Site visit inspection report on compliance with HTA licensing standards

St Pancras Public Mortuary

HTA licensing number 12445

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**

6 March 2019

Summary of inspection findings

This is the first inspection of this establishment against the HTA's revised licensing standards, which came into force on 3 April 2017.

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

Although the HTA found that St Pancras Public Mortuary had met the majority of the HTA's standards, three major and thirteen minor shortfalls were found against standards for Governance and Quality, Traceability and Premises, Facilities and Equipment.

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

St Pancras Public Mortuary (the establishment) has been licenced by the HTA since May 2007, this report describes the third routine inspection with a non-routine inspection following refurbishment works occurring in February 2015. The current DI has been in post since February 2019 and this is their first HTA site visit inspection as DI.

The mortuary admits bodies from the local community via two local Coroner's contracted funeral director companies. Access to the mortuary by funeral directors (FDs) is via concertina doors and an adjacent pedestrian access door off a main road and pedestrian walkway. This entrance is overlooked by a new high-rise housing development on the opposite side of the road. The doors open into a canopied external car port area leading to a key code access door at the rear of the mortuary. FDs access the car port area through the pedestrian door and open the concertina doors using keys kept in the doors. Vehicles reverse into this area and the entrance doors are pulled to the vehicle to help shield activity occurring in the car port area from public oversight (see shortfall against PFE1(e)).

There is a platform lift to raise bodies on FD trolleys up to the level of the entrance door of the mortuary and steps for pedestrian access. A key pad controlled door also leads from this area to the viewing gallery of the post mortem (PM) suites. Once inside the mortuary FD's have access to the main body store area which is controlled by electric doors. A lockable door prevents access by FDs to the rest of the mortuary and other body store areas outside of normal working hours.

Out-of-hours FDs admitting bodies from the community are responsible for identifying a fridge location and transferring the body into refrigerated storage. A body admission sheet is completed and placed into the plastic wallet for the relevant fridge location and placed into the door pocket of the corresponding fridge. Two banks of fridges are identified with black and yellow tape which should be used first by FDs bringing bodies in from the community. Once these banks of fridges are full or if the body is of bariatric size, two further adjacent fridges are used. During working hours, the mortuary staff review the mortuary occupancy checklist and complete body identity checks of all bodies admitted to the mortuary.

Release of bodies is only conducted by the mortuary staff in normal working hours. The establishment is contracted to facilitate a PM examination service for two Coronial districts. There are two visiting pathologists who attend the establishment to conduct PM examinations authorised by either of the two Coroners the mortuary serves. There are two full-time Anatomical Pathology Technologists (APTs) and a locum APT. One of the full-time APTs is the Mortuary Manager and current DI.

The establishment receives approximately 400 bodies per year from the community, all of which are for PM examination, including high-risk (up to biological hazard group 3) and defence (second PM examination) cases. Forensic PM examinations are also performed and

material is held under the Police And Criminal Evidence Act 1984 (PACE) at the establishment. No perinatal or paediatric cases are received into this establishment.

The body store consists of 69 refrigerated spaces, ten of which are suitable for bariatric cases and a further three which can accommodate super-bariatric cases. All the refrigerated units can switch to freezers but generally only ten are used as freezers when required. In addition, there are ten dedicated freezer spaces and the main body store area can be converted to a cold room with temporary racking for an additional 24 bodies to be refrigerated.

All fridges and freezers are alarmed with upper and lower trigger points, which when triggered sound in the mortuary and calls a dedicated mobile phone carried by the Mortuary Manager or on-call APT in her absence. If the dedicated phone is not answered the alert call is diverted to personal mobile phones of the two permanent members of staff (see shortfall against PFE2(e)).

The mortuary has two PM suites, one of which is used for high-risk and forensic PM examinations. The main PM suite has three height adjustable downdraught PM tables and three height adjustable dissection benches (see *Advice* item 7). The pathologist completes each PM examination prior to commencing the next to help mitigate the risk of mixing-up organs and tissue samples (see *Advice* item 6). The Coroner's Office email authorisation for a PM examination to the mortuary and the pathologist. The pathologist and APT check the identity of the body before the external examination and evisceration of the body (see shortfall against T1(c)).

Material retained at PM examination for histological analysis is labelled, documented, packaged and sent to other HTA-licensed establishments. A telephone call is made by the mortuary to the receiving establishment to inform them samples are being sent. In the event that samples are not received by the receiving establishment, a telephone call is made to the mortuary to inform them the samples have not arrived. Relatives' wishes with regards to the fate of any tissue retained following PM examination is managed by the Coroner's Office. The pathologist informs the Coroner of what material has been retained which is then communicated to the family. Consent for the fate of any tissues retained at PM examination is initially taken verbally and then confirmed in writing by the Coroner's Office. The Coroner's Office inform the mortuary and the establishment analysing the retained material of the families wishes (see shortfalls against T2(a) and T2(d)). Spleen and other tissues are sometimes taken in cases which may have a future bearing on family members; this material is retained at the establishment in a dedicated -80^{o}C freezer. Where appropriate consent has been given, blocks and slides are stored for use for scheduled purposes at the HTA licenced establishments where analysis is completed.

Description of inspection activities undertaken

Traceability audits of body identifiers, storage locations and mortuary checklist details were conducted for four adult bodies, these included two bodies from the freezer. The names of the bodies were written on the admission paper work and Coroner's PM examination authorisation paperwork held in the plastic folder in the door sleeve of the relevant fridge or freezer door. Discrepancies in the spelling of the first name of one body audited was found between the two wrist bands attached to the body.

In addition, tissue removed during PM examination for seven cases between 2015 and 2018 were audited for traceability. Material removed is recorded on the histology record sheet and held in the file for the individual case. A list of fresh frozen material retained following a PM examination is held by the establishment and updated when material is disposed, however no records of tissue which has been disposed are held (see shortfall against T2(d)). Of the seven cases audited, for one case, tissue was being retained despite wishes from the family for disposal. A further two cases from 2017 were identified where no consent wishes were available at the time of inspection for review (see shortfall against T2(a)).

Interviews were conducted on the day of the site visit inspection with the Mortuary Manager (the DI); an APT; Pathologist and Coroner's Officer's Manager (by telephone).

Material held for the police

Under s39 of the Human Tissue Act 2004, relevant material held for criminal justice purposes is outside the scope of HTA regulation and is not subject to the licensing requirements for storage. However, in response to a recommendation resulting from the 2012 report of the Association of Chief Police Officers' audit of tissue held under police authority, police exhibits held on HTA licensed premises are included within the regular HTA inspection process. Police holdings stored at the establishment were reviewed by the HTA during the inspection. Any findings in relation to police holdings have been shared with the Home Office, but do not appear in this report as they are outside the scope of the HT Act.

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

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.	While the establishment has a number of the required SOPs in place, they lack sufficient detail or attention to wording, these include but are not limited to: • Preparation of bodies for PM examination by the APT carried out on behalf of a supervising pathologist SOP - Does not state what three identifiers on the body should be checked and cross referenced against the Coroner's instruction for PM examination; • Body viewing SOP - Does not state that three identifiers should be obtained from those wishing to view a body and that this information should be cross referenced with the information on the wristband of the body prior to viewing; • Body Storage SOP – States the fridge to freezer units are set with an upper temperature limit of -2^{o}C and lower limit of -7^{o}C. The SOP should be adjusted to reflect the recommended temperature range for the long-term storage of bodies; • Management of retained material at St. Pancras Public mortuary – refers to the previous DI. This should be reviewed and updated to reflect current arrangements; • Disposal SOP – states all identifiers should be removed from containers containing relevant material and stored until the material can be sent for lawful and sensitive disposal. The removal of all identifiers from containers containing relevant material present a risk of the inadvertent disposal of the wrong tissue and loss of traceability. All SOPs require review to ensure they are robust and reflective of current practice.	**Minor**

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	The majority of SOPs are not version controlled and do not identify an authoriser who should be someone different from the author. They also do not state an active from date or a review date. Hard copies of the SOPs are printed and are available for reference by staff. The lack of document version control increases the risk of staff deviating from local procedures due to incorrect versions of SOPs being used as a reference.	**Minor**
e) There is a system for recording that staff have read and understood the latest versions of these documents	While there is a signatory sheet at the back of each SOP to state users have read and understood the SOP, at the time of inspection staff had not signed these sheets. Therefore the DI cannot be assured that staff are aware and following the procedures that govern their work.	**Minor**

GQ2 There is a documented system of audit		
a) There is a documented schedule of audits	While there is a schedule of audits, staff adherence to establishment SOPs is not monitored. The DI can therefore not be assured that current procedures are being followed and deviations from set procedures are identified and corrective actions are undertaken.	**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	While staff are trained for the tasks they perform, staff are not regularly competency assessed to ensure they are following procedures correctly.	**Minor**
d) Staff have annual appraisals and personal development plans	Staff do not have annual appraisals or documented personal development plans.	**Minor**

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	While paper copy records are held for each individual case on site, there is no system in place which determines how records should be kept, how long they should be stored and where or how they should be stored. Historic case records are currently stored in the PM suite viewing gallery, access to which is through a key code entry system. However, the code for this area is the same as the one used by FDs who bring bodies from the community to the mortuary.	**Minor**
b) There are documented SOPs for record management which include how errors in written records should be corrected.	No SOP was available at the time of inspection that details how records should be maintained or how written records should be corrected.	**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	While risk assessments are conducted for a number of procedures, not all risks have been identified for each procedure and not all procedures have an associated risk assessment. These include but are not limited to: • Conducting a PM examination on the wrong body; • Viewing of the wrong body; • Inadvertent disposal or retention of tissue against the wishes of the family; • Major equipment failure; • Serious security breach.	**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	Three identifiers are not used to identify bodies prior to commencement of a PM examination. The wrist band on bodies brought in from the community have the name (if known), address or place found and Coroner's reference number. Until the Coroner's authorisation documentation has been received the mortuary are unable to use the Coroner's reference number as an identifier for the deceased. Establishment staff only use two identifiers which can be found on the wristband on the body and the Coroner's PM examination authorisation form. In addition, bodies are viewed after staff are provided with only verbal communication of the identity of the deceased from those visiting the mortuary. No further identification check of the body is performed prior to the viewing. These practices increase the risk of conducting a PM examination or viewing of a wrong body. The establishment is required to review its current systems to ensure three identifiers are available to identify a body prior to PM examination and viewing.	**Major**

T2 Disposal of tissue is carried out in an appropriate manner and in line with the HTA's codes of practice.		
a) Tissue is disposed of as soon as reasonably possible once it is no longer needed, such as when the	During the inspection cases were identified where tissue taken at PM examination had been retained despite the Coroner's authority being concluded	**Major**

coroner's or police authority over its retention ends or the consented post-mortem examination process is complete.	and the wishes of the family is for all tissue to be disposed of sensitively. The establishment is required to complete the audit of tissues undertaken by the inspection team and provide evidence to the HTA.	
b) There are effective systems for communicating with the Coroner's Office, which ensure tissue is not kept for longer than necessary	A number of cases were identified where the notification of completion of the Coroner's authority was not known and tissue was continuing to be retained. Cases were identified where it is more than 18 months since the PM examination.	**Major**
d) The method and date of disposal are recorded	While records are kept for the repatriation or return of tissues to a family following PM examination, no centralised records are kept for tissue disposed of by the establishment. This means that the establishment cannot readily provide evidence that tissue has been disposed of as requested.	**Minor**

PFE1 The premises are secure and well maintained and safeguard the dignity of the deceased and the integrity of human tissue.		
e) Security arrangements protect against unauthorized access and ensure oversight of visitors and contractors who have a legitimate right of access	The purpose built car port area is currently used by the DI to park their car. This prevents the FDs from reversing their vehicles fully into this area so the outer concertina doors cannot be closed. There is a risk that unauthorised persons could access the mortuary and residents and passers-by could view movement of bodies in and out of the mortuary.	**Minor**

PFE2 There are appropriate facilities for the storage of bodies and human tissue.		
a) Storage arrangements ensure the dignity of the deceased	Bodies stored for more than 28 days are moved to the freezer storage facilities. When no permanent freezer storage spaces are available, a designated bank of fridges are converted to freezers. However, these convertible fridge/freezer units are currently set with an upper temperature limit of -2^{o}C and lower limit of -7^{o}C when in freezer mode. This temperature is not sufficient to help prevent the deterioration of bodies and therefore should be lowered to the recommended -20^{o}C (+/- 4^{o}C).	**Minor**

e) Fridge and freezer units are alarmed and the alarms are tested regularly to ensure that they trigger when temperatures go out of upper or lower set range	The fridge/freezer alarm system is not manually challenged by the establishment staff. The cold room contingency storage system has never been activated or the alarm system challenged for functionality. The fridge/freezer alarm system is only challenged once annually as part of the routine maintenance testing and may not necessarily provide the DI with sufficient assurance that the alarm will trigger when required. In addition, all alarm challenges should be recorded.	**Minor**

Advice

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

No.	Standard	Advice
1.	GQ4(a)	All records relating to bodies, tissue retained at PM examination and communications from the Coroner's Office are currently stored as individual paper files for each case. The DI is advised to review the robustness of this system and the ease of identifying retained material that should be disposed of in accordance with the family's wishes.
2.	GQ6(a)	There is no mortuary register book and the information stored on the daily checklist is not held electronically. Staff rely on the documents held in the fridge door pockets and the daily checklist to identify the bodies currently being stored by the establishment. The DI is advised to risk assess not using an electronic system for the back-up of the daily checklist and consider the benefits of storing this information electronically
3.	T1(c)	The unique mortuary number is used as an additional identifier for bodies while in the care of the mortuary once the Coroner's reference number has been received. The DI may wish to consider adding the unique mortuary number to the wrist band of bodies at the point of booking in. This number will help distinguish unknown bodies until they are formally identified or differentiate bodies with same and/or similar names.
4.	T1(c)	The DI may wish to consider adding the address information to the daily check sheet list held for all bodies in the mortuary. This would provide an additional identifier for the deceased to be identified while in the care of the mortuary and the Coroner's information has not been received.
5.	T1(d)	While a laminated coloured card is added to the record file in the door holder of anybody with a same/similar name, the DI may wish to consider adding a coloured wrist band to the body. This would highlight to those identifying the body extra caution should be taken on checking the identity, thus helping to mitigate the risk of misidentification of the body.
6.	T1(g)	The DI may wish to consider using a labelling system for bowls used to collect organs during the PM examination procedure to further mitigate the risk of organ mix-up during examination.
7.	PFE1(a)	The design of the height adjustable dissection benches has meant there are gaps between the sides of the benches. This could pose an issue for cleaning between

		the benches and therefore sufficient decontamination of the PM suite. The DI is therefore advised to explore options to seal these gaps between the benches.
8.	PFE1(b)	The area outside the PM suite is currently a transitional area from the PM room to the changing rooms for staff. While staff remove all over gowns and boots in a designated area, staff still have to walk down a corridor to the changing facilities to remove clothing potentially contaminated during the PM examination. This area is also used by staff to move between areas of the mortuary. The DI is therefore advised to put up signage to identify this area as transitional to reflect its current use.
9.	PFE1(e)	While security arrangements are in place for access to the mortuary, the entry codes are not regularly updated and therefore poses a risk that staff no longer having authorised access are able to access the establishment premises.

Concluding comments

Despite the number of shortfalls identified, areas of good practice were observed during the inspection. The establishment demonstrated a commitment to the continual improvement of practices and compliance with the HT Act. Areas of good practice include:

- Isolated main fridge room for bodies brought in from the community out of hours.
- Use of mortuary identification number in combination with the Coroner's number to use as a unique identifier of a body following a PM examination. The Coroner's number is provided to FDs and used as an identifier for release;
- The daily checklist identifies who is in the mortuary in real time, making it easy to determine those bodies requiring movement in to long- term storage and easy identification of those already in long term storage.
- Photographs of locations and forms are incorporated into SOPs making them easy to follow.

There are a number of areas of practice that require improvement, three major shortfalls and thirteen 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: 25 March 2019

Report returned from DI: 2 April 2019

Final report issued: 9 April 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: 26 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 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.