



Site visit inspection report on compliance with HTA licensing standards

The Ipswich Hospital NHS Trust

HTA licensing number 30017

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**

5 October 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 Ipswich Hospital NHS Trust (the establishment) had met the majority of the HTA standards, two major and three minor shortfalls were found against the premises facilities and equipment standards in relation to the condition of one block of fridges and the post-mortem (PM) room, and fridge and freezer temperature monitoring and alarm testing.

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 DI 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 Ipswich Hospital is located on the ground floor of the main hospital building; the management of which falls under the NHS Trust. The DI is employed as Histopathology Service manager by The North East Essex and Suffolk Pathology Service; and is also employed, independent from this contract, by Ipswich Hospital for four hours per week to undertake the role of DI. The CLH contact is the hospital Chief Executive.

The establishment receives over 2,000 bodies each year from the hospital and the community, and performs up to 600 post mortem (PM) examinations annually. The majority of PM examinations are undertaken on behalf of the Coroner for Suffolk, including a small number of Home Office PM examinations. 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 bereavement staff who have 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 is sought using the information leaflet and consent form from the receiving establishment. All perinatal and paediatric deceased come straight to the mortuary and there is no storage in maternity or the gynaecology wards.

The mortuary body store comprises 126 fridge spaces located across three separate areas. The fridges range in size to accommodate different body dimensions and there is a walk in bariatric fridge that can accommodate a bariatric hospital bed. There are a further seven freezers, 3 of which can accommodate bariatric bodies. One of the blocks of fridges is kept as contingency storage and clear signage is employed when they are not in active use to ensure the porters do not use them accidentally. There is a designated area in one of the fridge blocks for pre-term babies and products of conception. The largest block of fridges is old and has rust internally where the racking system attaches to the stone floor and there is exposed wood integral to the structure of the doors (see shortfall against standard PFE3(a)).

All the fridges and freezers are alarmed by a remote monitoring system that contacts an agreed list of people when triggered. The temperatures are recorded electronically and records are kept by the estates department, but they are not reviewed by mortuary staff for trends (see shortfall against standard PFE2(f)). The alarms are not subject to testing outside of annual maintenance (see shortfall against standard PFE2(e)).

Hospital porters transfer the deceased from within the hospital to the mortuary. Mortuary staff train all the porters individually to ensure they are aware of mortuary practices. Bodies of those who die in the community are brought in by funeral directors appointed by the Coroner. If the funeral directors require access to the mortuary out of hours, the porters meet

them to admit the body and enter the relevant details into the mortuary register. The entrance used by the funeral directors has one-way glass so staff can easily see who is outside but people outside cannot see in. This area is also protected by closed circuit television (CCTV) and a fixed canopy that ensures activity is not overlooked by other departments in the hospital.

The mortuary use plastic folders ('Patient Passport') for each body in their care which holds any information about location, PM examination activity, viewings and the documents used for collection by the funeral director. Additionally there is an electronic system that staff complete but this is only for laboratory purposes and does not form part of the mortuary processes or checks (see *Advice*, item 5). Same or similar name checks are done manually by staff and an audit of how long each body has been in the mortuary is completed by staff (see *Advice*, items 1 and 5).

The PM suite has six post-mortem tables, five fixed porcelain and one stainless steel height adjustable table. A 'one-at-a-time' system is in effect in order to avoid mix up of organs during PM examination. The PM suite shows significant signs of rust, particularly around the drainage system, but also around the bases on the dissection benches, the height adjustable table and above the dissection areas (See shortfall against PFE3(a)). The air ventilation system does not meet the required air changes per hour (see shortfall against standard PFE3(c)). There is a cleaning schedule in place but the level of cleanliness in the PM suite at the time of inspection indicated that this is not sufficiently detailed (see *Advice*, item 7).

Viewings of the deceased are always undertaken by the on-call staff. The staff member who prepares the body is the person who meets with the family. There is a visitor's log which is used to confirm the details of who the family have come to see and to request feedback on the service.

The release of the deceased to funeral directors is always undertaken by mortuary staff who check that three points of identification supplied by the undertaker match those on the body. However, the SOP considers first name and surname to be two separate identifiers (see *Advice*, item 6).

Description of inspection activities undertaken

The establishment has been licensed since 2007 and this was the third routine site-visit inspection. The HTA conducted a visual inspection of the premises, reviewed documentation and carried out interviews with the Designated Individual and establishment staff.

As part of the inspection, an audit of the body store was undertaken, where four bodies were selected at random, including one from the freezer and one from the perinatal fridge. Details

from the body identification tags and the physical location of the bodies were crosschecked against the establishment's paper and electronic mortuary register. Additionally, details of tissue retained during three PM examinations, including a hospital consented one, were compared with records documenting the wishes of the family and tissue stored in the mortuary. One anomaly was found during these audits (see *Advice*, item 5).

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

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	The inspectors noticed areas within the PM suite where cleaning was not up to the expected standard. <i>See advice item 7</i>	Minor
PFE2 There are appropriate facilities for the storage of bodies and human tissue.		
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 fridges and freezers are alarmed but they are not tested outside of annual maintenance. Staff are unaware of the lower temperature trigger.	Minor
f) Temperatures of fridges and freezers are monitored on a regular basis	There is a remote temperature monitoring system, which is managed by estates, but the temperatures are not reviewed by mortuary staff for trends that would identify potential issues with the fridge and freezer temperatures.	Minor
PFE3 Equipment is appropriate for use, maintained, validated and where appropriate monitored		

<p>a) Items of equipment in the mortuary are in good condition and appropriate for use</p>	<p>The largest bank of fridges is old, has rust patches internally, and wood incorporated into the fridge doors.</p> <p>The PM suite is also old and shows significant areas of rust on a lot of the metal work.</p> <p>These present a health and safety risk for staff as these areas cannot be decontaminated properly.</p> <p>The HTA is aware that there are plans to replace the fridges and update the PM suite in the near future.</p>	<p>Major</p>
<p>c) The ventilation system provides the necessary ten air changes per hour and is checked and maintained at least annually</p>	<p>The ventilation system currently runs at 6-7 air changes per hour. Whilst the establishment send high risk PM examinations to another HTA licensed establishment and risk assess each PM, this still presents a significant risk to staff if there are undiagnosed infections.</p>	<p>Major</p>

Advice

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

No.	Standard	Advice
1.	GQ1(a)	<p>The mortuary staff check the duration of stay for bodies that have been with them for longer than expected and contact bereavement services to advise them to follow up with families after four weeks. The DI is advised to formalise this process with bereavement and to contact them earlier, for example when a body has been in storage for 20 days. This will allow more time for the mortuary to decide whether transfer to the freezer units is appropriate.</p>
2.	GQ1(a)	<p>There is a lone working policy but it does not consider the risks of lone viewings, when staff may be vulnerable if families become aggressive. The DI is advised to further consider the risks when staff are undertaking viewings out of hours. This is particularly important as some members of staff have not attended the hospital 'Personal Safety Awareness' training course.</p>
3.	GQ3(f)	<p>The DI is advised to consider adding information about the type of incidents that need to be reported to the HTA to the porter training package. Additionally, the DI may wish to consider structuring the Anatomical Pathology Technologist training sign off process to ensure incremental progress is demonstrated.</p>
4.	GQ6(a)	<p>Risk assessments do address the majority of the HTARI categories but more consideration of the risks of accidental damage to the deceased should be taken. The DI is advised to further examine the risks of accidental damage in mortuary procedures.</p>

5.	T1(a)	The DI is advised to consider if the use of an electronic database/commercial software would facilitate allocation of a unique mortuary/identification number and associated record keeping. This could help facilitate a connection with the laboratory system, which would reduce duplication of work for mortuary staff.
6.	T1(c)	Release practices require that funeral directors provide sufficient identifiers. However, the SOP for release refers to first name and surname as two separate identifiers. The DI is advised to ensure that the number of identifiers are consistent within SOPs and that it is made clear that first name and surname are counted as one identifier.
7.	PFE1(a)	There is a cleaning schedule and SOP for the PM suite but it requires sufficient details to ensure all areas within the suite are fully cleaned. The DI is advised to consider adding a checklist to be completed after each clean.
8.	PFE1(e)	The DI is advised to further consider the risks to staff during lone viewings.
9.	PFE2(e)	Whilst the fridge and freezer alarms are tested during annual maintenance and when they occasionally trigger, there are no formalised scheduled tests. The DI is advised to test the system more regularly and ensure that these tests are recorded.
10.	PFE2(f)	The fridge and freezer temperature records are held by estates, the DI is advised to ensure mortuary staff have regular access to reports to allow for trend monitoring.

Concluding comments

Staff involved in the inspection demonstrated a sensitive approach to their work and dedication to providing a good service. Staff also demonstrated a willingness for continual improvement and compliance with the regulatory requirements, and were open to the advice given by the HTA. A number of areas of good practice were observed during the inspection:

- The establishment are in the process of developing a form that can be given to the family, which the funeral directors will need to provide for release. This form records the key identifiers necessary for release and provides assurance that the funeral director that collected the body was the one selected by the family;
- the use of the visitors form for viewings captures sufficient identifiers for the deceased to mitigate the risk of a viewing of the wrong body, whilst also offering families the opportunity to give feedback on their experience;
- the freezers are always locked to ensure they are not used accidentally;
- the use of one way glass at the entrance used by funeral directors allows the staff clear visibility of who is outside before opening the doors while ensuring that others cannot see in to the mortuary, ensuring the privacy of the deceased;
- good relationships have been developed with the Coronial services, which were complementary about the establishment.

There are a number of areas of practice that require improvement, including two major and three 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: 1 November 2017

Report returned from DI: 15 November 2017

Final report issued: 7 December 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: 7 November 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
<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> <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.</p> <p>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.</p> <p>g) The establishment uses an agreed and ratified consent form to document that consent was given and the information provided.</p> <p><i>Guidance</i></p> <p><i>This may be based on the HTA's model consent form for adult post-mortem examinations</i></p>

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 draught) are subject to regular maintenance and records are kept.

Guidance

This includes fridges in Maternity where fetuses or stillborn 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.