Site visit inspection report on compliance with HTA licensing standards

Taunton and Somerset NHS Trust

HTA licensing number 12083

Licensed under the Human Tissue Act 2004 for the

- **making of 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**

29 January 2019

Summary of inspection findings

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

Although the HTA found that Taunton and Somerset NHS Trust (the establishment) had met the majority of the HTA's standards, five minor shortfalls and two major shortfalls were found against the Consent, Governance and Quality systems, Traceability and Premises, facilities and equipment standards.

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

Taunton and Somerset NHS Trust (the establishment) has been licensed by the HTA since April 2007. The establishment is licensed for the making of a post mortem examination, removal of relevant material from the deceased and storage of bodies of the deceased, and relevant material, for use for scheduled purposes. The DI is a Pathologist, the Corporate Licence Holder (CLH) is Taunton and Somerset NHS Trust and the CLH contact is the Chief Executive of the Trust.

The mortuary admits approximately 1,700 bodies per year from the hospital and surrounding area. The establishment conducts approximately 400 post mortem (PM) examinations each year, the majority of which are performed under coronial authority. High-risk cases (category 3), forensic cases and perinatal/paediatric cases are transferred to other HTA-licensed establishments for PM examination.

The hospital offers hospital consented PM examinations of which approximately two are performed per year. Consent for hospital PM examinations is sought by trained members of staff within the bereavement team, in the presence of clinical staff who have been involved in the treatment of the deceased in life. Consent forms are adapted from the HTA's model consent form for adult hospital PM examinations and are accompanied by an information leaflet. Consent for perinatal/paediatric PM examinations is sought by the Bereavement Midwife in the presence of clinical staff. The consent form and information leaflet is based on the Stillbirth and Neonatal Death (Sands) charity documentation.

The mortuary has recently undergone a full refurbishment. It is located in a stand-alone building within the hospital grounds. The entrances to the mortuary are secured by key code access and there is an intercom system to allow entry to visitors (see *Advice,* item 11).

The mortuary receives bodies from the hospital and the community. Bodies from the hospital have a printed identification wristband and are accompanied by a 'Mortuary Admission Form' that has been completed by ward staff. Both the wristband and form contain patient identification details, including their unique hospital number. Portering staff are responsible for the transfer of bodies from hospital wards to the mortuary. On arrival, porters place bodies in an available refrigerated space and complete the bottom section of the accompanying paperwork and leave this form in a designated tray for mortuary staff to check. Bodies admitted from the community have a handwritten wristband attached to the body and a 'Coroners Admission Form', both are completed by police. The details that are included on these are variable (see shortfall against T1(c)). Mortuary staff perform checks of all bodies, verifying the identification on the bodies against the accompanying paperwork and make sure all bodies are appropriately shrouded. Mortuary staff input details into a mortuary register and an electronic database. They are assigned a unique mortuary number, which is used to provide traceability of samples retained at PM examination. Mortuary staff

carry out daily visual checks of the fridges, noting details of any bodies with same and/or similar names and write in a different colour pen on the whiteboard and place a sticker on the fridge door and wristband to alert staff of these bodies. The mortuary only release bodies during normal working hours. Funeral directors must present three identifiers to mortuary staff before a body can be released (see *Advice*, item 8).

The mortuary has 58 refrigerated body spaces, including eight bariatric spaces and five dedicated spaces for the storage of perinatal/paediatric cases. In addition, there are five freezer spaces for bodies that require long-term storage, which can also operate as a fridge, should the establishment require additional refrigerated storage capacity. Body storage temperatures are continually monitored and there is an automated alarm call-out procedure in the event of temperature deviation. One bank of fridges within the main mortuary is not maintained on the automatic temperature monitoring system so staff check and record storage temperatures daily on working days, however, this bank of fridges is connected to the alarm system. The mortuary fridges are new and are currently under warranty after which they will be maintained on service contracts (see *Advice,* item 14). There is an overflow body store facility with temporary units that can accommodate up to 24 bodies. Although this was not in use at the time of the inspection, the temporary units are not alarmed when in use (see shortfall against PFE2(e)).

The PM suite has three PM tables including one for bariatric bodies and three downdraft benches for the preparation of wet tissue samples. The external examination and identification of bodies is always checked by the pathologist and an APT prior to evisceration. Tissue samples taken for histopathological analysis are transferred to the establishment's Pathology Department. PM tissues are tracked by the unique mortuary number. Tissue samples may be kept, if appropriate consent has been given for retention or for use for scheduled purposes, but the establishment does not routinely store samples for use for research.

There is a fridge in the Maternity Department that is used for the storage of fetuses prior to being transferred to the mortuary. The fridge is not currently temperature monitored or connected to an external alarm (see shortfall against PFE2(e)).

Removal of relevant material from bodies takes place in the Accident and Emergency (A&E) Department in cases of sudden unexpected death in infancy and children (SUDIC) under pre-emptive coronial authority. The A&E Department manages approximately ten SUDIC cases each year. In such cases, body fluids and swabs are removed by paediatric consultants in a specified area within the department; documented procedures are available for staff to refer to. Samples are packaged with pre-printed identification labels and transferred immediately to the Cellular Pathology Department.

Inspection activities undertaken

The last HTA site visit inspection of Taunton and Somerset NHS Trust was in July 2015. This report describes the third, routine site visit inspection of the establishment. The inspection team interviewed staff involved with licensable activities, reviewed documentation and conducted a visual inspection of the mortuary, the Maternity Department and the storage areas of PM tissue blocks and slides.

Audits were conducted for four bodies in refrigerated storage; two from the hospital, one from the community and one perinatal case. Body location and identification details on bodies were crosschecked against the information recorded in the mortuary register and relevant documentation. Although no discrepancies were found, the community body and perinatal case only had two identifiers on the wristband (see shortfall against T1(c)).

Audits of traceability were conducted for tissue blocks and slides from four PM cases, including audits of the consent documentation for the retention of these tissues. No discrepancies in the traceability of these tissues were found. However, a discrepancy was identified in the consent documentation in one case; the family had agreed to both disposal and retention of PM tissue, and part three of the consent form had been omitted (see shortfall against T2(c)).

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
C1 Consent is obtained in accordance with the requirements of the Human Tissue Act 2004 (HT Act) and as set out in the HTA's codes of practice		
a) There is a documented policy which governs consent for post-mortem examination and the retention of tissue and which reflects the requirements of the HT Act and the HTA's Codes of Practice.	The Trust policy detailing the procedure for hospital consented PM examinations does not accurately reflect the consent requirements of the HT Act 2004. Although there is reference to the hierarchy of qualifying relationships, the policy also refers to the next of kin. *The HTA did not find evidence that the establishment has removed, used or stored relevant material without consent from the appropriate person under the HT Act; however, the establishment's procedures, if followed, have the potential to result in a statutory breach of the HT Act.* In addition, the document DGM_1050 'Request for hospital post mortem' references the HTA's old Code of Practice for Consent, Code 1. (see *Advice,* item 1*)*	**Minor**
b) There is a documented SOP detailing the consent process (including who is able to take consent, what training they must receive, and what information must be provided to those giving consent for post mortem examination).	The mortuary SOP detailing the procedure for hospital consented PM examinations does not accurately reflect the consent requirements of the HT Act. The procedures for requesting a PM examination and gaining informed consent refer to the next of kin, not the correct person in the hierarchy of qualifying relationships. SOP DTP_S010 details that blood samples can be taken without consent if either pathologist or APT injures themselves during the PM procedure. *The HTA did not find evidence that the establishment have removed, used or stored relevant material without consent from the appropriate person under the HT Act; however, the establishment's procedures, if followed, have the potential to result in a statutory breach of the HT Act.* (Refer to *Advice,* item 1)	**Minor**

GQ2 There is a documented system of audit

c) Regular audits are carried out of tissue being stored so that staff are fully aware of what is held and why and enable timely disposal of tissue where consent has not been given for continued retention.	Although the establishment have a documented schedule of audits, they do not cover audits of PM tissue (histological blocks and slides). (Refer to *Advice,* item 5)	**Minor**

GQ3 Staff are appropriately qualified and trained in techniques relevant to their work and demonstrate competence in key tasks		
c) Staff are assessed as competent for the tasks they perform.	Staff are competency assessed for the jobs that they undertake, however, there is no schedule of competency refreshment; this should be included as part of continued staff development and training.	**Minor**

T1 A coding and records system facilitates traceability of bodies and human tissue, ensuring a robust audit trail		
c) Three identifiers are used to identify bodies and tissue, (for example post mortem number, name, date of birth/death), including at least one unique identifier.	Although the SOP states that three identifiers are checked prior to PM examination or release of a body to funeral directors, community and perinatal bodies are not consistently identified using three identifiers. During the HTA audit, two bodies were identified using only two identifiers. In addition, families are not being asked to provide three identifiers when attending the establishment to undertake viewings, often only the name is requested. There is a risk of releasing, performing a PM examination or viewing a wrong body if they are not sufficiently labelled or checked using three identifiers. (see *Advice,* items 8 and 9)	**Major**

T2 Disposal of tissue is carried out in an appropriate manner and in line with the HTA's Codes of Practice		
c) Disposal is in line with the wishes of the deceased's family.	One of the four PM cases audited during the inspection was a hospital consented case. The consent form had been completed incorrectly; the option for disposal and retention has been completed, making the consent for retention and use of the tissue ambiguous. The inspection team could not find any evidence that the tissue had been used for scheduled purposes. The tissue should be disposed of unless appropriate consent for its retention and use is obtained.	**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 and lower set range.	The fridge in the Maternity Department which may be used for the temporary storage of fetuses, is not temperature monitored or connected to an external alarm, to alert staff to deviations in temperature or if it is failing. There is a freezer within the mortuary that stores material as part of medical records. It is not temperature monitored or connected to an external alarm. Although not in use at the time of the inspection, the contingency body store facility is not temperature monitored or connected to an external alarm when in use.	**Major**

Advice

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

No.	Standard	Advice
1.	C1(a)	The 'next of kin' may not be the person ranked highest in the hierarchy of qualifying relationships under the Section 27(4) of the HT Act. Policies, SOPs, consent forms and information leaflets should all reflect this. Information on the consent requirements of the HT Act can be found in HTA Code of Practice A – Guiding Principles and Fundamental Principle of Consent, which is available on the HTA's website.
2.	GQ1(e)	Although SOPs are reviewed regularly, if there are no changes to the document they are not redistributed to staff. The DI is advised to redistribute all SOPs regularly as part of refresher training for staff even when processes are unchanged.
3.	GQ1(g)	Although there are people responsible for oversight of licensable activities in the Maternity Department and in the A&E Department, the DI is advised to formally add them as Persons Designated (PD) to the licence and include them in HTA-related meetings.
4.	GQ2(a)	The most recent audit (November 2018) was carried out against the HTAs old standards. The DI is advised to audit against the new standards that came into force on April 2017.
5.	GQ2(c)	In addressing the shortfall against standard GQ2(c), the DI should audit the tissue being stored so that staff are fully aware of what is held and why and enable timely disposal of tissue where consent has not been given for continued retention. Audits should include a review of the consent documentation to identify any discrepancies that may identify areas where additional training may be needed.
6.	GQ6(a)	As with SOPs, the DI is advised to redistribute all reviewed risk assessments to relevant staff even when they remain unchanged.

7.	T1(a)	Although there is a unique mortuary number assigned to bodies, it is not included on the wristband. The DI may wish to add the unique number to the wristband to help strengthen traceability of bodies while in the care of the mortuary.
8.	T1(c)	The DI may wish to consider introducing a standardised release form for funeral directors that is completed by them prior to arrival at the mortuary and brought in addition to other documentation brought by the funeral director. This form could contain the required three identifiers to release a body.
9.	T1(c)	The DI may wish to consider introducing a form for viewings that relatives complete with the required three identifiers. By recording this information, these identifiers can be checked when preparing the body and immediately prior to a viewing taking place to help mitigate the risk of viewing a wrong body.
10.	PFE1(c)	The mortuary has cleaning records for the PM room and body store area. However, the fridges and freezers are cleaned as and when they are empty. The DI is advised to implement a cleaning schedule and record the cleaning of body store fridges to help ensure that all fridges are cleaned on a rotational basis.
11.	PFE1(d)	The establishment have told the HTA that CCTV is being fitted as part of a security review, the DI is advised to ensure that this work is carried out in a timely manner.
12.	PFE1(d)	The procedure for lone working appears sufficient for the rare occasions mortuary staff are required to work alone, particularly out-of-hours, However, although lone working is rare, the DI is advised to look at ways in which the safety of staff can be improved. For example, using a personal alarm in addition to carrying a mobile phone.
13.	PFE2(i)	Although the establishment's contingency storage is sufficient to meet their needs during peak times the DI is advised to formalise arrangements (with funeral directors or neighbouring hospitals) should the establishment reach maximum capacity.
14.	PFE3(f)	The DI should ensure that when the warranties expire for key items of equipment (such as fridges, freezers, trollies and PM tables) they are subject to regular maintenance, records are kept and these are available to the mortuary staff.
15.	N/A	The DI is advised to suggest to all staff working under the licence to subscribe to the HTA monthly newsletter, via the HTA website, to keep abreast of relevant information for the areas they work in.

Concluding comments

The HTA observed some areas of strength and good practice throughout the inspection. 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 continuous improvement and compliance with the regulatory requirements, and were open to the advice given by the HTA.

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

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

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

Report sent to DI for factual accuracy: 22 February 2019

Report returned from DI: 08 March 2019

Final report issued: 14 March 2019

Completion of corrective and preventative actions (CAPA) plan

Based on information provided, the HTA is satisfied that the establishment has completed the agreed actions in the CAPA plan and in doing so has taken sufficient action to correct all shortfalls addressed in the Inspection Report.

Date: 01 July 2019

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.