mix-up of organs and tissue samples removed during PM examination.

### **Description of inspection activities undertaken**

The establishment has been licensed by the HTA since May 2007. Previous routine site visit inspections took place in October 2009 and November 2012. This report describes the third routine site visit inspection in August 2017. Formal interviews were conducted with the DI, CLHc, Mortuary Manager, Trainee APT, Support Services Supervisor, Coroner's Officer, Consultant Histopathologist and PM examination consent seekers (adult and perinatal). A visual inspection of the mortuary, including the body stores, PM room and viewing suite was also conducted. An audit of body identifiers, storage locations, mortuary register details and associated documentation was carried out for four adult bodies (two hospital and two community). A minor anomaly was found; two of the bodies audited with same/similar names were not highlighted in the mortuary register, as detailed in the SOP. However, both were highlighted on the fridge door and mortuary whiteboard. In addition, an audit of four PM examination cases, including one hospital (consented) PM examination where histology had been taken, were conducted. Records were reviewed to establish the relatives' wishes for the tissue and if these had been complied with. No anomalies were found.

### **Material held for the police**

Although the establishment conducts Home Office PM examinations, at the time of the inspection there were no specimens held on site under the Police and Criminal Evidence Act (PACE).

## Inspection findings

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

Advice and guidance was given to the DI to further improve practices following the last inspection in 2012. During the current inspection similar areas for improvement were identified, and are captured in the shortfalls below.

## Compliance with HTA standards

| <b>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 code of practice.</b>             |  |              |
|---|--|--------------|
| e) Where consent is sought for tissue to be retained for future use, information is provided about the potential uses to ensure that informed consent is obtained | <p>The Human Tissue Act 2004 requires appropriate and valid consent to be in place when tissues are to be stored for use for scheduled purposes following a PM examination. After a Coroner's post-mortem examination where tissue has been retained, the Coroner's officer informs families that, with their consent, tissues will be stored for medical research or education, or in case they are of future use to the family. If the family consents to continued storage, the archive option is selected on the Coroner's 'Post Mortem and Tissue Retention Form'. In addition families should be made aware that if there is no research or education purpose for the tissue it would be disposed of.</p> <p>There is an understanding between the establishment staff and the Coroner's office with respect to the use of the word 'archive'. However, the DI needs to assure himself of what information families are given by the Coroner's Officers to make an appropriate and valid decision. Currently, there is no documented evidence which clarifies that the Coroner's officers' discussions with families includes adequate explanation of consent for continued storage of tissues for scheduled purposes (see <i>Advice</i>, item 3).</p> | <b>Minor</b> |

| <b>GQ6 Risk assessments of the establishment's practices and processes are completed regularly, recorded and monitored</b>  |   |              |
|---|---|--------------|
| a) All procedures related to the licensed activities (as outlined in standard GQ1) are risk assessed on a regular basis   | The risk assessments are predominantly related to health and safety matters. There are some risk assessments in relation to some licensed activities but they do not cover the potential risks to the deceased, tissue or traceability (see <i>Advice</i> , item 10). | <b>Minor</b> |
| 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 | The risk assessments in place do not always include all the factors to mitigate the identified risk (see <i>Advice</i> , item 11)   | <b>Minor</b> |

| <b>PFE2 There are appropriate facilities for the storage of bodies and human tissue.</b>   |   |              |
|--|---|--------------|
| 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 fridge in the maternity unit is not connected to an alarm which will alert staff to a temperature deviation out of the accepted ranges (see <i>Advice</i> , item 16). | <b>Minor</b> |

| <b>PFE3 Equipment is appropriate for use, maintained, validated and where appropriate monitored</b>                       |   |              |
|---|---|--------------|
| c) The ventilation system provides the necessary ten air changes per hour and is checked and maintained at least annually | The ventilation system was last serviced and checked in 2015 (see <i>Advice</i> , item 17). | <b>Minor</b> |

## Advice

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

| No. | Standard | Advice   |
|-----|----------|--|
| 1.  | C1(a)    | The SOP CP/MORT/642.03 'Hospital Post Mortem Consent' (page four) and the 'Hospital Consent Post Mortem' Trust policy (page three), both refer to the HTA's old Codes of practice. The HTA published new Codes and licensing standards on 3 April 2017. The DI should ensure that all documents reference the HTA's new Codes of practice and standards where necessary. |

|    |        |  |
|----|--------|--|
| 2. | C1(b)  | The document CP/MORT/642.03 'Hospital/Consented Post Mortem Request' (page two), which is completed by the clinicians, refers to the 'Next of Kin details for arranging consent'. As the form does not detail information about the hierarchy of 'qualifying relationships' as defined in the HT Act, there is a risk of consent being sought from the incorrect person. The DI is advised to amend this form to include information of who can give consent, to ensure the details of the correct person is recorded. In addition the term 'Next of Kin' should be changed.   |
| 3. | C1(e)  | The DI is advised to discuss with the Coroner's Office the possibility of amending their 'Post Mortem and Tissue Retention Form' to include more detailed information about the families wishes; for example, separate options for research and medical education. If this isn't feasible, the DI is advised to obtain written information from the Coroner's Office in relation to the discussions and information given to families about their options for retained tissue. The DI will then have assurance that appropriate and valid consent has been sought, and that families are fully informed.   |
| 4. | C1(f)  | <p>The DI is advised to amend the following consent documentation to state a consistent time period for families to contact the establishment should they change their minds in relation to consent for a PM examination:</p> <ul style="list-style-type: none"> <li>• SOP CP/MORT/642.03 'Hospital Post Mortem Consent' (states 24 hours).</li> <li>• 'Consent form for post mortem examination of an adult' (states 48 hours).</li> <li>• 'A simple guide to a post mortem examination' (states up until 9am on the date of the PM examination).</li> </ul> <p>The HTA recommends a 24 hour period for relatives to reflect on their decision.</p> |
| 5. | GQ1(d) | <p>To ensure consistency of document control, the various forms used by the establishment should be subject to the same management as the SOPs, for example, author, authoriser and version number. In addition, the author and authoriser of SOPs should be different.</p> <p>The DI is advised to ensure that the version numbers displayed in the footer of SOPs are correct and match the version references in the titles of the documents. For example, SOP CP/MORT/642.03 'Hospital Post Mortem Consent' states the version number as '04' in the footer.</p>   |
| 6. | GQ1(g) | The DI is advised to appoint a PD in A&E to maintain sufficient oversight of the licensed activities undertaken there. Once appointed, the PD should attend and contribute to the quarterly HTA governance meetings.   |
| 7. | GQ2(c) | The establishment undertakes a monthly and annual audit of all stored tissue. The DI is advised to include more horizontal and vertical audits in relation to traceability of tissues and bodies. For example, an audit of bodies admitted in to the mortuary through to release ensuring all checks and documentation have been completed; or an audit of the 'Histopathology Request' forms and 'Mortuary Tissue Traceability' forms to ensure tissue has been dealt with in accordance with the families' wishes.   |
| 8. | GQ3(a) | The training documentation for the support services staff refers to the transfer of bariatric bodies to the mortuary using an oxygen mask on the face (which   |



|     |        |   |
|-----|--------|---|
|     |        | is no longer the procedure); the competency assessment refers to the new procedure using the 'XC-cube' system. The DI is advised to update the training documentation to reflect current practices.   |
| 9.  | GQ5(a) | The SOP CP/MORT/647.03 'Referring Human Tissue Authority Reportable Incidents' details out-of-date information on how to report HTARIs. This is now done via the Portal available on the HTA website. The DI is advised to update this SOP.   |
| 10. | GQ6(a) | <p>The DI is advised to ensure that the licensed activities outlined in GQ1 and the HTARI categories are risk assessed to provide a comprehensive set of risk assessments.</p> <p>In particular, risks to the dignity and integrity of bodies and stored tissue should be covered.</p> <p>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.</p>  |
| 11. | GQ6(b) | The risk assessment form currently used by the establishment does not lend itself well to recording all the information required for a thorough risk assessment. Some risk assessments did not list all existing risk control measures, or suggest any further steps which could be taken to further mitigate risks. For example, the risk assessment on releasing bodies could include periodic audits of the release process to provide additional assurance that procedures are being complied with and are robust. The current risk assessment form is hand written and therefore cannot be adjusted and amended easily. In addition, sticky labels have been used to cover and amend dates when a risk assessment has been reviewed and no change is required. The DI is advised to use an electronic form that can be easily adapted and completed. Electronic risk assessments can be uploaded on to the existing Q-Pulse system where a record of their review and acknowledgement can be kept. Where necessary, hard copies can be printed but should be version controlled and dated to ensure staff are using the most up-to-date version. |
| 12. | T1(b)  | <p>i) The DI and mortuary manager may wish to consider utilising the mortuary register number ('M' number) subsequently generated for a body admitted to the mortuary on all documentation. This will help make existing traceability systems more robust and will help to uniquely identify 'unknown' bodies until their identities are confirmed.</p> <p>ii) To strengthen the identification system in place for fetuses and pregnancy remains, the DI is advised to use the mother's hospital number on the 'Baby room fridge tracker' form, in addition to mother's name,</p>  |
| 13. | T1(c)  | Where SOPs state that identification or identifiers need to be checked, these should consistently detail what those identifiers could be. There should be a minimum of three identifiers, one being unique. For example, the SOP CP/MORT/606.05 'Releasing bodies from the mortuary' simply states that identification should be checked.   |
| 14. | T1(g)  | Once PM tissue has been processed by the histopathology laboratory (in to blocks and slides) it should be returned to the mortuary for traceability records to be updated and completed. Blocks and slides are then distributed to the relevant pathologist by the mortuary staff. As the DI is based at the  |

|     |         |   |
|-----|---------|---|
|     |         | establishment, the laboratory staff are providing the slides directly to the DI and 'by-passing' the mortuary, meaning traceability records are completed retrospectively. This could lead to errors and loss of traceability. The DI is advised to ensure the laboratory staff are following the documented procedure for all blocks and slides.   |
| 15. | PFE2(a) | The freezer spaces are not clearly labelled as such. The DI is advised to label the freezer spaces to help staff identify them, and to mitigate the risk of bodies being placed in there by mistake.<br><br>The DI is advised to amend the lower trigger point for the fridges from 0°C to 2°C to prevent the freezing of bodies in storage.  |
| 16. | PFE2(e) | All fridges (and freezers) used to store bodies should be alarmed in the event of any significant temperature deviation or power failure (optimum range 4-6°C). This will alert staff in a timely manner and prevent the condition of any bodies stored in there being compromised. In addition, the DI should ensure that the fridge alarm in maternity is regularly challenged, in line with the regular testing in the mortuary. |
| 17. | PFE3(c) | The DI is advised to continue with the plans to have the ventilation system serviced in Sept 2017, and is also advised to ensure this happens on a yearly basis.  |

### Concluding comments

The mortuary team are enthusiastic and conscientious, demonstrating a high level of compassion and care for the work they undertake. This is demonstrated by the individual praise staff have received from service users and awards the staff have received as a team. In addition, the mortuary staff have excellent working relationships with service users, both internal and external to the Trust. There are numerous examples of strengths and good practice:

- Different coloured pens are used on the body store white board to signify when activities have been carried out or completed. For example, when a body has been checked and measured;
- The use of the 'Deceased Management Board' in the mortuary office to provide 'at a glance' information for bodies in storage, is particularly useful in the management of bodies in long-term storage;
- Traceability systems and records for PM tissue are particularly robust. They include a monthly check of the tissue log to follow up any outstanding tissue instructions;
- The 'Post Mortem Room and Dirty Utility Decontamination Log' contains a 'Comments' section, which is used to record any issues and/or defects identified after each PM examination session. This ensures any problems are reported for action as soon as possible.

In addition, the mortuary, bereavement and maternity staff appear to provide excellent support, and a wide range of bereavement information and keep-sakes, for the bereaved families.

There are a number of areas of practice that require improvement, including five minor shortfalls.

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

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

**Report sent to DI for factual accuracy: 19/09/2017**

**Report returned from DI: No redactions or comments on factual accuracy received.**

**Final report issued: 23/10/2017**

#### **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: 02 March 2018**

## Appendix 1: HTA licensing standards

The HTA standards applicable to this establishment are shown below; those not assessed during the inspection are shown in grey text. Standards that are not applicable have been excluded.

|   |
|---|
| <b>Consent</b>  |
| <b>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</b>   |
| <p>a) There is a documented policy which governs consent for post-mortem examination and the retention of tissue and which reflects the requirements of the HT Act and the HTA's Codes of Practice.</p> <p>b) There is a documented standard operating procedure (SOP) detailing the consent process.</p> <p><i>Guidance</i></p> <p><i>This should include who is able to seek consent, what training they should receive, and what information should be provided to those giving consent for post-mortem examination. It should make reference to the use of scanning as an alternative or adjunct to post-mortem examination.</i></p> <p>c) There is written information for those giving consent, which reflects the requirements of the HT Act and the HTA's codes of practice.</p> <p><i>Guidance</i></p> <p><i>Information on consent should be available in different languages and formats, or there is access to interpreters/translators. Family members should be given the opportunity to ask questions.</i></p> <p>d) Information contains clear guidance on options for how tissue may be handled after the post-mortem examination (for example, repatriated with the body, returned to the family for burial/cremation, disposed of or stored for future use), and what steps will be taken if no decision is made by the relatives.</p> |

- 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 or signs of decomposition.*

*If identification of the body is to take place before a post-mortem examination, if available, a Police Family Liaison or Coroner's Officer should have a discussion with the family about the injuries and let them know that reconstruction may be required.*

*However, the Pathologist should see the body without any changes being made, so if there is a need to reconstruct or clean a body before the post-mortem examination, it should be with the agreement of both the Pathologist and the Coroner. In Home Office cases, a viewing cannot normally take place until after the post-mortem examination.*

- d) Policies and SOPs are reviewed regularly by someone other than the author, ratified and version controlled. Only the latest versions are available for use.
- e) There is a system for recording that staff have read and understood the latest versions of these documents.
- f) Deviations from documented SOPs are recorded and monitored via scheduled audit activity.
- g) All areas where activities are carried out under an HTA licence are incorporated within the establishment's governance framework.

#### *Guidance*

*These areas include maternity wards where storage of fetuses and still born babies takes place, areas where material is stored for research, the Accident and Emergency Department where removal of samples may take place in cases of sudden unexpected death in infancy. There should be an identified Person Designated in areas of the establishment remote from the main premises.*

- h) Matters relating to HTA-licensed activities are discussed at regular governance meetings involving establishment staff.

#### *Guidance*

*Meeting minutes should be recorded and made available to staff.*

### **GQ2 There is a documented system of audit**

- a) There is a documented schedule of audits.

#### *Guidance*

*As a minimum, the schedule should include a range of vertical and horizontal audits checking compliance with documented procedures, the completion of records and traceability.*

- b) Audit findings document who is responsible for follow-up actions and the timeframe for completing these.

*Guidance*

*Staff should be made aware of the outcomes of audits and where improvements have been identified.*

- c) Regular audits are carried out of tissue being stored so that staff are fully aware of what is held and why and to enable timely disposal of tissue where consent has not been given for continued retention.

*Guidance*

*Audits of stored tissue should include samples held under the authority of the police, where applicable.*

**GQ3 Staff are appropriately qualified and trained in techniques relevant to their work and demonstrate competence in key tasks**

- a) All staff who are involved in mortuary duties are appropriately trained/qualified or supervised.

*Guidance*

*This includes portering staff, who have responsibility for bringing bodies to the mortuary out of hours and who may not be aware of the potential risks to the deceased during transfer into refrigerated storage, and unqualified mortuary 'assistant' staff.*

*APTs should be trained in reconstruction techniques to ensure that the appearance of the deceased is as natural as possible. APTs should be encouraged to work towards the achievement of the RSPH Level 3 Diploma in Anatomical Pathology Technology.*

- b) There are clear reporting lines and accountability.  
c) Staff are assessed as competent for the tasks they perform.

*Guidance*

*Assessment of competence should include the standard of APTs' reconstruction work.*

- d) Staff have annual appraisals and personal development plans.  
e) Staff are given opportunities to attend training courses, either internally or externally.

*Guidance: attendance by staff at training events should be recorded.*

- f) There is a documented induction and training programme for new mortuary staff.



- g) Visiting / external staff are appropriately trained and receive an induction which includes the establishment's policies and procedures.

*Guidance*

*The qualifications of locum staff should be checked prior to them commencing work in the mortuary and their competency to undertake each task should be assessed.*

*Contractors, visiting and temporary staff and funeral service staff bringing bodies out of hours should be required to read relevant standard operating procedures and sign to confirm their understanding.*

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

- a) There is a system for managing records which includes which records must be maintained, how they are backed up, where records are kept, how long each type of record is retained and who has access to each type of record.

*Guidance*

*Records include mortuary registers, PM examination records, tissue retention forms and records of transfer and return of organs/tissue sent elsewhere for examination.*

- b) There are documented SOPs for record management which include how errors in written records should be corrected.
- c) Systems ensure data protection, confidentiality and public disclosure (whistle-blowing).

**GQ5 There are systems to ensure that all untoward incidents are investigated promptly**

- a) Staff know how to identify and report incidents, including those that must be reported to the HTA.

*Guidance*

*HTA-reportable incidents must be reported within five days of the date of the incident or date of discovery.*

*Incidents that relate to a failure of hospital staff to carry out end of life care adequately should be reported internally and the incidence of these monitored.*

- b) The incident reporting system clearly outlines responsibilities for reporting, investigating and follow up for incidents.
- c) The incident reporting system ensures that follow up actions are identified (i.e. corrective and preventative actions) and completed.

- d) Information about incidents is shared with all staff to avoid repeat errors.
- e) The establishment adopts a policy of candour when dealing with serious incidents.

**GQ6 Risk assessments of the establishment's practices and processes are completed regularly, recorded and monitored**

- a) All procedures related to the licensed activities (as outlined in standard GQ1) are risk assessed on a regular basis.

*Guidance*

*Risks to the dignity and integrity of bodies and stored tissue should be covered. The HTA's reportable incident categories provide a good basis for risk assessments. Risk assessments should be reviewed at regular intervals, for example every 1-3 years or when circumstances change. Staff should be involved in the risk assessment process.*

- b) Risk assessments include how to mitigate the identified risks. This includes actions that need to be taken, who is responsible for each action, deadlines for completing actions and confirmation that actions have been completed.

*Guidance*

*Relevant staff should have knowledge of risks and the control measures that have been taken to mitigate them.*

- c) Significant risks, for example to the establishment's ability to deliver post-mortem services, are incorporated into the Trust's organisational risk register.

**Traceability**

**T1 A coding and records system facilitates traceability of bodies and human tissue, ensuring a robust audit trail**

- a) Bodies are tagged/labelled upon arrival at the mortuary.

*Guidance*

*The condition and labelling of bodies received in body bags should always be checked and their identity confirmed. They should be labelled on the wrist and/or toe. Body bags should not be labelled in place of the body.*

- b) There is a system to track each body from admission to the mortuary to release for burial or cremation (for example mortuary register, patient file, transport records).

*Guidance*

*Body receipt and release details should be logged in the mortuary register, including the date and name of the person who received/released the body and, in the case of release, to whom it was released. This includes bodies sent to another establishment for PM examination or bodies which are sent off site for short-term storage which are subsequently returned before release to funeral service staff.*

- c) Three identifiers are used to identify bodies and tissue, (for example post mortem number, name, date of birth/death), including at least one unique identifier.

*Guidance*

*Identification details should not be written on bodies. Where bodies are moved off site for contingency storage the DI should ensure that suitable systems are in place to identify same or similar names.*

- d) There is system for flagging up same or similar names of the deceased.
- e) Identity checks take place each time a body is moved whether inside the mortuary or from the mortuary to other premises.

*Guidance*

*Mortuary white boards containing the names of the deceased give potential for error if wiped clean (such as when visitors attend for reasons of confidentiality), and should not be relied upon as the sole source of information about the locations of bodies.*

*Fridge/freezer failures that require bodies to be moved temporarily whilst repairs take place present a risk to traceability. Full identification checks should be made when they are placed back into normal storage.*

- f) There are procedures for releasing a body that has been in long term storage and is therefore not in the current register.
- g) Organs or tissue taken during post-mortem examination are fully traceable, including blocks and slides (including police holdings). The traceability system ensures that the following details are recorded:
  - i. material sent for analysis on or off-site, including confirmation of arrival
  - ii. receipt upon return to the laboratory or mortuary
  - iii. the number of blocks and slides made
  - iv. repatriation with the body
  - v. return for burial or cremation
  - vi. disposal or retention for future use.

*Guidance*

*Consent information which covers retention/disposal of tissues should be made available to the other site, as appropriate.*

- h) There are documented procedures for transportation of bodies and tissue anywhere outside the mortuary, (such as to the lab or another establishment), including record-keeping requirements.

*Guidance*

*Formal written agreements with funeral services are recommended. Coroners usually have their own agreements for transportation of bodies and tissue; however, documentation for traceability purposes must still be maintained by the establishment for these cases.*

**T2 Disposal of tissue is carried out in an appropriate manner and in line with the HTA's codes of practice.**

- a) Tissue is disposed of as soon as reasonably possible once it is no longer needed, such as when the coroner's or police authority over its retention ends or the consented post-mortem examination process is complete.
- b) There are effective systems for communicating with the Coroner's Office, which ensure tissue is not kept for longer than necessary.
- c) Disposal is in line with the wishes of the deceased's family.

*Guidance*

*Organs and tissue returned to the body prior to its release should be contained in clear viscera bags, which prevent leakage, are biodegradable and pose no issues for crematoria in relation to emissions and pollution. Clinical waste bags or household bin bags should not be used for this purpose.*

*Tissue blocks and glass slides should not be placed inside the body for the purpose of reuniting tissues with the deceased. Blocks and slides should be placed in a suitable container and transported with the body should the family wish to delay the funeral until the slides are returned.*

- d) The method and date of disposal are recorded.

**Premises, facilities and equipment**

**PFE1 The premises are secure and well maintained and safeguard the dignity of the deceased and the integrity of human tissue**

- a) The premises are clean and well maintained.

*Guidance*

*Floors, walls and work surfaces should be of non-porous construction and free of cracks and chips. The premises should be subject to a programme of planned preventative maintenance, which ensures that the premises, facilities and equipment remain fit for purpose.*

- b) There is demarcation of clear, dirty and transitional areas of the mortuary, which is observed by staff and visitors.
- c) There are documented cleaning and decontamination procedures and a schedule of cleaning.
- d) The premises are secure (for example there is controlled access to the body storage area(s) and PM room and the use of CCTV to monitor access).

*Guidance*

*Relatives who visit for a viewing should not be able to access the body store area. Security systems and lone working arrangements should take into account viewings which take place out of hours.*

- e) Security arrangements protect against unauthorized access and ensure oversight of visitors and contractors who have a legitimate right of access.

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

- a) Storage arrangements ensure the dignity of the deceased.

*Guidance*

*Refrigeration of bodies should be at a temperature of approximately 4 degrees Celsius. The optimal operating temperature for freezer storage is around -20 Celsius, +/- 4 degrees.*

- b) There is sufficient capacity for storage of bodies, organs and tissue samples, which takes into account predicated peaks of activity.

*Guidance*

*Capacity should be regularly reviewed, particularly if contingency arrangements are used for an extended period.*

- c) Storage for long-term storage of bodies and bariatric bodies is sufficient to meet needs.

*Guidance*

*There should be sufficient frozen storage for the long-term storage of bodies; the HTA advises that bodies should be moved into frozen storage after 30-days in refrigerated storage if there is no indication they are soon to be released or further examined, or before, depending on the condition of the body. Where there is insufficient freezer storage to meet needs, there should be arrangements with other establishments, or other contingency steps, to ensure that bodies can be stored appropriately.*

*Bodies in long-term storage should be checked regularly; this should include confirmation of their identity and the reason for their continued storage.*

*Where new fridges are installed, these should measure 24"-26" in width and consideration should be given to the proportion that should be larger to accommodate bariatric bodies.*

- d) Fridge and freezer units are in good working condition and well maintained.
- e) Fridge and freezer units are alarmed and the alarms are tested regularly to ensure that they trigger when temperatures go out of upper or lower set range.
- f) Temperatures of fridges and freezers are monitored on a regular basis.

*Guidance*

*Temperature monitoring should enable the establishment to identify trends and may mitigate the risk of a possible fridge failure.*

- g) Bodies are shrouded or in body bags whilst in storage.
- h) There is separate storage for infants and babies. If not, special measures are taken for the bodies of infants and babies.
- i) There are documented contingency plans in place should there be a power failure or insufficient numbers of refrigerated storage spaces during peak periods.

*Guidance*

*Where contingency arrangements involve the transfer of bodies to other premises, these should be assessed to ensure that they are suitable and that traceability systems are of the required standard. Stacking bodies on the same fridge tray is not considered suitable practice.*

*Establishments should have documented agreements with any funeral services that they may use for contingency storage. Consideration should be given to whether the funeral service provides contingency storage for other mortuaries. SOPs should address issues such as risk assessments and same/similar name systems.*

*The hire of temporary storage units should not be the sole contingency arrangement for an establishment. Establishments should put in place other formally agreed arrangements for contingency storage. Where the hire of temporary storage facilities*

*forms part of establishments' contingency arrangements, consideration should be given well in*

*advance and steps taken to ensure availability of funds, and of units for hire.*

*Establishments should consider entering in to Mutual Aid Agreements*

*with neighbouring organisations in order that they can provide and obtain support during periods of capacity shortages.*

**PFE3 Equipment is appropriate for use, maintained, validated and where appropriate monitored**

a) Items of equipment in the mortuary are in a good condition and appropriate for use:

- i. fridges / freezers
- ii. hydraulic trolleys
- iii. post mortem tables
- iv. hoists
- v. saws (manual and/or oscillating)

*Guidance*

*Equipment should be made of material that is easy to clean, impervious, non-rusting, non-decaying and non-staining.*

b) Equipment is appropriate for the management of bariatric bodies.

c) The ventilation system provides the necessary ten air changes per hour and is checked and maintained at least annually.

*Guidance*

*COSHH requires a thorough examination of the ventilation system at 14-month intervals, and sets out what the examination should cover.*

d) Staff have access to necessary PPE.

*Guidance*

*Where face masks should be worn, they should be face fitted.*

e) Where chemicals are used for preservation of tissue samples, there is adequate ventilation.

f) Key items of equipment, including fridges/freezers, trolleys and post mortem tables (if downdraught) are subject to regular maintenance and records are kept.

*Guidance*

*This includes fridges in Maternity where fetuses or still born babies are stored prior to examination. Maintenance records may be held by the mortuary or centrally by the Trust, such*

*as the Estates Department. They should be available for review during inspection by the HTA.*



## Appendix 2: Classification of the level of shortfall

Where the HTA determines that a licensing standard is not met, the improvements required will be stated and the level of the shortfall will be classified as 'Critical', 'Major' or 'Minor'. Where the HTA is not presented with evidence that an establishment meets the requirements of an expected standard, it works on the premise that a lack of evidence indicates a shortfall.

The action an establishment will be required to make following the identification of a shortfall is based on the HTA's assessment of risk of harm and/or a breach of the HT Act or associated Directions.

### 1. Critical shortfall:

A shortfall which poses a significant risk to human safety and/or dignity or is a breach of the Human Tissue Act 2004 (HT Act) or associated Directions

*or*

A combination of several major shortfalls, none of which is critical on its own, but which together could constitute a critical shortfall and should be explained and reported as such.

A critical shortfall may result in one or more of the following:

- (1) A notice of proposal being issued to revoke the licence
- (2) Some or all of the licensable activity at the establishment ceasing with immediate effect until a corrective action plan is developed, agreed by the HTA and implemented.
- (3) A notice of suspension of licensable activities
- (4) Additional conditions being proposed
- (5) Directions being issued requiring specific action to be taken straightaway

### 2. Major shortfall:

A non-critical shortfall that:

- poses a risk to human safety and/or dignity, or
- indicates a failure to carry out satisfactory procedures, or
- indicates a breach of the relevant CoPs, the HT Act and other relevant professional and statutory guidelines, or
- has the potential to become a critical shortfall unless addressed

*or*

A combination of several minor shortfalls, none of which is major on its own, but which, together, could constitute a major shortfall and should be explained and reported as such.

In response to a major shortfall, an establishment is expected to implement corrective and preventative actions within 1-2 months of the issue of the final inspection report. Major shortfalls pose a higher level of risk and therefore a shorter deadline is given, compared to minor shortfalls, to ensure the level of risk is reduced in an appropriate timeframe.

### **3. Minor shortfall:**

A shortfall which cannot be classified as either critical or major, but which indicates a departure from expected standards.

This category of shortfall requires the development of a corrective action plan, the results of which will usually be assessed by the HTA either by desk based or site visit.

In response to a minor shortfall, an establishment is expected to implement corrective and preventative actions within 3-4 months of the issue of the final inspection report.

### **Follow up actions**

A template corrective and preventative action plan will be sent as a separate Word document with both the draft and final inspection report. You must complete this template and return it to the HTA within 14 days of the issue of the final report.

Based on the level of the shortfall, the HTA will consider the most suitable type of follow-up of the completion of the corrective and preventative action plan. This may include a combination of

- a follow-up site-visit inspection
- a request for information that shows completion of actions
- monitoring of the action plan completion
- follow up at next desk-based or site-visit inspection.

After an assessment of your proposed action plan you will be notified of the follow-up approach the HTA will take.