

Site visit inspection report on compliance with HTA minimum standards

St Pancras Public Mortuary

HTA licensing number 12445

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 February 2015

Summary of inspection findings

St Pancras Public Mortuary (the establishment) has recently undergone significant renovation of the mortuary premises, and a non-routine inspection was carried out to assess compliance with HTA standards relating to premises, facilities and equipment.

The establishment was found to have met all HTA standards that were assessed during the inspection. The Designated Individual, the Licence Holder, and the premises were also found to be suitable in accordance with the requirements of the legislation.

Since the last routine inspection, the establishment has updated its risk assessments to include areas of risk relating to licensable activities and not just health and safety.

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 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 establishment is a public mortuary that only carries out adult post mortem (PM) examinations on behalf of the Coroner, including forensic cases. Paediatric or perinatal cases and consented PM examinations are not carried out. Tissue samples removed during PM examination may be held at the establishment for a short period awaiting courier collection, but no human tissue is permanently stored on site.

The last routine inspection was carried out in July 2012. This non-routine inspection was scheduled following a period of several months of significant renovation of the mortuary premises when no licensable activity was being carried out. The inspection focused on the premises, facilities and equipment, along with the documentation that supports the use and maintenance of these, to ensure HTA licensing standards are still being met. The standards assessed during the inspection are shown in black text in Appendix 1.

The inspection comprised a visual inspection of the premises, review of documentation and interviews with two key members of staff. No bodies or tissue samples were being stored by the establishment at the time of the inspection so an audit was not conducted. Observation of licensable practices was also not possible as the mortuary was not operational.

Documentation relating to the validation and calibration of the new facilities and equipment in the mortuary was not available during the inspection but were provided to the inspection team prior to the issue of the draft report. These included documentation for the fridges, trolleys, CCTV, air handling and alarm systems.

Since the last inspection the establishment had addressed the minor shortfall relating to risk assessments. The remarks in the previous report relating to signs of wear and tear in the PM room are now redundant due to the complete renovation of this facility.

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

All applicable HTA standards have been assessed as fully met.

Advice

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

No.	Standard	Advice
1.	GQ1	<p>The standard operating procedures (SOPs) have release and review dates but do not have version numbers. The DI is advised to add version numbers to all documents (including signs) to help ensure that staff know which is the latest version. The DI is also advised to include references within SOPs to other documents to which they relate. For example, sensitive disposal of human tissue is covered in a separate SOP from that about waste management, but there is no indication in the latter that the first document exists and should be followed for the disposal of all human tissue.</p> <p>The DI is reminded that the SOP for reporting incidents to the HTA via the portal should refer to HTARIs rather than sudden untoward incidents.</p>
2.	GQ1, GQ8	<p>Staff have been provided with a new lone working alarm; however, this only alerts others within the building and therefore does not alert anyone externally if a member of staff attending the mortuary out of hours requires assistance. The establishment has a lone working document in place but this is not specific on who should be informed when a member of staff enters and leaves the premises out of hours. The risk assessment relating to lone working notes that the personal alarm should be connected externally.</p> <p>The DI is advised to further develop the procedure for attending the mortuary out of hours and test its effectiveness to ensure it is reliable, and/ or ensure the lone working alarm is connected externally. The DI should also ensure the risk assessment in place includes a risk score and reflects the risk of a security breach.</p>
3.	GQ2	<p>A significant number of documents have been updated while the mortuary has been renovated to ensure they reflect the changes that have occurred. Once the mortuary is fully operational and these procedures are being carried out by staff, the DI is advised to audit these to ensure staff understand the new procedures and that the SOPs accurately reflect working practices.</p>

		An audit of the admission and release of body procedures was reviewed. The DI is advised to include the actions taken where any anomalies were found, so that it is clear that these have been satisfactorily addressed.
4.	PFE2	The DI has implemented record sheets for each area of the mortuary, to be completed when the area has been cleaned. The majority of these sheets indicate how frequently the area must be cleaned, but this has been omitted on a few and needs to be added for clarity.

Concluding comments

Following the previous inspection, risk assessments were carried out and documented for mortuary activities using the HTA reportable incident categories as a framework. These document how risks are mitigated by the establishment's staff to help prevent incidents.

The establishment staff have worked hard to maximize the benefit of the building renovations so that risks to staff and the deceased are reduced, the working environment is improved and the service it provides to the Coroner, the police and the public is enhanced. The mortuary building has been extended and completely refurbished to provide new separate entrances for staff and the bereaved. The entrance for funeral directors has been reorganised by the removal of a ramp and installation of a lifting platform to allow sufficient space for vehicles to enter and the gates be closed behind, so that the deceased can be transported into the mortuary out of public sight and with greatest dignity and security.

The premises have been designed so that they can function in two halves through the use of sliding doors. This means that forensic cases may be attended to in the main mortuary area, whilst the other half of the body store is still accessible for funeral directors to deliver and collect the deceased for routine Coroner's cases. The capacity of the body store has been increased and the area in front of one set of fridges can also be chilled should additional temporary storage be required. Bariatric fridges have been installed and one has a single extra wide tray for severe bariatric cases and trolleys which facilitate the handling of these. All the fridges and freezers are monitored with alarms that notify staff on call if they are out of range. The post mortem stations use the trays from the body store to minimise manual handling and have their own dedicated dissection, height adjustable bench at the foot of the post mortem station to reduce the likelihood of loss of traceability.

A number of the SOPs have been updated to reflect the changes to the premises. Pictures have been included in several of these, providing a visual aid on what is required of the user.

The HTA has given advice to the Designated Individual on a range of issues and assessed the establishment as suitable to be licensed for the activities specified.

Report sent to DI for factual accuracy: 18/03/15

Report returned from DI: No factual accuracy or request for redaction comments were made by the DI

Final report issued: 07/04/15

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.

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
<ul style="list-style-type: none">Documented policies and SOPs cover all mortuary/laboratory procedures relevant to the licensed activity. These may include:<ul style="list-style-type: none">post-mortem examination, including the responsibilities of the APTs and Pathologists (e.g. evisceration) and management of high risk casesrecord keepingreceipt and release of bodies, which reflect out of hours arrangementslone working in the mortuarytransfer of bodies and tissue (including blocks and slides) to other establishments or off siteensuring that tissue is handled in line with documented wishes of the relativesdisposal of tissue (including blocks and slides)<i>(Note that individual SOPs for each activity are not required. Some SOPs will cover more than one activity.)</i>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
<ul style="list-style-type: none">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
<ul style="list-style-type: none"> • 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
<ul style="list-style-type: none"> • 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
<ul style="list-style-type: none"> • 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
<ul style="list-style-type: none"> • 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.)

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.