Site visit inspection report on compliance with HTA minimum standards

UCL Hospitals NHS Foundation Trust

HTA licensing number 12054

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**

18, 19, 20 March 2014

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 University College London (UCL) Hospitals NHS Foundation Trust (the establishment) had met the majority of the HTA standards, a shortfall was found in relation to the HTA consent standards, specifically the need to develop formal procedures, in line with the Trust Policy, for seeking consent for adult hospital post mortem (PM) examination and training for members of staff involved in the process.

This inspection provided an opportunity to verify that the establishment has implemented corrective and preventative actions identified during the previous HTA inspection.

Examples of strengths and good practice are included in the concluding comments section of the report. Advice is provided in areas where the HTA identified opportunities for improving existing systems and procedures.

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 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

The inspection covered licensable activities taking place at University College London Hospitals NHS Foundation Trust. The establishment comprises a hub comprising the Mortuary and PM suite at University College Hospital and three separate satellite premises:

- Department of Cellular Pathology, UCL Medical School;
- the laboratory and offices at the Department of Clinical Parasitology located within the Hospital for Tropical Diseases; and
- the Mortuary, PM room, laboratories and offices at Ormond House and The National Hospital for Neurology and Neurosurgery, Institute of Neurology, Division of Neuropathology.

The Mortuary and Department of Cellular Pathology form part of University College London, Department of Pathology.

The establishment conducts adult and paediatric consented PM examinations and coronial PM examinations under, primarily, the jurisdiction of Senior Coroners for St Pancras and Westminster. As a result of its specialisms in paediatric PM examination and neuropathology,

it is also involved in PM examinations under the jurisdiction of Senior Coroners for other districts.

The suite of post mortem rooms at University College Hospital includes a separate high risk room with dedicated changing room, equipment and air supply.

The Department of Clinical Parasitology is also the Public Health England National Parasitology Reference Laboratory. It provides a wide range of investigative services in connection with the diagnosis of human parasitic disease. It also operates the UK NEQAS (National External Quality Assessment Service) Parasitology Laboratory and the associated NEQAS teaching function. In addition to holding samples for diagnosis and reference samples, the laboratory is involved in a number of research projects. The research is primarily subject to recognised research ethics committee approval. However, the HTA licence enables the laboratory to store relevant material for the purpose of research should relevant ethics committee approval lapse or should the laboratory wish to hold relevant material for the benefit of future research. This satellite premises also houses a collection of preserved specimens. These specimens, of parasitic infection of human tissue / organs, fall under the HTA category of existing holdings and were received from the Royal Army Medical College Museum when it closed.

The satellite premises at Ormond House and The National Hospital for Neurology and Neurosurgery include neuropathology services. These services extend to specialist PM examination in connection with neurodegenerative disease, inflammatory diseases of the central nervous system, prion disease and adult and paediatric neuromuscular diseases. Human tissue that has been examined for diagnostic purposes or to determine the cause of death may then be provided for research, with appropriate consent. Human tissue coming to the satellite premises under this licence, 12054, may also be provided for the purpose of research under HTA research licence: 12198 which is also held under the Trust.

The Department of Cellular Pathology is fully accredited under the UK Clinical Pathology Accreditation (CPA) scheme. The last CPA inspection took place during 2013.

This was the establishment's second routine HTA site-visit inspection. The timetable for the inspection was developed with due consideration of the establishment's licensing history, the outcome of the previous inspection and pre-inspection discussion with the Designated Individual (DI). The HTA inspected the four sets of premises covered by this licence; held interviews with the DI and Persons Designated associated with licensable activities across all four sets of premises; and reviewed relevant standard operating procedures (SOPs), documents, registers and databases. Discussions were also held with members of the team working in the maternity unit. These discussions focused on the process for obtaining consent for hospital consented post mortem examinations; bereavement services; the process for dealing with early (intrauterine fetal and neonatal) deaths and the process for respectful disposal of fetal remains and products of conception.

The scope of inspection included traceability audits of stored bodies, tissues, samples and related records across all four licensed sites.

Traceability audits were completed as part of the inspection as detailed below:

- Two bodies were selected from the white board and found to be in the specified location in the Mortuary using the identification tag on the deceased. The information was also verified with the Mortuary register and database.
- Details of a consented hospital adult PM examination where tissue had been removed for histology was selected. Tissue blocks from this case were traced through the histopathology laboratory database, the PM examination register and relevant paperwork, and the relative's wishes for the disposal of this tissue were verified.

- A case from the National Hospital for Neurology and Neurosurgery for a limited hospital adult PM examination, where tissue and a whole organ were retained for medical research, was selected. Tissue was traced from the PM suite, histology laboratory database, relevant paperwork to storage of the organ, blocks and slides, to check it was in line with the family's wishes.
- A traceability audit of a PM examination under the authority of the Coroner was also verified by the above process and checks made that tissue had been disposed of in line with the family's wishes.
- At the Department of Clinical Parasitology, two cases where brain, kidney and spleen samples were stored for research were reviewed to verify the audit trail from storage through to records on the Department's secure database. A minor anomaly was noted, whereby a spleen sample had not been captured on the database. This was immediately addressed at the time of inspection through verification against stored tissue and supporting identification labels.

Across all four licenced premises, the methods used to identify, record, track, trace and classify bodies, body parts and tissue were found to be suitable and, based on the traceability audits conducted during inspection, robust. Advice is offered endorsing plans to back up information recorded in the Mortuary register and record sheets onto a secure database.

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

Consent

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 Code of Practice.	The Trust policy, "Post-Mortem Examination Policy for Medical Staff", summarises relevant steps of the required process for seeking consent in accordance with HTA standards and codes of practice; however, there is no formal procedure setting out the mechanism for seeking consent for adult hospital post mortem examinations. There is ongoing discussion between members of Bereavement Services and Mortuary staff to develop a procedure. However, at present the DI does not have the necessary assurance that systems are in place to ensure that consent for all adult hospital PM examinations will consistently and reliably meet Trust and HTA requirements. Advice is provided below to help the DI address this shortfall.	**Minor**

C3 Staff involved in seeking consent receive training and support in the implications and essential requirements of taking consent.	In the absence of the formal ways of working, described under the shortfall against consent standard C1 above, the process for training in taking consent is awaiting development and implementation. There is ongoing discussion regarding the training needs of core staff within Bereavement Services and the Mortuary. There has also been discussion regarding a process for the induction training and refresher training of medical registrars who may take consent and how the members of Bereavement Services and / or the Mortuary may witness the process of seeking consent so that registrars who may not routinely be involved in this process are supported by members of staff who are experienced in answering any questions that the family of the deceased may wish to ask. Advice is provided below to help the DI address this shortfall. *(NB it is noted, post inspection, that the Mortuary Manager and the Head of Bereavement Services have attended the AAPTUK consent training day held during May 2014 and plan to conduct in-house consent training using materials provided at the training day).*	**Minor**

Advice

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

No.	Standard	Advice
1.	C1 Mortuary and Department of Cellular Pathology	Good links are being established between the Mortuary and Bereavement Services. The DI is advised to support this initiative to further the development of a robust system and procedures for obtaining consent for adult hospital PM examinations. HTA experience of inspecting other licensed establishments has identified that the consent seeking process benefits from having an appropriately trained member of Bereavement Services or the Mortuary present so that medical registrars who may not routinely be involved in this process are supported in answering any questions that the family of the deceased may wish to ask.
2.	C3 & GQ3 Mortuary and Department of Cellular	Once the formal process and procedure for seeking consent is approved by the DI, the DI is advised to implement a programme of training. The DI is advised that the training should include, but not necessarily be limited to: • Induction and subsequent refresher training for members of the Bereavement Services and Mortuary staff involved in the process;

	Pathology	• Induction and refresher training for consultants and medical registrars who may be involved in the process; Evidence of training should be included within the respective trainer and trainee files and the DI should document their authorisation of the training programme as confirmation that she has the necessary assurance that the level and extent of consent training meets Trust and HTA requirements.
3.	PFE3 Mortuary at UCH and at NHNN	On occasions, the Mortuary receives bodies without shrouds. The HTA endorses the DI's ongoing exercise to audit and evaluate these occurences to determine whether these are sporadic one-off events or there is a systemic cause that can be formally addressed. The HTA supports the DI's point of principle that, where bodies of the deceased are being transferred to body bags, the persons responsible for this transfer should use shrouds to maintain the dignity of the deceased.
4.	PFE3 Mortuary at UCH	The HTA notes the ongoing review of fridge holding arrangements for fetuses and babies and the containers used for return to originating hospitals or funeral directors. There is a good initiative to introduce appropriately sized boxes to hold the remains of the deceased rather than to continue using standard size pouches, which on occasions can be oversized for the task. The HTA advises the DI to implement these planned changes.
5.	PFE1 & PFE3 Mortuary at UCH and at NHNN	The DI is advised to check the in-built trigger point for fridge alarms in the body stores at University College Hospital and The National Hospital for Neurology and Neurosurgery, to ensure that the threshold for a high temperature alarm is set at a limit that will set off the alarm before the fridge temperature reaches a level that would have a deleterious effect on the conditions of bodies stored in the fridge.
6.	PFE2 Mortuary at UCH and at NHNN	The DI is advised to add an additional column to the "cleaning record sheet for the post mortem suite" to capture the initials / signature of the person responsible for this task.
7.	GQ4 Mortuary at UCH and at NHNN	The HTA advises the DI to implement plans to collate information from the Mortuary register and record sheets within a secure database. This will provide useful back up and should improve access to information in the event of enquiries and during audit.
8.	GQ1 Mortuary at UCH	The DI is advised to review the process and SOPs covering out of hours release of bodies from the Mortuary. Specifically, the DI should ensure that, for out of hours release, the SOPs describe the links with the site portering staff and Site Manager and their respective SOPs. The aim of this exercise should be to ensure that relevant SOPs, across departments, are aligned in order to safeguard against any adverse incident relating to out of hours release of bodies.
9.	GQ1 & GQ7 Mortuary and Department of Cellular Pathology	The DI is advised to update the SOP on HTA reportable incidents (HTARIs) to reflect the minor change to classification of HTARIs – accidental damage to the body of a deceased person has recently been updated.

10.	PFE3 Department of Cellular Pathology	Storage of boxes of wax blocks needs to be improved to prevent potential damage to contents. The stacking of cardboard boxes in the location known as: 'B42' was resuting in the outer boxes failing to support the weight. The DI is advised to look into options for the introduction of racking to resolve this issue. It is noted that this location is currently used for the storage of wax blocks for diagnostic purposes and, as such, the storage of this tissue is outside the remit of the licence. However, the principle of suitable storage of wax blocks applies across the Department and advice is offered in this regard.
11.	Licence Conditions Department of Cellular Pathology	The DI is advised that, in accordance with the standard condition 9 of Annex B of the licence, the licence for the establishment should be on display within all areas where licensable activities take place; for example, there is currently no licence displayed where relevant material is being stored, under this licence, in ultra low temperature freezers in room 204. It is noted that this room has a licence on display that relates to the storage of relevant material under another licence held by the Trust.
12.	GQ1 Mortuary at UCH and at NHNN	The DI is advised to introduce the additional safeguard of a visible warning, with the deceased, that there is an individual with the same or similar name. This may be in the form of a coloured wrist band or warning notice next to the deceased. This will complement the existing system of flagging similar / same names within the Mortuary register and by using a system of coloured magnetic disks on the Mortuary white board.
13.	GQ8 & PFE1 Department of Clinical Parasitology	The DI is advised to conduct a formal risk assessment of the premises to cover measures that are in place to safeguard stored relevant material. The risk assessment exercise should include, but may not necessarily be limited to: • Prevention of unauthorised access; • Control of authorised access out of normal working hours to include members of staff, members of the site cleaning team and members of site security; • Maintenance and monitoring relevant material in controlled temperature storage; • Measures in place to prevent unauthorised disposal of relevant material.
14.	PFE3 Department of Clinical Parasitology	At the Department of Clinical Parasitology, the DI is advised that existing holdings that have lost some of their preserving fluid should be assessed for replenishment of the fluid to avoid damage to specimens. Following risk assessment of the process for topping up preservative solution of retained pathology specimens, the DI is advised to implement a programme of restoration, prioritising those specimens that have been identified during audit as being most at risk of deterioration.
15.	PFE2 & GQ6 Department of Clinical Parasitology	At the Department of Clinical Parasitology, the DI is advised that the periodic defrosting and cleaning of the freezers, which includes the temporary transfer of specimens to another freezer, should be documented; the aim being to provide a full audit trail of the movement of samples whilst held by the establishment.
16.	GQ1 Department of Clinical Parasitology	The DI is advised to include the quality representative from the Department of Clinical Parasitology within the 'HTA Group', quality network, set up across the remainder of the hub and satellite premises.

17.	GQ8 & PFE1 Institute of Neurology	The DI is advised to conduct a formal risk assessment of the access route for removal of bodies of the deceased from the body store at The National Hospital for Neurology and Neurosurgery. This should allow the DI to set mimimum requirements under which bodies of the deceased can be safely and securely transferred from the body store to the Funeral Directors' vehicles.
18.	GQ6 Institute of Neurology	The HTA advises the DI to implement plans to use password protection for the worksheet used by members of staff at the Institute to track and trace pathology samples.
19.	GQ8 & PFE1 Institute of Neurology	The DI is advised that the shared space within the basement of The Institute should be the subject of a formal risk assessment to determine whether this area needs to be designated space for storage of relevant material as originally intended and in accordance with the standards set out in the establishment's document entitled: "Retention of Clinical Material and Quality Records".
20.	Licence Conditions Institute of Neurology	The DI is advised that, in accordance with standard condition 9 of Annex B of the licence, the licence for the establishment should be on display within all areas where licensable activities take place (IQ Path laboratory; B35; electron microscopy laboratory).
21.	GQ6 & GQ4 Institute of Neurology	During the course of conducting a traceability audit at the Institute, members of staff could not locate a log book covering the period October 2010. The DI is advised to proceed with enquiries into the whereabouts of the slide retrieval log book for 2010 detailing access to slide archive and temporary retrieval of microscope slides for comparative review.

Concluding comments

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

The DI and Persons Designated (PDs) demonstrate a good understanding of regulatory requirements. There is a wide and varied amount of licensable activity taking place across the hub and three satellite premises and the DI has assigned PDs to all areas of the Trust where licensable activities take place.

The inspection identified a number of areas of licensable activity where the DI and the PDs have influenced and promoted good practice. There is evidence of good communication and teamwork amongst members of staff who are involved in licensable activities. The extended team's strong commitment to quality is supported by a dedicated Quality Manager and effective use of an HTA Committee. HTA Committee meeting attendees include DIs with oversight of other HTA licenced activity within the Trust and provide a good forum for sharing information, experience and ideas relating to, for example, HTA standards, codes of practice and inspections.

There are a number of new initiatives being introduced through the new Mortuary Manager. The HTA endorses the ongoing plans to enhance links with Bereavement Services. There is also a good planned security safeguard to extend the use of CCTV in the corridors adjacent to the Mortuary. The maternity unit has sound procedures and practices in place for instances of intrauterine foetal death or neonatal death. There is a strong emphasis on the health and

wellbeing of the mother, respecting the wishes of the mother / parents and showing great sensitivity towards the deceased child and the process for sensitive disposal of remains following pregnancy loss.

Additional examples of good practice include:

- perinatal facilities for viewings within the Mortuary at UCH;
- collaborative working between members of staff within the Mortuary and Bereavement Services and Maternity;
- weekly audits of 'length of stay' for adults and babies within the Mortuary;
- detailed flow chart describing, and providing ease of reference to disposal routes for tissue;
- daily team meetings in UHNN providing updates and discussion on status of projects for all relevant members of staff;
- comprehensive database for brain tissue held within UHNN;
- comprehensive perinatal consent process and supporting documentation;
- Mortuary housekeeping;
- Mortuary 'long stay' SOP.

The inspection provided an opportunity to verify corrective actions that were taken as a result of the previous HTA inspection. The establishment's approach has been comprehensive and included actions taken in response to an item of HTA advice.

There is one area of practice where a shortfall against relevant HTA standard was identifed. This relates to the systems in place for taking consent for, adult, hospital, consented, post mortem examinations and the training of members of staff who may be involved in taking this consent. The HTA has given advice to the Designated Individual with respect to the procedure for training individuals who may be involved in the taking of consent for a post mortem examination.

The HTA requires that the Designated Individual addresses the two minor shortfalls against HTA consent standards 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.

In addition a number of pieces of advice have been provided to the DI where the HTA identified opportunities for improvement to existing systems and procedures.

Report sent to DI for factual accuracy: **6 June 2014**

Report returned from DI: **9 June 2014**

Final report issued: **30 June 2014**

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: 30 March 2015

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
• 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.

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.