Site visit inspection report on compliance with HTA licensing standards

Queen Alexandra Hospital

HTA licensing number 12237

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**

3 August & 7 November 2017

Summary of inspection findings

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

Although the HTA found that Queen Alexandra Hospital (the establishment) had met the majority of the HTA's licensing standards, two minor shortfalls were found against the 'Governance and quality systems' and 'Traceability' standards. Specifically, these related to HTA reportable incidents and the use of identifiers to support traceability.

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

The HTA's regulatory requirements

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

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

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

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

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

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

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

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

Background to the establishment

The mortuary at Queen Alexandra Hospital is based in the Pathology building, which is connected to the main hospital building by a link bridge. The licensable activities fall under the oversight of the Cellular Pathology department. The DI is a Consultant Pathologist and the Corporate Licence Holder contact is Director of Corporate Affairs and Business Development.

The mortuary receives approximately 3,500 bodies each year from the hospital and the community, and performs up to 1,150 post mortem (PM) examinations annually. The majority of PM examinations are undertaken on behalf of the Portsmouth and South East Hampshire Coroner. Occasional hospital (consented) PM examinations are also carried out at the establishment. Consent for adult hospital PM examinations is sought by clinicians with the support of bereavement staff who have a clear understanding of what is involved in the process and of the requirements of the Human Tissue Act 2004.

Perinatal PM examinations are also undertaken at the establishment; consent is sought by a trained midwife using the Stillbirth and Neonatal Death charity (Sands) information leaflets and consent forms, along with additional local information sheets.

The body store at the mortuary is comprised of 135 fridge and four freezer spaces; this includes space for standard and bariatric storage.There are dedicated fridges allocated for high-risk and perinatal cases. The majority of fridges are ‘double-ended’ for direct access in to the post mortem room. The mortuary has a temporary storage unit, accommodating up to 12 bodies, for use during periods of increased activity. The fridges and freezers are temperature alarmed and operate using a call out system which is connected to the Trust’s switchboard. The alarm system is tested on a regular basis and the results are documented. However, the alarm trigger parameters for the upper temperature is too high(see *Advice*, item 7). There is a digital display control panel in the mortuary office that shows the temperatures of the fridges and although the control panel is regularly viewed by staff, the temperatures observed are not documented. Therefore, staff are unable to review temperature trends that could indicate if there was a potential issue with a fridge bank (see *Advice*, item 8).

Porters admit all bodies into the mortuary (including out of hours), completing the ‘mortuary empty spaces log’ to indicate where any new admissions have been placed. The next working day, the mortuary staff check the identification of each deceased against the wrist band and cross-reference the ‘yellow sticker’ sent with the body (hospital deaths) and the condition of all bodies. The mortuary register and relevant sections of the ‘Body store’ computer system are then completed. At this stage, any issues (for example, with identification, body condition or shrouding) are addressed directly with the ward and a ‘Datix’

incident is logged. Issues with identification of community bodies are raised with the Coroner's office.

Bodies of those who die in the community are brought in by funeral directors appointed by the Coroner. If the funeral directors require access to the mortuary out of hours, they contact the porters who are responsible for admitting the body in to the mortuary. Mortuary staff train porters individually to ensure they are aware of mortuary practices.

In addition to a paper mortuary register that the porters and mortuary staff complete, there is an electronic system that manages the tracking of the deceased in the mortuary's care. This system records the consent preferences in relation to tissue taken as part of the PM examination and the deceased are not flagged for release on the system until this field has been completed. This electronic system informs staff exactly how long a body has been in their care and changes colour when the number of days is above ten. Mortuary staff will contact the funeral directors to collect the deceased if they have been in the Mortuary's care for 10 days or more. If the funeral director does not attend on the agreed day, there is a further contact with them and, if they are still unresponsive, then the Mortuary Manager contacts the family directly to see if they need any assistance arranging the funeral.

The main PM suite has seven height adjustable PM tables. A 'one-at-a-time' system is used to avoid mix-up of tissue samples and organs removed during PM examination. There is a separate high risk PM room with one PM table. Protective equipment for conducting both routine and high-risk PM examinations is available. The number of air changes in the PM suite exceeds the required 10 changes per hour.

Viewings of the deceased are arranged with the mortuary. During working hours, the Anatomical Pathology Technologists (APTs) accompany visitors to the viewing suite in the mortuary. Out of hours viewings are undertaken by the on-call APT. There are occasional lone viewings and there are two panic alarms for staff, which alert security if triggered. The doors from the viewing room to the rest of the mortuary are lockable.

Mortuary staff check three points of identification upon release; however, some of these points of identification are cross-checked against the mortuary's own internal documentation rather than the documentation supplied by the funeral director (see shortfall against standard T1(c)). Staff ask funeral directors to sign a specific document to confirm that they are happy with the condition of the deceased.

Description of inspection activities undertaken

The establishment has been licensed since 2007 and this was the third routine site-visit inspection. The inspection took place over two separate site visits. The HTA conducted a visual inspection of the premises, reviewed documentation and carried out interviews with the Designated Individual and key staff involved in licensable activities.

As part of the inspection, an audit of the body store was undertaken, where 12 bodies were selected at random, including two from the freezer. Details from the body identification tags and the physical location of the bodies were cross-checked against the mortuary electronic and paper registers. Additionally, details of tissue retained during three PM examinations were compared with records documenting the wishes of the family and tissue stored in the laboratory. No anomalies were found during these audits. Process audits of the establishment releasing two bodies from the mortuary to funeral directors were also undertaken.

Inspection findings

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

Compliance with HTA standards

Standard	Inspection findings	Level of shortfall
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	There is no standard operating procedure for HTA reportable incidents. This means that staff may not be aware of the different types of incidents that should be reported to the HTA, the timeframes within which they should be reported, or how to report them.	**Minor**

T1 A coding and records system facilitates traceability of bodies and human tissue, ensuring a robust audit trail		
b) 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	Some of the establishment's procedures rely on a minimum of two points of identification, rather than the required three, for checking the identity of the deceased before release. In addition, only one point of identification is confirmed before a viewing take place. This poses the risk that the wrong body may be released or viewed. In the tissue donation SOP, forename and surname are listed as two separate identifiers. A number of other documents refer to checking the identity of the deceased, but do not contain information about which identification details to check or that a minimum of three identifiers should match.	**Minor**

Advice

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

No.	Standard	Advice
1.	GQ1(a)	The DI is advised to review relevant SOPs to ensure there is clarity around the process of identification and document how many identifiers should be used.
2.	GQ1(a)	A number of the SOPs describe what is done rather than the process itself; the DI is advised to review the SOPs to ensure they also contain sufficient detail to enable somebody to undertake that particular task.
3.	GQ1(a)	Bodies classified as 'high risk' should always be kept in body bags until PM examination (and thereafter). This will ensure any potential infection risk is contained and prevent contamination of the fridge if the body were to leak. The DI is advised to ensure the relevant SOP is updated to reflect this.
4.	GQ1(a)	Funeral directors are informed if a body is a potential infection risk but are not told of the possible route of transmission of the infection, for example, blood borne. The DI is advised to include this important information on release of a body, to ensure that funeral service staff use appropriate PPE.
5.	GQ1(c)	Mortuary staff who were interviewed consistently outlined the procedure to follow if the condition of a body was found to be unsatisfactory. However, this is not documented in the relevant SOPs for admission and release of bodies. The DI is advised to include this information to ensure the documented procedure reflects mortuary practice.
6.	GQ1(g)	None of the mortuary staff are identified to the HTA as a Person Designated (PD); the DI is advised to add the Mortuary Manager as a PD under the licence to ensure the HTA has their contact details.

7.	GQ4(b)	The inspection team noticed a couple of places in the mortuary register where corrections had been made. The DI is advised to ensure that all staff are aware that the standard for corrections should be a single strikethrough which is initialled by the individual making the correction. This will help identify the amendment made and who it was made by.
8.	GQ6(a)	A number of risks to the deceased have been assessed, but there is no reference to accidental damage. The DI is advised to formally assess the risk of accidental damage to the deceased.
9.	T1(a)	Identification details of bodies within the freezer are written on the outside of the body bag. Although the bodies themselves are also labelled, there is a potential risk that the identification details on the bag are used to release a body, rather than physically checking the identification on the body. The DI is advised to cease this practice.
10.	T1(c)	Hospital bodies are always identified with three identifiers or more. However, this is not consistent practice for community bodies admitted to the mortuary. The DI is advised to ensure a third unique identifier is used to identify all community bodies, for example, address or place of death.
11.	PFE1(a)	There is a separate room, accessible via the PM suite, with the block printer; the DI is advised to ensure this room is added to the cleaning checklist after PM examinations.
12.	PFE2(c)	Although bodies in long-term storage are generally frozen before the recommended 30 days (or, if required, before this time), this process is not documented. The DI is advised to include this in the SOP MORPROT002 'Storage of Bodies'.
13.	PFE2(e)	Upon the manufacturer's advice, there are two alarm triggers for the higher temperature deviations; the first is set to alarm when the temperature reaches 10 degrees Celsius and stays at that temperature for over 30 minutes. This is above the sector norm of 7-8 degrees celsius. The DI is advised to reduce this temperature as the time delay should account for temperature variations when the fridge doors are opened for receipt and release.
14.	PFE2(f)	The DI is advised to ensure that the fridge temperatures are regularly monitored for trends, which would help identify any potential issues with the fridges. This will enable to establishment to plan maintenance of the fridges before a problem occurs.

Concluding comments

The mortuary appears to be run to a high standard. Staff appear dedicated to providing a good service and there is an open culture for reporting any issues. A number of areas of good practice were observed during the inspection:

- The use of different colours in the mortuary register to highlight cases where toxicology, histology or organs have been taken and for deceased with same or similar names, clearly highlights to staff where extra steps are to be taken before release of the deceased;

- the duration of stay of the deceased is well managed, which helps to maximise the capacity of the body store;
- a new form has recently been introduced that records when parents have made the decision not to consent to a PM in perinatal cases. This means that each case has a form, reducing the risk of miscommunication about whether a PM examination is requested or not;
- Consent forms for hospital PM examinations are checked for accuracy upon receipt at the mortuary. Staff at the mortuary confirm that the consent seeker has been trained and any errors on the form are recorded against the consent seeker details. The consent seeker is informed of any errors and must rectify them with the individual giving consent. If the same consent seeker submits a further two forms with an error, then they are removed from the approved consent seeker list;
- the audit schedule is a very comprehensive with a number of audits each month;
- security at the hospital is rigorous and includes security staff dressing in plain clothes and attempting to gain access to the mortuary by tailgating or pretending to be a doctor, funeral director or family member. This means that staff are particularly vigilant, ensuring only those that should have access to the mortuary are admitted.

There are a couple of areas of practice that require improvement, including two 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: 23 November 2017

Report returned from DI: 6 December 2017

Final report issued: 8 December 2017

Completion of corrective and preventative actions (CAPA) plan

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

Date: 12 February 2018

Appendix 1: HTA licensing standards

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

Consent

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

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

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

Guidance

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

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

Guidance

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

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

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

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

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

Guidance

This may be based on the HTA's model consent form for adult post-mortem examinations available on the HTA website, or in relation to infants, the resources pack developed by the Stillbirth and neonatal death charity, Sands. The consent forms should record the consent given for the post-mortem examination and for the retention and future use of tissue samples.

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

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

Guidance

Refresher training should be available (for example annually).

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

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

d) Competency is assessed and maintained.

Governance and quality systems

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

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

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

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

   iii. practices relating to evisceration and reconstruction of bodies;

iv. systems of traceability of bodies and tissue samples;

v. record keeping;

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

vii. lone working in the mortuary;

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

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

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

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

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

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

xiv. contingency storage arrangements.

Guidance

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

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

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

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

Guidance

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

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

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

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

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

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

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

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

Guidance

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

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

Guidance

Meeting minutes should be recorded and made available to staff.

GQ2 There is a documented system of audit

a) There is a documented schedule of audits.

Guidance

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

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

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

Guidance

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

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

Guidance

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

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

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

Guidance

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

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

b) There are clear reporting lines and accountability.

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

Guidance

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

d) Staff have annual appraisals and personal development plans.

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

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

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

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

Guidance

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

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

understanding.

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

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

Guidance

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

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

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

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

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

Guidance

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

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

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

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

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

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

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

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

Guidance

Risks to the dignity and integrity of bodies and stored tissue should be covered. The HTA's reportable incident categories provide a good basis for risk assessments. Risk assessments should be reviewed at regular intervals, for example every 1-3 years or when circumstances change. Staff should be involved in the risk assessment process.

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

Guidance

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

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

Traceability

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

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

Guidance

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

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

Guidance

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

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

Guidance

Identification details should not be written on bodies. Where bodies are moved off site for contingency storage the DI should ensure that suitable systems are in place to identify same or similar names.

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

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

Guidance

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

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

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

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

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

ii. receipt upon return to the laboratory or mortuary

iii. the number of blocks and slides made

iv. repatriation with the body

v. return for burial or cremation

vi. disposal or retention for future use.

Guidance

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

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

Guidance

Formal written agreements with funeral services are recommended. Coroners usually have their own agreements for transportation of bodies and tissue; however, documentation for traceability

purposes must still be maintained by the establishment forthese cases.

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

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

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

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

Guidance

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

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

d) The method and date of disposal are recorded.

Premises, facilities and equipment

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

a) The premises are clean and well maintained.

Guidance

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

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

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

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

Guidance

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

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

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

a) Storage arrangements ensure the dignity of the deceased.

Guidance

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

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

Guidance

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

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

Guidance

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

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

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

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

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

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

Guidance

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

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

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

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

Guidance

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

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

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

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

Establishments should consider entering in to Mutual Aid Agreements

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

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

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

   i. fridges / freezers

   ii. hydraulic trolleys

iii. post mortem tables

iv. hoists

v. saws (manual and/or oscillating)

Guidance

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

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

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

Guidance

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

d) Staff have access to necessary PPE.

Guidance

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

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

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

Guidance

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

Appendix 2: Classification of the level of shortfall

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

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

1. **Critical shortfall:**

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

   or

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

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

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

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

   (3) A notice of suspension of licensable activities

   (4) Additional conditions being proposed

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

2. **Major shortfall:**

   A non-critical shortfall that:

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

   or

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

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

3. **Minor shortfall:**

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

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

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

Follow up actions

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

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

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

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