Site visit inspection report on compliance with HTA licensing standards

Weston General Hospital

HTA licensing number 30013

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**

10 and 11 October 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 Weston General Hospital had met the majority of the HTA's standards, three major and seven minor shortfalls were found against the Governance and Quality, Traceability and Premises, Facilities and Equipment standards.

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

The HTA's regulatory requirements

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

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

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

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

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

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

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

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

Background to the establishment

Weston General Hospital (the establishment) has been licensed by the HTA since February 2010. It is licensed for the making of a post mortem (PM) examination, removal of relevant material from the deceased and storage of bodies of the deceased and relevant material for use for scheduled purposes.

The mortuary is staffed by one Anatomical Pathology Technologist (APT) and PM examinations are only undertaken when he is on site. A Medical Laboratory Assistant (MLA) from the Histopathology Laboratory assists the APT in the release of bodies and attends the mortuary for one day per week although this is not protected time (see Advice, item 11).

The establishment undertakes approximately 40 adult PM examinations per year under the authority of the Coroner for West Somerset including high-risk PM examinations. The establishment does not undertake perinatal or forensic PM examinations; these are undertaken at other HTA-licensed establishments. Consent for perinatal PM examinations is sought by clinical staff using a consent form and information leaflet based on those provided by the Stillbirth and Neonatal Death (Sands) charity (see Advice, item 1). During the inspection, the establishment staff confirmed that no adult hospital (consented) PM examinations are undertaken at the establishment.

Mortuary facilities at the establishment consist of a body store, a PM suite and viewing room. The mortuary is secured by swipe card access with access by designated staff only. The access corridor from the hospital, which allows access to all Trust staff, is cordoned off during viewings to allow for the dignity of the deceased. There is no CCTV or intercom system in place to identify visitors but there is a procedure in place to ensure access is only granted to identified individuals (see Advice, item 9). The mortuary has storage capacity for 32 bodies, including four spaces for bariatric bodies and four spaces which may be used as an isolation fridge or a freezer. The establishment has an arrangement for storage of bodies at a funeral services premises as part of an escalation plan in the event that additional storage is required during peak periods; however, the documented contingency arrangements are inadequate (see shortfall against PFE2(b) and Advice, item 10).

There is monitoring (both paper records and short-term electronic monitoring) of the storage facility's temperatures and an alarm system for the fridges which is linked to the switchboard. The Estates Department are responsible for acting on the alarm out of hours. This system has not been challenge tested to ensure the call out procedure is adequate (see shortfall against PFE2(a)).

The mortuary uses a paper register to record details of bodies, including admission and release of bodies (see Advice, item 7). This paper record is backed up by an electronic

register, which is completed by the APT with details of any valuables. There is a system to identify same or similar names.

Bodies from the community are transferred to the mortuary by the Coroner's contracted funeral director (FD). Out of hours, the contracted FD admits the bodies into storage after being given access to the mortuary by the portering staff (see shortfall against GQ3(a) and Advice, item 5) and completes the paper mortuary register. Bodies are transferred from hospital wards by portering and nursing staff, who enter details into the mortuary register (see Advice, item 4). All paperwork is checked the following day by the APT and details entered onto the electronic register. Products of conception are transferred from the Histopathology Laboratory and are stored in a dedicated area before sensitive disposal or are returned to the Early Pregnancy Unit for collection. Perinatal and paediatric cases are transferred directly to the body store or to another HTA-licensed establishment for PM examination and are not stored elsewhere in the hospital. Bodies are released from the mortuary only by mortuary staff or the trained MLA.

The PM suite has two downdraft tables and a dedicated bench for preparation of organ and tissue samples. Only one PM is performed at a time. Tissue samples are transferred to cassettes in the PM suite so that only minimal tissue is taken during PM examination. Material taken during PM examination is transferred to the establishment's Pathology Laboratory for histological analysis or to other establishments for toxicology or other tests. Tissue from PM examination carried out at another HTA-licensed establishment is also processed and stored at the establishment. Tissue samples may be stored, if appropriate consent is in place, for use for scheduled purposes. The establishment does not routinely store organs for use for scheduled purposes. At the time of the inspection, the establishment was storing PM blocks and slides. Samples are stored in the Pathology Laboratory, which is secured by swipe access, and in the mortuary.

Sampling of tissues from deceased children - in cases of sudden unexpected death in infancy (SUDI), under coronial authority - is performed in designated areas of the hospital; specifically the Accident and Emergency department (A&E) and in a designated children's ward (see Advice, item 2).

The establishment uses paper records and electronic databases to record sample details, disposal records and 'next of kin' wishes for the fate of the samples once coronial authority has ended (see Advice, item 8). Paper records are scanned and stored electronically.

Home Office forensic PM examinations are not conducted at the establishment. However, material from forensic PM examinations is processed and stored at the establishment. Procedures for Home Office PM examinations and management of tissues and organs taken for criminal justice purposes were not reviewed by the HTA at this site visit inspection.

Description of inspection activities undertaken

This report describes the fourth, routine site visit inspection of Weston General Hospital. The inspection team interviewed staff involved with licensable activities, reviewed documentation and conducted visual inspections of the mortuary, Pathology Laboratory and A&E department.

A traceability audit was conducted for three adult bodies, including one with the same surname as another body within the establishment's body store. These audits included checks of storage locations, identity tags and mortuary records. There were no bodies stored in the freezer at the time of inspection. Full traceability was found.

Audits of traceability were conducted for tissue blocks and slides stored in the Pathology Laboratory from four cases under authority from the West Somerset Coroner (2016/2017), where PM examinations were performed at the establishment and four cases under the authority of the Avon Coroner (2017) where PM examinations were performed at another HTA-licensed establishment. Four discrepancies were found (see shortfall against T1(g)).

Further traceability audits were conducted for material stored separately in the mortuary (blocks and slides) from 2011 to 2016. The database records were scrutinised to determine if the tissue remained under coronial authority and if the deceased's family's wishes had been received by the establishment. Major discrepancies were found between the database records and retention or the disposal of tissue. The establishment has a plan to deal with these samples and they have been quarantined to ensure that they are not used for a scheduled purpose without consent (see shortfall against standard T2(b)).

Inspection findings

Compliance with HTA standards

GQ1 All aspects of the establishment's work are governed by documented policies and procedures		
a) Documented policies and SOPs cover all mortuary/laboratory procedures relevant to the licensed activity, take account of relevant Health and Safety legislation and guidance and, where applicable, reflect guidance from RCPath.	Many of the SOPs covering key mortuary procedures do not contain sufficient detail of the procedures that staff must follow. For example: • SOPs describing the process for identifying bodies do not state the minimum number of identifiers to be used and how the identification check should be performed. If any discrepancy is found, the SOP should also state how any discrepancy is acted upon; however this was not the case; • the SOP for non-hospital body admission states that it is the duty of the person admitting the body to ensure the body is correctly labelled and personal details are entered in the mortuary register. The SOP does not state what information should be recorded in the register; • the SOP for General Autopsy states that at least two APTs should laterally move the deceased from the trolley. This does not reflect current practice as there is only one APT working at the establishment. This is not an exhaustive list of the amendments required to SOPs, and to fully address this shortfall, the establishment should review all SOPs relating to licensed activities to ensure that they are accurate and contain sufficient details of procedures. This lack of detail means there is a risk that procedures are not undertaken in a consistent manner.	**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 had not followed its procedure for auditing and following up when Coroner's authority for storage of PM samples has ended and whether samples should be disposed of. As a result, the establishment had built up a backlog of PM tissue blocks and slides from PM examinations, some dating back to 2011. The establishment has identified some cases where it is not known whether a Coroner's authority has ended or whether consent has been given for continued storage. These samples are stored pending either disposal or, where consent for storage of tissue can be evidenced. The establishment is following up these cases and has a plan to ensure timely disposal of samples where a Coroner's authority has ended and consent has not been given for continued storage. The HTA did not find evidence that samples have been used for a scheduled purpose without consent. *Refer to shortfall against standard T2(b), and Advice, item 3.*	**Major**

GQ3 Staff are appropriately qualified and trained in techniques relevant to their work and demonstrate competence in key tasks		
g) Visiting / external staff are appropriately trained and receive an induction which includes the establishment's policies and procedures	The Funeral Director for the West Somerset Coroner admits bodies from community deaths to the mortuary. There is no evidence that these visiting staff, who may admit bodies out of hours, have been trained in the use of equipment (such as hydraulic trolleys) or procedures to enter the details of the body into the mortuary register. This poses a health and safety risk to visiting staff and poses a potential risk that a body may be damaged by improper use of equipment or that traceability may be lost though in appropriate completion of the establishment's paperwork. *See* Advice, item 4.	**Minor**

GQ6 Risk assessments of the establishment's practices and processes are completed regularly, recorded and monitored		
a) All procedures related to the licensed activities (as outlined in standard GQ1) are risk assessed on a regular basis	The establishment does not have documented risk assessments of all procedures related to licensed activities. When risk assessments have been completed, the assessments of risks and the measures put in place to mitigate against them should be incorporated into mortuary procedures and practices.	**Minor**

T1 A coding and records system facilitates traceability of bodies and human tissue, ensuring a robust audit trail		
c) Three identifiers are used to identify bodies and tissue, (for example post mortem number, name, date of birth/death), including at least one unique identifier	The establishment's procedure for identification of the deceased who have died in the community relies on only two identifiers (name and date of birth). This includes identification checks prior to PM examination, viewing of the deceased and release from the mortuary. This poses a risk of misidentification of the deceased. *See* Advice, item 7.	**Minor**
g) Organs or tissue taken during post-mortem examination are fully traceable, including blocks and slides (including police holdings).	The establishment's procedures do not provide for full traceability of PM material. During the traceability audit of blocks and slides stored in the Pathology Laboratory, four minor discrepancies were found: • some blocks were filed in the incorrect storage box; • the number of slides returned from the pathologist were recorded in the wrong database field; • some slides returned from the pathologist were not recorded in the database; • an incorrect number of blocks were recorded in the database; The establishment could not therefore demonstrate full traceability of blocks and slides. *See* Advice, item 8.	**Minor**

T2 Disposal of tissue is carried out in an appropriate manner and in line with the HTA's codes of practice.		
b) There are effective systems for communicating with the Coroner's Office, which ensure tissue is not kept for longer than necessary	The establishment had not followed its procedure for following up when a Coroner's authority over PM examination samples has ended and whether samples should be disposed of or stored. As a result, the establishment has built up a backlog of PM tissue blocks and slides from PM examinations, some dating back to 2011. The establishment has previously identified this and disposed of samples where a Coroner's authority had ended and consent had not been given for continued storage. The establishment also identified some cases where it is not known whether a Coroner's authority has ended or whether consent has been given for continued storage of the tissue. The establishment is following up these cases to ensure timely disposal of samples where the Coroner's authority has ended and consent has not been given for continued storage. *Refer to shortfall against standard GQ2(c). See Advice, item 7.*	**Major**

PFE2 There are appropriate facilities for the storage of bodies and human tissue.		
e) Fridge and freezer units are alarmed and the alarms are tested regularly to ensure that they trigger when temperatures go out of upper or lower set range	The alarms are not challenge tested regularly. Without tests to verify that the alarms operate, and are responded to, appropriately there is a potential risk that failure of the fridges or freezers, or deviation from the acceptable storage temperatures may go unnoticed for a period of time, which may impact on the integrity of the bodies stored in these units.	**Minor**
i) There are documented contingency plans in place should there be a power failure or insufficient numbers of refrigerated storage spaces during peak periods	The current documented contingency plans are inadequate and the establishment has applied for funding for a contingency storage unit. The current plan to accommodate bodies in the PM room utilises porous material, will impede autopsy activity and the bodies will not be stored within acceptable temperature ranges. This will lead to an increased risk of damage to the bodies, loss of traceability and loss of dignity of the deceased. *See Advice, item 10.*	**Major**

PFE3 Equipment is appropriate for use, maintained, validated and where appropriate monitored		
c) The ventilation system provides the necessary ten air changes per hour and is checked and maintained at least annually	Air changes within the PM suite are not monitored. Any incorrect functioning of the ventilation system in the PM suite could pose a significant risk to the health and safety of staff working in this environment and staff and visitors in the surrounding areas.	**Minor**

Advice

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

No.	Standard	Advice
1.	C1(c)	The establishment has a midwife-led maternity unit, resulting in very few perinatal PM examination referrals. There is written information for those giving consent for perinatal PM examination which reflects the requirements of the HT Act and the HTA's Codes of Practice. The DI is advised to review the information given to those from whom consent is being sought to assure himself that only up to date and correct information is given and that staff seeking consent undergo refresher training to keep up to date with the consent requirements of the HT Act and Codes of Practice.
2.	GQ1(g)	The DI is advised to appoint Persons Designated in the Accident and Emergency Department, where removal of relevant material takes places as part of the SUDI protocol. This will ensure that all activities carried out under the licence are incorporated within the establishment's governance framework and that the DI has a point of contact who has oversight of these activities.
3.	GQ2(a)	To address the shortfall against standard GQ2(c), the DI should ensure that, as a minimum, the audit schedule should include a range of vertical and horizontal audits checking compliance with documented procedures, the completion of records and traceability.
4.	GQ3(a)	All staff who are involved in mortuary duties must be appropriately trained or supervised. During inspection, a discrepancy was noted in the mortuary register that had been completed by nursing staff. Transcription errors by nursing staff were also identified on the last mortuary horizontal audit dated 25/8/16. Nursing staff who admit bodies to the body store and complete the mortuary register should be trained appropriately and understand the regulatory requirements for traceability. The DI may wish to consider offering refresher training or communicate the importance of following the correct procedure in staff updates.
5.	GQ3(g)	Visiting / external staff must be appropriately trained and receive an induction which includes the establishment's policies and procedures. Staff working for contracted funeral services admit bodies from the community into the body store out of hours. The DI is advised to ensure that these

		individuals are appropriately trained in the use of the establishment's equipment and procedures for completing the establishment's documentation. This will help to mitigate any risks involved with using the equipment and completing the documentation.
6.	T1(b)	The DI is advised to consider introducing the use of wristbands to indicate bodies where tissues are required to be repatriated prior to release of the body from the mortuary, in addition to the whiteboard labels currently used. This would provide an additional visual trigger for staff when managing these bodies to ensure that bodies are not released from the mortuary prior to repatriation of tissues, where this is required.
7.	T1(c)	The release note issued by the Bereavement Office currently states the name and date of birth of the deceased. The DI is advised to ensure the Bereavement Office amends the release note issued to the family to include a third identifier such as a medical record number (MRN) or NHS number. This will mean that three identifiers are available to mortuary staff when releasing bodies. The Coroner's release form currently states the name of the funeral director appointed by the family, the name and the age of the deceased. The DI is recommended to liaise with the Coroner to amend the release form to include three identifiers, for example name, date of birth and address of the deceased. The three points of identification used for hospital admissions and the identification of bodies within the mortuary are name, date of birth and MRN number. The current mortuary register does not include a field for date of birth. The DI is advised to update the mortuary register so that this information can be recorded and used as an identification tool. This will mean that there will be three identifiers on the body and in the establishment's documentation. Use of three points of identification when receiving, moving, conducting PMs, conducting viewings and releasing bodies will help to mitigate the risks of misidentification of the deceased and loss of traceability.
8.	T1(g)	The DI should ensure that the traceability system for PM samples includes that records relating to the following are recorded and updated appropriately: • material sent for analysis on or off-site, including confirmation of arrival; • receipt upon return to the laboratory or mortuary; • the number of blocks and slides made; • repatriation with the body; • return for burial or cremation; and • disposal or retention for future use.
9.	PFE1(d)	The establishment does not currently use CCTV to monitor external access to the mortuary where bodies are admitted and released although there is a process in place for the identification of visitors. The DI is advised to risk assess the lack of monitoring of this entrance during lone working. The access corridor to the mortuary within the hospital is accessible to all Trust staff and is used as a short cut. The DI is advised to consider arrangements for the security of this corridor when viewings are taking place to help assure himself that the dignity of the deceased is maintained. The DI may

		wish to further restrict access to only certain individuals in the future meaning the use of the corridor by non-mortuary staff is minimised.
10.	PFE2(b)	The DI should review arrangements with the two local funeral directors for provision of contingency storage and determine whether they also provide arrangements for contingency storage of bodies for other establishments This may impact on their ability to assist during peak periods, for example, over the winter months. The DI should also assure himself of the suitability of the premises, storage conditions and procedures at these funeral services. 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 by other establishments. The DI should risk assess 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.
11.	N/A	The DI is advised to keep staffing levels of the mortuary and Cellular Pathology Department under regular review to ensure that they are sufficient to provide safe and effective services and to ensure staff are working at the appropriate level, with documented levels of authority and responsibility

Concluding comments

An area of good practice and several strengths were seen during the inspection including the following:

- A new team is in place and practices are being updated in accordance with the HTA Codes of Practice. As part of this, a new swipe card access system has been introduced to the mortuary to provide more robust levels of security and to restrict access to designated individuals only.
- The APT has worked hard since his arrival to implement changes to mortuary procedures in an effort to improve practices and compliance with the regulatory standards.
- Staff at the establishment had been aware of some of the issues subsequently raised during this inspection and had been trying to rectify these. Staff also demonstrated a commitment to improvement and compliance with the regulatory requirements and were open to the advice given by the HTA.

There are a number of areas of practice that require improvement, including three major shortfalls and seven minor shortfalls against governance and quality, traceability and premises, facilities and equipment standards.. In addition, advice and guidance was also

given in relation to consent, governance and quality systems, traceability and premises, facilities and equipment.

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

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

Report sent to DI for factual accuracy: 20 November 2017

Report returned from DI: 13 December 2017

Final report issued: 14 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: 24 October 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

d) 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.

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

f) 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.

g) Staff have access to necessary PPE.

Guidance

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

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

i) 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.