Site visit inspection report on compliance with HTA licensing standards

Queen Elizabeth Hospital Birmingham

HTA licensing number 12329

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**

26 September 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 Elizabeth Hospital Birmingham had met the majority of the HTA's standards, one major and seven minor shortfalls were found in relation to staff training, tissue traceability and audits.

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

The HTA's regulatory requirements

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

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

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

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

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

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

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

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

Background to the establishment
This report refers to activities carried out at the mortuary at Queen Elizabeth Hospital Birmingham (the establishment). The Designated Individual (DI) is a Consultant in Cellular Pathology; the Corporate Licence Holder (CLH) is University Hospitals Birmingham NHS Foundation Trust; and the CLH contact is the Executive Chief Operating Officer.

The mortuary is staffed by three full time mortuary staff, which includes a Mortuary Manager and two Anatomical Pathology Technologists (APT).

The establishment undertakes approximately 20 post-mortem (PM) examinations every year. The majority of these cases are hospital (consented) PM examinations. Occasionally, some high risk PM examinations (for example, in possible variant Creutzfeldt-Jakob Disease cases) are performed on behalf of the Coroner. Paediatric PM examinations are not routinely performed at the establishment; instead, these cases are performed at a nearby HTA-licensed establishment.

Consent for adult hospital PM examinations is sought by pathology doctors, with the assistance of either mortuary staff, or nursing staff, who can answer any additional questions the family may have. All staff who seek consent are trained (see *Advice*, item 2).

The mortuary body store has 87 fridge spaces. Of these 87, nine are for bariatric bodies and a further three are allocated for infectious bariatric bodies. Perinatal/paediatric cases do not routinely come to the mortuary; however, on occasion this may happen. A tray has been allocated for perinatal/paediatric cases. The establishment has two additional storage units, each with 12 spaces, for contingency storage. There are no freezer spaces at the mortuary (see *Advice*, item 13).

All fridges are monitored over 24 hours via an audible alarm which is linked to a remote call-out system. Out of hours, when temperatures exceed set limits, the system will alert security who will interrogate the system to determine the nature of the alarm. Where necessary, the maintenance company are alerted and they will attend the mortuary. All fridges are serviced every three months, and alarms are challenged to ensure the remote call out system is working appropriately. When in use, the contingency storage is linked to a separate remote call-out system which will alert the histology on-call department. In addition, staff manually record temperatures of all fridges on a daily basis and review for any concerning trends.

Access to the mortuary is controlled by swipe card access, authorised by the Mortuary Manager. Funeral directors use a video intercom to alert staff of their arrival. They are admitted to a dedicated area, which is secured from the surrounding areas with a roller shutter door.

Bodies are only received from the hospital; community death cases are sent to a nearby Public Mortuary, licensed by the HTA. Working in pairs, porters trained in mortuary

procedures admit bodies to the mortuary, both in and out of hours. Porters are trained by the Mortuary Manager; however, competency is not recorded (see Shortfall GQ3(c)). Porters will select an empty space in a fridge and write the surname of the deceased on the fridge door and the mortuary white board, and attach the notification of death form to the door using a magnet. They will complete a porters body depository record sheet, which is checked by mortuary staff. The identification tags, the condition of the body, information on the porters body depository record sheet, the notification of death form and the whiteboard are checked by mortuary staff. The deceased's information is entered into the mortuary ledger and a bespoke database which is also accessed by bereavement staff. As it is in the process of being developed, the database is being used in tandem with paper records to ensure traceability is maintained. The database is used, in conjunction with visual checks, to highlight same/similar names. A magnet is used on fridge doors to alert staff to same/similar names, as well as two red dots beside the names in the mortuary ledger (see *Advice*, item 8).

During working hours, bodies are released by mortuary staff. Out of hours releases are performed by porters, with the assistance of clinical staff, and occasionally histology staff (see Shortfalls under GQ3(a) and (c)). During normal working hours funeral directors will arrive, and two APTs will confirm the identity of the deceased with the funeral director by checking at least three identifiers on the identification tags against the release paperwork. An APT involved in the release, and the funeral director will sign the mortuary ledger upon release. If any discrepancies are identified, or if the funeral director does not have the appropriate paperwork then the body will not be released.

Families liaise with bereavement staff to arrange viewings. Bereavement staff will contact the mortuary to confirm that the body is in the mortuary, and that it has not been transferred to the Public Mortuary for a Coronial PM examination, and that the viewing may commence. Occasionally clinical staff and porters will conduct out of hours viewings (see Shortfalls under GQ3 (a) and (c)).

The PM suite has two downdraft tables and a dedicated area for the dissection of organs. A high risk suite is used for high risk cases, and appropriate personal protective equipment is supplied to staff. The identification of the deceased is checked by an APT and the pathologist prior to the PM examination beginning.

Following analysis, histology samples taken during PM examination are stored in the pathology department, or disposed of in accordance with the family's wishes.

Description of inspection activities undertaken

This was the third routine site visit inspection of the establishment. The first and second inspections took place in 2011 and 2014, respectively. The inspection included a visual inspection of the body store, PM suite, viewing area, histology laboratory. The DI confirmed that no removal of relevant material for a scheduled purposes occurs in areas external to the

mortuary, for example A&E or maternity, so these areas were not visited. Interviews with members of staff, and a documentation review were undertaken. Audits of three bodies in storage were conducted where body location and identification details on the body were cross referenced against the information in the mortuary ledger, paper records and the online database. No anomalies were found.

Audit trails of three hospital (consented) PM cases, where histology and/or whole organs were retained, were also conducted. Relevant paper records, consent forms and location of samples in histology were checked. One anomaly was found (see Shortfall under T1 (g)).

A release of one body to a funeral director was observed during the inspection and processes were checked against SOPs. No discrepancies were found.

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

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		
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.	A consent form examined as part of the tissue traceability audit was incorrectly completed, meaning that it is not clear whether the family wished for the tissue to be retained, or disposed of.	**Major**

C2 Staff involved in seeking consent receive training and support in the essential requirements of taking consent		
b) Records demonstrate up-to-date staff training	Although staff involved in seeking consent have attended a training session held by the DI, documented evidence is available for this, it was not seen during the inspection but was provided as a scanned document afterwards.Refresher training is not provided.. *See Advice, item 4*	**Minor**

Governance and Quality

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	A number of SOPs reviewed during the inspection do not provide adequate detail to ensure the process is followed, and wording may lead to confusion. For example: • PPM_S002, Disposal of Post Mortem Tissues, refers to disposing only of 'wet tissue' and that 'blocks and slides may be retained as part of the medical record as the PM was conducted for 'diagnostic' purposes (providing that appropriate consent is in place)'. Tissue may only be stored with appropriate consent in place. The current wording presents the risk of relevant material being inappropriately retained following a PM examination; • the HTARI SOP should be updated to include the full list of HTARI categories and all references to SAEARS should be removed as these are not applicable to the PM sector. The SOP lists the details of a member of staff who no longer works at the HTA and this should be removed to ensure all incidents are reported to the appropriate member of staff within the set time frame; and • the SOP governing the transport of relevant material following PM examination, 'PMO_S015, Transportation of specimens', does not detail who is responsible for transporting tissue to histology following a PM examination. SOPs lacking appropriate detail increase the risk of a procedure being inappropriately and inconsistently performed. *See Advice, items 6 and 9*	**Minor**

GQ2 There is a documented system of audit		
c) Regular audits are carried out of tissue being stored so that staff are fully aware of what is held and why and to enable timely disposal of tissue where consent has not been given for continued retention	The establishment have developed a schedule of audits which include procedural audits, however audits of tissue traceability, or audits of consent documentation for completeness and accuracy are not currently being undertaken. *See Advice, item 8*	**Minor**

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	Staff, including clinical site staff and histology staff are occasionally involved in mortuary procedures, including the release and viewing of bodies. Training for staff involved in these procedures is not documented.	**Minor**
c) Staff are assessed as competent for the tasks they perform	While porters attend training provided by mortuary staff, observation of practice is not recorded. Clinical site staff and histology staff are not competency assessed in mortuary procedures.	**Minor**

T1 A coding and records system facilitates traceability of bodies and human tissue, ensuring a robust audit trail		
g) Organs or tissue taken during post-mortem examination are fully traceable, including blocks and slides (including police holdings).	During the traceability audit of one case where tissue taken at PM examination, the laboratory system had not been updated to reflect the number of additional slides cut for special staining.	**Minor**

PFE1 The premises are secure and well maintained and safeguard the dignity of the deceased and the integrity of human tissue		
d) The premises are secure (for example there is controlled access to the body storage area(s) and PM room and the use of CCTV to monitor access).	The door in the viewing room opens to a corridor leading to the body store. This door can be unlocked from the inside, which may lead to unauthorised access to the mortuary. *See Advice, item 11*	**Minor**

Advice

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

No.	Standard	Advice
1.	C1(a)	When seeking consent for PM examination, the pathologist will usually do so in person, however, on occasion, this is done over the phone and the consent seeker will document the conversation. The document 'Procedure for consent to examination or treatment' does not detail this process sufficiently. The DI is advised to review this document to ensure the consent seeker is aware of the requirement to document the conversation, as well as details of the information sent to the family where consent is sought over the phone. This document should also be updated to include page numbers.
2.	C1(a)	The establishment conducts approximately 20 hospital (consented) PM examinations per year. There are three pathologists trained in seeking consent; however, usually only one pathologist, the DI, seeks consent. The DI has developed a checklist, and a training presentation for those involved in seeking consent, including pathologists or nurses who may sit in on the conversation. References to 'the closest ranked relationship' should be removed and replaced with 'the person ranked highest in the hierarchy of qualifying relationships'. Documentation should be dated and version controlled to ensure the most up to date version is being used by staff.
3.	C1(f)	The consent form and SOPs do not specify the exact timeframe during which the consent-giver can change their mind after giving their consent for the PM examination, with some documents stating 24 hours, and others stating 'an appropriate timeframe'. The DI is advised to review all documentation associated with consent, including consent forms, to ensure it is clear how long the family have to change their mind before the PM examination is undertaken. The HTA recommends 24 hours.
4.	C2(b)	While staff involved in seeking consent have been trained, refresher training is not currently undertaken. Refresher training should be provided on a regular basis, for example, annually. The DI may wish to consider using the HTA webinars which can be found on the HTA website. Some staff may undertake this activity infrequently; in which case, more frequent refresher training will help to ensure that they are familiar with the establishment's procedures for seeking consent and the requirements of the HT Act and the HTA standards and Codes of Practice. The DI is advised to ensure that training is recorded and documented as this provides evidence that staff have up-to-date training in undertaking this procedure.
5.	C2(d)	Staff involved in seeking consent are not routinely assessed for their competency. A regular schedule of competency assessment should be implemented where staff involved in seeking consent are observed and this will provide the DI with assurances that staff seeking consent are doing so appropriately and confidently.
6.	GQ1(a)	All policies and procedures relating to licensed activates should be reviewed and updated to ensure that they accurately reflect practices and contain up to date details of the procedures that should be followed. References to retaining blocks and slides as part of the medical record should be removed. The DI is advised to ensure all documents reflect the requirements

		of the HT Act and guidance contained in the HTA's Code of Practice and Standards and Guidance document. *See Advice, item 9*
7.	GQ1(d)	When reviewing documentation, it was noted that some documents were out of date, and not all documents and forms in use were version controlled. This increases the risk of an out of date procedure being followed. The DI should ensure that all policies and SOPs are version controlled, and that only the latest version is in use.
8.	GQ2(a)	While there is a regular schedule of audits in place, the establishment is behind on the completion of the majority of these. The DI is advised to review the schedule to ensure that it is appropriate and achievable for staff. The schedule and audit findings should be discussed at regular governance meetings, and any issues with achieving deadlines highlighted.
9.	GQ2(c)	The DI should perform an audit of all retained material to ensure that appropriate consent is in place. Tissue which is thought to be held as part of the medical record, and which does not have appropriate consent in place should be disposed of. The DI is advised to ensure tissue traceability audits are routinely performed. The audits should include a review of consent documentation and mortuary records for completion and accuracy, as well as a review of the laboratory system used to record the number of blocks and slides for each case. Where discrepancies in completion of consent forms is noted, this should be recorded and followed up.
10.	GQ6(a)	The DI is advised to review the establishment's risk assessments to ensure all HTARI categories are considered. 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.
11.	T2(d)	A spreadsheet, held and updated by histology staff, is used to record disposal of blocks, slides and excess wet tissue following PM examination. The DI is advised to ensure that this spreadsheet is routinely updated with the method and date of disposal.
12.	PFE1(d)	The DI is advised to ensure arrangements for viewing of a body by the family are covered by risk assessment/s, taking into account the security of the viewing room and adjacent areas, and measures to safeguard the dignity of the deceased during viewings. The DI may wish to consider moving the lock to the other side of the door, or installing a curtain which will hide the door from view.
13.	PFE2(c)	The establishment does not have any freezer storage on site. Contingency arrangements are in place with the local Public Mortuary; however, this is not formally documented, which increases the risk of bodies not being appropriately stored in times of high capacity. In addition, if the freezers at the Public Mortuary are full, the establishment cannot store bodies there. The DI is advised to risk assess the suitability of this arrangement and to ensure appropriate agreements are in place with the local Public Mortuary to mitigate the risk of a body being stored at inappropriate temperatures when in long term storage. The DI should review the establishment's contingency storage arrangements to ensure that they provide sufficient contingency storage capacity, protect the dignity of the deceased, and mitigate the risks of incidents resulting from changes to normal working practices. Further advice on contingency storage arrangements can be found in the HTA's guidance document 'Storage capacity

		and contingency arrangements in mortuaries: Guidance for DIs in HTA-licensed establishments', which is available on the HTA's website. To strengthen arrangements for contingency storage capacity, the DI is advised to consider entering into a Mutual Aid Agreement with relevant organisations, including other Trusts, NHS commissioners and local authorities. Mutual Aid Agreements set out the arrangements that may be invoked when one or more of the organisations experiences an emergency or business continuity event that they are not able to deal with on their own. The HTA has seen this model adopted successfully by other establishments. The DI is advised that transfer of bodies to other premises for storage increases the risk of loss of traceability of bodies. Contingency storage arrangements should be documented, and a risk assessment undertaken and reviewed on a regular basis.

Concluding comments

A number of areas of good practice were noted on the inspection, including:

- The notification of death form, which was developed in collaboration with the mortuary, bereavement services and nurses. This encourages discussions across departments, and allows staff to collect relevant information in one form.
- Mortuary staff have developed a visual reminder for mortuary fridge doors which alerts staff to the status of the body, for example if lines remain in situ, or whether the body has been cleared for release.
- When seeking consent, the pathologist will have a discussion with the family regarding their expectations. This provides the family with an opportunity to realise the aims of the PM examination, and to understand that the PM examination may not provide every answer.

There are a number of areas of practice that require improvement, including one major and seven 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 October 2017

Report returned from DI: 03 November 2017

Final report issued: 06 November 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: 18 May 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 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.