Site visit inspection report on compliance with HTA licensing standards

Northampton General Hospital

HTA licensing number 12253

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**

24 & 25 April 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 Northampton General Hospital had met the majority of the HTA's standards, five major and thirteen minor shortfalls were found against the Consent, Governance and quality systems, Traceability and Premises, facilities and equipment standards. These related to the form used to record hospital (consented) post-mortem (PM) examinations; seeking consent for perinatal/paediatric PM examinations; standard operating procedures (SOPs); audits; porter training; risk assessments; the use of three identifiers; same and similar name procedures; traceability of tissues; cleanliness of premises; long-term storage; temperature alarms; alarm testing; PM room ventilation and personal protective equipment (PPE).

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

The HTA's regulatory requirements

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

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

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

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

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

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

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

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

Background to the establishment

Northampton General Hospital (the establishment) is a large district general hospital. This report refers to the activities carried out at the mortuary of the establishment. The mortuary is managed by the Pathology Directorate. The DI is the Deputy Head of Pathology and Quality Manager. The Corporate Licence Holder contact is the Head of Pathology. The establishment is licensed under the Human Tissue Act 2004 (HT Act) for: 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 scheduled purposes.

The establishment receives approximately 2100 bodies each year from the hospital and the community and performs around 450 post-mortem (PM) examinations annually, the majority of which are conducted for HM Coroner for Northamptonshire. The total figure for PM examinations undertaken includes high-risk (up to category three) and around four hospital (consented) PM examinations. Paediatric/perinatal PM examinations are transferred to another HTA-licensed establishment. Consent for paediatric/perinatal PM examination is sought at the establishment by clinicians who may have received some training in the seeking of consent and trained bereavement midwives (see shortfall against C2(a)). Consent for adult hospital consented PM examinations is sought by the mortuary manager and bereavement officers who have received training in the seeking of consent (see *Advice*, item 3). The consent form for adult hospital PM examinations is predominantly based on the HTA's model consent form (see shortfall against C1(f)). The consent form and information leaflet used for paediatric/perinatal PM cases is based on the SANDs documentation.

The establishment has a total of 131 refrigerated body spaces including ten semi-bariatric spaces, four bariatric spaces, twenty spaces within a 'cool room' area (that can be utilised when required) and twelve spaces within a temporary refrigerated storage unit owned by the Trust, located in an unused PM room (see shortfall against PFE2(a)). The majority of these fridges are 'double-ended' for direct access in to the PM room. In addition, there are five semi-bariatric freezer spaces (see shortfall against PFE2(c)) and a dedicated fridge for the storage of pregnancy remains.

Portering staff transfer and admit all hospital bodies using a concealment trolley. All hospital bodies are transferred to the mortuary with two 'mortuary cards' in addition to the identification bands on the body, which are kept with the bodies. Community bodies are transferred and admitted to the mortuary by the Coroner's contracted funeral directors, both in and out-of-hours (see *Advice*, item 9). Upon admission, an appropriately-sized fridge is selected. The mortuary register, the fridge door and body store location whiteboard details are completed by the porters or funeral directors, respectively. The mortuary staff complete body identification checks as soon as possible on the day, or the next working day if the

body was admitted out of hours. Bodies may be released from the mortuary using two identifiers (see shortfall against T1(c)).

Training in mortuary practice and procedures is provided to all porters and contracted funeral staff by mortuary staff (see shortfall against GQ3(a)).

Access to the mortuary is controlled by swipe card and there is a CCTV camera and intercom system at the external door so mortuary staff can visually verify who is requesting access. The Coroner's contracted funeral directors have keys to the mortuary for out-of-hours access; the use and terms of holding the keys are outlined in a Service Level Agreement (SLA).

The PM suite contains three PM tables, only two of which are in use and each has an associated dissection area. The establishment are planning to remove the third table and utilise the area for extra temporary body storage (see *Advice*, item 22). In addition, there have been issues with the drains within the PM suite and there was a noticeable odour during the inspection (see shortfall against PFE1(a)). When removing bodies from refrigerated storage for PM examination, APTs carry out initial identification checks against coronial or consent documentation and prior to the external examination. A final check of the external examination and identification is carried out with the pathologist before evisceration commences. Pathologists complete each PM examination before commencing the next case to help mitigate against any risk of a mix-up of organs and tissue samples between cases.

The PM suite and body store floor are showing signs of wear, with the edges of the PM suite floor and around the bases of the PM tables requiring attention (see shortfall against PFE1(a)).

A private company that employs independent Consultant Histopathologists from other Trusts to undertake PM examinations at the establishment, on a rotational basis, is used by the Trust. Tissues retained at PM examination are recorded in the 'Autopsy Book', from the whiteboard used to record this information during a PM session. The histopathology laboratory at the establishment processes all histological tissue removed at PM examination. Slides are sent to, or collected by, the relevant Histopathologist for examination (see shortfall against T1(g)). All slides are returned to the establishment to be dealt with in accordance of the relatives' wishes.

The mortuary is staffed by the Mortuary Manager, an APT (Anatomical Pathology Technologist), Trainee APT and a Mortuary Assistant.

The establishment has a maternity unit, where there is a fridge for the storage of fetuses and neonatal bodies prior to transfer to the mortuary. The fridge is located in a secure room. Details of all bodies within the fridge are recorded and checked daily, along with the fridge

temperatures; however, the fridge is not connected to an alarm system (see shortfall against PFE2(e)).

In addition to the storage activities described above, the removal of tissue samples from the body of a deceased child occasionally takes place in the Accident and Emergency Department (see *Advice*, item 10). The process and documentation for these cases was reviewed as part of the inspection and found to be compliant with current guidelines.

Description of inspection activities undertaken

The establishment has been licensed by the HTA since May 2007. Previous routine site visit inspections took place in September 2010 and April 2015. This report describes the third routine site visit inspection visit in April 2018. Formal interviews were conducted with the DI, mortuary manager, mortuary staff, a Consultant Histopathologist, staff involved in the seeking of consent (adult and perinatal), portering staff, funeral staff and a Coroner's Officer. The inspectors also carried out a visual inspection of the mortuary, including the body store areas, post mortem room and viewing suite.

An audit of body identifiers, storage locations, mortuary register details and associated documentation was carried out for three adult bodies (one body from the freezer) and one set of pregnancy remains. Three anomalies were found:

- the body within the freezer did not have an identification band attached. There was a identification band through the zip loops of the body bag and one loose inside the body bag (see *Advice*, item 15);
- the mortuary card for one body was not with the body. It was assumed this had been disposed of due to contamination with body fluids;

In addition, it was identified that one of the bodies audited should have been placed into frozen storage as the person had died two months previously (see shortfall against PFE2(c)).

Audits of four PM examinations where tissue had been removed were conducted (two adult hospital consented cases and two Coroner's cases). The consent forms and documentation were reviewed for the all cases to establish the relatives' wishes for the tissue and to investigate if these had been complied with. Three anomalies were found.

- In one case, the 'Autopsy Book' had not been completed with the type or amount of tissue blocks taken. In addition, the blocks and slides had not been entered into the electronic laboratory system;
- In two cases, the blocks and slides had not been entered into the electronic laboratory system and one stated a PM examination had not been completed; (see shortfall against T1(g)).

Inspection findings

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

Standard	Inspection findings	Level of shortfall
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		
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	Although it is documented that relatives can withdraw their consent. The timescale for this (the date and time) is not recorded for the relatives to refer to.	**Minor**

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	Clinicians who may seek consent for paediatric/perinatal PM examination may have had PM consent training as part of their medical training, but there is no evidence they have received any refresher training. Both bereavement midwives who predominantly seek consent for paediatric/perinatal PM examination have undergone training, however, one midwife last had training three years ago and no refresher training had been offered or undertaken. (see *Advice*, item 5)	**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.	Although the establishment has a good range of SOPs, some require further detail or clarification. Examples include, but are not limited to: • CPM030, 'Weekly Check of Body Status', does refer to the follow-up procedure if bodies have been in refrigerated storage for more than three weeks, however it does not include detail about placing bodies into frozen storage; • CPM008, 'Post Mortem Procedure', is not clear that the pathologist will undertake an external examination of a body prior to any evisceration by APTs; • CPM002, 'Reception of Bodies', states that surnames can be same or similar names and does not reference forenames; • CPM002, Reception of Bodies' and CPM005, 'Release of Bodies from the Mortuary', refers to checking for bodies with same surnames only. In addition, it states that cremation forms can be used to release a body. Paperwork generated by the hospital should not be used to release bodies. In practice, bodies are released using the 'Request for Release of Deceased from NGH Mortuary' form. • CPM021, 'PM Samples for referral and Sendaway Process' does not include details of how histology slides are sent to pathologists and their subsequent return, or reference the SOP that does; • CPM045, 'Mortuary Emergency Procedures', does not include instructions for informing the porters or contracted funeral directors if there has been a fridge failure to help mitigate the risk of them placing bodies in the failed units. All SOPs require review to ensure they contain sufficient detail and reflect current practices.	**Minor**

f) Deviations from documented SOPs are recorded and monitored via scheduled audit activity.	During the inspection, it was noted that one body had not been fully undressed prior to PM examination. All bodies should be completely undressed prior to external examination and evisceration, and appropriately shrouded following PM examination, regardless of condition. The procedure for dealing with contaminated clothing and the shrouding of bodies is covered in SOP CPM008, 'Post Mortem Procedures'. In this case, the deviation from the SOP had not been recorded.	**Minor**

GQ2 There is a documented system of audit		
c) Regular audits are carried out of tissue being stored so that staff are fully aware of what is held and why and to enable timely disposal of tissue where consent has not been given for continued retention	Although quarterly audits of retained tissues are carried out, these audits do not include checking the electronic laboratory system to ensure that specimens have been entered correctly. Issues with the recording of specimens entered onto the electronic laboratory system were identified during the tissue audits undertaken during the inspection, which may have been identified by the establishment if audits of the electronic records were taking place. (see shortfall against T1(g))	**Minor**

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	The establishment demonstrated that regular training in mortuary procedures has been delivered to porter and funeral staff. However, a number of porters require refresher training from January 2018 to April 2018 which has not been undertaken. In addition, training records require signing by the trainee to record their attendance at the relevant training event. (see *Advice*, item 12)	**Minor**

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

a) All procedures related to the licensed activities (as outlined in standard GQ1) are risk assessed on a regular basis	Risk assessments for each procedure within the mortuary are included at the end of each SOP. However, a review of the risk assessments demonstrated that not all risks to the deceased or tissues have been considered, or are not included in the relevant SOP. For example, accidental damage is not included within the SOPs for the receipt and release of bodies, or PM procedures. The risk assessment included in the SOP for lone working does not consider the risks for staff who work alone. The risk assessments require review to ensure that all potential hazards are identified, appropriately assessed and measures to mitigate them are identified and implemented. (see *Advice*, item 14)	**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	Hospital bodies are released from the mortuary using only two identifers. The identifying information stated on the mortuary release form matches only two identifiers on the identification band of hospital bodies (name and DOB). The mortuary cards (which state the date of death) and transferred with bodies to the mortuary, are not usually attached to the shroud of the body and they are left on the fridge tray. In addition, hospital bodies that require a PM examination can only be identified using two identifiers. (see *Advice,* item 17) When families attend for viewings, only the name of the deceased is checked with relatives. (see *Advice,* item 18)	**Major**
d) There is system for flagging up same or similar names of the deceased	The current system for identifying same or similar names includes only checking surnames. Checks for same or similar forenames names are also required.	**Minor**

g) Organs or tissue taken during post-mortem examination are fully traceable, including blocks and slides (including police holdings).	i) The electronic laboratory system is not always completed for tissues taken at PM examination. However, tissue blocks are still processed and tissue slides generated for review by the Histopathologists. There is currently a 'gap' in the records of traceability for PM tissues which has not been highlighted through the establishments tissue traceability audits. ii) Tissue slides sent to pathologists via the post are recorded on a spreadsheet specifically for this purpose and sent recorded delivery and with a 'tissue receipt' form for them to return to acknowledge receipt of the slides. This form is not always returned to the laboratory and checks are not made of the recorded delivery to ensure they have been received.	**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	Issues were identified with the following area: • Where there are joins in the body store flooring covering, they are starting to come apart and become uneven; • The raised edge of the body store flooring immediately below the fridge doors is significantly chipped; • There are marks and damage to the walls within the body store; • The cupboard unit within the body store is chipped, exposing bare porous wood; • The edges of the PM room floor and around the base of the PM tables require attention and may need re-sealing. Some cracking was also noted; • The inspection team noted that there was some blood spots on the PM room floor, in a few areas that had not been removed during cleaning; • Staff had reported issues with the drains, possibly involving the third unused PM table, and a noticeable odour from the drains was evident within the PM room. It was noted that the metal grates covering the drains were screwed down and they had not been cleaned. The issues identified above, in addition to inadequate cleaning and disinfection routines within the PM suite, pose a risk that cleaning and decontamination may not be effective.	**Major**

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

a) Storage arrangements ensure the dignity of the deceased	i) Staff access the viewing room, when required, through the door directly into the body store. The use of this door may allow unintentional viewing of mortuary activities within the body store. ii) There is a large gap between the body store door and frame into the viewing room. Relatives may be able to see through this gap and it does not prevent noise from the body store infiltrating the viewing room. (see *Advice*, item 21) In addition, the current procedure for viewings means that relatives are left unattended within the viewing area which presents a risk to the safety of visitors. ii) The temporary refrigerated storage unit and the 'cold room' area are not linked to the hospital generator back-up system in the event of a power failure. If a power failure occured, a significant amount of refrigerated storage would be affected. This could impact on the establishment's storage capacity, especially during peak times.	**Minor**
c) Storage for long-term storage of bodies and bariatric bodies is sufficient to meet needs	The establishment currently has five semi-bariatric freezer spaces for the long-term storage of bodies. This is not sufficient to meet the needs of the service, to ensure that all bodies can be satisfactorily stored to prevent unnecessary deterioration in their condition. At the time of inspection, there were nine bodies that required frozen storage..	**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	i) The mortuary fridge and freezer alarms are not regularly tested to provide assurances they will trigger in the event of deviations in temperatures from their expected ranges. All alarm tests should be recorded ii) The fridge located on the maternity unit is not connected to an alarm system.	**Minor**
i) There are documented contingency plans in place should there be a power failure or insufficient numbers of refrigerated storage spaces during peak periods	The establishment currently has only oral/verbal agreements for contingency storage with two nearby hospitals. These agreements require formalising to help assure the DI that the additional storage can be utilised if required.	**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	The instrument used to remove bone marrow during PM examinations is rusty and needs replacing as the rust means that the instrument cannot be effectively cleaned and decontaminated.	**Minor**
c) The ventilation system provides the necessary ten air changes per hour and is checked and maintained at least annually	The establishment does not have any records of the ventilation system being tested. By not having the system tested (at least annually), the establishment cannot be assured it is working to the required standard and is providing the necessary ten air changed per hour. However, testing of the ventilation system has been scheduled for May 2018.	**Major**
d) Staff have access to necessary PPE	Staff and pathologists are not currently using FFP3 masks, when required, in the PM room. In addition, masks should be face-fitted to safeguard against exposure to airborne pathogens. Where staff have facial hair, they cannot be face-fitted and require fully ventilated hoods.	**Minor**

Advice

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

No.	Standard	Advice
1.	C1(a)	The SOPs CPM005, 'Release of Bodies from the Mortuary' and CPM012, 'Coroner's Post Mortem Tissue Consent', refer to the 'next of kin' (NOK) and 'personal representative of the deceased' in relation to consent for tissue retention. The DI is advised to develop a procedure through which they can be assured that the person giving consent for the continued retention and use of tissues for scheduled purposes, is a person formally nominated by the deceased prior to their death or a person ranked highest in the hierarchy of qualifying relationships, as outlined in the HT Act 2004.
2.	C1(c)	The DI is advised to update the establishment's documentation that is used to record consent so that the the full title of the information leaflet given to relatives relating to PM examinations is reflected.
3.	C2(a)	The DI may wish to consider identifying alternative training for the staff who are responsible for seeking consent for adult consented PM examination. This may help to provide assurance their knowledge is up-to-date and they have sufficient understanding of the consent requirements under the HT Act. This training would need to be refreshed periodically. In addition, as the seeking of consent for hospital consented PM examination is infrequent, the DI is advised to increase the frequency of refresher training so that it takes place annually.
4.	C2(a)	The DI is advised to implement a system to assure themselves that refresher training for paediatric/perinatal consent seeking is undertaken regularly, for example, every two years.

5.	C2(a)	To ensure that clinicians who seek consent for paediatric/perinatal PM examination are suitably trained, or are accompanied by someone who is trained, the DI is advised to consider: • Clinicians attending training at the establishment where PM cases are sent to; • Bereavement midwives who have undergone suitable training, cascade this training to the clinicians, with support from the Sands training material; • Bereavement midwives accompanying clinicians when consent is sought and record their attendance during the process. Any training should be recorded and regularly refreshed, for example, every two years.
6.	C2(b)	The DI may wish to consider being notified when staff have undergone training for the seeking of consent (adult and paediatric/perinatal) to provide assurance the training is regularly refreshed,
7.	C2(d)	Although the bereavement midwives regularly seek consent for perinatal PM examination, the DI is advised to develop a procedure through which the midwife's competency in this task is assessed and recorded regularly, for example, every two years.
8.	GQ1(a)	The DI is advised to review the establishment's SOPs and where'next of kin' (NOK) is referenced to update them to reflect the consent requirements of the HT Act 2004.
9.	GQ1(a)	The DI may wish to consider implementing a form to be completed for bodies admitted out-of-hours to ensure that information regarding these bodies is communicated efficiently to mortuary staff; for example, when there is a risk of infection or other pertinent information.
10.	GQ1 (g)	The DI is advised to appoint a Person Designated (PD) within the A&E department who has sufficient oversight of the processes for the removal of samples in sudden unexpected death of an infant (SUDI) cases to act as a link to this licensable activity.
11.	GQ2(b)	The establishment carries out process audits of procedures; however, the mortuary manager is generally the person observed during these audits. The DI is advised to include other mortuary staff in these audits to help assure themselves that all staff are undertaking the correct procedures and that the procedural documentation remains an accurate reflection of actual practices. These audits can also be used as another check of staff competency.
12.	GQ3(a)	The DI is advised to consider increasing the frequency of porter and funeral staff training to every two years, instead of every three years. This may help to provide the DI with an assurance that both these groups are sufficiently up to date with the establishment's procedures. In addition, the DI is advised to assure themselves that all contracted funeral staff who admit bodies to the mortuary have undergone training in mortuary procedures.
13.	GQ5(a)	When unsure if an incident relating to mortuary activities requires reporting to the HTA, the DI is advised to seek advice from the HTA who will advise accordingly.
14.	GQ6(a)	In addressing the shortfall identified against standard GQ6(a), the DI is advised to assure themselves that all the licensed activities outlined in GQ1 and the HTARI categories are risk assessed to provide a comprehensive set

		of risk assessments. In particular, ensuring the risks to the dignity and integrity of bodies and stored tissue are included. The HTA's publication 'Regulation of the Post Mortem Sector: What we have learned' (October 2016) provides guidance and information in relation to risk assessments. This is available on the HTA's website.
15.	T1(a)	SOP CPM005, 'Release of Bodies from the Mortuary', refers to patient identification being on the exterior of the body bag. Although the SOP says that the identification of the body should be checked, there is a potential risk that the identification details on the bag are used to release a body, rather than physically checking the identification on the body. In addition, identification bands placed through the zip loops of body bags may prevent the physical checking of the identification on a body.
16.	T1(b)	To further strengthen traceability of bodies and tissue while in the care of the mortuary, the DI may wish to consider using the mortuary register number of the deceased on the fridge doors in addition to the full name. The mortuary register number is unique to that body, acting as an additional identifier while in the care of the mortuary. This can also be helpful when distinguishing between bodies with same or similar names and bodies of unknown identity.
17.	T1(c)	In addressing the shortfall identified against T1(c), the DI may wish to consider liaising with the nurse managers to request placing the DOD on the deceased's identification bands during last offices procedures. The last offices policy is currently under review by the Trust, therefore it may be a suitable time to review what procedures are included. This may help identification of bodies by providing another point of identification which can be used on receipt of the body, prior to PM examination and release of the body from the mortuary. In addition, the DI may wish to consider liaising with the contract funeral staff to request that the DOD is placed on the identification bands of bodies admitted to the mortuary from the community. This could act as another identifier if the name, DOB or address of a body is unknown.
18.	T1(c)	In addressing the shortfall identified against standard T1(c), the DI may wish to strengthen the procedure for viewings by introducing a form to be completed by relatives when they attend. This can include relevant information to check the identification on the deceased, before the viewing takes place. This may help to mitigate the risk of misidentification and relatives viewing a wrong body.
19.	T1(d)	To further strengthen the the procedure for same or similar names, the DI is advised to highlight all bodies with same or similar names in the mortuary register, to act as another visual cue for staff when releasing bodies. This may help to further mitigate the risk of bodies with same or similar names being incorrectly identified.
20.	T1(g)	The DI may wish to consider scanning and saving copies of the histology request forms associated with specimens taken at PM examination, in line with other request forms sent to the laboratory. This will provide an electronic record of the specimens that were sent to the laboratory and can be included as part of the establishment's tissue traceability audits.
21.	PFE1(d)	The DI is advised to consider ways to reduce the risk of people undertaking viewings of the deceased being able to see into other areas of the mortuary through the gaps in the door frames. In addition, the DI may also wish to develop procedures to alert establishment staff to viewings so that noise levels

		within other areas of the mortuary are reduced while viewings are being undertaken.
22.	PFE2(b)	The DI is advised to review their plans regarding the placement of the additional temporary body store unit within the PM room to assure themselves that : • space within this area is not compromised; • cleaning and disinfection of the PM room can still be effectively carried out; • access to these fridges is controlled during PM sessions, observing appropriate demarcation rules for 'clean' and 'dirty' areas.
23.	PFE3(d)	The DI is advised to reinforce the requirement for the contracted funeral staff to use the PPE that is available to them, for example, disposable gloves, when handling bodies.
24.	N/A	When mortuary staff release bodies that pose a potential or known infection risk, the DI is advised to develop a procedure to assure themselves that the establishment does not disclose information about the infection status of a body. This includes not writing the type of infection on the body store whiteboard. The route of infection transmission may be disclosed (i.e. inoculation or inhalation) to ensure the appropriate PPE is used but the type of the infection should not. Information about deceased patients should be treated in confidence.
25.	N/A	SOP CPM026, 'High Risk Cases', states that bodies with Creutzfeldt-Jacob Disease (CJD) is a hazard group two pathogen. CJD is a hazard group three pathogen. The DI is advised to update the SOP to reflect this.

Concluding comments

The mortuary team appear to work well together, demonstrate enthusiasm, and care for the work they undertake. They appear to have good communication and relationships with service users, both internal and external to the Trust and received praise from different people interviewed throughout the inspection. The following demonstrates areas of strength and good practice:

- The use of whiteboards in the mortuary office to record pertinent information, for example, long-term bodies and when relatives instructions for tissues have been received and disposal of tissues;
- The use of the tissue traceability spreadsheet and colour-coding sections to signify which staff have responsibility to complete each section;
- The weekly meeting with the Coroner's Office to discuss long-term bodies and any other relevant issues;
- The weekly meeting with the bereavement midwives to help assure the establishment that pregnancy remains are being appropriately and efficiently dealt with.

There are a number of areas of practice that require improvement including five major shortfalls and thirteen 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: 24/5/18

Report returned from DI: 3/6/18

Final report issued: 27/6/18

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: 1/4/19

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.