Site visit inspection report on compliance with HTA licensing standards

Basildon University Hospital

HTA licensing number 12051

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**

29 and 30 November 2017

Summary of inspection findings

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

Although the HTA found that Basildon University Hospital had met the majority of the HTA's standards, five minor shortfalls were found against the Traceability and Premises, facilities and equipment standards. These related to issues with tracking samples that had been transferred to the histology laboratory, the flooring inside the Post Mortem suite, the potential to view bodies being moved to and from the rear entrance of the mortuary, and the location and temperature ranges for refrigerated body storage within the mortuary.

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

Basildon University Hospital (the establishment) is part of the Basildon and Thurrock University Hospitals NHS Foundation Trust. The establishment has been licensed by the HTA since March 2007 and this is the third routine site inspection carried out by the HTA, the last occurring in March 2014.

The establishment receives approximately 2000 bodies each year from the hospital and community, performing around 650 post-mortem (PM) examinations, the majority of which are routine coronial cases conducted on behalf of HM Coroner for Essex. Paediatric/perinatal cases are transferred to another licensed establishment for PM examination but consent is undertaken on site by qualified staff in the maternity unit. There have been no adult hospital (consented) PM examinations performed for several years; however, mortuary staff are trained and would seek consent with the support of clinicians and bereavement staff. Consent forms for adult hospital PM examinations are based on the HTA's model consent form, while the consent forms used for paediatric/perinatal PM cases are provided by the referring establishment and based on the SANDs consent form. Both forms are fully compliant with statutory and regulatory requirements.

The establishment has a total of 118 refrigerated spaces, 23 of which can accommodate bariatric cases. There is a separate freezer bank with five spaces, none of which are designed for bariatric bodies. The refrigerated spaces 1-70 and freezer spaces 71-75 are the original units in the establishment and are maintained by the Hospital Estates services, while a newer bank of body spaces 76-118 are maintained by the commercial supplier (see *Advice*, item 12). The establishment has recently purchased a standalone unit for perinatal/paediatric cases and pregnancy remains (see *Advice*, item 10). The establishment owns two temporary storage units, each with 12 spaces, that are used for contingency storage. As the temporary storage units are regularly used during busy periods, they have been customised with additional insulation to improve their functionality. At the time of the inspection, these units were not in use but had recently been activated to confirm they maintained the correct temperature, standard procedure during periods where they are not in use. The establishment also leases an additional two temporary storage units, which provide 12 spaces each.

All four temporary storage units are kept in a room below the mortuary. This location is inconvenient to reach and bodies are transferred to this area by mortuary staff to increase available refrigerated space in the main body store. There is no computer in the contingency storage room, and staff log information into the computer system on their return to the mortuary (see *Advice*, item 5). At the time of the inspection there were visible drips of fluid from a rusted and corroded air handling/vent system over one of the two leased units, which had been covered with protective sheeting. In addition to condensation from the corroded venting system, it appeared that the leaking fluid contains waste from the PM room drainage

system (see shortfall against PFE2(a)). Hospital Estate services had been informed and were due to replace the corroded metal plating of the system.

Swipe card access is required for both external doors to the mortuary; additionally, a key is required for out of hours access, as well as standard key locks. Both doors are covered by CCTV and have an intercom system allowing mortuary staff to verify who is requesting access. CCTV coverage extends into the surrounding corridors and there are several monitors in the mortuary office allowing staff constant views of the surrounding areas.

Portering staff that transfer deceased patients to the mortuary have been individually trained by the mortuary staff. Bodies are transferred from the wards using concealment trolleys via lifts to a staff/service corridor. Perinatal cases and pregnancy remains are transferred to the mortuary using a dedicated and customised remains carrier. No perinatal/paediatric bodies are kept on the maternity ward and are always transferred immediately to the mortuary. Where possible, the porters use restricted access corridors to transfer bodies away from general view and the porters maintain their own records of all bodies transferred to the mortuary.

Bodies from the community are brought into the mortuary through a vertical, metal sliding door entrance onto a lift system that raises the body trolley to the mortuary level. During office hours, funeral directors and ambulances are met by mortuary staff who will open the metal door, while hospital porters will receive bodies out of hours. Porters complete paper records when bodies are received out of hours; mortuary staff will confirm identities the following day and enter their details into the bespoke electronic system. The rear entrance is visible from the maternity ward and is opposite some office space, raising the possibility of bodies being visible to the public during transfer to the mortuary. This was noted on the previous inspection and advice given to consider erecting screening around the entry to prevent sight of bodies being delivered to, or released from, the mortuary (see shortfall against PFE 1(d)).

Perinatal cases are recorded in a separate section of the mortuary electronic system, to separate records from adult body records. Trained staff at the maternity unit will take consent for paediatric PM examinations but all procedures take place at a separate licensed establishment. Due to staff turnover, there is currently one member of staff trained for perinatal PM consent seeking (see *Advice*, item 2).

In addition to the storage activities described above, the removal of tissue from the body of a deceased child occasionally takes place in the Emergency Department. Any samples collected are immediately transferred for clinical assessment, following clear regional guidelines.

The PM suite contains three height adjustable downdraft PM tables. The floor of the room was uneven with pooling of water in some areas of the room (see shortfall against PFE1 (a)).

Checks, including of the condition of the body and identification against a minimum of three points of identification, are carried out on all bodies prior to a PM examination, viewing of a body or releasing a body. Where viewings are booked in advance, and with scheduled PM examinations, these checks occur prior to the viewings or the PM examinations, and often the evening before. In some circumstances, bodies scheduled for PM examination early the following day are left overnight, fully shrouded, in the PM suite (see *Advice*, item 4).

Mortuary staff process any tissue retained from PM examinations in the PM suite and transfer cassetted tissue to the histology laboratory for subsequent analysis. Samples are recorded in the customised electronic system prior to transfer and taken with a paper histology request form. After analysis, the blocks and slides are returned to the mortuary for retention, disposal or to be reunited with the body; in accordance with the consent form and wishes of the deceased individuals family.

Description of inspection activities undertaken

This report describes the third routine site visit inspection in November 2017. Formal interviews were conducted with the DI, the LH and other key members of staff working under the licence. A visual inspection of the mortuary including the body store, viewing room, PM suite and temporary contingency body store, and the Histopathology Laboratory was conducted.

In the body store, traceability audits of body identifiers, storage locations and register details were carried out for four adult bodies (one from the hospital and three from the community), including one body in long term storage, and one perinatal body. No anomalies were found.

As part of the inspection, tissue collected during the PM examinations of three individuals in early 2017 was audited for compliance with the associated consent. In addition to the standard hematoxylin and eosin slides, samples for one of the three individuals audited had an additional seven immunology slides processed from their blocks, for which there were no readily available records (see shortfall against T1 (g)).

Inspection findings

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

Compliance with HTA standards

While the majority of the HTA standards were fully met by the establishment, five minor shortfalls were identified against the HTA’s licensing standards.

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).	Tissue samples taken during PM are processed in the laboratory and slides are sent to the pathologist for assessment. The pathologist will use an additional paper request form to request additional slides if necessary. Residual blocks and processed slides remain in the histopathology storage area until they are returned to the mortuary for disposal or retention as per the consent documentation. While all tissue audited was traceable, there were no formal records of what slides had been cut from each block. However, the paper request forms and processing records within the laboratory enables reconstruction of the process. At the time of audit, one of three tissue sets assessed had immunology slides in addition to the standard slides routinely processed, with no records of how many additional slides had been generated from the tissue.	**Minor**

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	While the premises were regularly cleaned and maintained, the floor of the PM suite was uneven, which resulted in the pooling of water that could not effectively drain into the waste system after cleaning. Several pools of liquid were located around the base of equipment and as a result the base of the wooden door frame, into the PM viewing area, was rotted and corroded.	**Minor**
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)	Funeral Directors and ambulances deliver and collect bodies from the rear entrance of the mortuary, which is visible from the maternity ward and directly overlooked by nearby offices. This has the potential to cause distress to indviduals who may witness the transfer of bodies and poses a risk to the dignity of the deceased.	**Minor**

PFE2 There are appropriate facilities for the storage of bodies and human tissue.		
a) Storage arrangements ensure the dignity of the deceased	On site contingency involves four temporary refrigerated units, stored in a separate basement room which is not readily accessible. One of the two units leased from the vendor is located under a rusted air vent system which was leaking fluid over one of the units. It appeared that some of the fluid contained waste from the PM suite drainage system, located directly above the room.	**Minor**
d) Fridge and freezer units are in good working condition and well maintained	While not monitored the ambient temperature in the body store was significantly higher than the refrigerated body spaces. As a result, temperatures within the refrigerated storage rapidly increased when opening the fridges; the establishment have subsequently set a 90 minute delay on the alarm system. The pass through refrigerated spaces are set to alarm at -1°C and +15°C while the single entry refrigerated spaces are set to alarm at -1°C to +10°C. See *Advice* item 8.	**Minor**

Advice

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

No.	Standard	Advice
1.	C1(b)	The draft SOP 'Post Mortem consent and the retention of anatomical tissues from deceased patients' is well written and provides extensive information on hospital and coroner's PM examinations. The DI is advised to review the document to ensure it clearly differentiates between hospital and coroner's PM examinations. For example, p.17 indicates that 'a copy of the report may be requested via the Coroner's Office' but does not provide information on hospital PM examinations. The DI is advised to consider including information on the consent form that tissue retained for research may be disposed of if there is no research that the tissue is suitable for, and to determine if this may also be amended on the Coroner's consent form.
2.	C2(a)	Consent for perinatal/paediatric Post Mortem examinations is sought by trained and experienced maternity unit staff. Due to recent staff turnover,r this consent is presently only sought by the Bereavement Specialist Midwife. The DI is advised to ensure that additional staff complete their training as soon as possible to ensure sufficient staff are available to take consent, taking into account holidays, sickness and any other periods of absence.
3.	GQ6(a)	While risk assessments are in place, they do not always consider the risks to the deceased. The DI is advised to review the establishment's risk assessments to ensure the cover the areas of risk identified in the HTA

		Reportable Incident categories (for examples see 'Regulation of the Post Mortem Sector: What we have learned' on the HTA website)
4.	GQ6(b)	Bodies scheduled for an early PM examination are occasionally left overnight in the PM suite, after the appropriate identity checks. The DI is advised to produce a documented risk assessment and procedure governing the practice of leaving bodies overnight prior to a PM examination. This should include details of when it is not appropriate to leave bodies out overnight, such as during the warmer summer months. The risks that the DI should consider include, but are not limited to, risks relating to suitable storage conditions for bodies in the PM suite, whether the PM suite requires chilling if it is routinely used to store bodies overnight and the dignity of the deceased.
5.	GQ6(b)	Mortuary staff log all patients into a customised, commercially available database. The system provides an overview of all bodies within the mortuary, and available spaces within the body store. However, the storage room containing the four temporary units of refrigerated body spaces does not have a computer system and all records must be transcribed into the database on return to the mortuary. The DI is advised to risk assess the possibility of transcription errors or failure to log details into the computer system or consider locating a computer within the room itself.
6.	T1(c)	Mortuary staff were observed undertaking several procedures. While it was apparent that staff were checking a minimum of three points of identification (as required by the HTA standards), associated SOPs did not explicitly state the forms of identification that should be checked. The DI is advised to review SOPs to ensure that they explicitly state that Full name, Date of Birth and Address/Hospital number should be checked at a minimum. This should be in addition to any other forms of identification routinely assessed.
7.	T1(c)	Mortuary staff assist with viewings of the deceased. Relatives contact the mortuary to provide details of the deceased they wish to visit and arrange a time for the viewing. The DI is advised to institute a method where the family provide the minimum identification required for the deceased.
8.	PFE2(a)	The refrigerated body spaces are set to alarm at a lower temperature of -1°C and either +10°C (for single entry spaces) or +15°C (for double ended pass through spaces) as a higher limit. Due to the high temperature of the body store itself, the alarm system has been set with a 90 minute delay. The DI is advised to consider options for lowering the ambient temperature of the body store and to ensure that bodies are maintained at an appropriate temperature, approximately 4°C for refrigerated body spaces.
9.	PFE2(b)	During the inspection, it was noted that the older fridges and freezer units had failed on several occasions, resulting in a temporary loss of storage space. Most recently, the refrigerated spaces had risen in temperature resulting in the entire bank (50 spaces) being lost for two days in March 2017. The banks of five freezer spaces failed in June 2017, resulting in bodies being moved to refrigerated spaces, and returned to the freezer units once they had been repaired. While there is significant contingency planning, the DI is advised to risk assess the potential loss of refrigerated/frozen body spaces due to the age of some of the units, particularly during busy periods, and consider any actions that may be undertaken to mitigate risk.
10.	PFE2(e)	The establishment has a separate refrigerator for fetuses and products of conception. This is not currently on the monitoring system and temperatures are recorded manually twice daily. The DI is advised to

		consider adding this refrigerator to the alarm monitoring system or to assess and document any risks associated with it not being on the monitoring system.
11.	PFE2(f)	While temperatures are routinely monitored for all equipment, the DI is advised to institute regular, documented, trending of the temperatures as this may provide advance information on the potential failure of the units. This trending should be performed by staff within the mortuary.
12.	PFE3(f)	All equipment was maintained, either by hospital estates or a commercial organisation. The DI is advised to ensure that details of the maintenance schedule and coverage, and any setting for the equipment, are also held within the mortuary. Mortuary staff should ensure that any settings are appropriate for the equipment in question.

Concluding comments

This report outlines the third routine site visit inspection of Basildon University Hospital. Although five minor shortfalls were identified, a number of strengths and areas of good practice were observed during the inspection, including:

- The team working under the HTA licence appear to engage, internally and with external contacts, extremely well and in a professional manner. This was particularly evident in interactions with the Coroner's Office and the portering staff at the hospital.
- The mortuary staff demonstrate an understanding and consideration for relatives of the deceased. They have raised funding to renovate the 'Dandelion' viewing room to a high standard and wear uniform outfits during viewings. Staff also have their pictures on display in the viewing room to inform visitors who they may interact with.
- Staff appear supported and empowered by senior management. This includes the provision of risk assessments that detail 'Staff Stress' and SOPs on how to reject inappropriate specimens.
- The mortuary has adopted bespoke software and customised it to a high standard, allowing a visual display that provides a wealth of information on occupancy and available spaces within the mortuary.
- There are several committees and groups that work to streamline processes and plan for peak periods, including a Winter Planning Committee.

There are a number of areas that require improvement, including five 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: 21/12/2017

Report returned from DI: 08/12/2018

Final report issued: 09/12/2018

Completion of corrective and preventative actions (CAPA) plan

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

Date: 07/01/2019

Appendix 1: HTA licensing standards

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

Consent
C1 Consent is obtained in accordance with the requirements of the Human Tissue Act 2004 (HT Act) and as set out in the HTA's codes of practice
a) There is a documented policy which governs consent for post-mortem examination and the retention of tissue and which reflects the requirements of the HT Act and the HTA's Codes of Practice. b) There is a documented standard operating procedure (SOP) detailing the consent process. *Guidance* *This should include who is able to seek consent, what training they should receive, and what information should be provided to those giving consent for post-mortem examination. It should make reference to the use of scanning as an alternative or adjunct to post-mortem examination.* c) There is written information for those giving consent, which reflects the requirements of the HT Act and the HTA's codes of practice. *Guidance* *Information on consent should be available in different languages and formats, or there is access to interpreters/translators. Family members should be given the opportunity to ask questions.* d) Information contains clear guidance on options for how tissue may be handled after the post-mortem examination (for example, repatriated with the body, returned to the family for burial/cremation, disposed of or stored for future use), and what steps will be taken if no decision is made by the relatives.

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

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

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

Guidance

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

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

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

Guidance

Refresher training should be available (for example annually).

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

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

d) Competency is assessed and maintained.

Governance and quality systems

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

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

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

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

iii. practices relating to evisceration and reconstruction of bodies;

iv. systems of traceability of bodies and tissue samples;

v. record keeping;

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

vii. lone working in the mortuary;

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

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

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

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

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

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

xiv. contingency storage arrangements.

Guidance

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

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

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

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

Guidance

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

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

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

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

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

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

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

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

Guidance

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

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

Guidance

Meeting minutes should be recorded and made available to staff.

GQ2 There is a documented system of audit

a) There is a documented schedule of audits.

Guidance

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

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

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

Guidance

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

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

Guidance

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

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

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

Guidance

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

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

b) There are clear reporting lines and accountability.

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

Guidance

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

d) Staff have annual appraisals and personal development plans.

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

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

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

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

Guidance

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

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

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

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

Guidance

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

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

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

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

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

Guidance

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

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

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

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

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

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

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

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

Guidance

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

change. Staff should be involved in the risk assessment process.

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

Guidance

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

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

Traceability

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

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

Guidance

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

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

Guidance

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

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

Guidance

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

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

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

Guidance

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

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

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

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

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

ii. receipt upon return to the laboratory or mortuary

iii. the number of blocks and slides made

iv. repatriation with the body

v. return for burial or cremation

vi. disposal or retention for future use.

Guidance

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

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

Guidance

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

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

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

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

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

Guidance

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

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

d) The method and date of disposal are recorded.

Premises, facilities and equipment

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

a) The premises are clean and well maintained.

Guidance

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

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

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

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

Guidance

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

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

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

a) Storage arrangements ensure the dignity of the deceased.

Guidance

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

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

Guidance

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

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

Guidance

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

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

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

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

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

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

Guidance

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

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

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

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

Guidance

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

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

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

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

Establishments should consider entering in to Mutual Aid Agreements

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

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

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

   i. fridges / freezers

   ii. hydraulic trolleys

   iii. post mortem tables

   iv. hoists

   v. saws (manual and/or oscillating)

Guidance

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

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

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

Guidance

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

d) Staff have access to necessary PPE.

Guidance

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

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

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

Guidance

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

Appendix 2: Classification of the level of shortfall

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

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

1. Critical shortfall:

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

or

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

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

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

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

(3) A notice of suspension of licensable activities

(4) Additional conditions being proposed

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

2. Major shortfall:

A non-critical shortfall that:

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

or

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

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

3. Minor shortfall:

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

departure from expected standards.

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

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

Follow up actions

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

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

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

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