Inspection report on compliance with HTA licensing standards
Inspection date: **22 and 24 February 2022**

PRINCESS ALEXANDRA HOSPITAL

HTA licensing number 12458

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 **Princess Alexandra Hospital**	Licensed	Licensed	Licensed
Mortuary	*Carried out*	*Carried out*	*Carried out*
Pathology lab			*Carried out*
Maternity		*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 Princess Alexandra Hospital (‘the establishment’) had met the majority of the HTA’s standards, five major and nine minor shortfalls were found against standards for Consent, Governance and quality systems, 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
GQ1 All aspects of the establishment's work are governed by documented policies and procedures		
a) Documented policies and SOPs cover all mortuary/laboratory procedures relevant to the licensed activity, take account of relevant Health and Safety legislation and guidance and, where applicable, reflect guidance from RCPath.	Standard Operating Procedures (SOPs) lack sufficient detail. Key steps are included but these do not specify the individual actions that need to be undertaken to accomplish each step. At the time of inspection, procedures observed by the inspection team were not consistent with that of the SOPs. These include, but are not limited to, SOPs detailing the process for: • admission of bodies; • post-mortem examination; • release; and • retention, disposal, and transfer of PM samples. This is not an exhaustive list of the SOPs requiring amendment. To fully address this shortfall the establishment should review all SOPs relating to mortuary activities to ensure that they are accurate and contain sufficient detail to reflect current practice.	**Major**

c) Procedures on body storage prevent practices that disregard the dignity of the deceased	At the time of the site visit, the establishment had very recently introduced a document to record the condition of bodies during the length of stay in the mortuary. However, on conducting the body audit, the inspection team identified at least three bodies in soiled sheets and one with excessive fluid leakage. These conditions were not recorded on the body condition check and indicates that the process was not yet embedded.	**Major**
GQ3 Staff are appropriately qualified and trained in techniques relevant to their work and demonstrate competence in key tasks		
c) Staff are assessed as competent for the tasks they perform	Although porters have been initially 'signed off' on completion of training, there is no on-going competency assessments. The establishment could not provide documentation showing that porters had received refresher training and competency (re)assessment.	**Major**
T1 A coding and records system facilitates traceability of bodies and human tissue, ensuring a robust audit trail		
b) There is a system to track each body from admission to the mortuary to release for burial or cremation (for example mortuary register, patient file, transport records)	Due to complexity of multiple paper and electronic recording systems, the inspection team were not assured that a robust system is in place which tracks bodies adequately from admission to release. This poses a risk of loss of traceability of bodies in storage.	**Major**

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	The establishment's procedure for release and viewing of bodies does not make clear that information provided by funeral directors and/or visiting families must include a minimum of three identifiers of the deceased. • During the inspection, the team observed the release of a body with no accompanying paperwork or sufficient details provided by the funeral director; • During the body audit, one body was found to have only two identifiers available; and • Staff are contacted verbally by the family to arrange viewings. Staff are provided with verbal communication of the identity of the deceased, for example name and Coroner's number. Three identifiers are not routinely recorded. No further identification check of the body is undertaken prior to the viewing. These practices further increase the risk of releasing or viewing of a wrong body.	**Major**

Minor Shortfalls

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 HTA's codes of practice		
g) The establishment uses an agreed and ratified consent form to document that consent was given and the information provided	The perinatal PM examination consent form does not adequately reflect the requirements of the HT Act. The form does not include the option for repatriation to the body or disposal of tissue. The consent form guidelines also refer to outdated HTA Codes of Practice.	**Minor**
GQ4 There is a systematic and planned approach to the management of records		
b) There are documented SOPs for record management which include how errors in written records should be corrected	The inspection team identified errors in mortuary written records which were illegible because of being overwritten. This was not in line with hospital procedure and means that some records are not fully auditable.	**Minor**
T1 A coding and records system facilitates traceability of bodies and human tissue, ensuring a robust audit trail		
d) There is system for flagging up same or similar names of the deceased	Although there is a procedure in place for same or similar names, the inspection team were not satisfied that this was robust enough to reduce the risk of releasing the wrong body.	**Minor**

e) Identity checks take place each time a body is moved whether inside the mortuary or from the mortuary to other premises	There was no evidence of documented procedures on the process of identity checks when moving patients within the mortuary. Fridge numbers are used but this does not form part of the documentation or checks.	**Minor**
g) Organs or tissue taken during post-mortem examination are fully traceable, including blocks and slides (including police holdings).	The establishment does not receive confirmation of receipt of cytogenetic samples that are sent away for analysis.	**Minor**
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	Viewing of the deceased takes place in a designated family area. Access to the body store is behind a curtain via a door with a manual lock. There is a risk that visitors may access the body store as the lock is visitor side facing.	**Minor**
PFE2 There are appropriate facilities for the storage of bodies and human tissue.		
a) Storage arrangements ensure the dignity of the deceased	As part of the body audit the inspection team audited a body stored on a tray in the freezer. The body had not been condition checked before being transferred into the freezer and the inspection team found the sheets had frozen to the tray. Identification bands were not fully visible on the body.	**Minor**
c) Storage for long-term storage of bodies and bariatric bodies is sufficient to meet needs	The mortuary does not have capacity for frozen storage of bariatric patients. There is an added risk as documented procedures do not include contingency plans if this storage was required.	**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 workbench and laundry bin in the body store and hand saws in the PM room have large areas of rust making it difficult to clean and decontaminate sufficiently. These are in need of replacement.	**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.

DI and CLH/LH suitability

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

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

Number	Standard	Advice
1.	C1(g)	The DI is advised to liaise with the referral establishment to ensure the perinatal consent form reflects the HT Act.
2.	GQ3(c)	The DI is advised to complete initial training on mortuary procedures for recently employed porters who have not yet received their induction.
3.	T1(f)	The DI is advised to use the year prefix on all documentation that uses the unique mortuary number. This will mitigate the risk of a body having the same number as another in long term storage.

4.	PFE1(d)	Swipe card access has recently been implemented in areas where bodies and tissues are stored. The DI is advised to ensure regular audits of the access list are undertaken to ensure only essential staff, that have received a mortuary induction, have access to these areas.
5.	PFE3(e)	The DI is advised to increase the lower limit alarm trigger point for the refrigerators to prevent unintentional freezing of the deceased should temperatures deviate from the acceptable range.
6.	T1(d)	The DI is advised to explore other options available to strengthen the current same/similar name system in operation.

Background

Princess Alexandra Hospital is licensed for the making of a PM examination, removal of relevant material from the deceased and storage of bodies of the deceased and relevant material for use for scheduled purposes.

Princess Alexandra Hospital has been licensed by the HTA since 2007. This was the third inspection of the establishment; the most recent previous inspection took place in December 2016.

Since the previous inspection, there has been a refurbishment of mortuary facilities including an increase in capacity. 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 included a review of the establishment's governance documentation relating to licensed activities. This included policies and procedural documents relating to licensed activities, cleaning records for the post-mortem room, records of servicing of equipment, ventilation reports, audits, risk assessments, meeting minutes, temperature monitoring for the storage units, reported incidents and training records for both the mortuary staff and porters.

Visual inspection
The inspection included a visual inspection of the mortuary body store, PM room, viewing room and tissue storage areas.

Audit of records
Audits were conducted for four bodies in refrigerated and frozen storage. Identification details on bodies were crosschecked against the information recorded in the mortuary register and associated paperwork. One minor discrepancy was identified (see advice and guidance).

Audits of traceability were conducted for tissue blocks and slides from four PM cases, including audits of the consent documentation for the retention of these tissues. No discrepancies were found.

Meetings with establishment staff
Staff carrying out processes under the licence were interviewed including the DI, mortuary manager, Anatomical Pathology Technologist, portering staff, maternity staff, and adult consent seeker.

Materials held for the police
Under section 39 of the HT Act, relevant material held for criminal justice purposes is outside the scope of HTA regulation and is not subject to the licensing requirements for storage. Any information provided by the establishment in relation to police holdings have been shared with the Home Office, but do not appear in the report as they are outside the scope of the HT Act.

Report sent to DI for factual accuracy: 04 April 2022

Report returned from DI: 13 April 2022

Final report issued: 19 April 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: 26 August 2022

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.