Site visit inspection report on compliance with HTA licensing standards

Leicester Royal Infirmary

HTA licensing number 12337

Licensed under the Human Tissue Act 2004 for the

- **making of a post mortem examination;**
- **removal from the body of a deceased person (otherwise than in the course of an anatomical examination or post-mortem examination) of relevant material of which the body consists or which it contains, for use for a scheduled purpose other than transplantation; and**
- **storage of the body of a deceased person or relevant material which has come from a human body for use for a scheduled purpose**

10 – 12 October 2018

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 Leicester Royal Infirmary had met the majority of the HTA's standards, five major and eleven minor shortfalls were found against standards for Consent, Governance and Quality, Traceability and Premises, Facilities and Equipment.

The shortfalls relate to post-mortem (PM) examination consent training and seeking procedures; standard operating procedures (SOPs); records management; storage of the deaceased; risks assessments for licensable activities; audits; traceability; maintenance of premises, equipment; security and body store alarms.

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.

Material held for the police

Under s39 of the Human Tissue Act 2004, relevant material held for criminal justice purposes is outside the scope of HTA regulation and is not subject to the licensing requirements for storage. However, in response to a recommendation resulting from the 2012 report of the Association of Chief Police Officers' audit of tissue held under police authority, that police exhibits held on HTA licensed premises should be included within the regular HTA inspection process, police holdings stored at the establishment were reviewed

by the HTA during the inspection. Any findings in relation to police holdings have been shared with the Home Office, but do not appear in this report as they are outside the scope of the HT Act.

Background to the establishment

Leicester Royal Infirmary (the establishment) is licensed under the Human Tissue Act 2004 (HT Act) for: carrying out post-mortem (PM) examinations; removal from the body of a deceased person of relevant material (for scheduled purposes) and storage of the body of a deceased person or relevant material which has come from a human body for use for scheduled purposes. The establishment, consists of a hub (Leicester Royal Infirmary (LRI)) and two satellite sites: Leicester General Hospital (LGH) and Glenfield Hospital (GH). The establishment has been licensed, by the HTA since January 2007 and this report describes the sixth routine inspection, with the previous inspection occurring in February 2017. The current DI was appointed just before this inspection, having been in post since September 2018.

Access to the mortuary from the hospital is on the ground floor of the main hospital next to the main reception area. Porters transferring hospital bodies and visitors wishing to view relatives in the mortuary use this same entrance. The porters also use the same lifts as visitors to the hospital but other staff and visitors are not allowed to travel in the lift at the same time as the bodies. The mortuary staff try to prevent delivery of hospital bodies to the mortuary while visitors are either entering or leaving the mortuary (see *Advice,* item 4). The initial entrance into the mortuary is secured by a proximity card system. Access for community deaths and funeral directors is via a concealed porch area with a shutter door. This door is kept closed to ensure security and privacy.

The door from the covered porch area enters onto a short corridor that leads to the main body store area. Funeral directors wait in this area to collect or deliver bodies. Located in this corridor is a fridge for the storage of pregnancy remains. A second unsecured door leads to a further short corridor in which the relatives waiting area for the viewing room is located. (see shortfall against PFE1(d)).

The establishment operates a post-mortem (PM) examination service. They conduct approximately 2000 PM examinations per year including high-risk (up to category 3) cases. The total figure includes: adult and paediatric/perinatal forensic, coronial and hospital consented PM examinations. These PM examinations are generally only undertaken at the LRI site, however, when demand requires or during refurbishment at LRI (as was required during the months of July and August 2017), PM examinations are undertaken at GH (see shortfall against PFE3(c)).

Hospital bodies are transferred by porters to mortuary and should have two wrist bands in place, with name, date of birth (DOB), address and hospital identity number (S number).

Community bodies are brought in by Funeral Directors (FDs) or by ambulance staff. These bodies will also have two wrist bands with name (or unknown male/unknown female), DOB (or date of death (DOD)), address or place of death. In normal working hours the mortuary staff receive the body and check the wrist band details and enter them into the electronic mortuary register and iLab system; and a unique mortuary number is generated for every body that enters the mortuary. Outside of normal working hours porters are responsible for receiving community bodies into the mortuary and they complete the patient reception register with available identifiers. The following working day mortuary staff check the bodies brought in out-of-hours and enter their details into the mortuary register and iLab system. Anyone who has previously been entered onto the hospital Health Information Support System (HISS database) will already have been allocated an S number; if they have not, a new S number is allocated to them. Bodies identified as having same and/or similar names will have an orange wrist band attached and an orange magnet on the fridge door identity plate. Infectious cases have an infection risk sticker placed onto the body bag detailing precautions that should be taken relevant to the infection risk. A risk of infection magnet is also applied to the fridge door identity plate.

Release of bodies occurs in normal working hours only and is undertaken by two members of mortuary staff. The FDs arrive with paperwork detailing the name, DOB and address of the body they wish to collect. This paperwork is cross checked against the details on the identity wrist bands; the wrist band details and the S number are then cross-checked with the HISS database information. This information and condition of the body is checked by both members of mortuary staff and the receiving FDs.

LRI has 127 refrigerated spaces, twelve of which can be converted to freezers, nine permanent freezer spaces and ten bariatric spaces. There are a further 24 refrigerated spaces located in the covered porch area. These spaces were originally for contingency storage but are now in routine use. The fridge and freezer temperatures are monitored by an integrated alarm system which at the time of inspection was not functional (see shortfall against PFE2(e)). When operational, the alarm system alerts security and the on-call APT of deviations outside the normal operating temperature range for greater than 15 minutes. At the time of inspection, a digital probe was being used to manually check the upper and lower temperature ranges of the body store.

The mortuary has two inter-connecting PM suites, one designated for forensic PM examinations, the other for all other PM examinations. The forensic PM suite has a single, height-adjustable down-draught table and designated dissection area. There is also a viewing room for the forensic PM suite only, in here is a storage cupboard containing material stored under Police and Criminal Evidence Act 1984 (PACE), (see shortfall against GQ2(b)). The main PM suite consists of seven sets of metal stands onto which the fridge trays are secured (see shortfall against PFE1(a)). Dissection of organs occur on small designated tables located at the top of the metal stands to help mitigate the risk of mixing up organs.

The Coroner's Officer faxes authorisation for a PM examination to the mortuary who then pass a copy to the pathologist. The pathologist and Anatomical Pathology Technologist (APT) check the identity of the deceased before the external examination and evisceration of the body (see shortfall against GQ1(b)). Material retained at PM examination for histological analysis is placed into pre-labelled cassettes, documented and packaged in the mortuary before being sent to the histopathology laboratory on site with a histology request form. Relatives' wishes with regards to the fate of any tissue retained following PM examination are managed by the deputy service manager, who enters details onto the electronic patient record that is accessible to mortuary and histology laboratory staff.

Stillbirths and perinatal cases are transferred to the mortuary from the maternity unit within a few hours by porters in a dedicated transfer bag. The establishment removes relevant material from deceased infants and children under the Sudden Unexpected Death in Infants and Children (SUDIC) protocol under pre-emptive authorisation of HM Coroner.

Leicester General Hospital (LGH)

The mortuary at LGH is located away from the main hospital in a separate building. This site is the main contingency storage site for LRI. It is also identified as a potential emergency mortuary site. The body store has 68 refrigerated spaces and has a dedicated fridge for pregnancy remains, which is not alarmed (see shortfall against PFE2(e)). The main refrigerated spaces are on the same external alarm system as at LRI. The alarm system contacts the switch board at LRI if the temperatures deviate outside the normal temperature ranges. No community bodies are received into this mortuary and PM examinations are not conducted at this site. There are two sets of fridges on each side of the body store which were installed at different times (see shortfall against PFE1(a)). Staff from LRI are present for 2.5 hours per day on a rota basis. Due to the location of the mortuary, staff attending this site out-of-hours are accompanied by security. Viewings are rarely undertaken but when they are, staff are sometimes left alone with relatives (see shortfalls against GQ1(a) and PFE1(d)).

Glenfield Hospital (GH)

The mortuary at GH is part of the main hospital building. The body store has 32 refrigerated spaces. Bodies stored are generally patients for the hospital, with occasional transfers from LRI when required. PM examinations are on occasion conducted at this site (see shortfalls against PFE1(a) and PFE3(c)). Staff from LRI are generally present for 2.5 hours per day on a rota basis. The fridges are on the same external alarm system as at LRI. Viewings are rarely undertaken at this site, however, the viewing room is not lockable from the outside allowing visitor access to the body store area (see shortfall against PFE1(d)). In addition, staff are sometimes left alone with relatives during viewings (see shortfalls against GQ1(a) and PFE1(d)).

All three sites are linked to the same electronic mortuary register system. The register tracks each body throughout its time in the mortuary and records what tissue has been taken as part of a PM examination. There is also a tissue retention book, which has different colour carbon copies to assist in traceability of tissue. There are procedures in place to ensure that all blocks and slides are accounted for and pathologists return all slides to the laboratory. Paper records such as the Tissue Retention Form and computer records are updated as appropriate once disposal has taken place. The establishment has an extensive archive of retained blocks and slides, which are stored in a secure area at the LRI site.

Description of inspection activities undertaken

An audit trail was undertaken at each of the sites cross referencing details in the electronic and paper based mortuary registers. The name, DOB, address, storage location and 'S' number were checked against those on the identity tags found on the body:

- LRI - five bodies (three adults and two babies) were audited; no discrepancies were identified;

- LGH - three bodies (two adults and one baby) were audited; one body was found not to be in the electronic register (see shortfall against T1(h)). No other descrepancies were identified;

- GH - two adult bodies were audited; no descrepancies were identified.

In addition, tissue removed during PM examinations for seven cases between 2017 and 2018 were audited for traceability. Material removed is recorded on the PM histology request form, in the mortuary register and onto the histology database once received into the laboratory (see shortfall against T1(g)). No discrepancies were found.

Interviews were conducted with: Consultant Histopathologist (the DI); Mortuary Manager; Lead consultant pathologist who overseas consent seeking for adult PM examinations; Consultant Obstetrician who oversees consent seeking for perinatal PM examinations; Consultant Paediatrician responsible for overseeing removal of material in A&E from SUDIC cases; Logistics Manager for porter activities; Deputy Service Manager; Forensic Pathologist regarding PACE material; Anatomical Pathology Technologist; mortuary Assistant Technical Officer; and a Coroner's Officer.

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

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	Those involved in seeking consent for perinatal/paediatric PM examinations do not always have adequate and up-to-date training. Records of those who have received training which addresses the requirements of the HT Act and the HTA codes of practice, are not held by the relevant departments. Therefore it is not possible for the DI to assure herself that appropriately trained staff are seeking consent for paediatric PM examinations. *Standards C2(b), C2(c) and C2(d) could not therefore be assessed.*	**Minor**

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.	While the establishment has a number of the required SOPs in place, they lack sufficient detail or attention to wording, these include but are not limited to: • SOP HM2 003 – describes how to identify bodies requiring transfer into the frozen storage but there is no system in place to readily identify how long a body has been in the mortuary. In addition, the SOP does not describe the process for moving bodies into long-term storage; A number of bodies were identified as being held in the refrigerated storage for longer than the recommended 30 day period (see shortfall against PFE2(c)). This was also identified as a shortfall in the previous site visit inspection and has not yet been addressed by the establishment. • SOP HM2 017 – Does not state that the external examination of the body should be undertaken by the pathologist prior to evisceration taking place;	**Major**

	• SOP HM2 020 – states that at no time will mortuary staff be left alone in the mortuary with a family. This part of the SOP is not always adhered to at the more remote sites of GH and LGH. All SOPs require review to assure the DI that they contain sufficient detail. This was identified as a shortfall in the previous site visit inspection and has not yet been addressed by the establishment.	
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	In the previous inspection advice was given that the practice of evisceration prior to a thorough external examination by the pathologist is contrary to 'Royal College of Pathologist's guidelines on the conduct of a PM examination'. The inspection team were told that pathologists are still instructing mortuary staff to eviscerate bodies prior to the pathologist conducting an external examination of the body.	**Major**

GQ2 There is a documented system of audit		
a) There is a documented schedule of audits	There is no schedule of regular audits of licensable activities undertaken in the mortuary to check compliance with documented procedures, including completion of records and traceability	**Minor**
c) Regular audits are carried out of tissue being stored so that staff are fully aware of what is held and why and enable timely disposal of of tissue where consent has not been given for continued retention	The establishment currently stores a number of whole organs held under PACE for the police. While a record of samples held is kept by the establishment, regular audits of this material is not included in existing tissue audits.	**Minor**

T1 A coding and records system facilitates traceability of bodies and human tissue, ensuring a robust audit trail		
g) Organs or tissue taken during post-mortem examination are fully traceable, including blocks and slides (including police holdings).	Tissue retained at PM examination and transferred to the histology laboratory is not signed for upon receipt.	**Minor**
h) There are documented procedures for transportation of the bodies and tissues anywhere outside the mortuary, (such as the lab or another establishment), including record-keeping requirements.	Fetal remains stored at GH were found not to be recorded in the electronic mortuary register. At all sites, records are not kept by the maternity unit, Paediatric Intensive Care Unit (PICU) or A&E departments for relevant material that has been collected and transferred to the mortuary. This poses a risk that traceability may be lost for bodies and relevant material sent between these departments and the mortuary.	**Major**

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	There were issues identified with the cleanliness and maintenance of the establishment, including but not limited to: • Hair, tissue debris and blood in the drains, on PM tables and various pieces of equipment at LRI and GH; • At GH, multiple areas of rust (the size of a tennis ball) were present on the PM table stands and there is exposed wooden door frames in the PM suite; Areas of exposed wood and rust make equipment/surfaces porous, meaning they cannot be adequately cleaned or disinfected.	**Minor**
c) There are documented cleaning and decontamination procedures and a schedule of cleaning	There are no documented cleaning schedules for any of the establishment sites.	**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)	The door to the pregnancy remains fridge at LRI is clear glass meaning patient identifiers on the cardboard boxes containing the remains could be seen by anyone waiting in the corridor where the fridge is located; Neither the door connecting the corridor in which the visitors waiting area and viewing room are located nor the door leading to the body store area are secured. Staff conducting viewings at LGH and GH are sometimes left alone with relatives with no personal or room alarms.	**Minor**

PFE2 There are appropriate facilities for the storage of bodies and human tissue.		
b) There is sufficient capacity for storage of bodies, organs and tissue samples, which takes in to account predicted peaks of activity	Currently, only one member of staff is responsible for the follow-up of the relatives wishes for material retained at forensic, coronial and hospital consented PM examination, to ensure that tissue is disposed of in accordance with the wishes of the family. The follow-up with both the Coroner and the relevant police forces (for forensic cases) is an extensive task; based upon the significant number of PMs undertaken and subsequently the amount of tissue and number of bodies to be managed. Loss or absence of this individual poses a risk that the follow-up of tissues will not occur and the efficient release of bodies would not be possible, resulting in a negative impact on the establishments ability to provide sufficient storage facilities for bodies. (see *Advice,* item 7)	**Minor**

c) Storage for long-term storage of bodies and bariatric bodies is sufficient to meet needs	Porters reported being told to leave bariatric bodies out as no refrigerated spaces were available to store them, indicating there may be insufficient bariatric storage facilities. This practice also poses a risk to the dignity of the deceased. While there has been an increase in the number of freezer storage spaces in the mortuary, there were limited numbers of spaces available at the time of the inspection. Adult bodies were identified that had been released by the Coroner but were still being stored in the mortuary fridges and beyond the recommended 30 day period, without being moved in to long-term storage. Furthermore, bodies were identified that had been released by the Coroner but were awaiting repatriation of organs. Fetal remains were found to be held in refrigerated storage in the mortuary more than 30 days after the confirmed route of disposal. No evidence was provided to demonstrate active follow up by the establishment where disposal of a body could occur but had not yet happened.	**Major**
d) Fridge and freezer units are in good working condition and well maintained	The body store fridges at GH are rusty and the door seals have deteriorated. At LGH, the door seals and wooden door trims on the older bank of fridges have also severely deteriorated. These issues make the units porous; so that they cannot be adequately cleaned or decontaminated.	**Minor**
e) Fridge and freezer units are alarmed and the alarms are tested regularly to ensure that they trigger when temperatures go out of upper or lower set range	The body store alarm system was not functional at the time of inspection. The system is only challenged once annually as part of the routine maintenance testing and may not necessarily provide the DI with sufficient assurance that the alarms will trigger when required. In addition, all alarm challenges should be recorded. The stand-alone pregnancy remains fridge at LGH is not on the alarm system, so the DI would be unaware of deviations from required temperatures outside the limited working hours for which staff attend this site.	**Minor**

PFE3 Equipment is appropriate for use, maintained, validated and where appropriate monitored		
c) The ventilation system provides the necessary ten air changes per hour and is checked and maintained at least annually	The ventilation system at GH was tested prior to use of the mortuary while the PM suite floor at LRI was replaced. The result of the testing identified the ventilation to be inadequate at 9.4 air changes per hour, and not the required 10 air changes per hour. The site was still used without addressing the inadequacies of the system. This poses a potential health and safety risk to all staff when performing PM examinations. The GH site should not be used for PM examinations until the issues with the ventilation system have been addressed and tested to provide assurance that it meets the required minimum standard. At LRI the inspection team observed the doors linking the main PM suite to the forensic PM suite being propped open whilst a PM examination was being undertaken. This would reduce the effectiveness of the ventilation system in that area and may prevent the system from achieving the required 10 air changes per hour.	**Major**
d) Staff have access to necessary PPE	Currently, only FFP3 face-fitted masks are available to staff for high-risk PM examinations. Some members of mortuary staff have facial hair, meaning the FFP3 masks cannot be adequately face fitted. There is no alternative respiratory protective equipment available for staff unable to be face-fitted or cannot tolerate the FFP3 face-fitted masks.	**Minor**

Advice

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

No.	Standard	Advice
1.	C1(d)	The consent form used for adult hospital PM examinations outlines all the options for tissue retained at PM examination, including the option at the bottom of the first page relating to the retention of tissue for the purpose of research. Directly underneath this option the form continues to explain that no future results may be obtained if consent to retain tissue is not given. This makes the information unclear to the consent giver as to what option they are choosing by ticking this box. The DI is therefore advised to review the consent form wording and layout to ensure options and related information are clear.
2.	GQ1(g)	No Persons Designated (PDs) have been identified to oversee the licensable activity of removal of relevant material from the deceased in areas remote to the mortuary. The DI is advised to appoint PDs in these areas to facilitate with oversight of licensable activities.

3.	GQ2(c)	Records for tissue held under PACE are held in a folder detailing each individual case. This record system does not allow the user to easily identify material which can be disposed of or requires further follow-up. The DI is therefore advised to develop a simple method for determining what is being held, the reason for continuing to hold the material and date received allowing staff to easily review the status of retained material.
4.	GQ6(a)	The DI is advised to risk assess and keep under review, the current location of the entrance to the mortuary as well as the impact of porters arriving with bodies to mortuary at the same time as visitors waiting to enter or leave the mortuary.
5.	T1(d)	The establishment uses an electronic mortuary register. The DI is advised to review the current system and determine if highlighting the following could be added, for example: same and/or similar names; the length of stay of a body in the mortuary; risk of infection; repatriation of organs and/or tissues before release.
6.	T1(g)	Currently tissue retained from PM examination is placed into cassettes and then into larger containers and delivered to the histology department. The DI is advised to ensure that the number of cassettes is checked against the histology request form at the point of receipt in the histology laboratory to verify records match material received. This will help to ensure full traceability of all PM examination tissue between departments.
7.	PFE2(b)	The DI is advised to involve and train others in the procedures for the management of organs and tissues following PM examination to provide resilience to this process and reduce the impact of this task not being effectively undertaken.
8.	PFE3(b)	The current equipment available to porters for the movement of hospital bariatric bodies is found to be cumbersome, flimsy and prone to potentially exposing the deceased in transit. The DI may wish to consider alternative options for equipment for the transfer of bariatric bodies to the mortuary, for example, a designated bariatric concealment trolley.

Concluding comments

Despite the number of shortfalls identified, areas of good practice were observed during the inspection. The establishment demonstrated a commitment to the continual improvement of practices and compliance with the HT Act. Areas of good practice include:

- Electronic mortuary register system;
- Good communication between the Leicester Coroner and the establishment.

All staff demonstrated a clear dedication to the role they undertake, a conscientious approach to the handling and traceability of relevant material and a compassionate approach to arranging viewings of the deceased at the mortuary sites. The Mortuary Manager and Deputy Laboratory Manager are long serving members of staff and very knowledgeable in the roles they undertake. There is a good level of interaction and effective communication between the DI and those carrying out licensable activities.

However, there are a number of areas of practice that require improvement, five major shortfalls and eleven 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: 06 November 2018

Report returned from DI: 20 November 2018

Final report issued: 23 November 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: 18 March 2020

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.