Site visit inspection report on compliance with HTA licensing standards

Royal Blackburn Hospital

HTA licensing number 12309

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**

21 - 22 February 2018

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 The Royal Blackburn Hospital had met the majority of the HTA's standards, two major shortfalls were found against the Premises, facilities and equipment standards and ten minor shortfalls were found against Governance and quality systems and Premises, facilities and equipment standards.

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

The HTA's regulatory requirements

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

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

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

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

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

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

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

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

Background to the establishment

This report refers to the activities carried out at the Royal Blackburn Hospital (the establishment) which has been licensed by the HTA since June 2008. It is licensed for the making of a post-mortem (PM) examination, removal from the body of a deceased person of relevant material for use for a scheduled purpose and storage of the body of a deceased person or relevant material for use for a scheduled purpose.

The Designated Individual (DI) is the Mortuary Manager and the Corporate Licence Holder is East Lancashire Hospitals NHS Trust. The mortuary is staffed by a Mortuary Manager and two Anatomical Pathology Technologists (APTs).

The establishment undertakes approximately 1,045 adult PM examinations per year including high-risk PM examinations. The establishment does not undertake perinatal PM examinations; these are transferred and conducted at another HTA-licensed establishment. Consent for perinatal PM examination is sought by clinical staff at another hospital within the establishment's Trust, using a consent form and information leaflet based on those developed by the Stillbirth and Neonatal Death (Sands) charity. No adult hospital (consented) PM examinations have been undertaken by the establishment since the last HTA inspection. There is a Hospital Consent Policy, documented procedure and consent form in place, which comply with the requirements of the Human Tissue Act 2004.

The establishment consists of a body store, a PM room and two viewing rooms. There is CCTV outside the mortuary which is used monitor the external entrance to the hospital. The mortuary is secured by swipe card or keypad controlled doors, with access restricted to designated Trust personnel and funeral directors (FDs). There is a panic alarm system, which is linked to security staff for use when staff are working alone in the mortuary or conducting out of hours viewings.

The mortuary has storage capacity for 92 bodies, including eight refrigerated spaces for bariatric bodies and four spaces which are used for frozen storage (see shortfall against standard PFE2(c)). The locations of bodies, including perinatal/paediatric cases are indicated on the body location whiteboard in the body store. Establishment staff record the temperatures of the storage fridges and freezers daily and review these records regularly so that any trends in performance can be identified. The establishment has an audible temperature alarm system to alert staff to temperature deviations from the expected ranges. If the storage temperatures deviate from the expected ranges during out of hours periods, the alarm system automatically alerts the Trust's security team who in turn, notify mortuary staff. Although the alarm system is tested regularly, these tests do not include verification that an out of hours alarm is responded to appropriately or that establishment staff are contacted as expected (see *Advic*e, item 11).

The establishment has a contingency escalation plan covering instances where additional storage capacity is required, for example, during busy periods. At the time of the inspection, this plan had been activated and a refrigerated temporary storage unit had been deployed. The unit was not alarmed and the temperature of the unit was not being regularly monitored (see shortfall against standard PFE2(f)).The unit was locked and was situated in an unlocked gated area; therefore, access to the refrigeration controls at the rear of the unit was not secure (see shortfall against standard PFE1(d)).

The mortuary uses a paper mortuary register to record details of bodies admitted to, and released from, the establishment. This paper record is backed up by an electronic system. The transfer of bodies into contingency storage is also recorded (see *Advice*, item 4). Bodies from community deaths are transported to the mortuary by the Coroner's contracted funeral director (FD), including during out of hours periods. The contracted FD completes the relevant paperwork and enters the fridge tray number onto a form which is posted into a secure box. During the following working day, mortuary staff check the identity details on the bodies against the paperwork and enter the deceased's details into the mortuary register. The establishment has a system to identify bodies with same or similar names to help minimise the risk of misidentification in such cases. Only trained mortuary staff release the deceased to FDs using details on the green release form or coroner's cremation/order for burial form.

The Maternity and Antenatal departments are located at another site within the Trust. Products of conception are transferred to the mortuary from the Histopathology laboratory and are stored in a dedicated area prior to either sensitive disposal or collection by the family. Perinatal and paediatric cases are transferred directly to the mortuary for transport to another HTA-licensed establishment for PM examination and are not stored elsewhere within the hospital.

The establishment's PM suite has three downdraft tables with dedicated areas on each table for the examination of organs and preparation of tissue samples. APTs complete the visual inspection of the body prior to evisceration by the pathologist (see shortfall against standard GQ1(b)). High risk PM examinations of bodies with known infections will be performed once all other PM examinations for that day have been completed. Tissue taken during PM examination is transferred to the establishment's Pathology laboratory for histological analysis or to other establishments for toxicological and other specialist analysis. If appropriate consent has been given, tissue may be stored within the mortuary for use for scheduled purposes. The establishment uses paper and electronic records to record sample details, disposal details and wishes of the family obtained by the Coroner regarding the fate of tissue once coronial authority has ended.

Removal of tissues from deceased children, in cases of sudden unexpected death in infancy is not performed at the establishment. These cases are transferred to another HTA-licensed establishment.

Description of inspection activities undertaken

This report describes the third, routine HTA site inspection visit of the Royal Blackburn Hospital. The inspection team conducted visual inspections of the mortuary, contingency body store, interviewed staff involved with licensed activities and reviewed documentation.

A traceability audit was conducted on three adult bodies and one paediatric body that were in the establishment's body storage facility. Of the adult bodies, one was from a community death, one had a similar name to another body in storage and one was in frozen storage. These audits included cross-checking records of storage locations and identifiers recorded in the paper mortuary register against the details on the bodies and their actual fridge/ freezer storage locations. No discrepancies were identified. A traceability audit was also performed on tissue taken during PM examinations and which had been retained. This included a review of records relating to the tissue held electronically and relevant consent documentation (coronial family wishes forms). No anomalies were found.

Inspection findings

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

Compliance with HTA standards

Standard	Inspection findings	Level of shortfall
GQ1 All aspects of the establishment's work are governed by documented policies and procedures		
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.	Some of the SOPs covering key mortuary procedures do not contain sufficient detail of the procedures that staff must follow. Examples include but are not limited to: • the point at which bodies are transferred into long-term storage is not covered in any SOP; • the SOP for viewing of bodies does not describe what information is required from the family which can be used by establishment staff to perform the identification checks when locating the deceased; • there are no lone working or incident reporting SOPs. All SOPs relating to licensed activities should be reviewed, and amended accordingly, so that they are accurate and reflect current practice. (see *Advice*, item 2)	**Minor**
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	The external examination of bodies prior to PM examination is performed by the Mortuary Manager or the APT rather that the pathologist. This practice is contrary to the Royal College of Pathologist's guidelines on the conduct of a PM examination. (see *Advice*, item 1)	**Minor**
h) Matters relating to HTA-licensed activities are discussed at regular governance meetings involving establishment staff	Although governance meetings are held by departments engaged in licensed activities, these meetings do not cover all matters relating to the HTA licence and the DI does not attend regularly or receive minutes. *(*see *Advice,* item 3)	**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 to enable timely disposal of tissue where consent has not been given for continued retention	The establishment has identified some cases where a Coroner's authority has ended and the family wish to collect and dispose of PM samples. Consent has not been given for continued storage and the samples are being stored pending collection. The establishment is advised to follow up these cases and ensure timely disposal of samples where families do not collect the samples within a defined timeframe.	**Minor**

GQ3 Staff are appropriately qualified and trained in techniques relevant to their work and demonstrate competence in key tasks		
g) Visiting / external staff are appropriately trained and receive an induction which includes the establishment's policies and procedures	Access to the mortuary and the undertaking of mortuary procedures should be restricted to those external staff (such as funeral directors admitting bodies out of hours) who have been trained, and their competencies assessed, by mortuary staff.	**Minor**

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	The establishment's documented risk assessments do not cover all mortuary activities and the risks of incidents associated with these activities. For example, the following risks have not been assessed: • accidental damage to a body; • viewing of the wrong body; and • PM examination on the wrong body. When risk assessments have been completed, the assessments of risks and the measures put in place to mitigate against them should be incorporated into mortuary procedures and practices. (see *Advice,* item 5)	**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	The establishment's procedures for identification of bodies do not always use a minimum of three identifiers. Examples of when three identifiers may not be used include identification checks when undertaking viewings and when releasing bodies to funeral directors This poses a risk of misidentification of the deceased. (see *Advice*, item 6)	**Minor**

PFE1 The premises are secure and well maintained and safeguard the dignity of the deceased and the integrity of human tissue.		
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)	The contingency storage unit, although locked, is located in an insecure area. Free access can be gained to the refrigeration unit controls at the rear of the unit, which poses a risk to the maintenance of storage conditions and integrity of bodies if these were to be inappropriately changed. (see *Advice*, item 8)	**Minor**

PFE2 There are appropriate facilities for the storage of bodies and human tissue.		
a) Storage arrangements ensure the dignity of the deceased	The temperature of refrigerated units within the body store is currently maintained at 8°C. The HTA's guidance states that body storage fridges should be at a temperature of approximately 4 °C. (see *Advice*, item 9)	**Minor**
c) Storage for long-term storage of bodies and bariatric bodies is sufficient to meet needs	The establishment has four freezer spaces for the long-term storage of bodies however one cannot be used due to the continual accumulation of ice, despite maintenance and one is left empty for forensic cases. This leaves only two available frozen storage spaces, which is not sufficient to meet the needs of the service; at the time of the inspection, the two freezer spaces were occupied and there were four bodies in refrigerated storage that required frozen storage. (see *Advice*, item 10)	**Major**

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 contingency storage unit, when in use, is not being monitored daily and is not alarmed. This poses a risk to the integrity of stored bodies.	**Major**
f) Temperatures of fridges and freezers are monitored on a regular basis		

PFE3 Equipment is appropriate for use, maintained, validated and where appropriate monitored		
c) The ventilation system provides the necessary ten air changes per hour and is checked and maintained at least annually	At the time of inspection, mortuary staff were unable to provide service records or other documentation confirming that the ventilation system provides the necessary ten air changes per hour.	**Minor**

Advice

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

No.	Standard	Advice
1.	GQ1(b)	The DI is should ensure that a thorough external examination of the body is carried out by the pathologist prior to evisceration in all cases. Related SOPs on PM procedures currently state this and should be adhered to in practice.
2.	GQ1(d)	At the time of inspection, many but not all SOPs were reviewed by someone other than the author. The DI is advised that all policies and SOPs should be reviewed regularly by someone other than the author. The DI is also advised to ensure all staff acknowledge they have read all updated documents.
3.	GQ1(h)	The DI is advised to make mortuary matters a standing item on the monthly Pathology Meeting agenda to raise awareness of HTA-related matters more widely.
4.	GQ4 (b)	When bodies are transferred to the contingency storage unit, this is recorded in the mortuary register in pencil. The DI is advised to record this in a more permanent way to help mitigate the risk of such records being inadvertently lost.
5.	GQ6(a)	The DI is advised that HTARI categories may provide a useful reference for staff when considering what risks may be present when undertaking licensed activities. The HTA's guidance document 'Regulation of the PM sector 2014-16; What we have learned' provides further advice on risk assessments in this sector which the DI may wish to consider.
6.	T1(c)	In addressing the shortfall identified against standard T1(c), the DI may wish to consider introducing a form to gather information regarding the identity of

		the deceased from the family in a way that is sensitive and that can be used when establishment staff identify bodies. The DI may also wish to consider implementing a standardised release form that could be given to bereaved families and passed onto their appointed funeral director. This form could be completed by the family and could include at least three identifiers which could be referred to by establishment staff when releasing bodies.
7.	T1(h)	The DI is advised to ensure there are documented procedures for transportation of bodies anywhere outside the mortuary, (such as another establishment), including record-keeping requirements.
8.	PFE1(d)	The DI is advised to secure the gated access to the contingency storage unit, which may help in increasing security around the unit.
9.	PFE2(a)	In addressing the shortfall identified against this standard, the DI is advised to investigate whether the refrigerator temperature probes are recording and reporting the actual fridge temperature accurately.
10.	PFE2(c)	In the event that a body cannot be moved into long-term freezer storage within the 30 days, the DI is advised to log the reason and make a note of the condition of the body as part of an audit of long stay bodies. The DI is advised to review the establishment's contingency plan for storage capacity to consider whether it could be strengthened by additional contingency arrangements. The contingency plan should include arrangements for frozen storage contingency capacity. Further advice on contingency storage arrangements can be found in the HTA's guidance document 'Storage capacity and contingency arrangements in mortuaries: Guidance for DIs in HTA-licensed establishments'.
11.	PFE2(e)	Although the mortuary storage units are connected to a temperature monitoring alarm and this system is tested during working hours, the alarm system is not tested regularly to verify that mortuary staff are notified by security out of hours.
12.	PFE3(d)	Although PPE is available to staff in the main facility, the DI is advised to consider providing gloves in the contingency storage area.

Concluding comments

- Staff demonstrated a willingness for continual improvement and compliance with the regulatory requirements, and were open to the advice given by the HTA.
- Staff working under the licence appeared to work well as a team with good communication.
- Staff involved in the inspection, including mortuary staff and clinical staff seeking consent for perinatal PM examinations, demonstrated a sensitive approach to their work and dedication to providing a good service.
- There is a sensitive and caring approach to the management of perinatal cases and delicately decorated caskets in a variety of sizes are available for families to use.

There are a number of areas of practice that require improvement, including two major shortfalls about the long-term storage of bodies and the monitoring of the contingency

storage unit, and ten minor shortfalls. Advice has been given against a wide range of standards.governance and quality, traceability and premises, facilities and equipment.

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.

Report sent to DI for factual accuracy: 22 March 2018

Report returned from DI: 5 April 2018

Final report issued: 16 April 2018

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: 20 June 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 they are placed back into normal storage.

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

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

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

   ii. receipt upon return to the laboratory or mortuary

   iii. the number of blocks and slides made

   iv. repatriation with the body

   v. return for burial or cremation

   vi. disposal or retention for future use.

Guidance

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

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

Guidance

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

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

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

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

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

Guidance

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

this purpose.

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

d) The method and date of disposal are recorded.

Premises, facilities and equipment

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

a) The premises are clean and well maintained.

Guidance

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

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

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

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

Guidance

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

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

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

a) Storage arrangements ensure the dignity of the deceased.

Guidance

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

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

Guidance

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

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

Guidance

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

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

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

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

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

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

Guidance

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

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

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

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

Guidance

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

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

assessments and same/similar name systems.

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

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

Establishments should consider entering in to Mutual Aid Agreements

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

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

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

   i. fridges / freezers

   ii. hydraulic trolleys

   iii. post mortem tables

   iv. hoists

   v. saws (manual and/or oscillating)

Guidance

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

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

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

Guidance

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

d) Staff have access to necessary PPE.

Guidance

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

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

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

Guidance

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

Appendix 2: Classification of the level of shortfall

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

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

1. Critical shortfall:

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

or

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

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

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

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

(3) A notice of suspension of licensable activities

(4) Additional conditions being proposed

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

2. Major shortfall:

A non-critical shortfall that:

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

or

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

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

3. Minor shortfall:

A shortfall which cannot be classified as either critical or major, but which indicates a

departure from expected standards.

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

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

Follow up actions

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

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

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

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