Inspection report on compliance with HTA licensing standards
Inspection date: **18 & 19 January 2023**

University Hospital Lewisham

HTA licensing number 12266

Licensed under the Human Tissue Act 2004

Licensed activities

The table below shows the activities this establishment is licensed for and the activities currently undertaken at the establishment.

Area	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	Storage of the body of a deceased person or relevant material which has come from a human body for use for a scheduled purpose
Hub site **University Hospital Lewisham**	Licensed	Licensed	Licensed
Mortuary	-	*Carried out*	*Carried out*
Pathology lab	-	-	*Carried out*
A&E	-	*Carried out*	-
Satellite site **Queen Elizabeth Hospital Woolwich**	Licensed	Licensed	Licensed
Mortuary	*Carried out*	*Carried out*	*Carried out*
Pathology lab	-	-	*Carried out*
Maternity	-	*Carried out*	-

A&E	-	*Carried out*	-

Summary of inspection findings

The HTA found the Licence Holder (LH) to be suitable in accordance with the requirements of the legislation.
As a result of the findings of this inspection, and the lack of engagement during the inspection process, the Designated Individual (DI) is not deemed to be suitable to remain in this statutory role.

Although the HTA found that University Hospital Lewisham ('the establishment') had met some of the HTA's standards, four critical, fourteen major and four minor shortfalls were found against standards for Consent, Governance and quality systems, Traceability and Premises, facilities, and equipment. These related to incident reporting, traceability systems, tissue disposal, storage capacity and procedures, dignity of the deceased, governance arrangements, staff training and competencies, Standard Operating Procedures (SOPs), equipment suitability and security arrangements.

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.

Compliance with HTA standards

Critical Shortfalls

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	The inspection team found that untoward incidents, in relation to HTA licensed activity, are not reported, investigated promptly, with mitigation applied and learning shared. The inspection team found several incidents which had not been reported to the HTA, these included incidents related to: • Unauthorised access by trust staff to the mortuary. • Faults with refrigerated storage equipment and equipment errors led to fridge being taken out of service. • Temporary body store alarmed as out of temperature range however the alarm was not responded to. These incidents require retrospective reporting to the HTA. • That the DI is not engaged in HTA activity, and there is only one Persons Designate (PD) over the two sites. As a result of this there is an apparent lack of oversight and incident reporting and resolution. • Not staff involved in licensable activities are aware of the HTAs Reportable Incidents (HTARI) reporting requirements and procedure. This included staff working in areas outside of the mortuary, such as Maternity and portering services.	**Critical (cumulative)**

b) The incident reporting system clearly outlines responsibilities for reporting, investigating and follow up for incidents	The HTARI SOP does not include the detail required to ensure that incidents are reported and followed up in line with HTA requirements. Information on incidents is not shared with the wider team working under the licence. The incident reporting system in place is not being used to share learning with relevant staff to avoid repeat errors. The inspection team noted incident reports where no feedback was given, and the management team had not signed them off.	
d) Information about incidents is shared with all staff to avoid repeat errors	Whilst mortuary minutes include information about incidents, not all staff working under the licence are invited to HTA meetings therefore full disclosure and learning is not in place.	
e) The establishment adopts a policy of candour when dealing with serious incidents	Whilst the establishment has a duty of candour policy in place, examination of the mortuary incident log identified several serious incidents that have not been reported to the HTA. Therefore, due to the number, and severity, of incidents unreported to the HTA, the inspection team are not assured the establishment adopts a policy of candour when handling serious incidents.	

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	The inspection team identified a trend, over the last year, of bodies being received into the mortuary with significant identification issues, these include: • A lack of correct information on the identification bands on the deceased. • A lack of correlation between information on the identification bands, death notice and patient. • Missing identification bands This poses both a risk of misidentification of the deceased and raises concerns about accuracy of patient identifiers more generally. The severity of this risk is increased due to the number of times bodies are moved both within and off-site, staff working alone in a very busy environment with constant interruptions, releases occurring from off-site storage and delays in ward staff coming to the Mortuary to correct identification errors.	**Cumulative critical**
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)	The systems used to track each body from admission to the mortuary, to release for burial or cremation are not robust and present a traceability risk to the deceased. This risk is further increased by the frequency of changes in storage locations to manage capacity issues. **Hub and Satellite** Temporary racking is utilised for storage on both sites, however individual storage positions for each body have not been assigned. This means that accurate recording of the deceased's location is not possible.	

	Hub The inspection team found errors in the paper records used to track the storage location of the deceased. Two different paper records are in use and the storage locations recorded for several bodies did not correlate with records. This risk is further increased as the storage location of bodies is frequently changed to manage capacity issues, and subsequently both records documenting the storage location are not kept up to date.	
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	**Hub** At Lewisham three pieces of identifying information relating to the deceased, are not consistently requested when booking a viewing. Furthermore, identity checks take place when preparing the body for viewing however there are no further checks prior to the family viewing the deceased. This creates a risk of viewing of the wrong body, the severity of which is increased as the department has two viewing rooms meaning several families could be attending the department simultaneously.	
g) Organs or tissue taken during post-mortem examination are fully traceable, including blocks and slides (including police holdings).	The inspection team are not assured that the Trust is aware of what relevant material is being held and that tissue taken during post-mortem examination is fully traceable. **Satellite** The inspection team identified material stored from both hospital and coroners' post-mortem examinations, however records indicating the type and quantity of samples are not available.	

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	The process for the movement of perinatal/neonatal deceased for offsite post-mortem examination does not ensure full and robust traceability as the receiving site does not acknowledge or record receipt of the deceased.	
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	The inspection team are not assured that the Trust is aware of what relevant material is being held, under the licence, and that its retention and disposal is in accordance with both the Human Tissue Act 2004 (HT Act) and the families' wishes. **Satellite** The inspection team identified material stored following hospital and coronial consented post-mortem examinations, however consent documentation and disposal records are not available. Furthermore, the staff are not aware of the tissue being stored after coronial post-mortem examinations. The inspection team are not assured that tissue is disposed of, or handled, in accordance with both family wishes and the requirements of the HT Act.	**Cumulative Critical**
b) There are effective systems for communicating with the Coroner's Office, which ensure tissue is not kept for longer than necessary	The establishment did not demonstrate a process for communicating with the Coroner's Office and are not aware of the tissue being stored from coronial post-mortem examinations. Therefore, the inspection team are not assured there are systems in place to ensure tissue is not kept for longer than necessary.	

c) Disposal is in line with the wishes of the deceased's family	The inspection team are not assured that disposal is in line with the wishes of the deceased's family as detailed in T2(a)	
d) The method and date of disposal are recorded	Documented records detailing both the method and date of disposal are not available.	
PFE2 There are appropriate facilities for the storage of bodies and human tissue.		
a) Storage arrangements ensure the dignity of the deceased	Storage at both sites does not ensure the dignity of the deceased, for example: **Both sites** • Racking is positioned against a side wall of the unit preventing lateral transfer of bodies posing a risk of accidental damage to the deceased and manual handling risks to the staff. • Some of the racking is made of porous wood and therefore cannot be effectively decontaminated due to the material used. • The racking is not suitable for bariatric bodies therefore these patients are being stored on hospital beds. **Hub** • The external container units have been inspected by the Trust's Health & Safety team, the resulting report states that the facilities pose a serious risk to the deceased and recommends that the units should be taken out of use. However, at the time of inspection, three of the four units were in use. • The establishment stores bodies at floor level on trays within the internal fridge units and stores bodies in coffins at floor level in the external refrigerated facilities. Appropriate manual handling equipment is not used in the movement of these deceased. This practice poses an increased risk of accidental damage to the	**Critical (cumulative)**

	deceased; bodies stored in these locations are subject to additional manual handling. • As part of the inspection process, the inspection team identified concerns relating to inappropriate and unrefrigerated storage conditions at the Satellite site. These concerns have since been addressed. All bodies had been relocated to appropriate storage by the time of the on-site element of the inspection. • Racking is being used in an unrefrigerated location. • In the event of insufficient storage for bariatric and non-bariatric patients the processes undertaken do not maintain the condition or the dignity of the deceased. • In the event of insufficient freezer storage, the processes undertaken do not maintain the condition or the dignity of the deceased. • Regular, documented, condition checking was not being undertaken throughout the stay of the deceased. Deterioration was noted on one body audited. • During the inspection process the HTA team noted storage capacity had been exceeded and that, in an attempt to maintain the condition of the deceased, the mortuary team had been rotating bodies through refrigerated and unrefrigerated storage. **Satellite** • This site has a Service Level Agreement with Walthamstow public mortuary for use of the post-mortem suite. In the event of insufficient storage for these deceased, current processes do not maintain the condition or the dignity of the deceased.	

	The inspection team could not assess the condition of all bodies in the care of the Satellite site as on the day of inspection, 60 deceased were being stored at off-site locations. Documented duty of care visits and evidence of condition checking at off-site locations were not made available to the inspection team as requested. Storage arrangements do not maintain the condition or the dignity of the deceased. They increase the risk of accidental damage and a loss of traceability of bodies in the Trust's care and increases the workload, and the risk of, manual handling injuries to the small mortuary team.	
b) There is sufficient capacity for storage of bodies, organs and tissue samples, which takes into account predicated peaks of activity	Both sites have insufficient and inappropriate storage as highlighted by the findings at PFE2a above. This is also evidenced by the satellite site records documenting storage of bodies in off-site locations. This has been in operation for several years.	
c) Storage for long-term storage of bodies and bariatric bodies is sufficient to meet needs	Storage for long-term storage and bariatric bodies is not sufficient to meet needs across both the hub and satellite sites. The inspection team noted: **Hub** • A bariatric patient was being stored on a hospital bed due to insufficient bariatric refrigerated storage capacity. **Satellite** • A bariatric body had been in the care of the satellite mortuary for more than 30 days and the deceased had started to show signs of deterioration, however, no plan was in place to transfer the deceased to freezer storage due to insufficient capacity. Capacity is frequently not sufficient to meet the demand to move bodies into long term storage. Lack of freezer storage poses significant risk of deterioration to bodies that could otherwise be preventable.	

Major Shortfalls

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		
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	The policy which governs consent for post-mortem examination and the retention of tissue does not reflect the requirements of the HT Act and the HTA's Codes of Practice. The inspection identified the following issues relating to the documented policy governing consent for post-mortem examination and the retention of tissue: **Hub site** The overarching consent policy is not fully reflective of the requirements of the HT Act or the HTA Codes of practice. Whilst the policy details that consent for post-mortem examination, removal of relevant material and the retention of tissue should be obtained from an appropriate person, the policy does not detail that those seeking consent should be trained and assessed as competent in the consent seeking procedure. **Satellite site** A policy governing the seeking of consent at the satellite site was not provided as part of the inspection.	**Major (cumulative)**
b) There is a documented standard operating procedure (SOP) detailing the consent process	The consent SOPs used on both sites for the seeking of consent for post-mortem examination does not fully reflect the consent process undertaken and does not detail how a change or withdrawal of consent would be communicated to the mortuary.	

c) There is written information for those giving consent, which reflects the requirements of the HT Act and the HTA's codes of practice	The written information for those giving consent does not fully reflect the requirements of the HT Act and the HTA's codes of practice: **Hub site** • The document contains out of date Hyperlinks and use of HTA logo, which should not be used without HTA authorisation. **Satellite site** • The term next of kin is used. This is not the appropriate terminology under the HT Act, which refers to the consent being given by the person highest in the statutory hierarchy of qualifying relationships. • The hierarchy of qualifying relationships detailed does not correspond with that given in the SOP detailing the consent process. • The information used during consent taking for paediatric/neonatal patients is not available for families to take away with them. .	
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	Information provided to those giving consent does not detail what steps will be taken if no decision is made by the relatives on how the tissue may be handled after the post-mortem examination.	
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	At the time of the inspection the establishment could not demonstrate that all staff seeking consent for post-mortem examination have undertaken relevant training on Human Tissue Act consent.	**Major (cumulative)**
b) Records demonstrate up-to-date staff training	The inspection team are not assured that staff involved in both the adult and perinatal consent seeking process have up-to-date training as there is no consistent record of training.	
c) If untrained staff are involved in seeking consent, they are always accompanied by a trained individual	The inspection team are not assured that staff involved in both the adult and perinatal consent seeking process are always accompanied by a trained individual.	
d) Competency is assessed and maintained	The inspection team are not assured that the competency of staff involved in both the adult and perinatal consent seeking process is assessed or maintained.	
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 the Royal College of Pathologists	On both sites SOPs lack sufficient detail. Key steps are included but do not specify the individual actions that should be taken to accomplish each step. These include, but are not limited to, SOPs detailing the process for: • Use of the Mortuary register • Admitting, storing and release of bodies • Post-mortem examination procedures • Condition checking • Use of post-mortem facilities by third parties Furthermore, SOPs are not aligned across the sites for similar procedures. This is not an exhaustive list of the SOPs requiring amendment. To fully address this shortfall the establishment should review all SOPs to ensure they contain sufficient detail and are reflective of current practice across the sites.	**Major (Cumulative)**

c) Procedures on body storage prevent practices that disregard the dignity of the deceased	The inspection team found that body storage procedures do not prevent practices that disregard the dignity of the deceased. **Hub and Satellite** • Regular, documented, condition checking was not being undertaken throughout the stay of the deceased. Deterioration was noted on one body audited. **Satellite** • No procedure for the care of the deceased when stored in off-site locations was made available to the inspection team, this includes movement to long term storage, condition checking and temperature monitoring. • Procedures for storing bariatric patients in the event capacity is reached involves storing the deceased on a hospital bed in an unrefrigerated location. • Procedures for storing non-bariatric patients in the event capacity is reached include storing the deceased in unrefrigerated, high traffic areas in the department. • Procedures for storing bodies from Walthamstow public mortuary transferred to the satellite site for post-mortem examination were not made available to the inspection team.	
f) Deviations from documented SOPs are recorded and monitored via scheduled audit activity	Deviations from documented SOPs are not recorded and monitored via scheduled audit activity for example: • Moving bodies to alternative storage locations occurs on a regular basis, however the process is not fully documented in an SOP and is not on the audit schedule. • The use of racking is not in the SOP; however, it is used regularly, and this process is not audited.	**Major**

g) All areas where activities are carried out under an HTA licence are incorporated within the establishment's governance framework	The inspection team are not assured that all areas where activities are carried out under the HTA licence are incorporated within the establishment's governance framework for example: • Staff involved in licensable activities, including staff working outside of the mortuary, such as in Maternity, Accident and Emergency, Histopathology departments and the porting staff, are not incorporated in the governance framework for HTA activity. • Governance frameworks for the sites are not aligned, the establishment has two sites which have separate procedural documents, risk assessments, staff training documents, competency assessments and audits for similar activities conducted under the license. • There are no PDs overseeing HTA activities in all relevant areas save for the mortuary at the hub site. This impacts the DIs ability to oversee licensed activity methodically and ensure consistency in standards across the sites. • Walthamstow Public Mortuary are undertaking post-mortem examinations under the University Hospital Lewisham HTA license, however this activity is not incorporated in the governance system.	**Major (cumulative)**
h) Matters relating to HTA-licensed activities are discussed at regular governance meetings involving establishment staff	There are no scheduled, formalised governance meetings involving the DI, PDs or staff working under the licence, outside of the Mortuary, therefore the inspection team were not assured that the DI has oversight of regulated activities taking place on both sites under the HTA licence. Furthermore, regular governance meetings are in place for the mortuary team however the DI does not attend. The inspection team is therefore not assured that the DI has oversight of all regulated activities on both sites.	

GQ2 There is a documented system of audit		
b) Audit findings document who is responsible for follow-up actions and the timeframe for completing these	**Hub and Satellite** Audit findings do not document who is responsible for follow-up actions, who is responsible for completing these actions, and a timeframe for completion.	**Major**
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	**Satellite** The inspection team identified material stored following hospital and coronial consented post-mortem examinations, however regular audits are not carried out and the staff are not aware of what is held and why. As a result, timely disposal of tissue, where consent has not been given for continued retention, is not taking place. *See critical (Cumulative) shortfalls T2 (a-d)*	**Major**

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 inspection team found that staff involved in mortuary duties are not all appropriately trained/qualified or supervised. For example: Several staff groups have either not been trained or their refresher training is out of date, these include: **Hub** • Clinical site manager for out of hours releases • New portering staff, refresher training • Domestic support staff being used to help undertake mortuary duties. **Satellite** • Clinical Site Manager for out of hours releases • Walthamstow staff, using the satellite mortuary facilities.	**Major (cumulative)**
c) Staff are assessed as competent for the tasks they perform	The inspection team found that staff are not assessed as competent for the tasks they perform. For example: **Hub** • Clinical site manager for out of hours releases. • New portering staff, refresher training. • Domestic support staff being used to help undertake mortuary duties. **Satellite** • Clinical Site Manager for out of hours release. • Walthamstow staff, using the satellite mortuary facilities.	

g) Visiting / external staff are appropriately trained and receive an induction which includes the establishment's policies and procedures	There was no evidence to assure the inspection team that visiting/external staff working in the Mortuary on the Satellite site are appropriately trained and receive an induction including the establishment's policies and procedures.	
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	The inspection team are not assured that risk assessments covering all licensed activities are undertaken. These included: • The use of non-mortuary trained staff. • All storage facilities, locations, and practices. • Use of PM facilities by third party. A number of risk assessments do not contain sufficient detail on how identified risks are mitigated, they are out of date for review and are not aligned across the sites for similar procedures.	**Major (cumulative)**
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	Whilst staff are able to demonstrate knowledge of the risks associated with licensed activity, the inspection team did not receive evidence that appropriate mitigations had been identified and/or implemented. For example, the risk assessment detailing the risks associated with transfer of tissue off-site identified actions that were not assigned to an individual and a completion date was not given.	
c) Significant risks, for example to the establishment's ability to deliver post-mortem services, are incorporated into the Trust's organisational risk register	Significant risks relating to staffing are not incorporated in the Trust's organisational risk register. The hub site has an establishment of 2 members of staff; however, it operates with a single member of staff on a regular basis. There is a risk to the mortuary service should a member of staff be unable to work.	**Major**

PFE1 The premises are secure and well maintained and safeguard the dignity of the deceased and the integrity of human tissue.		
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)	**Hub** During the external inspection of the premises, the inspection team found that access to the condenser units, which maintain the power supply to the external refrigeration units, was not controlled. These units are located in a carpark and next to a public right of way, therefore access is not controlled or monitored. Uncontrolled access to the main electrical breaker switches poses a risk of access by unauthorised personnel and the power supply to Mortuary 2 being interrupted. **Satellite** CCTV is installed in this department however the mortuary team do not have access to review CCTV footage relating to licensed activity including access.	**Major**

e) Security arrangements protect against unauthorized access and ensure oversight of visitors and contractors who have a legitimate right of access	The inspection team found that security arrangements on both sites do not protect against unauthorised access. **Hub** On the day of inspection, doors leading from the viewing waiting area into the viewing room, then into the mortuary were not secured. This meant that access could have been gained to a temporary body storage unit, the viewing room and the main body store. The outside public parking area overlooks the external refrigerated storage units, posing the risk of oversight of the deceased. **Satellite** The viewing rooms at the satellite sites do not have systems in place for staff to be able to raise an alarm should this be required. This may pose a risk of visitors accessing the rest of the mortuary if staff security is compromised. All access doors should be effectively secured, currently there is a risk of unauthorised access.	**Major**
PFE2 There are appropriate facilities for the storage of bodies and human tissue.		
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	**Satellite** The fridges located in the maternity department are not alarmed.	**Major (cumulative)**
f) Temperatures of fridges and freezers are monitored on a regular basis	**Satellite** The temperatures of the fridges located in the maternity department are not monitored.	

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	Items of equipment in the mortuary are not appropriate for use, for example: **Hub and satellite** • Racking is positioned against a side wall of the unit preventing lateral transfer of bodies and posing a risk of accidental damage to the deceased and manual handling risks to the staff. • Some racking is made of porous wood which potentially compromises the effectiveness of decontamination processes due to the material used. **Hub** • The units have been inspected by the Trust's Health & Safety team, the resulting report states that the facilities pose a serious risk to the deceased and recommends that the units should be taken out of use. However, at the time of inspection, three of the four units were in use. See shortfall PFE 2a above.	**Major (cumulative)**
b) Equipment is appropriate for the management of bariatric bodies	**Hub and satellite** • The racking is not suitable for bariatric bodies therefore these patients are being stored on hospital beds if capacity is reached.	

Minor Shortfalls

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

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	Policies and SOPs are not reviewed regularly by someone other than the author.	**Minor**
e) There is a system for recording that staff have read and understood the latest versions of these documents	**Satellite** The induction documentation records that staff have read and understood documented policies and procedures for the mortuary activities they are undertaking, however there is not a system in place to record subsequent amendments or that revised or new SOPs have been read and understood.	**Minor**
GQ4 There is a systematic and planned approach to the management of records		
a) There is a system for managing records which includes which records must be maintained, how they are backed up, where records are kept, how long each type of record is retained and who has access to each type of record	The inspection team were not given evidence and therefore are not assured that there are documented systems for managing records which comply with HTA standards.	**Minor**
PFE2 There are appropriate facilities for the storage of bodies and human tissue.		
g) Bodies are shrouded or in body bags whilst in storage	The inspection team found evidence of soiled shrouding on one body at the satellite site, therefore not preserving the dignity of the deceased.	**Minor**

The HTA requires the DI 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.

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

Number	Standard	Advice
1.	GQ2(a)	The DI is advised to add traceability audits of the records in maternity to the existing audit schedule.
2.	GQ2(a)	The DI is advised, when compiling the audit schedule, to include audits of tissue in storage and the consent in place.
3.	PFE1(d)	The DI is advised to replace the bolt to the body store door at the hub site and the key lock to the viewing room at the satellite site with a mechanism which does not require manual deployment.
4.	PFE1(d)	The DI is advised to ensure that access to CCTV and swipe card access data is available, on both sites, to conduct security audits and investigate incidents.
5.	PFE1(e)	At the hub site the DI is advised to review the model rules for contractors as the access arrangements outlined are no longer in practice
6.	N/A	The DI is advised to consider the activities being undertaken under the licence at the hub and satellite site with a view to determining which licenses are required.
7.	N/A	The DI is advised to display all three HTA certificates in the Mortuary.
8.	N/A	The DI is advised to consider a ward level improvement project focused on the accuracy of patient identification bands.

Background

Lewisham University Hospital has been licensed by the HTA since August 2007, Greenwich Hospital was added to this licence as a satellite site in November 2013. This was the fourth inspection of the establishment; the most recent inspection took place in December 2017.

Since the previous inspection, there has been a change to the role of DI.
Four additional, externally sited, refrigerated storage units are in use at the hub site and several internal units have been added to the internal storage capacity at the satellite site.

The Pathology departments on both sites are now managed by the East and South East London Pathology partners.

The satellite site has a service level agreement which permits Walthamstow public mortuary to carry out post-mortem examinations, using the satellite mortuary facilities including storage and post-mortem suite.

Description of inspection activities undertaken
The HTA's regulatory requirements are set out in Appendix 1. The inspection team covered the following areas during the inspection:

Standards assessed against during inspection
All 72 HTA licensing standards were covered during the inspection (standards published 3 April 2017).

Review of governance documentation
The inspection team reviewed the establishment's self-assessment document provided by the DI in advance of the inspection. Policies and procedural documents relating to licensed activities were reviewed. This included cleaning records for the mortuary

and post-mortem room, records of servicing of equipment, fridge and freezer alarm testing records, ventilation reports, audits, risk assessments, meeting minutes, temperature monitoring for the storage units, reported incidents, and staff training and competency records. Consent seeking policies and procedures, information for relatives giving consent and current consent forms in use for both adult and perinatal PM examination were also reviewed.

Documentary evidence requested by the HTA was not submitted in full by the establishment prior to the inspection.

Visual inspection
The inspection included a visual assessment of all body and tissue storage and viewing facilities on the hub and satellite sites. The inspection team observed the processes for admission, release and viewing of bodies within both the hub and satellite mortuaries. On the satellite site the inspection team also assessed the post-mortem examination facilities and the Maternity department, in relation to HTA licensable activities.

Audit of records
The inspection team undertook audits of traceability for six bodies in storage on both the hub and satellite sites. This included a perinatal case, bodies with same/similar name and bodies in long term storage. The audit covered deceased stored in all the body stores. Traceability details were crosschecked between the identification bands on the deceased, information on the door of the storage unit, the mortuary register and paperwork. Inaccuracies in recording the storage location of the deceased was noted at the hub site.

Audits were conducted of tissue taken at post-mortem examination in six cases on the hub site and 12 at the satellite site.

Hub
Information was crosschecked between the mortuary documentation, Coroner's paperwork, family wishes forms and tissue blocks and slides being stored at the hub site. Retention and disposal of tissue had been completed in line with the wishes of the family and compliant with HTA requirements. Full traceability of tissues was demonstrated for all six cases.

Satellite

Mortuary documentation, Coroner's paperwork and family wishes forms were not available to cross check against tissue blocks and slides being stored at the satellite site. Retention and disposal of tissue had not been completed in line with the wishes of the family and were not compliant with HTA requirements.

Meetings with establishment staff

The inspection team met with staff carrying out processes under the licence from both sites, including the DI, Senior Anatomical Pathology Technician, consent seekers for both adult and perinatal hospital post-mortem examinations, bereavement midwives, porters, laboratory staff, a pathologist and the sudden unexpected death in childhood representative for the Trust.

Report sent to DI and CLHc for factual accuracy: 9 March 2023

Report returned from DI and CLHc: 27 March 2023

Final report issued: 12 April 2023

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: 15 November 2024

Appendix 1: The HTA's regulatory requirements

Prior to the grant of a licence, the HTA must assure itself that the DI 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 DI 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 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.

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 Human Tissue Act 2004 (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 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:

   - A notice of proposal being issued to revoke the licence
   - 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.
   - A notice of suspension of licensable activities
   - Additional conditions being proposed
   - 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 Codes of Practice, 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 review or at the time of the next inspection.

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. Establishments 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 inspection
- a request for information that shows completion of actions
- monitoring of the action plan completion
- follow up at next routine inspection.

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