Inspection report on compliance with HTA licensing standards
Inspection date: **27 September 2023**

St Pancras Public Mortuary
Licence 12445

Licensed under the Human Tissue Act 2004

Licensed activities

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

Area	Making of a post-mortem examination	Removal from the body of a deceased person (otherwise than in the course of an anatomical examination or post-mortem examination) of relevant material of which the body consists or which it contains, for use for a scheduled purpose other than transplantation	Storage of the body of a deceased person or relevant material which has come from a human body for use for a scheduled purpose
Hub site **St Pancras Public Mortuary**	Licensed	Licensed	Licensed
Mortuary	Carried out	Carried out	Carried out

Summary of inspection findings

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

Although the HTA found that St Pancras ('the establishment') had met some of the HTA's standards, one critical, four major and one minor shortfalls were found against standards for Governance and quality systems and Premises, facilities and equipment.

These related to storage procedures, dignity of the deceased, governance arrangements, Standard Operating Procedures (SOPs), and security arrangements.

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

Compliance with HTA standards

Critical Shortfalls

Standard	Inspection findings	Level of shortfall
GQ1 All aspects of the establishment's work are governed by documented policies and procedures		

c) Procedures on body storage prevent practices that disregard the dignity of the deceased	The mortuary SOP relating to body storage does not contain procedures to ensure adequate condition checking and suitable follow up action, The procedure to manage the journey of bodies through the mortuary is not clear or robust. Whilst there is a documented procedure for the following-up of bodies in storage, this is held by bereavement and the procedure for following up with funeral directors when bodies are ready for collection was not being followed, which resulted in bodies staying at the establishment for longer than necessary. As a consequence of this shortfall, storage arrangements at the time of the inspection did not maintain the condition or the dignity of the deceased. They increased the risk of accidental damage through decomposition. (See also PFE2(a) below)	**Critical**

Major shortfalls

Standard	Inspection findings	Level of shortfall
GQ2 There is a documented system of audit		
a) There is a documented schedule of audits	Whilst an audit schedule is in place, at the time of the inspection there was no formal security audit in place.	**Major**
GQ6 Risk assessments of the establishment's practices and processes are completed regularly, recorded and monitored		

b) Risk assessments include how to mitigate the identified risks. This includes actions that need to be taken, who is responsible for each action, deadlines for completing actions and confirmation that actions have been completed	Low staffing levels indicate a risk to provision of service in the event of sickness or staff absence. There is no evidence that this has been risk assessed. The lone working risk assessment identifies risks to staff in the event of accident or emergency but does not record sufficient risk mitigation. Whilst staff describe a buddy support system, this is not included as mitigation in the risk assessment.	**Major**
c) Significant risks, for example to the establishment's ability to deliver post-mortem services, are incorporated into the Trust's organisational risk register	Risk to delivery of service due to low staffing levels is not incorporated into the organisational risk register.	**Major**
PFE1 The premises are secure and well maintained and safeguard the dignity of the deceased and the integrity of human tissue.		
e) Security arrangements protect against unauthorized access and ensure oversight of visitors and contractors who have a legitimate right of access	The premises are secure with keypad access and CCTV installed. Contracted funeral directors and out of hours key holders have been given key code access to the mortuary out of hours. The DI does not have full oversight of how many staff access the site and there is currently no audit of entry notification in comparison with CCTV footage.	**Major**

PFE2 There are appropriate facilities for the storage of bodies and human tissue.

a) Storage arrangements ensure the dignity of the deceased	The inspection team identified ten bodies that had not been placed into frozen storage after 30 days. These bodies were in varying states of decomposition. Available contingency freezer storage had not been utilised. Storage arrangements at the time of the inspection did not maintain the condition or the dignity of the deceased. They increased the risk of accidental damage through decomposition. The establishment took immediate action to transfer these bodies to available contingency frozen storage. (See GQ1C above)	**Major**

Minor Shortfalls

Standard	Inspection findings	Level of shortfall
GQ1 All aspects of the establishment's work are governed by documented policies and procedures		
h) Matters relating to HTA-licensed activities are discussed at regular governance meetings involving establishment staff	The DI holds regular meetings with staff working under the licence but these are not minuted.	**Minor**

The HTA requires the DI to submit a completed corrective and preventative action (CAPA) plan setting out how the shortfalls will be addressed, within 14 days of receipt of the final report (refer to Appendix 2 for recommended timeframes within which to complete actions). The HTA will then inform the establishment of the evidence required to demonstrate that the actions agreed in the plan have been completed.

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

Number	Standard	Advice
1.	GQ1(a)	The DI is advised to review the St Pancras Public Mortuary Code of Practice document and consider the addition of standards of behaviour relating to photographs and social media.

Background

St Pancras Public Mortuary has been licensed by the HTA since 2 May 2007. This was the fourth inspection of the establishment; the most recent inspection took place in March 2019.

Since the previous inspection, there have been no changes to the licence.

Description of inspection activities undertaken

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

Standards assessed against during inspection
HTA standards relating to governance and quality and premises facilities and equipment were assessed. Standards relating to consent and traceability were not fully assessed during the inspection as the inspection was halted following the discovery of a critical shortfall (standards published 3 April 2017).

Review of governance documentation
The inspection team reviewed the establishment's self-assessment document provided by the DI in advance of the inspection.

Policies and procedural documents relating to licensed activities were reviewed. This included standard operating procedures, risk assessments, audits, incidents and equipment servicing reports.

Visual inspection
The inspection team undertook a visual inspection of the premises which included the mortuary body storage areas, the PM suites, and viewing facilities.

Audit of records
The inspection team undertook a review of bodies in storage. Records indicated that the ten freezer spaces were all in use and an additional ten bodies requiring frozen storage had not been transferred to contingent frozen storage. The ten bodies requiring frozen storage were viewed by the inspection team and found to be in varying states of deterioration ranging from minor to advanced decomposition. The inspection team halted the inspection and traceability audits for bodies and tissue in storage were not completed.

Interviews
The inspection team met with the Designated Individual to discuss activities taking place under the licence. The other permanent staff member who is an APT was not available prior to the inspection nor when the inspection team were on site.

Report sent to DI for factual accuracy: 16 October 2023

Report returned from DI: 27 October 2023

Final report issued: 14 November 2023

Completion of corrective and preventative actions (CAPA) plan

Based on information provided, the HTA is satisfied that the establishment has completed the agreed actions in the CAPA plan and in doing so has taken sufficient action to correct all shortfalls addressed in the Inspection Report.

Date: 22 December 2023

Appendix 1: The HTA's regulatory requirements

Prior to the grant of a licence, the HTA must assure itself that the DI is a suitable person to supervise the activity authorised by the licence and that the premises are suitable for the activity.

The statutory duties of the DI are set down in Section 18 of the Human Tissue Act 2004. They are to secure that:

- the other persons to whom the licence applies are suitable persons to participate in the carrying-on of the licensed activity;
- suitable practices are used in the course of carrying on that activity; and
- the conditions of the licence are complied with.

Its programme of inspections to assess compliance with HTA licensing standards is one of the assurance mechanisms used by the HTA.

The HTA developed its licensing standards with input from its stakeholders. They are designed to ensure the safe and ethical use of human tissue and the dignified and respectful treatment of the deceased. They are grouped under four headings:

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

This is an exception-based report: only those standards that have been assessed as not met are included. Where the HTA determines that there has been a shortfall against a standard, the level of the shortfall is classified as 'Critical', 'Major' or 'Minor' (see Appendix 2: Classification of the level of shortfall). Where HTA standards are fully met, but the HTA has identified an area of practice that could be further improved, advice is provided.

HTA inspection reports are published on the HTA's website.

Appendix 2: Classification of the level of shortfall

Where the HTA determines that a licensing standard is not met, the improvements required will be stated and the level of the shortfall will be classified as 'Critical', 'Major' or 'Minor'. Where the HTA is not presented with evidence that an establishment meets the requirements of an expected standard, it works on the premise that a lack of evidence indicates a shortfall.

The action an establishment will be required to make following the identification of a shortfall is based on the HTA's assessment of risk of harm and/or a breach of the Human Tissue Act 2004 (HT Act) or associated Directions.

1. **Critical shortfall:**

   A shortfall which poses a significant risk to human safety and/or dignity or is a breach of the HT Act or associated Directions

   or

   A combination of several major shortfalls, none of which is critical on its own, but which together could constitute a critical shortfall and should be explained and reported as such.

   A critical shortfall may result in one or more of the following:

   - A notice of proposal being issued to revoke the licence
   - Some or all of the licensable activity at the establishment ceasing with immediate effect until a corrective action plan is developed, agreed by the HTA and implemented.
   - A notice of suspension of licensable activities
   - Additional conditions being proposed
   - Directions being issued requiring specific action to be taken straightaway

2. **Major shortfall:**

   A non-critical shortfall that:

   - poses a risk to human safety and/or dignity, or
   - indicates a failure to carry out satisfactory procedures, or
   - indicates a breach of the relevant Codes of Practice, the HT Act and other relevant professional and statutory guidelines, or

- has the potential to become a critical shortfall unless addressed

or

A combination of several minor shortfalls, none of which is major on its own, but which, together, could constitute a major shortfall and should be explained and reported as such.

In response to a major shortfall, an establishment is expected to implement corrective and preventative actions within 1-2 months of the issue of the final inspection report. Major shortfalls pose a higher level of risk and therefore a shorter deadline is given, compared to minor shortfalls, to ensure the level of risk is reduced in an appropriate timeframe.

3. **Minor shortfall:**

   A shortfall which cannot be classified as either critical or major, but which indicates a departure from expected standards.

   This category of shortfall requires the development of a corrective action plan, the results of which will usually be assessed by the HTA either by desk based review or at the time of the next inspection.

   In response to a minor shortfall, an establishment is expected to implement corrective and preventative actions within 3-4 months of the issue of the final inspection report.

Follow up actions

A template corrective and preventative action plan will be sent as a separate Word document with both the draft and final inspection report. Establishments must complete this template and return it to the HTA within 14 days of the issue of the final report.

Based on the level of the shortfall, the HTA will consider the most suitable type of follow-up of the completion of the corrective and preventative action plan. This may include a combination of

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

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