Site visit inspection report on compliance with HTA licensing standards

Queen Elizabeth Hospital King's Lynn

HTA licensing number 12298

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**

19th July 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.

The Queen Elizabeth Hospital King's Lynn (the establishment) was found to have met all HTA 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

The mortuary is located at the Queen Elizabeth Hospital Kings Lynn, incorporated with the Bereavement Relative Support Office. Both are part of the Cancer, Diagnostics and Care Services Division of the Queen Elizabeth Hospital King's Lynn NHS Foundation Trust. The Corporate Licence Holder contact is the Chief Executive of the Trust; the Designated Individual (DI) is the Legal Services Manager.

The establishment receives approximately 1,600 bodies each year from the hospital and the community and performs around 350 adult post mortem (PM) examinations annually. This figure includes high-risk (up to category 3) cases, forensic adult cases and a few adult (consented) cases. Routine adult cases are performed under the authority of HM Coroner for Norfolk. Routine paediatric/perinatal cases are transferred to other licensed establishments; however, consent for paediatric / perinatal cases is obtained on site.

There are currently four independent Consultant Histopathologists who conduct PM examinations two days per week at the establishment, on a rotational basis. All consultants are based at Norfolk and Norwich University Hospitals NHS Foundation Trust (NNUFT). The Histopathology laboratory used by the establishment is also located at NNUFT. Specimens are collected from pathology reception at Queen Elizabeth Kings Lynn and sent to Histopathology at NNUFT via hospital transport. Records of traceability are kept by the mortuary. The mortuary is staffed by one senior APT (mortuary lead), a trainee APT and a mortuary assistant.

The establishment has 52 fridges in the main body store, including spaces for bariatric and super bariatric bodies. Four of the bariatric fridge spaces can be converted into freezers when required and are appropriately signed when operating as a freezer. Paediatric and perinatal bodies are kept in specifically allocated fridge spaces. There are an additional 16 permanent fridge spaces adjacent to the PM room, providing accommodation for standard and bariatric bodies. In addition, a Flexmort cooling blanket for super bariatric bodies is available for use in this area. All fridge and freezer units are remotely alarmed, monitored and tested regularly. In the event of an alarm, the estates department and switchboard staff are alerted and contact the mortuary, including on-call mortuary staff member out of hours. These fridges and freezers are also linked to the Trust's back-up generators in case of power failure. Access to the mortuary from the hospital is via double doors controlled by swipe cards held by mortuary staff and porters. Funeral directors access is via an external door with a triple lock. All doors are covered by CCTV and included in regular security patrols.

Consent forms for both paediatric and adult PM examinations are based on the Sands and HTA's model consent forms, respectively, therefore are fully compliant with statutory and regulatory requirements (see advice item 4). Consent is sought by two APTs trained to undertake this task in collaboration with clinical staff for adult hospital PM examinations (see

advice items 2 and 5). Consultant clinicians and senior midwives who have undertaken training for post mortem consent seek consent for perinatal and paediatric PM examinations. This training is recorded and refreshed annually.

Porters transfer and admit all hospital bodies to the mortuary. Mortuary staff complete patient identification checks and the admission process as soon as possible, or the next working day, using the 'Mortuary identification Card' transferred with each body. Mortuary staff work on-call and are responsible for admitting Coroner's cases out of hours, completing the 'Mortuary Admittance Form for Community Deaths' form. Details of all bodies are entered in to the 'Mortuary Declaration of Identity' book and each body is allocated a unique mortuary register number. An additional wristband is placed on the body displaying this number and their allocated fridge space. Subsequently, mortuary staff complete the mortuary register and the electronic APEX system. Bodies are released from the mortuary using release forms provided by the Coroner's office for post mortem cases, and by the hospital for completion by local funeral directors. Out of area funeral directors provide a copy of the green disposal order. Three identifiers are used to identify bodies, cross referencing with the release form and the 'Mortuary Declaration of Identity' book. This book is then signed by the funeral director and mortuary staff. The mortuary staff use 'Warning' indicators on the body store whiteboards as a visual cue when tissue has been retained at post mortem or there is a risk of infection (see advice item 12). Subsequently, the mortuary spreadsheet and APEX system is updated by the mortuary staff.

The mortuary's post mortem suite contains two post mortem tables and two dissection units. Two APTs carry out initial identification checks of bodies when removing them from the fridges, and again with the pathologist prior to any evisceration. A 'one at a time' system' is used to avoid mix-up of organs and tissue samples removed during PM examination.

The hospital's maternity unit utilises cold cots to allow bereaved parents to spend time with their baby prior to the transfer of the body to the mortuary. Deceased infants and their associated documentation are organised and transferred to the mortuary by the porters and maternity unit staff.

On occasion, the removal of tissue samples from the body of a deceased child occasionally takes place in the Accident and Emergency Department (A&E). The process and documentation for these cases was reviewed as part of the inspection.

Description of inspection activities undertaken

The establishment has been licensed by the HTA since August 2007. Previous routine site visit inspections took place in December 2008 and March 2012. This report describes the third routine site visit inspection visit in July 2017. Formal interviews were conducted with the Designated Individual, Corporate Licence Holder contact, Mortuary Lead, Trainee APT, Coroner's Officer, Consultant Histopathologist and post mortem consent seekers (adult and

perinatal). The inspectors also carried out a visual inspection of the mortuary, including the body store, post mortem room and viewing suite. An audit of body identifiers, storage locations, mortuary register details and associated documentation was carried out for two adult bodies (one hospital and one community) and one perinatal body in the mortuary. No anomalies were found. In addition, an audit of two post mortem cases where histology had been taken and returned to the establishment (from NNUFT) were conducted. Records were reviewed to establish the relatives' wishes for the tissue and if these had been complied with. No anomalies were found. The Histopathology department of NNUFT was contacted after the inspection to follow up the process and confirm traceability of the tissue sent there by the establishment. Currently, any tissue with instruction for disposal is disposed of at NNUFT. However, the establishment is in the process of changing this procedure so that all tissue will be returned to the mortuary for disposal and records of disposal maintained by the mortuary.

Material held for the police

The establishment conducts approximately six Home Office PMs annually; at the time of the inspection there were two PACE specimens being held on site from recent forensic cases. There are no long-term specimens being stored.

Inspection findings

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

Compliance with HTA standards

All applicable HTA standards have been assessed as fully met.

Advice

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

No.	Standard	Advice
1.	C1 (a)	The 'Mortuary Consent Procedure' (MORTSOP31, p5) refers to the hierarchy of qualifying relationships as set out in the Human Tissue Act 2004. However, parent/child has been given equal ranking as spouse/partner (highest). The DI is advised to amend this to reflect the correct order of the hierarchy. Furthermore, a reference to the hierarchy of qualifying relationships on page five could be included on page three, after the paragraph about nominated representatives to demonstrate the correct successive order. The DI is advised to avoid using the term 'next of kin' (NOK) when consent is required from a person in the highest qualifying relationship to a deceased. For example, the SOP 'PM Procedure' (MORTSOP20, p5) refers to the next of kin when stating the consent requirements for post mortem testing of bodies where staff receive a needle stick injury. NOK is also referred to in the SOP 'Disposal of Tissue' (MORTSOP017).
2.	C1 (b)	The document 'Hospital Post Mortem Administration' (MORTSOP01, p2) refers to a minimum 24 hour 'cooling off' period for relatives to change their minds in relation to a consented post mortem examination. However, the 'Mortuary Consent Procedure' (MORTSOP31, p4) states there is a minimum 48 hour 'cooling off' period. The DI is advised to decide which is the most appropriate period of time and update all documentation (including that given to relatives) accordingly. In addition, if relatives decide they would like whole organs returned to the body before the funeral, they must be advised that this is likely to delay any funeral arrangements. The DI is advised to include this in 'Hospital Post Mortem Administration SOP, (MORTSOP01,p3, 'When taking consent').
3.	C1 (d)	The document 'Patient's Wishes re Pregnancy Tissue up to 12 weeks' refers to 'recommendations of the Human Tissue Act 2004' in relation to the retention of blocks and slides for up to 30 years. This statement is incorrect; the Royal College of Pathologists (RCPath) issued these guidelines in April 2015, 'The Retention and Storage of Pathological Records and Specimens' (5th Edition): https://www.rcpath.org/resourceLibrary/the-retention-and-storage-of-pathological-records-and-specimens--5th-edition-.html The second part of the form (section (b)) states that if the mother wishes to make her own funeral arrangements, she must do so within two years. The HTA has developed guidance in relation to pregnancy remains and their disposal, which should not exceed 12 weeks. Refer to the following link: https://www.hta.gov.uk/policies/hta-guidance-sensitive-handling-pregnancy-remains The DI is advised to liaise with the relevant maternity unit staff to correct this document and include information in line with guidance developed in this area.
4.	C1 (g)	The establishment uses the model HTA consent form for adult consented post mortem examinations. The DI is advised to remove the highlighted sections referring to guidance for establishments and enter the establishment's name in the footer of the document (electronically).
5.	C2 (d)	The DI is advised to ensure mortuary staff who complete consent forms for consented post mortem examinations are fully conversant with the forms and complete them correctly.

6.	GQ1 (a)	In SOP 'Release of Deceased' (MORTSOP09, p2, second paragraph), the wording is misleading. It implies that a body has already been released to a funeral director. The DI is advised to review the wording to avoid confusion. The Trust policy 'Dealing with Deceased and the Bereaved', sections 10 'Organ and Tissue Donation' and 12, 'PM Examinations' refer to the HTA's old codes of practice. This document needs updating to reference the HTA's new codes of practice. The SOP 'Forensic Post Mortem' (MORTSOP24) includes the transfer of bodies for CT or MRI scanning. The DI is advised to include the process of how bodies are transferred to and from the mortuary. This task is performed infrequently; therefore, it is important that the SOP covers procedures in sufficient detail for staff to refer to when needed. Where personal protective equipment (PPE) is referred to in SOPs, the DI is advised this should consistently detail what PPE is required for a particular task. This will help ensure staff are aware of the level of protection required for mortuary procedures.
7.	GQ1 (d)	The front pages of numerous SOPs were found to be displaying the latest version number but subsequent pages displayed the previous version number in the footer of the document. For example, the SOP 'PM Procedure' (MORTSOP20), the version number on the first page is 1.4 but subsequent pages are version 1.3. In addition, the Quality Manual's review date is 9th May 2017. The DI and mortuary lead are advised to review all current SOPs to check the version numbers are consistently correct and that review dates of each document have not been exceeded.
8.	GQ1 (g)	The DI is advised to 'officially' appoint Persons Designated (PDs) in the mortuary, maternity unit and Accident and Emergency Department by formally informing the HTA. Regular minuted meetings with PDs covering HTA-related activities should also be implemented. In addition, the mortuary PD (Senior APT) is advised to register for the portal for the HTA website to enable them to report HTARIs. This is especially important in the absence of the DI, as all HTARIs must be reported to the HTA within five working days of discovery
9.	GQ2 (a)	The mortuary lead is advised to document the daily body checks undertaken in the mortuary as further evidence of audits carried out within the department.
10.	GQ5 (a)	The Quality Manual (LHMORT350) is dedicated to the mortuary and divided in to the HTA standards. However, section GQ5, 'There are systems to ensure that all untoward incidents are investigated promptly' does not mention the reporting of HTARIs and who would do this. The DI is advised to include this information.
11.	T1 (c)	Where SOPs state that identification or identifiers need to be checked, these should consistently detail what those identifiers could be. There should be a minimum of three identifiers, one being unique. For example, the SOP for viewings (MORTSOP018) simply states that identification should be checked. In addition, the SOP 'Taking Samples' MORTSOP16, should detail what identifiers and information is required when labelling specimens ensuring accurate traceability.
12.	T1 (d)	The DI may wish to consider using fridge door signs or magnets that highlight bodies with same/similar names and tissue retained. Wristbands for bodies with same/similar names could also be used. This will strengthen existing processes for identifying bodies with same/similar names and tissues retained at post mortem.

Concluding comments

The mortuary team are very enthusiastic and conscientious, demonstrating a high level of compassion and care for the work they undertake. They are supported by a DI and senior management team who recognise the importance and significance of mortuary practice.

There were several areas of strength and good practice:

- The letter 'H' (for 'histology') is written in green next to the relevant name on the body store whiteboard to indicate when tissue has been taken at post mortem examination. Once tissue instructions have been received the letter 'H' is 'ticked';
- In addition, all bodies from which tissue has been taken are given an additional wristband (on the same wrist as the identification wrist band). This acts as a visual cue to staff to ensure instructions have been received for retained tissue before the body is released;
- In addition to mortuary documentation, spreadsheets are used to record all mortuary admissions/releases (which is reviewed to assess potential long stayers), cases for post mortem examination and tissue taken;
- Mortuary whiteboards displaying body identification and locations are covered by a roller blind to ensure confidentiality. This is particularly important as the mortuary may deal with high profile cases;
- There is a 'traffic light' system for demarcation of dirty, transitional and clean areas and which PPE should be worn in each area. Signs are displayed highlighting this system and coloured dots are used on doors as a visual cue for the type of area being entered;
- The 'cube' system used by the porters to cover and transfer bodies to the mortuary is efficient, effective, reduces manual handling and ensures dignity of bodies;
- All visitors to the mortuary have to read and sign the 'Mortuary Visitor Guidelines' which details important information and rules while in the department;
- The porter training includes routinely measuring the width of bodies to allocate an appropriately sized fridge, reducing the risk of accidental damage of bodies;
- The premises are exceptionally clean, tidy and well organised.

The mortuary team has received praise from numerous sources and the HTA recognised their professional and proactive approach.

The HTA has assessed the establishment as suitable to be licensed for the activities specified.

Report sent to DI for factual accuracy: 15/08/17

Report returned from DI: 25/08/17

Final report issued: 05/09/17

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.