Site visit inspection report on compliance with HTA licensing standards

Wythenshawe Hospital

HTA licensing number 12203

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**

1 – 2 November 2017

Summary of inspection findings

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

This was the first inspection of this establishment against the HTA's revised licensing standards, which came into force on 3 April 2017. Although the HTA found that Wythenshawe Hospital had met the majority of the HTA's licensing standards, shortfalls were found against the Consent, Governance and quality systems, and Premises, facilities and equipment standards, including four major and nine minor shortfalls.

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

The HTA's regulatory requirements

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

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

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

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

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

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

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

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

Background to the establishment

Wythenshawe Hospital (the establishment) is part of Manchester University NHS Foundation Trust. The establishment has been licensed by the HTA since December 2010. The establishment is licensed for the making of a post mortem (PM) examination, removal of relevant material from the deceased and storage of bodies of the deceased and relevant material for use for scheduled purposes.

The mortuary is staffed by three Anatomical Pathology Technologists (APTs), including the Mortuary Manager and one trainee APT. The mortuary has been understaffed at times (refer to *Advice*, item 31). On occasion, staff from Bereavement Services undertake some mortuary activities and locum APTs may also work in the mortuary.

The mortuary operates as a hospital mortuary and does not routinely admit bodies from the community. The establishment undertakes approximately 320 adult PM examinations each year. The majority of PM examinations are performed under coronial authority. Adult hospital (consented) PM examinations take place very occasionally; the establishment undertook one hospital PM examination in 2016. The establishment undertakes high-risk PM examinations (cases known or suspected to involve up to hazard group 3 biological agents) (refer to *Advice*, item 29). Home Office PM examinations are not undertaken at this establishment. Perinatal and paediatric cases are transferred to another HTA-licensed establishment for PM examination.

Consent for adult hospital PM examinations is sought by clinical staff with support from either a Consultant Pathologist or member of Bereavement Services trained in the consent seeking procedure (refer to *Advice*, item 3). Consent for adult hospital PM examinations is sought using a consent form and information leaflet based on the HTA's model documentation. Consent for perinatal PM examinations is sought by clinical staff using a consent form and information leaflet based on those provided by the Stillbirth and Neonatal Death (Sands) package and modified by the establishment. Staff receive training in seeking consent for perinatal/paediatric PM examination as part of their clinical training.

The mortuary is located within the main hospital building and is secured by locked doors with swipe card or key access. The rear access to the mortuary is secured by a key and is in an area secured by a locked gate with intercom access. There is closed-circuit television (CCTV) monitoring of some mortuary areas (refer to *Advice*, item 23). The mortuary has personal and wall-mounted panic alarms which are linked to the security team. The mortuary has undergone some refurbishment work since the last HTA inspection in 2014, including replacement of the PM suite floor, replacement of some fridge units and installation of a temperature monitoring and alarm system. Some further maintenance works are required to the mortuary premises, facilities and equipment (refer to minor shortfalls against standards PFE1(a) and PFE3(a)).

The mortuary has 82 spaces for refrigerated storage of bodies, including three spaces for bariatric bodies, eight spaces for semi-bariatric bodies and nine spaces designated for perinatal/paediatric cases. There are three spaces for frozen storage of bodies; this storage capacity is not sufficient to meet the establishment's requirements (refer to major shortfall against standard PFE2(c)). There is a storage temperature monitoring and alarm system for the mortuary fridges and freezers (refer to minor shortfall against standard PFE2(e)). Staff record the storage temperatures and total occupancy rate of the mortuary units on a daily basis, including at weekends (refer to *Advice*, item 27).

The establishment has arrangements to hire a temporary storage unit with space for refrigerated storage of eight bodies. This storage unit has a temperature monitoring alarm which sounds locally only (refer to *Advice*, item 26). The establishment also has arrangements for storage of bodies at other HTA-licensed establishments and a funeral services premises (refer to *Advice*, item 28).

There is a facility in the Maternity Department for the storage of perinatal/paediatric cases prior to transfer to the mortuary. This facility is located in a Bereavement Room, which is managed by a specialist Bereavement Midwife (refer to *Advice*, item 31). The room is secured by key access and there is one locked fridge with space for four cases. Storage temperature is checked and recorded by staff each day, and the fridge is connected to a temperature alarm which sounds locally and can be heard by staff at the midwife station, which is manned at all times. The establishment could not provide evidence of regular servicing and preventative maintenance for this fridge or of the parameters of the temperature monitoring alarm (refer to minor shortfalls against standards PFE2(d) and PFE2(e)).

Bodies are transferred from hospital wards to the mortuary by portering staff (refer to *Advice*, item 5). Perinatal and paediatric cases are transferred from the Maternity Department to the mortuary by clinical staff. Bodies are released from the mortuary by mortuary or Bereavement Services staff. The mortuary and Maternity Department use paper records to record details of bodies, including admission and release of bodies (refer to *Advice*, item 12).

The PM suite has three tables, including one table for bariatric cases. Each PM table has a dedicated bench assigned for the preparation of organs and tissue samples. Tissue samples are transferred to cassettes in the PM suite so that only minimal tissue is taken during PM examination.

Material taken at PM examination may be transferred to the establishment's Histology Department for analysis or to other establishments for toxicology or other tests. Tissue from PM examinations conducted at another HTA-licensed establishment is sent to this establishment to be processed and analysed. PM samples may be kept, with consent, for use for scheduled purposes. Samples are stored in the Histology Department, which is located in a separate building on the hospital site and is secured by swipe card and key code access.

Archived PM samples are stored in a separate facility, which is located within the main hospital premises and is secured by key access. The establishment uses paper records and electronic databases to record sample details, including storage location, details of transport where samples are sent from and to other organisations, and the family's wishes for the fate of the samples. There is a nominated person who manages the storage and disposal of PM samples and acts as a point of contact with Coroner's Offices (refer to *Advice*, items 9 and 20).

Removal of relevant material from the deceased does not take place other than in the mortuary. All cases where this activity is required, for example in cases of sudden unexpected death in infancy (SUDI), are transferred to the mortuary for this to take place.

Description of inspection activities undertaken

This report describes the HTA's third, routine site visit inspection of Wythenshawe Hospital. The inspection team interviewed staff involved with licensable activities, reviewed documentation and conducted visual inspections of the mortuary, Bereavement Room in the Maternity Department and the Histology Department, including the archive store.

A traceability audit was conducted for five adult bodies and three paediatric cases, including fridge and freezer storage. These audits included checks of storage locations and identifiers recorded in the mortuary records. The following discrepancies in traceability were found:

- Traceability of one body in freezer storage could not be confirmed because the identification tag was not accessible.
- There was no identification tag attached to the body in one case (although there were two body identification cards stored securely with the body).
- The storage location recorded on the mortuary register form for one case had not been updated when the body was transferred from fridge to freezer storage.
- The name on the mortuary register form was spelled incorrectly for one case.

Audits of traceability were conducted for tissue blocks and slides from seven PM cases, including checks of the consent documentation for storage of the samples and disposal records for one case where consent had not been given for storage or use of the samples after the end of the coronial authority. There were no discrepancies in traceability of these samples. For one case, the establishment is storing the samples pending notification from the Coroner's Office of the family's wishes for the fate of the samples (refer to *Advice*, item 9).

Consent forms for two adult hospital PM examinations were reviewed. No discrepancies in the completion of these forms were found.

Inspection findings

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

Compliance with HTA standards

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		
b) There is a documented SOP detailing the consent process (including who is able to take consent, what training they must receive, and what information must be provided to those giving consent for post-mortem examination.	Some of the standard operating procedures (SOPs) do not accurately reflect the consent requirements of the HT Act. • The SOPs for high-risk cases ('Dealing with high-risk bodies') and PM examination (HI-S-MO-1) describe that the Pathologist may test the deceased for the presence of infectious agents without consent. Staff informed the HTA that this procedure has not been undertaken. • The SOP for PM examination (HI-S-MO-1) states that consent for retention of tissue should be sought from the next of kin. The HTA did not find evidence that the establishment has removed or used relevant material without consent from a person who is not an appropriate person under the HT Act; however, these procedures, if followed, have the potential to result in a statutory breach of the HT Act. *Refer to Advice, item 1.*	**Major**

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.	Many of the mortuary SOPs do not accurately reflect current practices and do not contain sufficient detail for staff on the procedures that must be followed. Particular examples include: • The SOP for admission of bodies to the mortuary (MO-S-12) does not describe how or when staff should perform the check to flag bodies with same or similar names. • The SOP for release of bodies from the mortuary (MO-S-13) does not include details of the minimum identifiers that must be checked to identify the deceased. This SOP does not reflect that funeral services staff are required to bring paperwork for release of bodies in all cases. • The SOP for viewings of bodies (MO-S-8) does not describe what information is required from the visitor and the minimum identifiers that must be used to identify the deceased. This means that the establishment cannot be assured that all mortuary procedures are undertaken in a consistent manner and in line with the requirements. A number of the discrepancies found by the HTA's traceability audits resulted from deviations from the documented mortuary procedures. This is not an exhaustive list of the amendments required to SOPs, and to fully address this shortfall, the establishment should review all mortuary SOPs to ensure that they are accurate and contain sufficient details of procedures. *Refer to Advice, items 4 and 16.*	**Major**
e) There is a system for recording that staff have read and understood the latest versions of these documents	Whilst there is a system for staff to record that they have read and understood the policies and SOPs relevant to the activities they undertake, Bereavement Services staff who undertake mortuary activities have not recorded that they have read and understood the SOPs relevant to the mortuary procedures they undertake. This poses the risk that they are not aware of the procedures they must follow and may not carry out their duties in accordance with the requirements.	**Minor**

h) Matters relating to HTA-licensed activities are discussed at regular governance meetings involving establishment staff	Whilst some governance meetings are held, governance meetings involving key staff engaged with activities conducted under the licence have not been held regularly. *Refer to Advice, item 7.*	**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	Some staff demonstrated a lack of awareness of the reporting requirements for HTA Reportable Incidents (HTARIs). The establishment's procedure for reporting incidents does not provide assurance that HTARIs reported by portering staff via the internal reporting system would be reported to the HTA. *Refer to Advice, item 13.*	**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	Whilst the establishment has a draft documented risk assessment of the risks related to the licensed activities, this has not been finalised or ratified. *Refer to Advice, item 14.*	**Minor**

PFE1 The premises are secure and well maintained and safeguard the dignity of the deceased and the integrity of human tissue.		
a) The premises are clean and well maintained	The mortuary has undergone some refurbishment work recently; however, some areas of the mortuary have not been maintained to a sufficient standard. • Areas of grouting on the body store floor have deteriorated, meaning that these areas are difficult to clean. • There is a small area of exposed plaster on the wall in the body store where a tile is missing. • There are holes in some ceiling tiles in the PM suite. *Refer to Advice, item 22.*	**Minor**

PFE2 There are appropriate facilities for the storage of bodies and human tissue.		
a) Storage arrangements ensure the dignity of the deceased	The freezer is set to operate at temperatures from minus 1°C to minus 5°C. This temperature is not cold enough for long-term storage of bodies. The establishment has observed deterioration in the condition of some bodies in freezer storage. Despite having noticed this and agreed in December 2016 to lower the operating temperature of the freezer to -20°C, this was not acted on and the freezer has continued to operate at these temperatures. This poses a significant risk to the integrity and dignity of the deceased requiring long-term storage. *Refer to Advice, item 24.*	**Major**
c) Storage for long-term storage of bodies and bariatric bodies is sufficient to meet needs	The establishment does not have sufficient freezer storage capacity. The establishment regularly operates at full freezer capacity with additional bodies requiring long-term storage for which there is no freezer capacity available. The establishment does not have a formal arrangement for frozen storage of bodies at other premises. This has resulted in delays transferring bodies to freezer storage. Some bodies have been stored in refrigerated storage for extended periods resulting in deterioration in the condition of these bodies. These arrangements pose a significant risk to the integrity and dignity of the deceased requiring long-term storage. *Refer to Advice, items 25 and 28.*	**Major**
d) Fridge and freezer units are in good working condition and well maintained	The establishment could not provide evidence of regular servicing and preventative maintenance for the mortuary fridges and freezer or the fridge in the Maternity Department used for storage of perinatal/paediatric cases.	**Minor**
e) Fridge and freezer units are alarmed and the alarms are tested regularly to ensure that they trigger when temperatures go out of upper or lower set range	The documented procedures describing temperature alarm arrangements for the mortuary and maternity storage units do not detail the temperature alarm trigger points or procedures for testing the alarm. Staff were not aware of the parameters for the temperature alarms.	**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 mortuary equipment are in a poor condition. • The trolley in the PM suite has extensive areas that are rusting. • There is some rusting of the bases of one bank of mortuary fridges. *Refer to Advice, item 22.*	**Minor**
c) The ventilation system provides the necessary ten air changes per hour and is checked and maintained at least annually	Whilst the establishment has some records of maintenance of PM suite ventilation system, these records do not provide evidence that the system provides the necessary ten air changes per hour.	**Minor**

Advice

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

No.	Standard	Advice
1.	C1(b)	The establishment must ensure that appropriate consent under the HT Act is given for the removal, storage and use of samples for scheduled purposes. The next of kin may not be the person highest in the list of qualifying relationships under the Section 27 (4) of the HT Act. Removal of relevant material from the body of a deceased person for use for a scheduled purpose is a licensed activity and must take place on licensed premises with appropriate consent. The DI is advised to refer to the HTA's Code of Practice B (paragraphs 122 - 123) for further information regarding removal of relevant material from the body of a deceased person for testing for infection status. Information on the consent requirements of the HT Act can be found in the HTA's Codes of Practice: • Code of Practice A – Guiding Principles and Fundamental Principle of Consent • Code of Practice B – PM Examination
2.	C1(b)	The DI is advised to review the SOP for seeking consent for adult hospital PM examinations to ensure that it contains sufficient details of the consent seeking process, including details of the written information provided to families and the consent training requirements for staff seeking consent. This will help to ensure that staff follow the expected procedure and the required standards are met.
3.	C2(a)	The DI is advised to continue with formalised annual refresher training, which was introduced this year, for the Bereavement Services team and Consultant Pathologists who may seek consent for hospital PM examinations. This training programme helps to provide documented evidence of appropriate training for staff in seeking consent for hospital PM examinations.

4.	GQ1(a)	The DI is advised to ensure that references to documents in the establishment's procedures are up-to-date, including references to the HTA's Codes of Practice and guidance from the Royal College of Pathologists. The DI is also advised to review the quality manual for the Histology Department to include details of the HTA licence and the establishment's arrangements for governance of the licence. This will help to ensure that staff are aware of the requirements of the HT Act and the HTA's advice and guidance.
5.	GQ1(a)	To help ensure compliance with documented procedures, the DI is advised to consider introducing a whiteboard for communication of non-urgent issues between staff, including mortuary staff and porters. The HTA has seen this in use at other establishments where it has been reported to work well to help improve communication between porters and mortuary staff.
6.	GQ1(c)	The DI is advised that the family's permission should be obtained for any invasive procedures; this includes, for example, for removal of a pacemaker device.
7.	GQ1(h)	The DI is advised to invite members from other departments engaged with activities under the licence to the governance meetings. For example, this may include the Bereavement Midwife and Porter Supervisor. This will help the DI to ensure appropriate oversight of licensed activities.
8.	GQ2(a)	The DI is advised to increase the frequency of mortuary audits. The DI is advised that examination audits of processes should be undertaken of a number of staff conducting procedures. Audits can help to ensure that procedures are performed in-line with SOPs and identify areas where additional training may be required or where a process may need to be amended. It may be beneficial for some audits to be undertaken by staff who do not perform the procedures regularly so that they can take a 'fresh eyes' approach to the audit.
9.	GQ2(c)	The DI is advised to increase the frequency of audits of PM tissue stored at the establishment and the frequency of communication with the Coroner's Offices. This will help to ensure that tissue is disposed of as soon as possible where consent has not been given for its retention and coronial authority has ended. The HTA has published a model communication flowchart to support good communication between Coroners and HTA-licensed establishments; this can be found in Code of Practice B (Annex B, pages 39-40 of version published April 2017).
10.	GQ3(a)	The DI is advised to keep under review the training and competency assessments for staff undertaking mortuary activities to ensure that these are conducted in a timely manner and that all training is documented. The DI is also advised to including training in the requirements of the HT Act and details of the HTA licence in the induction training package for mortuary staff. This will help to raise awareness of the requirements of the HT Act and the establishment's arrangements for governance of the licence.
11.	GQ3(f)	The DI is advised to ensure that there are documented training plans for staff returning to work after an extended period of absence. This will help to ensure that staff are trained and competency assessed in up-to-date mortuary procedures. Where staff have not been trained and assessed as competent in mortuary procedures, they should be supervised by appropriately trained staff.

12.	GQ4(b)	The HTA found examples of minor written amendments of records for traceability of bodies and PM samples, which had not been completed in accordance with the establishment's procedure. The DI is advised to remind staff of the procedure for making written amendments to records to help to ensure that that amendments for records are completed in a consistent manner and that full traceability of records is maintained. This is particularly important for amendments to traceability records.
13.	GQ5(a)	As part of the corrective and preventative actions to address the shortfall against standard GQ5(a), the DI should ensure that all staff undertaking licensed activities are aware of the HTARI reporting requirements and the establishment's procedures for reporting incidents. This includes ensuring that staff who manage the establishment's internal incident reporting system are aware of the HTARI reporting requirements. The DI is advised include signage in the mortuary to remind staff of the requirements and procedures for reporting incidents, including near-miss incidents. The DI is advised that further information on HTARIs, including the up-to-date HTARI categories can be found on the HTA website.
14.	GQ6(a)	To address the shortfall against standard GQ6(a), the DI should ensure that all procedures related to licensed activities are risk assessed on a regular basis. The DI is advised that the HTA's 'Regulation of the Post Mortem Sector 2014 – 16: What we have learned' review may also be useful to help identify further risks and actions to mitigate these risks: www.hta.gov.uk/policies/regulation-post-mortem-sector-2014-16-what-wehave-learned.
15.	T1(a)	The DI is advised to review the SOP for admission of bodies to the mortuary (MO-S-12) to describe how bodies from the community are labelled. Whilst the mortuary does not frequently receive bodies from the community, this will help to ensure that all staff working in the mortuary are aware of the procedure to follow and that the traceability standards are met in these cases.
16.	T1(c)	As part of the corrective and preventative actions to address the shortfall against standard GQ1(a), the DI is advised that SOPs describing the procedure for checking the identification of bodies should describe, as a minimum,: • the minimum number of identifiers that must be used and what these identifiers are expected to be; • what records or information are required for the identification check; • how the identification check should be performed, including against what records the body identification tag should be checked against; and • the actions to take in the event of any discrepancies in the identifiers.
17.	T1(c)	The DI may wish to consider strengthening the procedure for viewings by introducing a form to record the information from the visitor used to identify the deceased. By recording this information at the time of making the arrangements for the viewing, these identifiers can be checked when preparing the body for the viewing and immediately prior to the viewing taking place to help to ensure that the required standards are met.

18.	T1(d)	The DI is advised to strengthen the procedure for alerting staff where there are bodies with the same or similar name by adding a coloured wristband to these bodies.
19.	T1(e)	The DI is advised to ensure that, as part of the procedure for transfer of bodies to frozen storage, staff record their confirmation that they have checked the identification of the deceased. By recording this as part of the traceability record, the establishment will ensure full traceability of records. The DI is advised to ensure that, when a body is transferred to frozen storage, the identification tag on the body is positioned so that it can be easily read. This will help to ensure that the identification of bodies in frozen storage can be checked periodically, and prior to release from the mortuary.
20.	T2(a)	The DI is advised to strengthen the system for the Histology Department to ensure that they receive notice of the family's wishes for the fate of samples from hospital (consented) PM examinations at the time of receiving the samples. This will help to ensure that the wishes of the family are acted on and samples disposed of in a timely manner where consent has not been given for their continued retention.
21.	T2(b)	The HTA has published a model communication flowchart to support good communication between coroners and HTA-licensed establishments; this can be found in Code of Practice B (Annex B, pages 39-40 of the version published in April 2017).
22.	PFE1(a)	As part of the corrective and preventative actions to address the shortfall against standard PFE1(a), the DI should keep the suitability of the mortuary facilities under regular review to ensure that they are fit for purpose, clean and well maintained.
23.	PFE1(d)	The DI is advised to review the mortuary security and access. In particular, the DI is advised to review the following arrangements. • The DI is advised to consider whether further CCTV monitoring may be required for the mortuary. • The DI is advised to review the security of the rear access door to the mortuary. This door is secured by key only and does not lock automatically when shut. This poses the risk that the door may be left unsecured inadvertently, which could result in unauthorised access to the mortuary. The DI is also advised to check who has a key to this door to ensure that only those legitimately requiring access to the mortuary have access. • The DI is further advised to ensure that the doors between the mortuary corridor and PM observation gallery and the body store and PM suite are secured. Whilst these doors are in access controlled areas, there remains a risk of staff working in the mortuary gaining inadvertent access to these restricted areas.
24.	PFE2(a)	The DI is advised that the HTA guidance is that optimal fridge temperature is approximately 4°C and freezer temperature is minus 20°C (plus or minus 4°C).

25.	PFE2(c)	The HTA advises that bodies should be moved into frozen storage after 30 days in refrigerated storage if there is no indication that they are soon to be released or further examined, or before, depending on the condition of the body. The DI is advised to conduct more frequent checks on the condition of bodies and consider the introduction of a documented checklist to record checks performed. This will provide assurance that the establishment's storage arrangements ensure the dignity of the deceased is maintained.
26.	PFE2(e)	The DI is advised to review the suitability of temperature storage alarms which sound locally only. Whilst the temperature alarm for the unit in the Maternity Department can be heard by staff in the area and the rental temporary storage unit is only used as a short-term storage facility, there remains a risk that alarming of these units may go unnoticed for a period. The DI is also advised to review signage in the mortuary to include details of the temperature monitoring and alarm arrangements and actions to be taken in the event of the temperature alarm sounding. This will help to ensure that temperature alarms are responded to promptly.
27.	PFE2(f)	The DI is advised to formalise the review of storage temperatures of fridges and freezers which is performed by staff. This may help to identify issues with the function of the storage units. The DI is advised to introduce periodic analysis of storage temperatures for the fridges and freezers. This will help to identify any trends in temperatures which may indicate the need for preventative maintenance of storage units.
28.	PFE2(i)	The DI is advised to review the establishment's contingency plan for storage capacity to consider whether this plan could be strengthened by additional contingency arrangements. The contingency plan should include arrangements for contingency freezer storage capacity. Further advice on contingency storage arrangements can be found in the HTA's guidance document 'Storage capacity and contingency arrangements in mortuaries: Guidance for DIs in HTA-licensed establishments': www.hta.gov.uk/sites/default/files/Capacity%20and%20Contingency%20Report%20Nov%2015.pdf.
29.	PFE3(d)	The DI is advised to review the availability of personal protective equipment for staff undertaking PM examinations for known or suspected high-risk cases (up to hazard group 3 biological agents).
30.	PFE3(f)	The establishment's Estates Department manages servicing and maintenance of the mortuary facilities and equipment. The DI is advised to ensure that the mortuary receives copies of servicing and maintenance records. This will help mortuary staff to ensure that maintenance schedules are appropriate and that the mortuary are made aware of any issues which may impact on operation of the mortuary.
31.	N/A	The mortuary has been understaffed at times. The DI is advised to keep staffing levels of the mortuary under regular review to ensure that they are sufficient to provide safe and effective services. The establishment has one Bereavement Midwife who oversees the storage facility in the Maternity Department and seeks consent for perinatal/paediatric PM examinations. The DI is advised to consider whether additional support for the Bereavement Midwife would help to ensure ongoing maintenance of these services.

32.	N/A	The DI is advised that copies of the HTA licence certificate should be displayed in all areas where licensed activities are carried out, including in the Histology Laboratory and storage facility, in order that it can easily be read by persons who are involved in the carrying out of those activities. This will help raise the awareness of staff and provide clarity as to where licensed activities are taking place.

Concluding comments

This reports describes the third site visit inspection of Wythenshawe Hospital. This was the first inspection of this establishment against the HTA's revised licensing standards, which came into force on 3 April 2017.

The HTA observed some areas of strength. Staff involved in the inspection demonstrated a sensitive approach to their work and dedication to providing a good service. Staff also demonstrated a willingness for continual improvement and compliance with the regulatory requirements, and were open to the advice given by the HTA. There are arrangements to facilitate good communication between the departments at the establishment engaged in licensed activities.

Mortuary staff involved in the inspection demonstrated that they have worked hard under staffing pressures. Some refurbishment works have been undertaken in the mortuary. The mortuary has facilities for bariatric cases, including a number of fridges for storage of bariatric and semi-bariatric bodies, a PM table for bariatric cases and specialist hoists. This allows the establishment to ensure continuity of services for bariatric patients in the hospital.

There is a specialist Bereavement Midwife who oversees the services for bereaved parents and has worked hard to provide a sensitive and caring facility in the Maternity Department for perinatal/paediatric cases and parents.

The Histology Department demonstrated robust procedures for management of PM samples, including a nominated person who is responsible for overseeing these samples.

Although the HTA found that the establishment had met some of the HTA's standards, shortfalls were found against the consent, governance and quality systems, traceability, and premises, facilities and equipment standards, with four shortfalls assessed as major and nine as minor (see Appendix 2 for information about the HTA's classifications of 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 November 2017

Report returned from DI: 06 December 2017

Final report issued: 07 December 2017

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: 21 May 2018

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 they are 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 for these 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.