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

**Royal Berkshire NHS Foundation Trust**

**HTA licensing number 12232**

**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**

**9th May 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.

The Royal Berkshire Hospital (the establishment) was found to have met all HTA 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

The mortuary at the Royal Berkshire Hospital is incorporated within and managed by pathology services. Recently this service has become part of the Berkshire Surrey Pathology Service (BSPS), with its legal entity being Frimley Health Foundation Trust.

The establishment receives approximately 2,000 bodies each year and undertakes up to 500 post mortem (PM) examinations per year, the majority of which are conducted for HM Coroner for Berkshire. Forensic PM examinations and a small number of adult hospital consented examinations are also conducted. Consent for adult hospital consented cases is sought by one of three specially trained clinicians, with support from mortuary staff. Consent for paediatric cases is undertaken on site by specially trained bereavement midwives who occasionally support consultants in this process; these cases are routinely sent to another HTA licenced establishment for PM examination.

Bodies from the community are brought in by funeral directors, contracted by the Coroner, through a dedicated secure area at the back of the mortuary, which is monitored by CCTV.

The mortuary has 93 fridges and five freezers for the storage of bodies. This includes spaces for bariatric and super bariatric bodies. The majority of the standard fridges are double ended, with direct access into the post mortem room. There is a separate fridge for the storage of paediatric/perinatal cases and pregnancy remains. Currently, there is a temporary Nutwell unit within the post mortem room for use during busy periods; this is hired every autumn in case of peaks in activity. In addition, the mortuary has purchased a Flexmort body storage system that can be housed within the body store if needed. These units provide an additional 12 spaces each.

The mortuary employs five full time Anatomical Pathology Technologists (APTs), including the mortuary manager and one trainee APT. The mortuary manager also oversees the bereavement service, with the assistance of two bereavement officers, one of whom is also a qualified APT.

The current DI is the Medical Director for the Trust. Prior to the inspection it was agreed that the Medical Director would become the Corporate Licence Holder contact and another suitable individual would be appointed as DI. This process is currently underwayin discussion with the HTA.

## Material held for the police

Although the establishment conducts Home Office PMs, at the time of the inspection there were no PACE specimens held on site.

**Description of inspection activities undertaken**

The establishment was first inspected in November 2009 and again in 2012. Both these inspections were routine themed inspections, focussing on specific standards. This report describes the third routine site visit conducted in May 2017, which was a full inspection covering all HTA standards. It included a visual inspection of the body store, post mortem room and viewing suite. The maternity and accident and emergency departments were also visited (see advice item 5). Formal interviews were conducted with the Designated Individual, Mortuary Manager, APT, Coroner's Officer, Consultant Histopathologist and post mortem consent seekers (adult and perinatal) . A number of traceability audits were conducted. The identification of four bodies stored in the mortuary were checked (two coroner's cases and two hospital cases, including bodies with same/similar names) and all associated paperwork was reviewed. No anomalies were found. In addition, an audit of a further three bodies where histology had been taken (two coroner's cases and one hospital consented case) were conducted. Records were reviewed to confirm that the relatives' wishes for the tissue had been complied with. A minor anomaly was found in relation to the number of blocks awaiting disposal in one case.

**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 (please see note above).

**Compliance with HTA standards**

All applicable HTA standards have been assessed as fully met.

**Advice**

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

| No. | Standard | Advice |
|---|---|---|
| 1. | C1 (a) | The 'Consent for Hospital Post Mortem in Adults' policy (CG412), paragraph 5.4.2.5, explains that special consideration should be given to those whose first language is not English but not how to deal with or record this. The DI is advised to include that consideration should also be given to those who have language, literacy or hearing difficulties. In each circumstance, details should |

| | | |
|---|---|---|
| | | be documented of how these difficulties were overcome as confirmation that valid consent was obtained.<br><br>In addition, the policy should be updated to reflect the process and training of staff involved in adult PM examination consent seeking. |
| 2. | C1 (c) | The document 'A guide to the hospital post mortem examination procedure' does not contain any document control information, such as author, review date, version number. The DI is advised to ensure the procedure is reviewed regularly and kept up to date, in line with the consent form used. |
| 3. | C1 (g) | The consent form for adult consented PM examinations – 'Consent for post mortem examination of an adult', Part 2 - includes the sentence: 'Note that this option may result in a delay to being able to make funeral arrangements'. This sentence does not apply to any of the options indicated. The DI is advised to remove this sentence to prevent confusion for consent seekers and relatives. |
| 4. | GQ1 (a) | The mortuary manager is advised to review and amend as necessary all SOPs to ensure:<br>• they reflect the HTA's revised codes and standards;<br>• the new diploma qualifications for APTs are referenced alongside the certificate and diploma of the 'old' qualifications. This is mainly in the introductory section of each SOP. |
| 5. | GQ1 (g) | The DI is advised to appoint Persons Designate (PD) within the A&E department. This will provide the DI with assurance that activities carried out under the licence in this area have sufficient oversight. They can also feedback any information or issues in relation to HTA related activities at the scheduled PD meetings with the DI. |
| 6. | GQ5 (b) | The SOP 'The Mortuary Office' (M3), paragraph 8.32, Incident Reporting, should be amended to state that all HTA Reportable Incidents (HTARIs) need to be reported to the HTA within five working days of discovery of the incident. Not all HTARIs are identified immediately after occurrence. |
| 7. | T1 (c) | During the visual inspection, the release of two bodies was witnessed. Only two identifiers were checked by the mortuary and funeral service staff. Three identifiers should be checked, including one that is unique to the deceased, especially when releasing patients with same/similar names. The mortuary SOP M1 'For admission and Discharge of the Deceased at the Royal Berkshire Hospital' states the requirement to check three identifiers. |

| | | |
|---|---|---|
| 8. | PFE2 (e) | The mortuary staff manually monitor fridge and freezer temperatures daily and have access to the temperature monitoring system via the mortuary computer. In addition, the mortuary manager reviews all the temperatures twice a week. Although the fridges and freezers are extensively monitored to identify any issues at the earliest opportunity, the alarms are not regularly tested to ensure they will trigger when temperatures go out of range. The mortuary manager is advised to schedule and record these tests. |

**Concluding comments**

The establishment team demonstrate commitment and dedication to delivering a high quality service. The mortuary staff have excellent working relationships with service users, both internal and external to the Trust. There are numerous examples of strength and good practice:

- The 'Hospital Post Mortem Consent' (October 2016) checklist ensures all information in relation to consent is collated and covered prior to and during the consent process.
- SOPs developed by the mortuary team are thorough and concise, making them easy to follow and to find relevant information. In addition, flow charts are included in some SOPs for ease of reference.
- Mortuary staff rotate on a weekly basis to cover mortuary office duties. This ensures there is consistency throughout the week for key activities. A formal handover is carried out at the end of every week.
- Daily mortuary staff briefings ensure relevant information is shared with all staff, including bodies with same/similar names and the status of any deceased who have been in the mortuary for longer than normal. Any concerns or issues can also be addressed promptly.
- During busy periods bodies are transferred to different fridges to allow space for overnight and weekend admissions. This process is well managed and includes body audits.
- The temporary body storage units are linked to the fridge temperature monitoring system when in use, allowing the temperature to be monitored with the permanent fridges.
- Portering, nursing and funeral services staff are trained in mortuary procedures by the mortuary team; training is documented and refresher training is provided when necessary.
- All documentation is held securely, including paperwork for all out of hours

admissions. There are two locked ‘red letter’ boxes for hospital and police deaths for this purpose.

- The signage within the mortuary is good, providing visual queues for service users.
- Magnets are used on fridge doors to identify patients with same/simaliar names, tissue retained and bodies not to be released.
- The colour of the white board marker is changed weekly to help identify any potential long stay bodies so they can be dealt with efficiently.
- Post mortem tables and organ bowls are colour coded to mitigate the risk of organs being returned to the wrong body.
- When releasing bodies only one funeral director at a time is allowed access to the mortuary. If they are collecting multiple bodies, mortuary staff will only deal with one body at a time, so body checks and signing of the register is completed after each body. This helps mitigate the risk of documentation being mixed up or signing for the wrong body.
- The facilities and equipment within the mortuary are exceptionally clean and well maintained.

The HTA has assessed the establishment as suitable to be licensed for the activities specified.

**Report sent to DI for factual accuracy: 01/06/17**

**Report returned from DI: No factual accuracy or request for redaction comments were made by the DI.**

**Final report issued: 28/06/17**

## Appendix 1: HTA licensing standards

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

**Consent**

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

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

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

*Guidance*

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

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

*Guidance*

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

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

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

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

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

*Guidance*

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

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

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

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

*Guidance*

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

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

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

d) Competency is assessed and maintained.

**Governance and quality systems**

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

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

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

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

iii. practices relating to evisceration and reconstruction of bodies;

iv. systems of traceability of bodies and tissue samples;

v. record keeping;

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

vii. lone working in the mortuary;

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

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

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

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

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

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

xiv. contingency storage arrangements.

*Guidance*

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

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

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

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

*Guidance*

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

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

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

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

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

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

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

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

*Guidance*

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

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

*Guidance*

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

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

a) There is a documented schedule of audits.

*Guidance*

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

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

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

*Guidance*

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

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

*Guidance*

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

*applicable.*

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

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

*Guidance*

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

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

b) There are clear reporting lines and accountability.

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

*Guidance*

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

d) Staff have annual appraisals and personal development plans.

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

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

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

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

*Guidance*

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

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

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

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

*Guidance*

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

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

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

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

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

*Guidance*

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

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

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

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

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

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

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

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

*Guidance*

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

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

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

*Guidance*

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

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

**Traceability**

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

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

*Guidance*

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

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

*Guidance*

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

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

*Guidance*

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

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

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

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

*Guidance*

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

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

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

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

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

ii. receipt upon return to the laboratory or mortuary

iii. the number of blocks and slides made

iv. repatriation with the body

v. return for burial or cremation

vi. disposal or retention for future use.

*Guidance*

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

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

*Guidance*

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

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

a) Tissue is disposed of as soon as reasonably possible once it is no longer needed, such as when the coroner's or police authority over its retention ends or the consented post-mortem examination process is complete.

b) There are effective systems for communicating with the Coroner's Office, which ensure tissue is not kept for longer than necessary.

c) Disposal is in line with the wishes of the deceased's family.

*Guidance*

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

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

d) The method and date of disposal are recorded.

**Premises, facilities and equipment**

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

a) The premises are clean and well maintained.

*Guidance*

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

b) There is demarcation of clear, dirty and transitional areas of the mortuary, which is observed by staff and visitors.

c) There are documented cleaning and decontamination procedures and a schedule of cleaning.

d) The premises are secure (for example there is controlled access to the body storage area(s) and PM room and the use of CCTV to monitor access).

*Guidance*

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

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

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

a) Storage arrangements ensure the dignity of the deceased.

*Guidance*

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

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

*Guidance*

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

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

*Guidance*

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

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

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

d) Fridge and freezer units are in good working condition and well maintained.

e) Fridge and freezer units are alarmed and the alarms are tested regularly to ensure that they trigger when temperatures go out of upper or lower set range.

f) Temperatures of fridges and freezers are monitored on a regular basis.

*Guidance*

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

g) Bodies are shrouded or in body bags whilst in storage.

h) There is separate storage for infants and babies. If not, special measures are taken for the bodies of infants and babies.

i) There are documented contingency plans in place should there be a power failure or insufficient numbers of refrigerated storage spaces during peak periods.

*Guidance*

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

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

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

*forms part of establishments' contingency arrangements, consideration should be given well in advance and steps taken to ensure availability of funds, and of units for hire.*

*Establishments should consider entering in to Mutual Aid Agreements*

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

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

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

   i. fridges / freezers

   ii. hydraulic trolleys

iii. post mortem tables

iv. hoists

v. saws (manual and/or oscillating)

*Guidance*

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

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

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

*Guidance*

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

d) Staff have access to necessary PPE.

*Guidance*

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

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

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

*Guidance*

*This includes fridges in Maternity where fetuses or still born babies are stored prior to examination. Maintenance records may be held by the mortuary or centrally by the Trust, such as the Estates Department. They should be available for review during inspection by the HTA.*

## Appendix 2: Classification of the level of shortfall

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

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

1. **Critical shortfall:**

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

   *or*

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

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

   (1) A notice of proposal being issued to revoke the licence

   (2) Some or all of the licensable activity at the establishment ceasing with immediate effect until a corrective action plan is developed, agreed by the HTA and implemented.

   (3) A notice of suspension of licensable activities

   (4) Additional conditions being proposed

   (5) Directions being issued requiring specific action to be taken straightaway

2. **Major shortfall:**

   A non-critical shortfall that:

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

   *or*

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

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

3. **Minor shortfall:**

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

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

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

## Follow up actions

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

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

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

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