Site visit inspection report on compliance with HTA minimum standards

York Teaching Hospital NHS Foundation Trust

HTA licensing number 12093

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**

20 - 21 May 2015

Summary of inspection findings

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

Although the HTA found that York Teaching Hospital NHS Foundation Trust (the establishment) had met the majority of the HTA standards, four minor shortfalls were found in relation to the governance arrangements; in addition, two major shortfalls were identified in relation to the security of the mortuary at Scarborough Hospital and the temperature monitoring arrangements of fridges at both mortuaries.

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 Designated Individual, Licence Holder, premises and practices are suitable.

The statutory duties of the Designated Individual (DI) are set down in Section 18 of the Human Tissue Act 2004 (HT Act). 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 licenses 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

York Teaching Hospital NHS Foundation Trust (the establishment) has been licensed by the HTA since June 2007. The licensing arrangements cover York Hospital (the hub) and Scarborough Hospital (the satellite). Scarborough Hospital was previously licensed under a separate HTA licence, which was revoked in September 2012 when the hospital became a satellite of this licence. 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 establishment conducts approximately 850 adult PM examinations each year - approximately 450 cases at York Hospital and 400 cases at Scarborough Hospital. High-risk and perinatal/paediatric cases are transferred to other HTA-licensed establishments for PM examination. Home Office PM examinations are conducted at York Hospital; no Home Office PM examinations are conducted at Scarborough Hospital. Most PM examinations at the establishment are performed under coronial authority.

Consent for adult hospital PM examinations is sought by clinicians, who are accompanied by a core team of staff who have received training in the requirements of the Human Tissue Act 2004 (HT Act). Consent is sought using the Trust's consent form and information leaflet. The establishment conducted four adult hospital PM examinations at York Hospital in 2014. No hospital PM examinations were undertaken at Scarborough Hospital in 2014.

Consent for perinatal/paediatric PM examinations is sought by clinical staff, who have received training in the requirements of the HT Act. Consent is sought using the consent form and information leaflet provided by the HTA-licensed establishment to which these cases are referred for PM examination.

The mortuaries at York Hospital and Scarborough Hospital operate under the same governance arrangements and are managed by a single Mortuary Manager. At the time of the inspection, work was ongoing towards standardising mortuary procedures across the two sites.

Both mortuaries admit bodies from the hospital and the community, and use the same body labelling and traceability systems. Bodies from the hospital have printed hospital identification wrist tags, which include the patient's unique hospital number. Bodies admitted from the community have wrist tags attached by the police or funeral director. In addition, body identification labels are placed alongside the deceased when they are placed into storage. The establishment uses a series of forms to record the details of body admission, PM examination, transfer to another establishment for PM examination, and release to a funeral director. Perinatal cases are labelled with the mother's name, hospital number or address, and a unique mortuary number. Perinatal cases are recorded in a dedicated mortuary register (refer to advice item 9).

Wet tissue samples taken for histopathological analysis are transferred to the hospitals' histopathology departments. Whole organs may be stored in the PM suite prior to transfer to other establishments for specialist analysis. Samples for toxicological analysis are sent to other HTA-licensed establishments. With appropriate consent, PM tissue blocks and slides are stored for use for scheduled purposes. The establishment maintains records of PM samples on a series of paper forms (refer to advice item 11). At York Hospital, records of PM samples are also stored on an electronic database.

York Hospital. The mortuary at York Hospital is located in the hospital building. Entrances to the mortuary are secured by swipe card access and are monitored by closed-circuit television (CCTV). Areas within the mortuary are secured by locked doors.

York Hospital mortuary has 90 fridge spaces; including two spaces in a designated bank that can operate in freezer mode should bodies require longer-term storage. Perinatal/paediatric cases are stored on dedicated trays within the adult fridges. Perinatal cases are stored in specialist bags. The storage temperatures of these fridges are continually monitored and there is an automated alarm call-out procedure in the event of temperature deviation. York Hospital mortuary has an additional ten fridge spaces in a stand-alone fridge located in a separate secure area of the mortuary. There is a separate fridge in the mortuary for temporary storage of perinatal cases prior to transfer to the main bank of fridges. The stand-alone fridge and perinatal fridge storage temperatures are checked and recorded by staff on weekdays (refer to shortfall for standard PFE3).

The PM suite at York Hospital has three PM tables and dedicated benches for the preparation of wet tissue samples. At the time of the inspection, the PM suite observation gallery was being used to store office furniture. There is a small crack in the floor of the PM suite (refer to advice item 13).

Visiting pathologists undertake Home Office PM examinations at York Hospital. Tissue samples may be stored at the establishment under police authority. There were no samples stored under police authority at the time of the inspection.

York Hospital plans to commence removal of samples from deceased children in cases of sudden unexpected death in infancy (SUDI) in the Accident and Emergency (A&E) department. The HTA inspection team gave advice to the establishment on the governance arrangements for this in relation to the HTA licence.

Scarborough Hospital. The mortuary at Scarborough Hospital is located in a separate building on the hospital site. Entrances to the mortuary are fitted with swipe card access. The door closure mechanism on the main entrance to the mortuary does not function properly, meaning that the door does not always close, thereby compromising the security of the mortuary. CCTV monitoring of the mortuary entrances is not functional. There is a large crack in the window to the PM suite changing room, and an external louvre window to the mortuary that cannot be adequately secured. The security arrangements for the mortuary at Scarborough Hospital are inadequate (refer to shortfall for standard PFE1).

The mortuary at Scarborough Hospital has two banks of fridges with 23 spaces. Perinatal/paediatric cases are stored on dedicated trays within the adult fridges. The main bank of fridges is showing signs of deterioration; including poorly sealed doors and some rust (refer to advice item 16). The storage temperatures of these fridges are continually monitored and there is an automated alarm call-out procedure in the event of temperature deviation. The establishment also has a refrigerator unit that can be erected at short notice to provide additional storage capacity and storage of bariatric bodies. This has been erected at Scarborough Hospital for approximately 18 months and has been in periodic use during this time. The refrigerator unit is located in a storeroom in a department adjoining the mortuary. The storage temperature of the fridge is checked and recorded daily on weekdays (refer to shortfall for standard PFE3).

The PM suite at Scarborough Hospital has recently been refurbished and has two downdraft PM tables and a dedicated bench for the preparation of wet tissue samples.

Sampling of tissues from deceased children in SUDI cases is performed in Scarborough Hospital A&E department by a core team of staff, under pre-emptive coronial authorisation (refer to shortfall for standard GQ1).

The last HTA site visit inspection of York Hospital was in February 2011 and of Scarborough Hospital in September 2012. This report describes the third, routine site visit inspection of the establishment. The inspection included visits to both York Hospital and Scarborough Hospital. The inspection team interviewed staff involved with licensable activities, reviewed documentation and conducted visual inspections of the mortuaries at both sites and areas in Scarborough Hospital A&E department where licensed activities take place.

Audits of traceability records were conducted for at York Hospital for one whole organ and tissue blocks from two PM cases. A traceability audit was conducted for one paediatric, one perinatal and three adult bodies. No discrepancies were identified. Consent forms for two perinatal and two adult hospital PM examinations were also audited. One consent form had been signed but not dated by the person seeking consent (refer to advice item 3). At Scarborough Hospital, a traceability audit of three adult bodies was conducted. Traceability records for tissue blocks from three PM cases were audited, including consent for tissue retention. No anomalies were identified.

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.	Standard operating procedures (SOPs) do not cover all mortuary procedures. Some SOPs relating to mortuary activities detail out of date processes and many do not contain sufficient details of procedures. Particular examples include: • there is no SOP describing the arrangements for the set up and use of the temporary refrigerator unit; • SOPs describing identification of the deceased should include details of this process, including the minimum number of identifiers and the minimum paperwork and information that must be checked; • SOPs describing labelling of bodies from the community should be reviewed to include details of the identifiers that must be recorded on wrist tags; and • the SOP describing procedures conducted by porters at Scarborough Hospital mortuary contains out-of-date information and processes. This is not an exhaustive list of the amendments required to SOPs, and to fully address this shortfall, the establishment should review all SOPs relating to mortuary activities at both hospitals.	**Minor**
	<u>Scarborough Hospital:</u> removal of relevant material from the deceased is undertaken in the A&E department. This activity is not fully included in the establishment's governance arrangements for activities taking place under the authority of an HTA licence. Staff undertaking these activities do not attend the establishment's HTA governance meetings. There is no Person Designated in the A&E department to support the DI in overseeing this activity.	**Minor**

GQ2 There is a documented system of quality management and audit.	Scarborough Hospital: the establishment does not undertake audits of traceability of the deceased, mortuary records or PM tissue samples stored in the histopathology department.	**Minor**
GQ8 Risk assessments of the establishment's practices and processes are completed regularly and are recorded and monitored appropriately.	The establishment has included documented risk assessments in some SOPs. However, risk assessments require further development to ensure that all risks have been identified and that all existing risk control measures are fully documented. Where additional mitigating measures are identified, these should be clearly described and have an assigned owner and completion date. *(Refer to advice item 12)*	**Minor**

Premises, Facilities and Equipment

Standard	Inspection findings	Level of shortfall
PFE1 The premises are fit for purpose.	Scarborough Hospital: deficiencies in the mortuary security arrangements were identified: • the door closure mechanism on the main mortuary entrance does not function properly, meaning that the door is frequently unsecured; • the temporary refrigerator unit for body storage is located in a storeroom of an adjoining department secured by a single lock, which does not provide an appropriate level of security; • the CCTV equipment monitoring the mortuary entrances is not functional; • there is a large crack in the window of the PM suite changing room; and • the louvre window to the mortuary cannot be secured adequately. The lack of robust security arrangements to prevent unrestricted access to the mortuary presents a risk to the dignity of the deceased and the safety of staff.	**Major**

PFE3 There are appropriate facilities for the storage of bodies, body parts, tissues and cells, consumables and records.	The stand-alone and perinatal fridges at York Hospital, and the temporary refrigerator unit at Scarborough Hospital are not connected to a temperature alarm. Storage temperatures are checked and recorded once daily by staff on working days only, meaning that a fridge failure or deviation in storage temperature may go unnoticed for a number of days over a weekend or holiday period. These storage arrangements present a significant risk to the integrity of the bodies stored and are therefore considered to represent a major shortfall against this standard. *(Refer to advice item 15)*	**Major**

Advice

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

No.	Standard	Advice
1.	C1	The DI is advised to remove references to the next-of-kin from the consent form for an adult hospital PM examination. The DI is also advised to review the establishment's documented consent policy and procedure to provide clarity on who may give consent for a hospital PM examination, thereby ensuring that consent is given by the appropriate person in the hierarchy of qualifying relationships set out in the HT Act.
2.	C1	The DI is advised to remind staff seeking consent for hospital PM examinations that they should date as well as sign the consent seeker section of the consent form. This may help to ensure that consent forms are completed in a consistent manner.
3.	C3	The establishment has developed a training programme for staff seeking consent for hospital PM examinations. The DI is advised to ensure that all new staff with this responsibility as part of their role complete this training programme and are assessed as competent prior to seeking consent for PM examination.
4.	GQ1	The DI is advised to place signage in the mortuary to raise awareness amongst all staff working there of the importance of reporting any incident, or near miss, through internal systems and, where applicable, to the HTA. The DI may also wish to consider placing signage to remind staff of the arrangements for storage of perinatal, paediatric and obese bodies.
5.	GQ3	The DI is advised to ensure that all porters working in the mortuary are trained in the mortuary procedures they undertake, and to crosscheck the records of porters entering the mortuary against training records to ensure this is the case. The DI should also establish a system to ensure that mortuary staff are notified when new porters start work in the mortuary so that they can arrange training, and ensure that porters working in the mortuary are notified of changes to mortuary SOPs and receive refresher training.

6.	GQ3	The establishment may wish to consider providing bereavement training to mortuary staff to support them in conducting viewings for relatives of the deceased.
7.	GQ6	The DI is advised to remind staff at York Hospital of the establishment's procedure for admitting bodies to the mortuary (detailed in 'MO-SOP-ADMISSION'), which requires the check of the identity of the deceased to include a check of the identifiers on the wrist tag, in addition the paperwork and body identification tag accompanying the deceased.
8.	GQ6	The DI is advised to remind staff at Scarborough Hospital of the establishment's procedure for releasing bodies from the mortuary (detailed in 'MO-SOP-BOD-RLESE'), which requires that bodies are only released when the funeral director presents the required paperwork, and never on a verbal request alone.
9.	GQ6	The DI is advised to ensure that traceability records for perinatal cases consistently include the mother's first and last name. The DI may also wish to consider reviewing the template used for the perinatal mortuary register to include a dedicated column to record the unique mortuary identification number and more space for recording traceability details.
10.	GQ6	The DI is advised to consider strengthening the existing systems for highlighting deceased persons with same or similar sounding names, or cases where tissues or organs need to be repatriated with the body prior to release to the funeral director, by, for example, using coloured stickers on the body identification tag and the mortuary register. Since mortuary staff may work at both sites, the establishment should adopt a consistent procedure at both mortuaries.
11.	GQ6	The establishment is advised to review its procedures for the traceability of PM tissue samples to ensure that: • unused pre-printed histology identification labels are discarded after each case so that samples cannot be inadvertently labelled with the wrong PM identification number; and • records of transfer and subsequent return of PM tissue blocks and slides to and from other departments within the hospital or other establishments are maintained. Any changes to procedures should be reflected in the establishment's SOPs.
12.	GQ8	The DI is advised that the HTA Reportable Incident (HTARI) reporting categories may be used as a starting point for identifying key risks to assess. Further advice on mitigating the risks associated with undertaking licensed activities can be found in the HTA's 'Sharing learning: lessons learned from HTARIs in the PM sector': www.hta.gov.uk/sites/default/files/HTARI_Review_2012-13.pdf.
13.	PFE1	The DI is advised to review the suitability of the PM suites at both hospitals to ensure that they remain fit for purpose. In particular the DI is advised to: • ensure that the planned repair of the small crack in the PM suite floor at York Hospital is completed within an appropriate timeframe; • remove the items of office furniture stored in the observation gallery of the PM suite at York Hospital to avoid contamination of these items and ensure that the PM suite air handling system functions as expected; and • replace the clinical waste bin in the PM suite at Scarborough Hospital, as this is showing signs of rust.

14.	PFE1	The viewing room at Scarborough Hospital mortuary is located near to the body store area. The DI is advised to consider placing a more prominent sign in the body store area to alert staff when the viewing room is in use so that they can ensure that noise is kept to a minimum. In relation to viewings at Scarborough Hospital mortuary, the DI is advised to keep the log of viewings in the mortuary office instead of the viewing room waiting area. The DI may also wish to consider ensuring that staff facilitating viewings consistently complete the time that the relatives leave the mortuary, to ensure that records of visitors to the mortuary are complete.
15.	PFE3	In order to address the shortfall for standard PFE3, the DI should extend the daily check and record of storage temperature for the fridges that are not connected to an automated call-out alarm to include weekends and holiday periods. Alternatively, the DI may wish to extend the existing temperature alarms to these fridges.
16.	PFE3	The DI is advised to keep under review the suitability of the arrangements for storage of the deceased at Scarborough Hospital mortuary. The main bank of fridges at this mortuary is currently functional and the establishment has not experienced any issues with the maintenance of storage temperatures. However, these fridges are showing signs of deterioration, including some areas of rust and poorly sealed doors leading to some condensation inside the fridges. This mortuary has also experienced issues with storage capacity. The DI should ensure that these issues are kept under review and appropriate preventative actions are taken before they impact on the operation of the mortuary and dignity of the deceased.
17.	PFE3	The dimensions of the storage space for the trays in the main bank of fridges at Scarborough Hospital mortuary are limited. The DI is advised to document the height and width of the storage space of trays in this fridge, and ensure that all staff working in the mortuary are aware of these dimensions. The establishment may also wish to consider creating a frame of the dimensions of the height and width of the trays that can be used to check the size of the deceased. This may help to ensure that these fridges are not used for storage of larger bodies, which may result in damage to the deceased.
18.	PFE3	The DI is advised to schedule manual checks of the storage temperature alarms to ensure that they are operating as expected. This should include checks that the system notifies the hospital switchboard as expected and that alarm notifications are responded to appropriately. These checks and any resulting actions should be documented.
19.	PFE3	The establishment is advised to conduct more frequent checks on the condition of bodies, for example, following PM examination or where bodies have been stored for longer than usual. The DI may wish to introduce a documented checklist to record checks performed. This will help to assure the DI that the establishment's storage arrangements ensure that the dignity of the deceased is maintained.
20.	D1	The HTA published updated guidance on the disposal of pregnancy remains shortly before the inspection. The DI is advised to refer to this guidance and review the establishment's policy and procedures in light of this. Further information on this guidance can be found on the HTA website: www.hta.gov.uk/faqs/disposal-pregnancy-remains-faqs.

Concluding comments

This report outlines the second HTA site visit inspection of York Teaching Hospital NHS Foundation Trust. Despite the shortfalls identified, areas of strength were observed. There is a good training programme for staff seeking consent for PM examination and staff are dedicated to ensuring that the consent process is handled sensitively. The mortuary staff seek to ensure that relatives of deceased children have a single point of contact for the mortuary to facilitate viewings. Staff undertaking removal of relevant material in SUDI cases at Scarborough Hospital A&E department have developed a clear procedure and dedicated box of equipment to facilitate a consistent approach to this procedure.

The DI continues working towards standardising processes at both sites covered by the HTA licence, and is well-supported by the Quality Manager.

A number of areas of practice require improvement, including two major shortfalls and four minor shortfalls. In addition, the HTA has given advice to the DI on a range of issues, including consent, traceability systems, mortuary facilities and disposal.

The HTA requires that the DI 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: 12 June 2015

Report returned from DI: 18 June 2015

Final report issued: 19 June 2015

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: 3 February 2016

Appendix 1: HTA standards

The HTA standards applicable to this establishment are shown below; those not assessed during the inspection are shown in grey text. 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
• 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
• Relatives are given an opportunity to ask questions. • Relatives are given an opportunity to change their minds and is it 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
• 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.

GQ5 There are documented procedures for donor selection and exclusion, including donor criteria.

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.