Site visit inspection report on compliance with HTA licensing standards

Wednesfield Public Mortuary Wolverhampton

HTA licensing number 12285

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**

27 & 28 February 2019

Summary of inspection findings

This is the first inspection of this establishment against the HTA's revised licensing standards, which came into force on 3 April 2017.

The previous inspection took place in June 2015, since then there has been a significant decline in compliance, with shortfalls identified across all four groups of standards, including three critical (cumulative major), twelve major and twenty minor shortfalls.

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 establishment consists of Wednesfield Public Mortuary (WPM) (the hub) and a satellite site New Cross Hospital (NCH). The establishment has been licensed by the HTA since August 2007. Post Mortem (PM) examinations are only performed at the hub. WPM is staffed by two full-time Anatomical Pathology Technologists (APTs). The mortuary at NCH is staffed by a Mortuary Manager and Mortuary Assistant who both work full-time and two Medical Laboratory Assistants (MLAs) for contingency cover, when required.

The hub performs around 326 adult coronial post-mortem (PM) examinations and one hospital consented adult PM examination annually, which is carried out on behalf of NCH.

The mortuary at WPM has 30 refrigerated body storage spaces and five freezer spaces for long-term storage of bodies (see shortfall against PFE2(c)). A service level agreement (SLA) is in place with NCH and funeral directors (FDs) for contingency storage (see shortfall against PFE2(i)). All fridges and freezers are connected to a remote monitoring system and have audible alarms, which are connected to the provider, who will notify the DI of temperature deviations from the set ranges outside of working hours (see shortfall against PFE2(e)).

The mortuary is located next to a police station and is set back from the main road. There is an entrance at the side of the building which is covered by CCTV. Access to the mortuary is by key which opens the door to the office area and to the body store at the side of the mortuary. The Coroner's contracted FDs transfer bodies to the mortuary in normal working hours only. Any bodies requiring a PM examination from NCH are transferred as part of a SLA.

Mortuary staff are responsible for checking all bodies that have been admitted, verifying identification details from the identification bands attached to the bodies against the information provided by the police or Coroner. Bodies with same and/or similar names are stored in different fridge banks (see shortfall against T1(d)). All details are logged in the mortuary register, which is updated when further information is provided by the Coroner.

The mortuary staff only release bodies during normal working hours. When bodies are released, the mortuary staff confirm the identity of the body with the FD by checking identification details on the identification bands on the body against the documentation brought by the FD. This is cross referenced against the information on the Coroner's release form sent directly to the mortuary (see shortfall against T1(c)).

The mortuary operates an appointment system for viewings during working hours, which are for formal identification purposes only. Mortuary staff do not liaise with the families directly this is done by the police. However, they are responsible for the preparation and

identification of the body prior to the formal identification occurring (see shortfall against T1(c)).

The PM suite has three down draught tables. There is a dedicated dissection bench for the preparation of tissue samples. PM examinations take place one at a time to help minimise the risk of organ and tissue mix-up between cases. The external examination and identification of bodies is performed by the pathologist and an APT prior to evisceration.

Mortuary staff have access to personal protective equipment (PPE) within the PM room and body store area (see shortfall against PFE3(d)). There is no demarcation of clean and dirty areas between the PM room and the body store (see shortfall against PFE1(b)). Material retained at PM examination for histological examination is placed into formalin-filled containers and the identifying information is written on the pre-printed container label by mortuary staff; a 'PM Histology Tracking' form is completed to record the number, weight and type of tissue taken at PM examination.

Tissue for histological analysis and toxicology samples are stored and sent by courier to the approved Coroner's testing laboratory and the pathologist's hospital histopathology department, respectively, for examination. There is a system in place to ensure that when relatives request that tissue or organs are repatriated to a body, this is carried out before the body is released (see shortfall against T1(g)).

New Cross Hospital (NCH)

The mortuary at NCH is located in a wing of the main hospital building. This site also functions as a contingency storage site for WPM. Portering staff are responsible for the transfer of bodies from hospital wards to the mortuary by a service lift which has swipe card access. No community bodies are received into this mortuary and PM examinations are not conducted at this site, however tissue retrieval is performed in a designated room, adjacent to the body store area (see shortfall against PFE1(a)).

The mortuary is accessed by a swipe card at both the main entrance to the building and the FDs entrance; both entrances are covered by CCTV. There are three temporary contingency refrigeration units erected in the FD service area of the mortuary, meaning FD vehicles cannot fully reverse into this area and the shutter door cannot be lowered (see shortfall against PFE1(e)).

The body store has 120 refrigerated spaces, including 24 bariatric spaces, four freezer spaces and a walk in cold room that can accommodate one super-bariatric body or a further eight standard spaces. The body store has two new separate fridges that are currently being commissioned for the storage of paediatric/perinatal bodies. At the time of inspection two dedicated banks of fridges were being used for this purpose. All fridges and freezers are connected to a remote monitoring system and have audible alarms, which are connected to

the provider, who will notify the on-call mortuary staff of temperature deviations from the set ranges outside of working hours. The maternity and gynecology services have a fridge for the temporary storage of pregnancy remains which is located in a room that requires swipe card access (see shortfall against PFE2(e)).

Consent is taken by clinicians for adult (consented) hospital PM examinations. Paediatric/perinatal cases are undertaken at another HTA licensed establishment; however, consultant obstetricians and bereavement midwives at NCH seek consent for these cases (see shortfall against C2(b)). Consent for paediatric/perinatal cases is recorded using documentation provided by the HTA establishment performing the PM examinations and parents are provided with Stillbirth and Neonatal Death (SANDS) information packs.

Removal of tissue from sudden unexpected death in infancy and children (SUDIC) cases is performed in the Emergency Department (ED) at NCH by paediatricians (see shortfall against C2(a)).

Foetuses over 16 weeks gestation are transferred to the mortuary by a member of the portering staff with a completed transport form, a copy of which is kept with the mother's file. These cases are only released from the mortuary during normal working hours.

Bodies are released only by the mortuary staff who confirm the identity of the body with the FD by checking identification details on the identification bands found on the body against the information brought by the FD and cross reference the information with the Coroner's forms and mortuary register to confirm identification of the body (see shortfall against T1(c)).

The mortuary operates an appointment system for viewings, which only take place during working hours and are conducted by mortuary staff (see shortfall against T1(c)).

Description of inspection activities undertaken

This was the third site visit inspection of the establishment; the previous inspection took place in 2015. The inspection team reviewed governance and quality system documentation, carried out interviews with key members of staff and visual inspection of the mortuary body store areas, PM rooms and viewing areas.

An audit trail was undertaken at each of the sites:

- WPM – four bodies (two adult community bodies and two adult hospital bodies) were audited; for one of the bodies audited, the date of transfer of the body from the fridge to the freezer was different on the body bag to the date recorded in the mortuary register. The inspection team were unable to physically check the identification of the body as the shrouding was stuck to the body.

- NCH – eight bodies (four hospital adults and four foetuses) were audited. In 40% of all cases in the 'baby mortuary register', the mother's hospital number was not recorded, which is used as an identifier for release of the body.

Audits of traceability were conducted for samples from eight PM examinations under coroner's authority and one hospital consented PM examination, including consent documentation for the retention of samples, consent forms for the hospital PM examination and disposal records. A number of discrepancies were identified:

- The establishment's written procedures state that histology forms should be faxed back to the mortuary to be filed with the Coroner's forms, however the inspection team found that approximately 50% of all cases in the PM Examination file dating back to 2011 did not have this form, nor was there any follow up by staff (see shortfall against T1(g));

- Although there were no discrepancies in the completion of the hospital PM examination consent form, a transcription error for the date of PM examination was identified;

- One case was identified where the families wishes for tissue retained at PM examination to be disposed of was not followed, with the inspection team finding that the blocks and slides were being stored in the laboratory storage area;

- In one Coroner's case, the family had requested that the organ be repatriated with the body. It was unclear from mortuary records and the correspondence with the analysing laboratory if the organ had been repatriated with the body before release.

In addition, it was identified that NCH is storing organs and tissue samples from a number of PM cases for which it is not known whether the Coroner's authority has ended and there is no procedure in place to actively follow-up these cases. Procedures for auditing these samples, to enable timely disposal where consent has not been given for continued retention, are not in place. This presents a risk that the establishment is storing PM material without the Coroner's authority or consent from the family (see critical shortfalls against standards GQ2(c) and T2(a)).

Inspection findings

Although the HTA found the Licence Holder and the Designated Individual to be suitable in accordance with the requirements of the legislation, the number and severity of shortfalls identified is of concern. Advice and guidance was given to the DI to further improve practices following the last inspection in 2015. During the current inspection similar areas for improvement were identified and are captured in the shortfalls below.

Although the DI has been deemed to be a suitable person to hold the role, the shortfalls

identified demonstrate that he has not ensured that there are suitable practices in place for the conduct of the licensed activities.

The HTA will monitor progress of these shortfalls through the Corrective and Preventative Action (CAPA) plan to be completed by the establishment and keep the suitability of the DI under review.

Compliance with HTA standards

Standard	Inspection findings	Level of shortfall
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	*NCH:* i) Consent training for adult hospital (consented) PM examination is available as a power point presentation, however, it refers to the out of date HTA Code of Practice 1. ii) At the time of the inspection, staff involved in the removal of tissue in ED appeared to be under the impression that the police can give authorisation for the removal of tissue in SUDIC cases and were apparently unaware of the authorisation arrangements already in place with the Coroner for these cases, indicating a lack of understanding of the consent requirements of the Human Tissue Act 2004 (HT Act).	**Major**
b) Records demonstrate up-to-date staff training	Consent training for both perinatal/paediatric and adult PM examination is to take place every two years. Training records for staff who seek consent for perinatal/paediatric PM examination were not seen at time of inspection as certification had not been uploaded to the online Trust staff training system; inspectors were verbally told that training takes place every two years. Training records for staff who seek consent for adult hospital (consented) PM examinations show that three members of staff do not have up-to-date training.	**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.	*WPM:* While a number of the required SOPs are in place, they are all out of review date and lack sufficient detail or attention to wording; these include but are not limited to: • 'Gen 12 Releasing Bodies from the Mortuary' - does not state the minimum number of identifiers to be used and how the identification check should be performed; • 'Gen 6 Long Term Body Storage' - does not explain the process of checking identification when moving bodies into long-term storage, or if the change of unit is recorded in the mortuary register. There is no documented system in place to readily identify how long a body has been in the mortuary; • 'Gen 17 Fridge and Freezer Temperature Arrangements' - does not detail the acceptable temperature ranges and alarm trigger points. There is also no detail on the call out arrangements if the wireless monitoring system triggers an alarm; • 'H&S 6 Adverse Incident Policy' - does not detail the processes for investigating and following up incidents through the establishment's incident reporting system. *NCH:* While a number of the required SOPs are in place, the majority have not been reviewed by the review date, and lack sufficient detail or attention to wording; these include, but are not limited to: • 'F2.M003P.CP Transfer and relocation procedure' – does not state the minimum number of identifiers to be used and how the identification check should be performed. The transfer form that is used only requires two identifiers to be recorded; • 'F2.M007P.CP Daily organisation of work in the mortuary/body store' – does not contain sufficient detail of the process of checking information is correct and complete on forms and where these are stored. There is no	**Major**

	process for the daily check of bodies to assess the condition of the bodies and if they need to be moved to long term storage; • 'F2.M004P.CP Viewing of the deceased' – does not give sufficient detail of the identification check before moving the body to the viewing room and does not state the minimum number of identifiers to be requested from the family before viewing or a list of what those identifiers could be. This is not an exhaustive list of the amendments required to all the SOPs and, to fully address this shortfall, the establishments should review all SOPs relating to mortuary activities to ensure that they are accurate, are cross referenced to the appropriate codes of practice and guidance, and contain sufficient detail of procedures. This was identified as a shortfall in the previous site visit inspection and has not yet been sufficiently addressed by the establishment.	
c) Procedures on body storage prevent practices that disregard the dignity of the deceased	*<u>WPM:</u>* As part of the body audit the inspection team observed the removal of a body stored on a tray on the floor of the freezer. The establishment staff removed the body from the freezer by manually pulling the tray at a steep angle onto the hoist. There is a risk that this practice could cause accidental damage to a body. The inspection team were unable to complete the body audit as checking the identification of the body posed a risk of causing accidental damage. *Refer to shortfall against standard GQ1(f).*	**Major**
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	Although WPM have a range of SOPs covering licensable activities, these documents have not been reviewed since 2015 when the previous site visit inspection occurred, and have the same author and authoriser for the majority of SOPs.	**Minor**
e) There is a system for recording that staff have read and understood the latest versions of these documents	NCH has a quality management system for recording when staff have read and understood SOPs, however, the Mortuary Assistant who started at the Trust in December 2018 has not acknowledged the mortuary SOPs that govern their work.	**Minor**

f) Deviations from documented SOPs are recorded and monitored via scheduled audit activity	Observations by the inspection team at both establishments show that establishment staff are not following SOPs, for example; Gen 6 (Long term body storage), Gen 7 (Deep freezing bodies), Gen 30 (checking of bodies), Gen 34 (care of bodies) and E3.M001P.CP (Long term body storage. As the establishment does not have a suitable or sufficient audit schedule, it has not been able to identify that staff are not following the procedures that govern their work. *See shortfall against GQ2(a)*	**Minor**
h) Matters relating to HTA-licensed activities are discussed at regular governance meetings involving establishment staff	Although the establishment have held some governance meetings relating to licensed activities including all PDs and the DI, the last one was held in February 2018. Lack of availability of the DI had apparently led the histopathology laboratory staff at NCH to set up their own governance meeting in February 2019.	**Major**

GQ2 There is a documented system of audit		
a) There is a documented schedule of audits	Although both establishments have undertaken audits, regular horizontal and vertical audits have not been undertaken of compliance with mortuary procedures, traceability of bodies and mortuary records.	**Cumulative Critical**
b) Audit findings document who is responsible for follow-up actions and the timeframe for completing these	WPM do not have a documented checklist for audits, or have a written report to identify non-compliances and an action plan to complete follow-up actions. NCH uses a quality management system to document who is responsible for follow-up actions. However, it was identified that a non-conformance raised on an audit against HTA GQ standards carried out in May 2018 has not been completed.	

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	*WPM:* While an audit schedule is in place and these audits have been completed, a number of discrepancies were identified by the inspection team when conducting the traceability audits. The discrepancies found had not been identified as part of the establishment's own routine audits: • We observed that in 50% of all PM cases dating back to 2011, the establishment had not received a fax back copy of the histology tracking form from NCH Histopathology laboratory; • In 90% of all cases, the establishment staff do not follow their procedures for printing and keeping a copy of the family consent wishes, emailed from the Coroner, to be kept with all other paperwork. This means that forms are not centrally located and easily accessible, increasing the risk of failing to identify bodies requiring repatriation of tissue taken at PM examination prior to release. • Two cases were identified in the PM examination folder through 'post it notes' only; details of cases and location of tissue could not then be located or identified at NCH. *NCH:* While an audit schedule is in place and these audits have been completed with no non-conformances raised, a number of discrepancies were identified by the inspection team when conducting tissue traceability audits: • there is a lack of documented consent wishes for tissue retained at PM examination between 2013 and 2017 and; • Tissue which should have been disposed of in-line with the families' wishes has been retained. *Refer to shortfall against standard T2(a) for further detail.*	

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	NCH has a document controlled competency criteria, however, for the most recent member of staff it is unclear if they have been signed off as competent to perform mortuary tasks.	**Minor**
c) Staff are assessed as competent for the tasks they perform	Mortuary staff at WPM undergo competency assessments when they begin working at the establishment, however, there is no formal system for ongoing competency assessments of new starters or existing staff. At the time of the inspection, there was no evidence that the most recent member of staff at NCH has completed relevant competency assessments. *The establishment has retrospectively completed an audit competency checklist for the mortuary assistant following the inspection.*	**Minor**
f) There is a documented induction and training programme for new mortuary staff	WPM uses a generic local authority induction form for new staff. There is no formal or specific induction training programme for conducting mortuary activities.	**Minor**
g) Visiting / external staff are appropriately trained and receive an induction which includes the establishment's policies and procedures	WPM has no induction or training programme that is provided to visiting pathologists or external visitors from NCH in the mortuaries' local policies.	**Minor**

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	At WPM there is a local authority record management system, however, this is not always followed and relies on in-house staff knowledge for how records should be maintained and kept. All mortuary records are in paper form and there is no back-up system in place, which could lead to loss of traceability. At NCH there is no SOP for record management.	**Minor**
b) There are documented SOPs for record management which include how errors in written records should be corrected.	At NCH mortuary correction fluid has been used in the mortuary register. The use of correction fluid does not allow for full auditability of any changes to a record.	**Minor**

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	Staff at both WPM and NCH are unaware of HTA Reportable Incidents (HTARIs), how they should be reported or who at the establishment can report these incidents to the HTA. The inspection team identified a number of incidents since the previous inspection which have not been reported to the HTA, some of which were highlighted at governance meetings but not reported through the internal incident reporting systems at either site. *Following the inspection, these incidents have been reported to the HTA for assessment and will be managed accordingly.*	**Cumulative Critical**
b) The incident reporting system clearly outlines responsibilities for reporting, investigating and follow up for incidents	The SOP at WPM does not include any detail of reporting incidents through the local authority incident system, who is responsible for the follow-up actions or who can report incidents in the DI's absence. *(as a result, standards GQ5 (c), (d) and (e) cannot be met)*	

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	*WPM:* Risk assessments of procedures related to licensable activities do not identify all of the associated risks, including those concerning bodies, tissue or traceability; examples include, but are not limited to: • mortuary security; • removal of tissue from a body without authorisation or consent; • PM cross-sectional imaging of a body; and • integrity of bodies and long-term storage arrangements. *NCH:* The documented risk assessments do not cover all risk associated with the licensable activities both performed in the mortuary and other departments. These include, but are not limited to: • accidental damage to a body; • viewing of the wrong body; and • release of a wrong body The establishment's risk assessments have have not been reviewed regularly. For example, risk assessment RA.070.HIS Mortuary Security was last assessed in January 2014.	**Major**
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	The establishments' risk assessments lack sufficient detail for what control measures have been implemented to reduce the risk score. Several of the risks identified are categorised as high (10 or above).	**Minor**

T1 A coding and records system facilitates traceability of bodies and human tissue, ensuring a robust audit trail		
c) Three identifiers are used to identify bodies and tissue, (for example post mortem number, name, date of birth/death), including at least one unique identifier	*WPM* i) At present, a variety of documentation is obtained from funeral directors which is used to identity a body before it is released. The wrist band routinely states name, date of birth (DOB) and address. The inspection team observed in the establishment mortuary register that 'Crem form 6' had been signed by mortuary staff and FDs, indicating that this was the document used to check identification of a body before release. However, this form does not contain three identifiers that can be checked against the information on the identity band attached to a body; it only states full name and age (age is not a robust identifier). ii) The establishment staff are not checking the Coroner's form brought by the police when carrying out formal identifications with families against the identification on the body prior to the body being viewed. In the rare circumstances when a body is of unknown identity, sufficient information should still be obtained to help ensure that the correct body has been prepared. For example, the date and location of where the body was found. *NCH* In addition, bodies are viewed after staff are only provided with verbal communication of the identity of the deceased from those visiting the mortuary, for example name and DOB. No further identification check of the body is performed prior to the viewing. These practices at both sites pose a risk of releasing or viewing a wrong body.	**Major**
d) There is system for flagging up same or similar names of the deceased	At WPM the SOP Gen 2 Receipt of Bodies into the Mortuary, does not provide any details of how and when bodies should be checked for same and/or similar names. The mortuary staff have an undocumented system of placing bodies with the same and/or similar names in different banks of fridges but these bodies are not flagged anywhere else, for example, in the mortuary register. A robust documented procedure is required for the management of bodies with same and/or similar names to help mitigate the risk of releasing a wrong body.	**Minor**

g) Organs or tissue taken during post-mortem examination are fully traceable, including blocks and slides (including police holdings).	WPM procedures do not provide for full traceability of PM organs or tissue. • SOP Gen 14 Histology Storage, states that a copy of the PM Histology tracking form should be faxed back to the hub from the satellite site and attached to the Coroner's PM form. The inspection team observed that this had not happened for approximately 50% of all the PM cases at WPM. There is no follow up by mortuary staff to ensure tissue has arrived at the testing site. There is no record kept at the mortuary for the number of tissue blocks sent off site for analysis. All the paperwork is sent with the material. This poses a risk that traceability of tissue may be lost between the establishments when being transferred. • Consent wishes are not routinely placed in the file for each case, and bodies requiring tissue or organ repatriation prior to release are not identified. This poses a risk of failure to repatriate tissue/organs to a body prior to release.	**Major**

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	NCH cannot provide assurance that tissue is being disposed of as soon as reasonably possible. There is no documented procedure in place for following up with third parties to determine when Coroner's Authority has ended. The establishment is storing whole organs, partial slices of organs and tissue samples from a number of PM cases where it is not known whether the Coroner's Authority for retention has ended. A number of these cases are dating back to 2013 and cases were identified up to 2017. Although in some cases, the family's consent for disposal or repatriation may have been obtained, the establishment has not undertaken periodic audits of these samples to establish which samples should be disposed of. • In one case, the establishment could not be assured that a whole organ had been repatriated to the body before burial. A statement on a photocopy of the Coroner consent forms stated that the whole organ had been returned, however, there was no indication if the organ had been returned to NCH or WPM, the date that the organ had been received at the establishment, or a signature by the person who received the organ. • When conducting a reverse traceability audit, one of the Coroner consent forms had stated the family's wishes were for the tissue to be disposed of, however, blocks and slides were still being retained. During the inspection, cases were identified where tissue taken at PM examination had been retained despite the Coroner's authority being concluded and the wishes of the family being for all tissue to be disposed of sensitively. The establishment therefore appear to be storing tissue without appropriate consent under the HT Act.	**Cumulative Critical**

b) There are effective systems for communicating with the Coroner's Office, which ensure tissue is not kept for longer than necessary	A number of cases were identified where tissue was being retained for a relatively long time after the PM examination and staff did not know if the notification of completion of the Coroner's authority had been received. Some cases were identified where more than 18 months has elapsed since the PM examination. There is a risk that the establishment is storing tissue without appropriate authority or consent under the HT Act.	
c) Disposal is in line with the wishes of the deceased's family	During the site visit a case was identified where the establishment could not provide sufficient assurance that repatriation of a whole organ was in accordance with the family's wishes prior to release of the body. While completing a body audit the inspection team reviewed paperwork where an organ was returned to the body, however, it was unclear on the consent wishes form if this was the family's wishes.	

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	*WPM:* Issues were identified with the cleanliness and maintenance of the establishment, making it difficult to adequately clean or decontaminate this area, posing a potential health and safety risk to mortuary staff and visitors. Issues include but are not limited to: • hair was found in the drains of the PM suite and dried blood spots were seen on the dissection table; • the floor of the body store and PM room are extensively cracked and split; • there are large areas of exposed plaster on the walls of the body store leading to the entrance of the PM room; • the skirting board was coming away from the walls in several areas of the body store resulting in gaps between the floor covering and the walls; • there are several areas of peeling paint on the walls of the body store; • areas of severe rust were seen on the sides of the sinks in the PM room; • A strip of wood has been fixed to the bottom of the door to prevent water from the PM room entering the office – this had peeling paint making it porous; • the doors to the PM room do not meet the floor and there is no barrier or drain to prevent water from entering the body store; • absorbent materials were stored on the floor of the body store area opposite the PM room. *NCH:* There is no PM suite at this site, however, removal of tissue from bodies is conducted in a small room adjacent to the body store area. This room does not provide suitable facilities for this activity or allow staff to adequately clean bodies if required. There is no drainage or barrier between the removal room and the body store area to prevent contaminated liquid from entering the body store.	**Major**

	The room also did not allow adequate cleaning of the floor after use as there were insufficient drainage facilities available.	
b) There is demarcation of clean, dirty and transitional areas of the mortuary, which is observed by staff and visitors	At WPM there is no demarcation of a transitional area between the PM room, the body store or the changing room, making it difficult for staff and visitors to determine clean areas from dirty areas of the mortuary. Staff walk from the PM room to the changing room area through the body store before contaminated footwear and clothing can be removed. Bodies have to be transferred from the PM room on trolleys into the body store area to place them back into refrigerated storage. This area is in constant use by both mortuary staff and FDs when they collect and bring bodies to the mortuary. No cleaning or decontamination of the body store area takes place between the movement of the bodies and staff from the PM room following or during PM examinations. *Refer to shortfall against PFE3(d)*	**Major**
c) There are documented cleaning and decontamination procedures and a schedule of cleaning	WPM has no documented cleaning schedule for the PM room, body store area or the fridges and freezers.	**Minor**
e) Security arrangements protect against unauthorized access and ensure oversight of visitors and contractors who have a legitimate right of access	At NCH mortuary temporary contingency refrigeration units are located in the garage area which prevents the FDs from reversing their vehicles fully into this area so the shutter door cannot be closed. There is a risk that unauthorised persons could access the mortuary and passers-by could view movement of bodies in and out of the mortuary. During the inspection it was observed that the shutter to this garage area was not lowered while a FD was collecting a body.	**Minor**

PFE2 There are appropriate facilities for the storage of bodies and human tissue.		
a) Storage arrangements ensure the dignity of the deceased	At WPM the doors to the PM suite are clear plastic allowing the unauthorised or unintentional oversight of PM room activities by FDs visiting the mortuary. The upper alarm trigger points for the main fridges in the body store is 10°C and -5ºC for the freezers. This will not ensure the alarms are triggered at appropriate temperatures to optimally maintain bodies stored in there.	**Major**
c) Storage for long-term storage of bodies and bariatric bodies is sufficient to meet needs	Due to the limited freezer storage facilities at both sites, bodies were identified as being held in refrigerated storage for longer than the HTA's recommended 30-days. At NCH, foetal remains were found to be held in refrigerated storage in the mortuary for more than 30 days, which is not in accordance with the HTAs recommended guidance for long term storage of bodies. *Refer to shortfall against standard PFE2(i).*	**Major**
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 mortuary staff at either site do not manually challenge the body store alarms on a regular basis. This does not provide assurance that the alarms will trigger when temperatures deviate from the expected range. At WPM the DI is the only person to be notified of any temperature alarms from the monitoring system. There is no cover in place for when the DI is on leave or if temperature alarms are triggered outside working hours. At NCH although the fridge on the maternity unit is monitored once a day, it is not does not have an alarm, meaning staff will not be alerted if temperatures deviate from the expected range.	**Major**
g) Bodies are shrouded or in body bags whilst in storage	At WPM bodies are not routinely fully shrouded; the heads are left exposed and body bags are left partially open.	**Minor**

i) There are documented contingency plans in place should there be a power failure or insufficient numbers of refrigerated storage spaces during peak periods	*WPM:* SOPs 'Gen 36 Contingency Planning' and 'Gen 37 Contingency Planning – Fridge Full' - lack sufficient detail about what procedure should be followed if there is a power failure at the mortuary. Both sites have a documented contingency plan stating all refrigerated bodies could be stored with FDs or the alternative site as set out in the SOPs and SLA, however there are insufficient contingency arrangements in place for the continued storage of frozen bodies.	**Minor**

PFE3 Equipment is appropriate for use, maintained, validated and where appropriate monitored		
a) Items of equipment in the mortuary are in good condition and appropriate for use	Some items of equipment at WPM are suffering from obvious signs of wear and tear and are otherwise not fit for purpose, for example: • the body hoists have small areas of rust and peeling paint from the equipment. The establishment has not taken appropriate action to maintain and repair them; • wooden instruments are used for measuring bodies in the mortuary - these are porous and therefore difficult to clean and decontaminate and are therefore not fit for purpose.	**Minor**
c) The ventilation system provides the necessary ten air changes per hour and is checked and maintained at least annually	WPM has been unable to provide the service records for the ventilation system and staff are not aware if the ventilation system is operating to the required standard. In addition, the doors to the PM room do not close fully and there is a gap of five centimetres between the PM suite doors and the floor. These gaps will mean that the ventilation system may not be working efficiently and maintaining the required ten air changes an hour. This poses a potential health and safety risk to all staff.	**Minor**

d) Staff have access to necessary PPE	i) The floorplan of the WPM means that the staff must walk through the body store from the PM room in dirty footwear to the clean changing room, making the body store area a dirty area. FDs are not provided with appropriate PPE, for example, disposable over-shoes on entry to the body store. PM examinations and access to the body store by FDs often coincide. ii) Staff are not provided with respiratory protective equipment (RPE) when performing PM examinations. This is particularly important for those cases where there is potential risk of category 3 airborne pathogens, for example, from pulmonary tuberculosis (TB). Currently there is a further risk as there is no assurance that the ventilation system is working to the required standard.	**Minor**
f) Key items of equipment, including fridges/freezers, trolleys and post mortem tables (if downdraught) are subject to regular maintenance and records are kept	WPM has been unable to provide the service records for key items of equipment, for example, fridge and freezers.	**Minor**

Concluding comments

Although the HTA found that the establishment had met some of the HTA's standards, significant shortfalls were found against the governance and quality systems, traceability and premises, facilities and equipment standards, with three shortfalls assessed as critical and twelve shortfalls assessed as major. The number and severity of shortfalls in meeting the HTA standards is of significant concern and indicates that the DI has failed to discharge their duty under section 18 of the HT Act to supervise the licensed activity; specifically that they have failed 'to secure that suitable practices are used in the course of carrying on that activity'.

The HTA has taken the decision, at this stage, not to remove the DI from his position but to keep his suitability under review. Progress to address the shortfalls identified during the inspection will be closely monitored to ensure they are addressed promptly and appropriately.

The HTA has written to the Site Director, who is the corporate licence holder contact, the DI, the Chief Executive for Wolverhampton Council and the Chief Executive for New Cross Hospital, outlining the actions that must be taken as a matter of urgency to address the critical and major shortfalls identified.

All shortfalls will be managed through the HTA's process for agreeing and overseeing corrective and preventative action (CAPA) plans. The HTA requires the DI to submit a completed CAPA plan 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 a corrective and preventative actions being implemented to meet the shortfalls identified during the inspection.

Report sent to DI for factual accuracy: 28.03.2019

Report returned from DI: 11.04.2019

Final report issued: 02.05.2019

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: 19.12.2019

Appendix 1: HTA licensing standards

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

Consent

C1 Consent is obtained in accordance with the requirements of the Human Tissue Act 2004 (HT Act) and as set out in the HTA's codes of practice

a) There is a documented policy which governs consent for post-mortem examination and the retention of tissue and which reflects the requirements of the HT Act and the HTA's Codes of Practice.

b) There is a documented standard operating procedure (SOP) detailing the consent process.

Guidance

This should include who is able to seek consent, what training they should receive, and what information should be provided to those giving consent for post-mortem examination. It should make reference to the use of scanning as an alternative or adjunct to post-mortem examination.

c) There is written information for those giving consent, which reflects the requirements of the HT Act and the HTA's codes of practice.

Guidance

Information on consent should be available in different languages and formats, or there is access to interpreters/translators. Family members should be given the opportunity to ask questions.

d) Information contains clear guidance on options for how tissue may be handled after the post-mortem examination (for example, repatriated with the body, returned to the family for burial/cremation, disposed of or stored for future use), and what steps will be taken if no decision is made by the relatives.

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

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

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

Guidance

This may be based on the HTA's model consent form for adult post-mortem examinations available on the HTA website, or in relation to infants, the resources pack developed by the

Stillbirth and neonatal death charity, Sands. The consent forms should record the consent given for the post-mortem examination and for the retention and future use of tissue samples.

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

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

Guidance

Refresher training should be available (for example annually).

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

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

d) Competency is assessed and maintained.

Governance and quality systems

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

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

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

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

iii. practices relating to evisceration and reconstruction of bodies;

iv. systems of traceability of bodies and tissue samples;

v. record keeping;

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

vii. lone working in the mortuary;

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

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

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

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

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

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

xiv. contingency storage arrangements.

Guidance

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

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

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

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

Guidance

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

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

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

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

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

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

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

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

Guidance

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

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

Guidance

Meeting minutes should be recorded and made available to staff.

GQ2 There is a documented system of audit

a) There is a documented schedule of audits.

Guidance

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

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

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

Guidance

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

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

Guidance

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

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

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

Guidance

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

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

b) There are clear reporting lines and accountability.

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

Guidance

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

d) Staff have annual appraisals and personal development plans.

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

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

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

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

Guidance

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

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

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

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

Guidance

Records include mortuary registers, PM examination records, tissue retention forms and

records of transfer and return of organs/tissue sent elsewhere for examination.

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

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

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

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

Guidance

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

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

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

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

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

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

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

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

Guidance

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

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

Guidance

Relevant staff should have knowledge of risks and the control measures that have been taken

to mitigate them.

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

Traceability

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

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

Guidance

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

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

Guidance

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

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

Guidance

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

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

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

Guidance

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

Fridge/freezer failures that require bodies to be moved temporarily whilst repairs take place

present a risk to traceability. Full identification checks should be made when theyare placed back into normal storage.

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

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

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

   ii. receipt upon return to the laboratory or mortuary

   iii. the number of blocks and slides made

   iv. repatriation with the body

   v. return for burial or cremation

   vi. disposal or retention for future use.

Guidance

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

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

Guidance

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

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

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

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

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

Guidance

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

this purpose.

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

d) The method and date of disposal are recorded.

Premises, facilities and equipment

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

a) The premises are clean and well maintained.

Guidance

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

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

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

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

Guidance

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

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

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

a) Storage arrangements ensure the dignity of the deceased.

Guidance

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

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

Guidance

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

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

Guidance

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

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

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

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

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

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

Guidance

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

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

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

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

Guidance

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

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

assessments and same/similar name systems.

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

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

Establishments should consider entering in to Mutual Aid Agreements

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

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

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

   i. fridges / freezers

   ii. hydraulic trolleys

   iii. post mortem tables

   iv. hoists

   v. saws (manual and/or oscillating)

Guidance

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

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

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

Guidance

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

d) Staff have access to necessary PPE.

Guidance

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

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

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

Guidance

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

Appendix 2: Classification of the level of shortfall

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

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

1. Critical shortfall:

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

or

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

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

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

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

(3) A notice of suspension of licensable activities

(4) Additional conditions being proposed

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

2. Major shortfall:

A non-critical shortfall that:

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

or

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

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

3. Minor shortfall:

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

departure from expected standards.

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

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

Follow up actions

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

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

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

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