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

**Heart of England NHS Foundation Trust**

**HTA licensing number 12366**

**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**

**19 & 20 July 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 Heart of England NHS Foundation Trust (the establishment) had met the majority of the HTA standards, three major and seven minor shortfalls were found against the governance and quality, traceability and premises facilities and equipment standards.

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

**The HTA's regulatory requirements**

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

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

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

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

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

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

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

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

**Background to the establishment**

For the purposes of HTA licensing, the establishment consists of a hub site, Birmingham Heartlands Hospital, and a satellite site, Good Hope Hospital in Sutton Coldfield. Post mortem (PM) examinations are not undertaken at Good Hope Hospital, where the mortuary operates as a body store only. Both hospitals' mortuaries come under the management of the Pathology Services at Birmingham Heartlands Hospital. The DI is a Consultant Pathologist and the Corporate Licence Holder Contact is the Director of Medical Safety.

***Birmingham Heartlands Hospital – hub site***

The mortuary is located in a separate building from the main hospital. Deceased patients from the hospital are transported to the mortuary in a specially adapted transfer van. Mortuary staff train all new porters and they are not provided with swipe card access to the mortuary until they have been signed off as competent to undertake mortuary duties.

The hub site does not receive bodies from the community; however, under agreement with the Coroner, it accepts around 70 coronial cases a year which provide an opportunity for training junior doctors. Occasional hospital consented PM examinations are also carried out at the establishment. Consent for adult hospital PM examinations is sought by clinicians with the support of the Designated Individual, who is a Consultant Pathologist with a clear understanding of what is involved in the process and of the requirements of the Human Tissue Act.

Perinatal and paediatric cases are sent to another HTA-licensed establishment for PM examination. Consent for these is sought by trained midwives using the Stillbirth and Neonatal Death charity (Sands) information leaflet, a leaflet with additional local information such as who to contact if they change their minds, and a consent form designed by the receiving establishment.

The mortuary body store comprises 98 fridge spaces, including eight that that can accommodate bariatric cases. There is a separate fridge for pre-term babies and products of conception. The fridges have a remote monitoring system that contacts a pre-agreed list of people when the alarm is triggered; however, the alarm follow-up process is not fully implemented and the exact steps to be taken rely heavily on one individual (see advice item 10). Upper fridge alarm temperatures are tested regularly; lower triggers have not been tested. Fridge temperatures are also recorded manually during the week.

The PM suite contains two trolley tables, both of which have signs of significant rusting to the wheels. Rust was also visible on a number of items of equipment in the mortuary, such as the cleaning trolley and metal cupboards. The establishment recently purchased a temporary

storage unit with space for 12 bodies, which was erected close to the door in the PM suite but was not in use at the time of this inspection. There is quite a low gradient on the PM suite floor which means that drainage can be quite slow. There is a concern that fluid could pool underneath the temporary storage unit and the lack of a regular cleaning schedule makes this a possible health and safety risk (see shortfall against standard PFE1(a)).

Pathologists from Heartlands hospital undertake PM examinations at another HTA licensed mortuary on behalf of the Coroner for Birmingham and Solihull and bring tissue back to Heartlands Hospital for processing and storage in line with familes' wishes. In these cases, excess wet tissue, in addition to blocks and slides, is stored rather than disposed of, which is the more common practice. The purpose of the storage of this tissue, and the authority under which it is being stored, is unclear (see shortfalls against standards T1(g) and T2(a)).

Receipt and release procedures are stringent; there is a two-person check of the identity details accompanying the deceased when they arrive from the hospital wards. There is a specific list of documents that can be accepted from funerals directors coming to collect a body, and if they cannot confirm a minimum of three identifiers, then the body will not be released into their care.

Viewings of the deceased are arranged via the hospital bereavement service or the wards. Family who have come for a viewing meet nursing staff on the ward and are escorted by them to the viewing room. There are always two members of staff present for viewings.

***Good Hope Hospital***

The mortuary at Good Hope Hospital is based on the ground floor of the hospital building and is secured by swipe card access. It receives bodies from the community, as well as deceased patients from the hospital. The body store consists of 77 fridge spaces, eight of which can accommodate bariatric bodies; there is no freezer storage, except for pre-term babies and products of conception. The hospital porters are also trained by the mortuary manager from Birmingham Heartlands Hospital. Staff rotate between the Good Hope and Birmingham Heartlands hospitals to provide cover during busy periods or while staff are ill or on annual leave; so practices are procedures are consistent across the sites.

**Description of inspection activities undertaken**

The establishment has been licensed since 2007 and this its fourth site-visit, the last visit being a joint UKAS inspection in 2014. The HTA conducted a visual inspection of the hub and the satellite, reviewed documentation and carried out interviews with the Designated Individual and establishment staff. The maternity departments at both sites and the

Emergency department at Good Hope Hospital were visited, as licensed activities take place in these areas.

As part of the inspection, audits of the body stores were undertaken; four bodies were selected at random at the hub site and three at the satellite site. Details from the body identification tag and the physical location of each body were cross-checked against the establishment's mortuary register and the location information on the fridge doors. Additionally, details of tissue retained during four PM examinations were compared with records documenting the wishes of the family and tissue stored in the mortuary. No anomalies were found during these audits. Process audits of the establishment releasing two bodies from the mortuary at Birmingham Heartland Hospital to funeral directors were also undertaken.

**Inspection findings**

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

**Compliance with HTA standards**

| Standard | Inspection findings | Level of shortfall |
|---|---|---|
| **GQ1 All aspects of the establishment's work are governed by documented policies and procedures** | | |
| c) Procedures on body storage prevent practices that disregard the dignity of the deceased | There is no freezer storage available across the trust and bodies are stored in refrigerated storage for up to seven weeks prior to a social services funeral (See advice item 2). | **Minor** |
| h) Matters relating to HTA-licensed activities are discussed at regular governance meetings involving establishment staff | Mortuary governance meetings used to take place regularly but ceased approximately nine months prior to inspection. | **Minor** |

| | | |
|---|---|---|
| **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 | Porters undertaking activities in the mortuary lack awareness of the establishment's incident reporting procedures and the reporting requirements for HTA Reportable Incidents (HTARIs). | **Minor** |

| **T1 A coding and records system facilitates traceability of bodies and human tissue, ensuring a robust audit trail** | | |
|---|---|---|
| g) Organs or tissue taken during post-mortem examination are fully traceable, including blocks and slides (including police holdings). | Wet tissue samples that are stored following PM examination at another licensed establishment are in pots that are not labelled with details on the type or amount of tissue they contain and therefore are not traceable. | **Major** |

| **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 | Tissue taken at PM examinations conducted at the establishment is processed into blocks and any residual wet tissue is disposed of. In the case of the tissue taken during PM examinations at the other licensed establishment, any residual wet tissue is stored. The purpose of the retention and storage of these samples is unclear, although in some cases it may be at the request of the family pending a medico-legal case.<br>*See advice item 8* | **Major** |

| **PFE1 The premises are secure and well maintained and safeguard the dignity of the deceased and the integrity of human tissue.** | | |
|---|---|---|
| a) Premises are clean and well maintained | The placing of the temporary storage unit in the PM suite means that the floor under the unit cannot be cleaned effectively. | **Minor** |
| c) There are documented cleaning and decontamination procedures and a schedule of cleaning | There is no cleaning schedule or checklist of cleaning that should take place after PM examinations have been undertaken. | **Minor** |

| **PFE2 There are appropriate facilities for the storage of bodies and human tissue.** | | |
|---|---|---|
| c) Storage for long-term storage of bodies and bariatric bodies is sufficient to meet needs | None of the hospitals within the Trust has freezer storage. This places bodies in the mortuary for longer than 30 days at risk of decomposition. | **Minor** |
| 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 temperatures of the fridges in both maternity units are monitored daily by maternity staff but neither is alarmed. | **Minor** |

| PFE3 Equipment is appropriate for use, maintained, validated and where appropriate monitored | | |
|---|---|---|
| a) Items of equipment in the mortuary are in good condition and appropriate for use | Key items of equipment in the PM suite at Birmingham Heartlands Hospital showed significant amounts of rust, including the PM trolleys and some tools used during evisceration. This means that the area cannot be properly decontaminated and presents a health and safety risk to staff. | **Major** |

### Advice

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

| No. | Standard | Advice |
|---|---|---|
| 1. | GQ1(a) ii | SOP S002 refers to long-term storage of bodies, but only states that bodies may be in the mortuary for an extended period and that these cases are investigated with Bereavement and funeral directors by mortuary staff, but there is no details as to how the bereavement office is notified, what information is given or how each case is managed. The DI is advised to add detail about this process so it could be easily followed by someone new to the mortuary. This should also include detail about the management of bodies that are in the care of the establishment for longer than 30 days.<br>The SOP should also be updated with details about the check-in process for bodies to ensure that it is clear what identity details should be checked and the information they should be checked against. Finally, the document should clarify how to identify deceased with same or similar names. |
| 2. | GQ1(c) | Currently, mortuary staff check the register to identify bodies that have been with them for three to four weeks and then contact the bereavement office to find out why there is a delay in their release. The DI is advised to start the process of contacting bereavement staff when anyone has been in their care for over two weeks. |
| 3. | GQ1(g) | The DI may wish to consider having Persons Designated in all areas where licensed activity takes place, such as the maternity units. |
| 4. | GQ1(h) | Whilst there are a number of informal meetings, there are no regular, formal meetings with the DI and PDs. The DI is advised to ensure that regular minuted meetings take place to discuss licensed activities. |
| 5. | GQ5(a) | The DI is advised to add information on HTARIs to the training for portering staff, so they are aware of what incidents need to be reported to the HTA and what the necessary timescales are. |
| 6. | GQ5(b) | There is a Trust policy on incident reporting but there is no mention of the HTA in the list of governing bodies who may need to be informed, nor is the HT Act mentioned in the list of relevant standards and legislation. The DI is advised to |

| | | |
|---|---|---|
| | | take steps to update this document so it is reflects the requirement of the HTA in relation to incident reporting. |
| 7. | GQ6(a) | Risk assessments are, in general, of a good standard; however the assessment that addresses the risks of releasing the wrong body lacks sufficient detail about mitigating factors. |
| 8. | T1(g) | The pots of tissue in storage from PM examinations conducted at other establishments are labelled with the identity details of the deceased but no details of the type tissue in storage. The DI is advised to liaise with the Coroner to ascertain the nature of each sample and whether its continued storage is warranted. On completion of this exercise tissue that is no longer required for either the Coroner's purposes or used by the family, for example in a medico-legal case, should be disposed of.<br><br>In cases where family have given consent to the tissue being used for research, and there is no research project requiring the tissue, then the tissue should be disposed of. The disposal should be clearly documented and include any blocks and slides in addition to the wet tissue. |
| 9. | T2(c) | The consent forms used by the Coroner to record the wishes of the family in relation to the fate of tissue taken to determine the cause of death allows families to request that tissue be used for research. However, there are currently no research projects, which leads to ambiguity on whether the tissue should be stored or not.<br><br>The DI is advised to liaise with the Coroner to review the options given to families to ensure they have all the relevant facts and an understanding of the options available to them in order to make an informed decision. |
| 10. | PFE1(d) | A new system for managing the fridge alarms is being developed; in the meantime the system is reliant on the Head Biomedical Scientist as the main point of contact for alarm triggers. The DI is advised to ensure that the process is documented and that a number of people are trained to ensure adequate cover should the fridges alarm. |
| 11. | PFE2(e) | The DI is advised to ensure lower alarm triggers are tested regularly. |
| 12. | PFE2(f) | Temperatures are monitored regularly but at the time of inspection it was noted that one block of fridges at Birmingham Heartlands Hospital was averaging around 6°Celcius, this is above the sector norm. The DI is advised to investigate why the fridge temperatures are running higher than recommended and to ensure they are adjusted to average at 4°Celcius. |
| 13. | PFE3(a) | The DI is advised to review all the equipment in the PM suite to ensure it is fit for purpose. |

## Concluding comments

The mortuary appears to be well-run and has an open culture, which encourages the reporting of any issues and helps ensure that lessons learned form past incidents are taken on board. A number of areas of good practice were observed during the inspection:

- New porters are only given swipe-card access to the mortuary when they have completed their training to the satisfaction of the mortuary manager;

- When anyone comes for a viewing they are asked to complete a small form about the identity of the person they have come to see; this helps mitigate the risk of a viewing of the wrong body;
- Details of the mother must be present on documentation about babies, and funeral directors must present this data when collecting the body, which mitigates the risk of release of the wrong body in perinatal cases;
- There is a comprehensive system of audit in place.

There are some areas of practice that require improvement, including three major and seven minor shortfalls.

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

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

**Report sent to DI for factual accuracy: 11 August 2017**

**Report returned from DI: 24 August 2017**

**Final report issued: 05 September 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: 05 February 2018**

## Appendix 1: HTA licensing standards

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

**Consent**

**C1 Consent is obtained in accordance with the requirements of the Human Tissue Act 2004 (HT Act) and as set out in the HTA's codes of practice**

a) There is a documented policy which governs consent for post-mortem examination and the retention of tissue and which reflects the requirements of the HT Act and the HTA's Codes of Practice.

b) There is a documented standard operating procedure (SOP) detailing the consent process.

*Guidance*

*This should include who is able to seek consent, what training they should receive, and what information should be provided to those giving consent for post-mortem examination. It should make reference to the use of scanning as an alternative or adjunct to post-mortem examination.*

c) There is written information for those giving consent, which reflects the requirements of the HT Act and the HTA's codes of practice.

*Guidance*

*Information on consent should be available in different languages and formats, or there is access to interpreters/translators. Family members should be given the opportunity to ask questions.*

d) Information contains clear guidance on options for how tissue may be handled after the post-mortem examination (for example, repatriated with the body, returned to the family for burial/cremation, disposed of or stored for future use), and what steps will be taken if no decision is made by the relatives.

e) Where consent is sought for tissue to be retained for future use, information is provided about the potential uses to ensure that informed consent is obtained.

f) The deceased's family are given an opportunity to change their minds and it is made clear who should be contacted in this event and the timeframe in which they are able to change their minds.

g) The establishment uses an agreed and ratified consent form to document that consent was given and the information provided.

*Guidance*

*This may be based on the HTA's model consent form for adult post-mortem examinations*

*available on the HTA website, or in relation to infants, the resources pack developed by the Stillbirth and neonatal death charity, Sands. The consent forms should record the consent given for the post-mortem examination and for the retention and future use of tissue samples.*

**C2 Staff involved in seeking consent receive training and support in the essential requirements of taking consent**

a) There is training for those responsible for seeking consent for post-mortem examination and tissue retention, which addresses the requirements of the HT Act and the HTA's codes of practice.

*Guidance*

*Refresher training should be available (for example annually).*

b) Records demonstrate up-to-date staff training.

c) If untrained staff are involved in seeking consent, they are always accompanied by a trained individual.

d) Competency is assessed and maintained.

**Governance and quality systems**

**GQ1 All aspects of the establishment's work are governed by documented policies and procedures**

a) Documented policies and SOPs cover all mortuary/laboratory procedures relevant to the licensed activity, take account of relevant Health and Safety legislation and guidance and, where applicable, reflect guidance from RCPath. These include:

i. post-mortem examination, including the responsibilities of Anatomical Pathology Technologists (APTs) and Pathologists and the management of cases where there is increased risk;

ii. practices relating to the storage of bodies, including long term storage and when bodies should be moved into frozen storage;

iii. practices relating to evisceration and reconstruction of bodies;

iv. systems of traceability of bodies and tissue samples;

v. record keeping;

vi. receipt and release of bodies, which reflect out of hours arrangements;

vii. lone working in the mortuary;

viii. viewing of bodies, including those in long-term storage, by family members and others such as the police;

ix. transfer of bodies internally, for example, for MRI scanning;

x. transfer of bodies and tissue (including blocks and slides) off site or to other establishments;

xi. movement of multiple bodies from the mortuary to other premises, for example, in the event that capacity is reached;

xii. disposal of tissue (including blocks and slides), which ensures disposal in line with the wishes of the deceased person's family;

xiii. access to the mortuary by non-mortuary staff, contractors and visitors;

xiv. contingency storage arrangements.

*Guidance*

*SOPs should reflect guidance contained in the HSE's document: Managing the risks of infection in the mortuary, post mortem room, funeral premises and exhumation.*

*Individual SOPs for each activity are not required. Some SOPs will cover more than one activity.*

b) Procedures on evisceration ensure that this is not undertaken by an APT unless the body has first been examined by the pathologist who has instructed the APT to proceed.

c) Procedures on body storage prevent practices that disregard the dignity of the deceased.

*Guidance*

*For example, placing more than one body on a tray, placing bodies unshrouded on trays, or storing bodies in unrefrigerated storage should not take place.*

*The family's permission should be obtained for any 'cosmetic' adjustments or other invasive procedures prior to release of bodies, for example, sewing the deceased's mouth to close it or the removal of a pacemaker. It is also good practice to discuss with the family any condition that may cause them distress, for example when viewing or preparing the body for burial, such as oedema, skin slippage of signs of decomposition.*

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

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

d) Policies and SOPs are reviewed regularly by someone other than the author, ratified and version controlled. Only the latest versions are available for use.

e) There is a system for recording that staff have read and understood the latest versions of these documents.

f) Deviations from documented SOPs are recorded and monitored via scheduled audit activity.

g) All areas where activities are carried out under an HTA licence are incorporated within the establishment's governance framework.

*Guidance*

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

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

*Guidance*

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

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

a) There is a documented schedule of audits.

*Guidance*

*As a minimum, the schedule should include a range of vertical and horizontal audits*

*checking compliance with documented procedures, the completion of records and traceability.*

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

*Guidance*

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

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

*Guidance*

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

*applicable.*

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

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

*Guidance*

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

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

b) There are clear reporting lines and accountability.

c) Staff are assessed as competent for the tasks they perform.

*Guidance*

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

d) Staff have annual appraisals and personal development plans.

e) Staff are given opportunities to attend training courses, either internally or externally.

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

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

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

*Guidance*

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

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

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

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

*Guidance*

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

b) There are documented SOPs for record management which include how errors in written records should be corrected.

c) Systems ensure data protection, confidentiality and public disclosure (whistle-blowing).

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

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

*Guidance*

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

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

b) The incident reporting system clearly outlines responsibilities for reporting, investigating and follow up for incidents.

c) The incident reporting system ensures that follow up actions are identified (i.e. corrective and preventative actions) and completed.

d) Information about incidents is shared with all staff to avoid repeat errors.

e) The establishment adopts a policy of candour when dealing with serious incidents.

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

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

*Guidance*

*Risks to the dignity and integrity of bodies and stored tissue should be covered. The HTA's*

*reportable incident categories provide a good basis for risk assessments. Risk assessments should be reviewed at regular intervals, for example every 1-3 years or when circumstances change. Staff should be involved in the risk assessment process.*

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

*Guidance*

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

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

**Traceability**

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

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

*Guidance*

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

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

*Guidance*

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

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

*Guidance*

*Identification details should not be written on bodies. Where bodies are moved off site for*

*contingency storage the DI should ensure that suitable systems are in place to identify same or similar names.*

d) There is system for flagging up same or similar names of the deceased.

e) Identity checks take place each time a body is moved whether inside the mortuary or from the mortuary to other premises.

*Guidance*

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

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

f) There are procedures for releasing a body that has been in long term storage and is therefore not in the current register.

g) Organs or tissue taken during post-mortem examination are fully traceable, including blocks and slides (including police holdings). The traceability system ensures that the following details are recorded:

i. material sent for analysis on or off-site, including confirmation of arrival

ii. receipt upon return to the laboratory or mortuary

iii. the number of blocks and slides made

iv. repatriation with the body

v. return for burial or cremation

vi. disposal or retention for future use.

*Guidance*

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

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

*Guidance*

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