Inspection report on compliance with HTA licensing standards
Inspection date: **17th and 21st March 2022**

St Helier Hospital
HTA licensing number 12345

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 Helier Hospital**	Licensed	Licensed	Licensed
Mortuary	*Carried out*	*Carried out*	*Carried out*
Pathology lab	-	-	-
Maternity	-	-	-
A&E	-	*Carried out*	-
Satellite site **Epsom Hospital**	Not licensed	Licensed	Licensed
Mortuary	-	*Carried out*	*Carried out*
Pathology lab	-	-	*Carried out*
A&E	-	*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 Helier Hospital ('the establishment') had met the majority of the HTA's standards, three major and three minor shortfalls were found against standards for Traceability and Premises, facilities and equipment.

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

Major shortfalls

Standard	Inspection findings	Level of shortfall
PFE1 The premises are secure and well maintained and safeguard the dignity of the deceased and the integrity of human tissue.		
a) The premises are clean and well maintained	<u>Hub Site</u> The post mortem suite walls are partially tiled with grout between the tiles. The porous nature of the grout makes it difficult to clean and achieve full decontamination. There is a temporary body storage unit situated within the post mortem suite making the area difficult to deep clean and decontaminate. The racking within the temporary unit used as a freezer is made from wood. The porous nature of the wood makes it difficult to clean. There is a temporary storage unit located in the mortuary chapel. This unit is sited on a carpeted floor, making cleaning and decontamination difficult. <u>Satellite Site</u> In the body store there is damage to the wall where a sink was removed, leaving areas of exposed plaster. The porous nature of the plaster makes cleaning the area difficult.	**Major**

d) The premises are secure (for example there is controlled access to the body storage area(s) and PM room and the use of CCTV to monitor access)	There is currently a temporary storage unit within the mortuary chapel, formerly used for viewings of the deceased. Due to the chapel now containing a temporary storage unit, viewings of the deceased are carried out in an adjacent room which was previously the waiting room. Although the entrance to this former waiting room from the hospital corridor is secure, the door between this room (where the viewings now take place) and the chapel does not lock. This means that visitors could gain access to the chapel containing the temporary body storage unit.	**Major**
PFE2 Storage arrangements ensure the dignity of the deceased.		
(b) There is sufficient capacity for storage of bodies, organs and tissue samples, which takes into account predicated peaks of activity.	There is insufficient capacity for the storage of bodies in permanent refrigerated storage units. There are currently two temporary refrigerated storage units in use within the establishment, one within the post mortem room which has been in use for over four years and one within the chapel which has been in use for over two years.	**Major**

Minor Shortfalls

Standard	Inspection findings	Level of shortfall
T1 A coding and records system facilitates traceability of bodies and human tissue, ensuring a robust audit trail		
c) Three identifiers are used to identify bodies and tissue, (for example post mortem number, name, date of birth/death), including at least one unique identifier	Although three identifiers are checked on the deceased when preparing a body for viewing, the procedure does not include a final check using a minimum of three points of identification of the deceased provided by the visitors prior to them entering the viewing room.	**Minor**

PFE1 The premises are secure and well maintained and safeguard the dignity of the deceased and the integrity of human tissue.		
b) There is demarcation of clean, dirty and transitional areas of the mortuary, which is observed by staff and visitors	The post mortem room contains a temporary refrigeration unit used to store the deceased. If a body is moved from this storage unit the body passes through the dirty area of the post mortem room preventing the demarcation between clean and dirty areas.	**Minor**
PFE3 Equipment is appropriate for use, maintained, validated and where appropriate monitored		
a) Items of equipment in the mortuary are in good condition and appropriate for use	The mobile post mortem tables within the post mortem suite are rusted, particularly around the central drains. Within the body store area there is rust to the hydraulic trolley.	**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.	C2(a)	Due to the COVID pandemic, face-to-face refresher training for staff taking consent for paediatric post-mortems has been delayed. This is being managed internally as part of a non-conformance. The DI is advised to complete the overdue training as soon as it is possible.
2.	PFE3(c)	Although the ventilation system provides an average of ten air changes per hour, regular checks show there are fluctuations and the DI is advised to consider whether the system needs replacing in the short to medium term.
3.	GQ1(a)	During release of the deceased three points of identification are checked with paperwork prior to release. This procedure is documented in the SOP for release of bodies. However, the DI is advised to amend the SOP so that it details what specific points of ID are checked (e.g. name, date of birth and hospital number) for clarity and consistency.

4.	GQ2(a)	The establishment's documented schedule of audit includes a security audit which reviews mortuary access. The DI is advised to include a cross check of legitimate rights of access to the mortuary against frequency, duration and patterns of attendance to ensure access is in line with the purpose for which it was granted.
5.	GQ6(a)	The establishment has a suite of risk assessments covering licensed activities. However, the DI is advised to: • Incorporate the risk of accidental damage to a body during post mortem into risk assessment HU.RA.146 as currently this only identifies the risk of sharps injuries incurred by staff; and • Incorporate the establishment's bariatric storage arrangements and equipment failure arrangements within the mitigating factors set out within risk assessment HU.RA.169 for accidental damage to the deceased (or address these risks by way of standalone risk assessments and include such mitigating factors therein).

Background

This report refers to the activities carried out at St Helier Hospital (the establishment), whose licensing arrangements cover St Helier Hospital (the hub) and Epsom Hospital (the satellite). The establishment has been licensed by the HTA since January 2008. This was the fourth inspection of the establishment; the most recent previous inspection took place in January 2017. The establishment has a single mortuary management structure and policies and procedures at both sites are substantially aligned.

Since the previous inspection, there have been no significant changes to the licence arrangements or the activities carried out under 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

All 72 HTA licensing standards were covered during the inspection (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 cleaning records for the mortuary and post-mortem room, records of servicing, ventilation reports, audits, risk assessments, meeting minutes, temperature monitoring for the storage units, reported

incidents, and staff training and competency records. Consent seeking procedures and information for relatives giving consent were also reviewed.

Visual inspection
The inspection team undertook a visual inspection of the hub and satellite premises which included the mortuary body storage areas, the PM room (Hub site only) as well as the storage arrangements for relevant material held within the facility.

Audit of records
Hub site

The inspection team undertook audits of traceability for three bodies in storage. This included a body in long term storage and a perinatal body. Traceability details were crosschecked between the identification band on the body, and information in the mortuary register. No discrepancies were identified.

Audits were conducted of tissue taken at PM examination for two cases. Information was crosschecked between the mortuary documentation, Coroner's paperwork, family wishes forms, the mortuary electronic database, and tissue being stored. Full traceability of tissues was demonstrated for both cases.

Satellite site

The inspection team undertook audits of traceability for three bodies in storage. This included a body in long term storage and a perinatal body. Traceability details were crosschecked between the identification band on the body and information on the mortuary register, as well as in mortuary paperwork. No discrepancies were identified.

Audits were conducted of tissue taken at PM examination for five cases (carried out in the Hub site). Information was crosschecked between the hospital's documentation, consent paperwork, the laboratory electronic database, and tissue being stored. No discrepancies were identified.

Meetings with establishment staff
The inspection team met with staff carrying out processes under the licence, including mortuary staff, pathologists who conduct PM examinations, maternity and bereavement staff as well as the DI.

Report sent to DI for factual accuracy: 20th of April 2022.

Report returned from DI: 25 July 2022

Final report issued: 16 August 2022

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: 5 January 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.