

Site visit inspection report on compliance with HTA minimum standards

William Harvey Hospital

HTA licensing number 30011

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**

6-7 December 2016

Summary of inspection findings

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

Although the HTA found that William Harvey Hospital (the establishment) had met the majority of the HTA standards, one major shortfall and four minor shortfalls were found in relation to the Governance and Quality Systems (GQS) and Premises, Facilities and Equipment (PFE) standards. Advice has been given on matters across the range of standards, including licence management.

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

The HTA's regulatory requirements

The HTA must assure itself that the DI, LH, premises and practices are suitable.

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.

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. The HTA inspects the establishments it licences against four groups of standards:

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

This is an exception-based report: only those standards that have been assessed as not met are included. Where the HTA determines that a standard is not met, 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 given to the DI.

Reports of HTA inspections carried out from 1 November 2010 are published on the HTA's website.

Background to the establishment and description of inspection activities undertaken

This report refers to the activities carried out at William Harvey Hospital (the establishment), whose licensing arrangements cover William Harvey Hospital (WHH, the hub site) in Ashford and Queen Elizabeth The Queen Mother Hospital (QEQMH, the satellite site) in Margate. The DI is a Consultant Cellular Pathologist; the LH is East Kent Hospitals University NHS Foundation Trust (EKHUFT), with the Medical Director acting as the named corporate LH contact (CLHC).

WHH and QEQMH are part of the East Kent Hospitals University NHS Foundation Trust, which is one of the largest hospital trusts in England, with five hospitals serving a local population of around 759,000 people. The pathology laboratory services operate as a pathology network and are part of the Clinical Support Services Division of the EKHUFT.

William Harvey Hospital – the hub site

At the hub site, licensable activities take place in the mortuary and the Cellular Pathology Department.

The mortuary at WHH has recently experienced significant staffing problems that occurred over a short period and were due to circumstances outside the mortuary's control. Currently,

it is staffed by one full-time APT, an APT who works 12 hours a week and a locum APT. The current team is under pressure to deliver a service to the same standard with fewer staff, which includes there being a member of mortuary staff on call at all times.

Around 700-800 PM examinations are undertaken at WHH mortuary per annum. The majority of these are conducted at the request of HM Coroner, who currently covers North East Kent (the Ashford and Margate areas), and include a number of Home Office cases. The mortuary accepts high-risk cases for short-term storage but bodies are sent to Brighton for PM examination. In addition to coronial PM examinations, consented adult PM examinations are occasionally undertaken. There are no paediatric/perinatal PM examinations conducted on site; these are transferred to other HTA licensed premises. Staff have access to personal protective equipment (PPE) when conducting routine PM examinations.

The body store consists of 60 refrigerated spaces, five permanent freezer spaces and ten refrigerated spaces suitable for bariatric bodies. Ten of the fridge spaces provide direct access to bodies from the PM suite. There is a dedicated bank of five storage spaces for the bodies of children and infants. These are also used for the storage of fetuses and placentas, the details of which are recorded on a separate whiteboard in the mortuary. In addition, the mortuary contains a full size bariatric fridge separate from the main body store that can potentially hold four trays and is accessible by roll-in trolley, and two permanent Nutwell storage units with a combined capacity of 24 fridge spaces.

In addition, the contingency plan for the Christmas period to mitigate any capacity issues consists of 16 temporary storage spaces at QEQM and 12 spaces at WHH which will be delivered mid December.

The mortuary does not contain designated storage spaces for high-risk cases but body bags and high risk tape are used and the mortuary whiteboard and register are marked with a notice of infection.

The body store and additional storage units are all temperature monitored by Tutela, an automated wireless temperature monitoring system that calls the mortuary when temperatures deviate from expected ranges. If no response is received, the Tutela system then contacts the on-call member of mortuary staff who can access the system remotely and evaluate the problem. There are monthly alarm tests on temperature monitoring and temperatures are reviewed each morning. Tutela also performs an annual check on the system.

The PM suite consists of three PM tables with adequate space and lighting to work at each table at the same time. The PM tables are not downdraft and the ventilation system has recently undergone maintenance work. Preliminary airflow test shows the system is achieving correct flow; however, maintenance records confirming the number of hourly air changes provided by the ventilation system in the PM suite were not available during the inspection, but were provided to the HTA subsequently.

Buckets at each cut-up table have been assigned a number to mitigate organ and tissue mix up; however, there are no corresponding numbers on the PM tables (see advice item 4).

Prior to evisceration, the pathologist checks the identification of the deceased with an APT using a PM check sheet; they also undertake a full external examination of the body. Tissue taken during the PM examination is recorded in a mortuary log book and sent to Histology (see advice item 3). Histology receipt and consent forms are sent with the tissue and a 'tissue

taken' alert is placed on the mortuary board. All PM histology is stored in a room adjacent to the mortuary after use.

Tissue and organs are occasionally sent offsite for specialist examination. Specimens are taken by a specific courier company, to either University College London Hospitals NHS Foundation Trust (brains) or St George's University Hospital NHS Foundation Trust (hearts). Samples sent for toxicological analysis are transported by a specific coroner's courier once a week to Kent Scientific.

The entrance to the mortuary used by funeral directors is screened from public view and CCTV monitors the entry point; however, the mortuary has no access to these monitors (see shortfall PFE1). Lone and out-of-hours unaccompanied working does occur at times and there are procedures and security arrangements in place to provide protection for staff.

Checks of the condition of the body and identification of the deceased are carried out on all bodies prior to PM examination, movement of a body within the body store, viewing of a body or release of a body. When a body is received into the mortuary from the hospital, it is brought in by the porters and checked in by mortuary staff using the patient's hospital number, name, DOB and NHS number. All bodies must be brought from wards in disposable shrouds with two identifying wristbands. A unique mortuary identifier is assigned to every body that enters the mortuary and an orange toe tag is placed on bodies that have been checked in by mortuary staff.

An overhead hoist is used to transfer bodies into refrigerated storage, and all porters and mortuary staff are trained in its operation. Porters complete a 'body map' sheet to record the condition of the body prior to placing it in the fridge, and they complete the porters' log book, which contains all details regarding to the admission of the body to the mortuary. If a body is brought down out of hours, the porters place the deceased into an available fridge bay, as indicated on the mortuary whiteboard, and leave the paperwork for the body to be checked in by mortuary staff in the morning.

When a body is received from the community, it is checked in using similar identifiers, with the exception of hospital and NHS number, and assigned a unique mortuary identifier.

Hospital and community deaths are usually stored on opposite sides of the mortuary and porters write patient details for both hospital and community cases on the whiteboard. For receipt out of hours, the funeral directors or ambulance crew contact the portering staff prior to arrival and are met at the door of the mortuary to gain access. Funeral directors and ambulance crew must record their details in the mortuary visitors book and the name of the deceased on the space on the whiteboard that corresponds to the fridge number that has been used.

On release of bodies, mortuary staff must confirm the identity of the deceased with the funeral director by checking at least three identifiers on the identification tags against the signed body release paperwork before releasing the body. Property of the deceased is also checked. If there are any discrepancies, mortuary staff will not release the body until the correct identification details are confirmed. Body release rarely takes place out of hours and is only ever done by mortuary staff.

Consent for adult hospital PM examinations is sought primarily by the clinician who was treating the deceased before they died. They first discuss the request for a PM examination with a pathologist, who can advise on its scope and answer any questions they may have. When seeking consent, they are accompanied by a relative support officer.

All those involved in seeking consent have undertaken the Trust's mandatory training on consent and are familiar with the forms used to record consent and the patient information leaflets used to support the consent seeking process.

Stillbirths are transferred from the maternity department to the mortuary as soon as possible, but in consideration of the needs and wishes of the parents. There is access to cold cots in the maternity department if required. The bereavement midwives are familiar with the requirements of the Human Tissue Act 2004 (HTA 2004) and have a documented consent procedure to follow, which reflects legal requirements. The person giving their consent is allowed the opportunity to change their mind within a 24-hour window and can call the bereavement services on a direct line if they change their mind. Maternity department staff are aware of the HTA's guidance on the disposal of pregnancy remains following pregnancy loss or termination and have implemented this guidance in their practice.

Queen Elizabeth The Queen Mother hospital – the satellite site

At the QEQMHS satellite premises, licensable activities take place in the mortuary and overall governance of this site is the same as at the WH site.

Around 1,100 PM examinations are undertaken at QEQMHS mortuary per annum. The majority of these are conducted at the request of the HM Coroner for North East Kent, including a number of Home Office examinations (12-15 cases across both sites a year). There are fewer than five consented hospital PM examinations across both sites a year. The mortuary accepts the same types of case as the WHH site and does not undertake paediatric/perinatal PM examinations. Staff have access to PPE when conducting routine PM examinations.

The body store has a total capacity of 75 refrigerated spaces, including four permanent freezer spaces and three refrigerated spaces suitable for bariatric bodies. 25 of the fridge spaces are pass through trays that are connected to the PM suite and are usually reserved for community deaths. The other side of the mortuary is primarily used for the storage of hospital deaths.

Fridges 1-25 are used for long-term storage. The HTA noted that these fridges maintain a temperature of 1.5-1 degrees Celsius, which is not cold enough for the long-term storage of bodies (see shortfall PFE3).

The body store is monitored by the same Tutela system as the WH site.

The PM suite consists of three PM tables with adequate space and lighting to work at each table at the same time. The PM tables are not downdraft; however, maintenance records relating to the ventilation system, provided to the HTA after the inspection, demonstrate adequate airflow changes in the PM suite.

There are no indicators on the PM tables that correspond to the cut up tables (see advice item 4). The pathologist checks the ID of a body, with an APT, and does an external examination before evisceration takes place. Tissue taken during the PM examination is recorded in a similar mortuary log book to that used at WHH, sent to Histology at the WHH where it is cassetted and examined (see advice item 3). Histology receipt and consent forms are sent with the specimens to Histology and a 'tissue taken' identifier is placed on the mortuary board.

Procedures for receipt and release of bodies from the hospital and the community are the same as those at the WHH site. Staff at each site use a different coloured pen each week to

record on the mortuary whiteboard the name of the deceased so that it is easy to identify when a body has been received.

The entrance to the mortuary used by funeral directors is not adequately screened from public view and there is no CCTV monitoring the entry point to the mortuary. The HTA observed that the mortuary entry point was left open and unmonitored during the release of a body during the inspection. There are several residential houses close by and the pathway to the mortuary is easy accessible.

The glass on the entrance is frosted and mortuary staff cannot confirm who is at the door before granting access to the mortuary (see shortfall PFE1), nor can they see who is outside due to the lack of surveillance. These combine to increase the risk to the safety of the staff and the risk of unauthorised access to the mortuary (see advice item 5). These concerns have been identified in a previous UKAS report.

Viewings are limited across both sites and out of hours viewings rarely occur. A member of mortuary staff is always present. Viewings are usually for police identification purposes and under these circumstances, family members are always accompanied by a coroner's officer. Very occasionally relatives request a viewing for a hospital deceased. This occurs during working hours and relatives are accompanied by the Relative Support Officer (RSO) who has arranged the viewing. Both viewing rooms are suitable and secure, with outside locks that prevent access to the mortuary.

Both sites are routinely cleaned. Fridges are cleaned when full and decontaminated once a month. The PM suite is cleaned daily by mortuary staff.

The inspection process

This was the second inspection of the establishment under the licensing arrangements incorporating the satellite site. The previous inspection of the William Harvey Hospital took place in 2013.

The inspection was routine, to assess whether the establishment is continuing to meet the HTA's standards and to provide the HTA with assurance about the suitability of the premises and facilities. The inspection timetable was developed after consideration of the establishment's previous inspection reports, compliance update information and discussions with the DI. It included a visual inspection of the body store at both sites, the post-mortem (PM) suites, viewing areas, histology department, and accident and emergency department at the WHH site. Interviews were held with: the DI; Persons Designated (Mortuary manager/APT and general pathologist); Quality Manager; Coroner's Officer; midwife and the CLHC (consultant paediatrician). A thorough review of governance and quality documentation was also undertaken.

During the inspection, several mortuary procedures were observed across both sites including the release of two bodies to contracted funeral directors and the receipt of three bodies (two from the hospital and one from the community). Processes were checked against mortuary SOPs and no discrepancies were found; however, the HTA did notice inconsistencies in practice, with porters and mortuary staff failing to wear gloves while moving bodies (see advice item 2).

The HTA conducted identification audit trails on three bodies stored in the refrigerators at the WHH site. Body location and identification details on body tags were cross-referenced against the information on the fridge doors, mortuary whiteboard and mortuary register. One

body in the fridge did not have a toe tag attached, despite having been checked in by a member of the mortuary staff (see advice item 4). No other discrepancies were found.

The HTA conducted identification audit trails on four bodies stored in the refrigerators at the QEQM site including three from body to records and one from records to body. Body location and identification details on body tags were cross-referenced against the information on the fridge doors, mortuary whiteboard and mortuary register. One body to records audit trail highlighted a noncompliance with the establishment's same/similar name procedure, as an incidence of this was not highlighted in the mortuary register. No other discrepancies were found.

Vertical traceability audits were carried out across both sites, on tissue removed during five PM examinations, including one hospital consented PM. Paper records (adult hospital consent form, Coroner's form for wishes of the deceased, PM histology request forms, mortuary tissue log) were compared against the number of blocks and H/E-stained slides held in the PM tissue storage area at the WHH site. All blocks and slides were accounted for in relation to the hospital consented PM examination; however, for a coroner's case, additional slides with special stains were discovered that had not been recorded on the histology request form. No other discrepancies were found.

The HTA considers that the errors found during its traceability audits could be attributed to the severe pressure on the mortuary caused by staffing issues and capacity problems. The sudden decrease in staff has increased the need for lone working and has had a profound impact on morale, both of which increase the risk of error (see shortfall GQ8).

There is no current contracted freezer contingency arrangements for either site. These do not meet the needs of the establishment, which is having to store bodies for long periods in fridges rather than freezers, which is not appropriate storage. Not only does this compromise staff members' ability to maintain the dignity of the deceased, it also makes their working environment unpleasant and at risk in the summer months (see shortfall PFE3).

The A&E department was visited at the WHH site to investigate tissue removal in cases of sudden unexpected death in infants (SUDI). The HTA was informed that if SUDI removal should take place, it is carried out by a clinician in the mortuary and there was no removal of relevant material taking place elsewhere. However, samples containing relevant material are taken in A&E at the time of resuscitation, prior to death being declared (see advice item 7).

Materials held for the police

Under s39 of the Human Tissue Act 2004, relevant material held for criminal justice purposes is outside the scope of HTA regulation and is not subject to the licensing requirements for storage. However, in response to a recommendation resulting from the 2012 report of the Association of Chief Police Officers' audit of tissue held under police authority, that police exhibits held on HTA licensed premises should be included within the regular HTA inspection process, police holdings stored in the PM suite were reviewed by the HTA during the inspection. Any findings in relation to police holdings have been shared with the Home Office, but do not appear in this report as they are outside the scope of the HT Act.

Inspection findings

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

Compliance with HTA standards

Governance and Quality

Standard	Inspection findings	Level of shortfall
GQ1 All aspects of the establishments work are supported by ratified documented policies and procedures as part of the overall governance process	<p>The HTA observed inconsistencies with regards to PPE as not all staff routinely wore gloves across both sites during receipt and release of bodies. Mandatory wearing of PPE is not included in the mortuary SOP.</p> <p>The HTA also observed the external mortuary entry door was left wide open during receipt and release of bodies into the mortuary, which presents a risk to the premises and staff. Monitoring access and closing the outside door during receipt and release are not included in the mortuary SOP (<i>see advice item 2</i>).</p>	Minor
GQ4 There is a systematic and planned approach to the management of records	<p>There is inconsistent reporting of tissue taken during PM on both sites. Tissue taken is recorded in a mortuary log with no electronic backup. The unique mortuary number is not always recorded and there is no record of what tissue has been taken (<i>see advice item 3</i>).</p>	Minor
GQ8 Risk assessments of the establishment's practices and processes are completed regularly and are recorded and monitored appropriately	<p>The impact of the current low staffing level on staff morale and service delivery, including lone working, has not been risk assessed and mitigating actions identified and taken.</p>	Minor

Premises, Facilities and Equipment

Standard	Inspection findings	Level of shortfall
PFE1 The premises are secure.	<p>There is no external surveillance of the mortuary accessible by mortuary staff, to inform them of who is on the premises and requesting entry at either site. The mortuary at QEQM is close to a residential area and is not adequately shielded from public viewing or access. The current security arrangements present a risk to the security of staff and premises (<i>see advice item 5</i>).</p>	Minor

PFE3 There are appropriate facilities for the storage of bodies, body parts, tissues and cells, consumables and records	The long stay fridge unit at QEQM is used to store bodies for extended periods of time and contains several decomposing bodies. This is an inappropriate facility for long-term storage of bodies that should be in freezer storage.	Major
---	--	--------------

Advice

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

No.	Standard	Advice
1.	C1 & C3	<p>Currently there is a policy in place only for paediatric/perinatal hospital consented post mortems. The DI is advised to create a policy specifically for adult hospital consented post mortems.</p> <p>In addition, the DI is advised to implement mandatory training for those seeking consent for hospital post mortems, separate from the Trust's consent training.</p>
2.	GQ1	The DI is advised that the mandatory wearing of PPE whilst handling bodies should be included in mortuary SOPs.
3.	GQ4	<p>The DI is advised to implement a standardised process for recording details of tissue taken during PM, ensuring that the same identifiers and details are recorded for each case and inconsistencies in records are avoided. This process should be documented in the SOP.</p> <p>Toxicology and organ transfer are logged electronically on a database. The HTA is aware that the DI is currently implementing this system for PM tissue, which should help standardise practice.</p>
4.	GQ6	<p>The HTA is generally assured that the establishment has an effective system of traceability. However, minor discrepancies at each site were noted by the HTA and the DI should consider additional steps to further mitigate the risk of loss of traceability and to ensure similar robust records of entry and management across both sites.</p> <ul style="list-style-type: none"> During the body audit, absence of a toe tag on a body which had been checked in and absence of a same/similar name identifier in the mortuary register were noted. The presence of a toe tag confirms that a body has been checked in and staff should ensure that this procedure is done correctly. The DI is advised to implement the coloured magnet system at WH that is presently at QEQM to identify same/similar name, risk of infection, do not release etc. A number of PM examinations are conducted simultaneously on a daily basis at both sites. The DI is advised to consider an identification system for both sites; for example, numbering or colour coding mortuary tables and the bowls used to move organs to/ from dissection boards may mitigate the risk of organs being inadvertently repatriated with the wrong body.

5.	PFE1	The DI is advised to consider installing CCTV outside each entry point of both mortuaries, reducing the risk of unauthorised access to the premises.
6.	PFE1	The HTA is aware that the DI is in the process of completing a business plan for new freezer storage space. The DI is advised to escalate mortuary capacity to senior management, with a view to its inclusion on the Trust's corporate risk register, if it not already included.
7.		Staff involved in HTA-licensed activities were not fully aware of the Trust's SUDI removal protocol and if and where this procedure happens. Currently only 'material from the living' is removed in A&E; however, were samples to be removed from the body of a deceased infant or child, it would be subject to licensing and the DI would need to assume responsibility for the activity.
8.	D1	The DI is advised to create a separate disposal policy for PM tissue only.

Concluding comments

The mortuary team are both committed and hard-working, particularly in times of severe stress due to capacity and staffing issues, and have the interest of the bereaved and care of the deceased as their priority. There were many areas of good practice that were observed throughout the inspection, some examples of which are given below.

- Both mortuary sites, including the body store and PM room, are extremely clean and in good condition.
- There is a high level of involvement by the DI, who is very hands on and is actively implementing new procedures to benefit the mortuary practice while striving to standardise processes across both sites.
- Extensive porter training is given by mortuary staff and detailed signage is provided in each body store informing them what to do if an incident occurs when they are in the mortuary. All porters in the hospital are trained in mortuary procedures including use of the overhead hoist.
- Porters must complete a body map when they admit bodies along with completing the porters log book. This gives protection to both the porters and the mortuary if an incident occurs, for example, accidental damage to a body during transport from the ward to the mortuary.

There are some areas of practice that require improvement, including one major and four minor shortfalls. The HTA has given advice to the Designated Individual with respect to Governance and Quality Systems and Premises, Facilities and Equipment standards.

The HTA requires that the Designated Individual addresses the shortfalls by submitting a completed corrective and preventative action (CAPA) plan within 14 days of receipt of the final report (refer to Appendix 2 for recommended timeframes within which to complete actions). The HTA will then inform the establishment of the evidence required to demonstrate that the actions agreed in the plan have been completed.

The HTA has assessed the establishment as suitable to be licensed for the activities specified subject to corrective and preventative actions being implemented to meet the shortfalls identified during the inspection.

Report sent to DI for factual accuracy: 13/01/2017

Report returned from DI: 27/01/2017

Final report issued: 03/02/2017

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: 2 August 2017

Appendix 1: HTA standards

The HTA standards applicable to this establishment are shown below/. Individual standards which are not applicable to this establishment have been excluded.

Consent standards
C1 Consent is obtained in accordance with the requirements of the Human Tissue Act 2004 (HT Act) and as set out in the code of practice
<ul style="list-style-type: none">• There is a documented policy which governs consent for post-mortem examination and the retention of tissue and reflects the requirements of the HT Act and the latest version of the HTA Code of Practice on consent.• 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).• There is written information about the consent process (provided to those giving consent), which reflects the requirements of the HT Act and the latest version of the HTA Code of Practice on consent.
C2 Information about the consent process is provided and in a variety of formats
<ul style="list-style-type: none">• Relatives are given an opportunity to ask questions.• Relatives are given an opportunity to change their minds and it is made clear who should be contacted in this event.• Information contains clear guidance on options for how tissue may be handled after the post-mortem examination (repatriated with the body, returned to the family for burial/cremation, disposed of or stored for future use).• Where consent is sought for tissue to be retained for future use, information is provided about the potential uses in order to ensure that informed consent is obtained.• Information on the consent process is available in different languages and formats, or there is access to interpreters/translators.
C3 Staff involved in seeking consent receive training and support in the implications and essential requirements of taking consent
<ul style="list-style-type: none">• There is a training programme for taking consent for post-mortem examination and tissue retention which addresses the requirements of the HT Act and HTA code of practice on consent.• Refresher training is available (e.g. annually).• Attendance at consent training is documented.• If untrained staff are involved in consent taking, they are always accompanied by a trained individual.

Governance and quality system standards

GQ1 All aspects of the establishments work are supported by ratified documented policies and procedures as part of the overall governance process

- Documented policies and SOPs cover all mortuary/laboratory procedures relevant to the licensed activity. These may include:
 - post-mortem examination, including the responsibilities of the APTs and Pathologists (e.g. evisceration) and management of high risk cases
 - record keeping
 - receipt and release of bodies, which reflect out of hours arrangements
 - lone working in the mortuary
 - transfer of bodies and tissue (including blocks and slides) to other establishments or off site
 - ensuring that tissue is handled in line with documented wishes of the relatives
 - disposal of tissue (including blocks and slides)
- (Note that individual SOPs for each activity are not required. Some SOPs will cover more than one activity.)*
- Policies and procedures are regularly reviewed (for example, every 1-3 years).
 - There is a system for recording that staff have read and understood the latest versions of these documents.
 - Deviations from documented SOPs are recorded and monitored.

GQ2 There is a documented system of quality management and audit

- There is a quality manual which includes mortuary activities.
- Policies and SOPs are version controlled (and only the latest versions available for use).
- There is a schedule for audits to be carried out (which may include vertical and/or horizontal audits).
- Audits include compliance with documented procedures, records (for completeness) and traceability.
- Audit findings document who is responsible for follow up actions and the timeframe for completing those actions.
- Regular audits of tissue being stored at the establishment ensure that staff are fully aware what material is held and why.
- There is a complaints system in place.

GQ3 Staff are appropriately qualified and trained in techniques relevant to their work and are continuously updating their skills

- Staff are appropriately trained/qualified or supervised.
- Staff have annual appraisals.
- Staff are given opportunities to attend training courses, either internally or externally.
- Attendance by staff at training events is recorded.

- There is a documented training programme for new mortuary staff (e.g. competency checklist).

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

- 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.
- There are documented SOPs for record management.

GQ6 A coding and records system facilitates traceability of bodies, body parts, tissues and cells, ensuring a robust audit trail

- Bodies are tagged/labelled upon arrival at the mortuary.
- There is a system to track each body from admission to the mortuary to release for burial or cremation (e.g. mortuary register, patient file, transport records).
- Organs and tissue samples taken during PM examination are fully traceable.
- Details of organs retained and the number of wax blocks and tissue slides made are recorded.
- The traceability system includes the movement of tissue samples between establishments.
- Details are recorded of tissue that is repatriated or released with the body for burial or cremation.
- Regular audits of tissue storage and traceability are undertaken to ensure compliance with operational procedures; tissue samples found which are not being stored with consent are disposed of with reference to the family's wishes.
- Multiple identifiers used, including at least one unique identifier (e.g. post mortem number, name, dates of birth/death, etc) to identify bodies and tissue.

GQ7 There are systems to ensure that all adverse events, reactions and / or incidents are investigated promptly

- Staff are trained in how to use the incident reporting system.
- Staff know how to identify incidents and near-misses which must be reported, including those that must be reported to the HTA
- The incident reporting system clearly outline responsibilities for reporting, investigating and follow up for incidents.
- The incident reporting system ensures that follow up actions are identified (i.e. corrective and preventative actions) and completed.
- Information about incidents is shared with all staff (including the reporter) to avoid repeat errors.

GQ8 Risk assessments of the establishment's practices and processes are completed regularly and are recorded and monitored appropriately

- All procedures related to the licensed activities (as outlined in standard GQ1) are risk assessed.
- Risk assessments include risks associated with non-compliance with HTA standards as well as health and safety risks.
- Risk assessments are reviewed regularly (along with SOPs), for example every 1-3 years.
- 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.

Premises, facilities and equipment standards

PFE1 The premises are fit for purpose

- There is sufficient space for the activities to be carried out.
- Refrigerated storage units are in good working condition and well maintained.
- Surfaces are made of non-porous materials.
- The premises are in reasonable condition (structure and cleanliness of floors, walls, entranceways).
- The premises are secure (e.g. there is controlled access to bodies, tissue, equipment and records).

PFE 2 Environmental controls are in place to avoid potential contamination

- There is clear separation of clean, transitional and dirty zones (e.g. doors, floor markings, signs).
- There is appropriate PPE available and routinely worn by staff.
- There is adequate critical equipment and/or PPE available for high risk post mortems.
- There are documented cleaning and decontamination procedures.
- There are documented cleaning schedule and records of cleaning and decontamination.

PFE3 There are appropriate facilities for the storage of bodies, body parts, tissues and cells, consumables and records.

- There is sufficient capacity for storage of bodies, organs and tissues.
- Temperatures of fridges and freezers are monitored on a regular basis.
- There are documented contingency plans in place should there be a power failure, or overflow.
- Bodies are shrouded whilst in storage.
- There is separate storage for infants and babies. If not, special measures are taken for the bodies of infants and babies.

PFE 4 Systems are in place to protect the quality and integrity of bodies, body parts, tissues and cells during transport and delivery to a destination

- There are documented procedures for transportation of bodies and tissue anywhere outside the mortuary (e.g. lab, other establishment), including record-keeping requirements.
 - There are written agreements in place with any external parties (e.g. undertaker, or courier) who transport bodies and/or tissue behalf of the establishment (laboratory or mortuary).
- (Note that coroners usually have their own agreements with external parties for transportation bodies and tissue; however, documentation for traceability purposes must still be maintained by the establishment for these cases.)*

PFE5 Equipment is appropriate for use, maintained, quality assured, validated and where appropriate monitored

- Items of equipment in the mortuary are in a good condition and appropriate for use:
 - fridges / Freezers
 - hydraulic trolleys
 - post mortem tables
 - hoists
 - saws (manual and/or oscillating)
 - PPE for high risk cases (e.g. respirators)
 - The use of porous materials is kept to a minimum and has been risk assessed
 - Maintenance/service records are kept for equipment, including fridges/freezers, trolleys, post mortem tables (if downdraught) and post mortem suite ventilation.
- (Note: These records may be held by the mortuary or centrally by the Trust, e.g. Estates Department.)*

Disposal Standards

D1 There is a clear and sensitive policy for disposing of human organs and tissue

- There is a documented Trust or mortuary/laboratory policy for the disposal of human tissue, which reflects the requirements of the HTA code of practice on disposal.
- The policy states the position with regard to the retention and use of microscope slides, and in particular that tissue slides must be disposed of or returned to the family in accordance with their wishes if consent is not obtained for their continued storage and future use once the PM has concluded.

D2 PM tissue is disposed of if consent is not given for its storage and use for scheduled purposes

- There are documented procedures for disposal of human tissue, which include methods of disposal for whole organs, wet tissue, wax blocks and microscope slides.
- Tissue is disposed of in accordance with the documented wishes of the deceased person's

family.

- Disposal details of organs and tissue blocks are recorded, including the date and method of disposal.
- There is a rolling programme of tissue disposal that ensures that tissue, including microscope slides, is disposed of in a timely fashion when it is no longer needed for the purposes of the Coroner or to determine the cause of death.

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.