Inspection report on compliance with HTA licensing standards
Inspection date: **28 June 2023**

Royal Albert Edward Infirmary

HTA licensing number 12175

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
Royal Albert Edward Infirmary	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 Royal Albert Edward Infirmary ('the establishment') had met the majority of the HTA's standards, one major and four minor shortfalls were found against standards for document management, tissue traceability, premises and fridge alarm testing.

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
PFE2 There are appropriate facilities for the storage of bodies and human tissue.		
a) Storage arrangements ensure the dignity of the deceased	Two of the body store units are located on a through road towards the mortuary, away from the main building. Transfer of bodies to and from these units and onto the funeral service vehicles is in full view of pedestrians, passing traffic and hospital wards. This poses a risk to the dignity of the deceased. Furthermore, the inspection team noted that bodies were removed from these units, on trolleys, via a ramp leading onto a main road in sight of oncoming traffic. This further increases the risk to both the dignity and accidental damage to the deceased.	**Major**

Minor Shortfalls

Standard	Inspection findings	Level of shortfall
GQ1 All aspects of the establishment's work are governed by documented policies and procedures		
d) Policies and SOPs are reviewed regularly by someone other than the author, ratified and version controlled. Only the latest versions are available for use	All SOPs are version controlled, reviewed and ratified. However, the inspection team identified SOPs that were past their review dates. These included SOPs for: • Consent; • Viewings; and • Transfer of bodies. This is not an exhaustive list of the SOPs requiring review. To fully address this shortfall the establishment should review all SOPs relating to mortuary activities to ensure that they are within their review dates.	**Minor**
T2 Disposal of tissue is carried out in an appropriate manner and in line with the HTA's codes of practice.		
b) There are effective systems for communicating with the Coroner's Office, which ensure tissue is not kept for longer than necessary	There is a procedure for following up with the Coroner to determine when their authority has ended but there is a backlog of material awaiting confirmation of the family's wishes for storage. The establishment has fallen behind in their communications with the Coroner's Office to obtain the family wishes forms for tissue removed during post-mortem examinations. During the site visit, the inspection team carried out an audit of retained tissues. Two of the cases selected for review had been stored since 2021 and there was no documented evidence that these cases had been followed up with the Coroner. This poses a risk of tissue being retained against the families' wishes.	**Minor**

PFE2 There are appropriate facilities for the storage of bodies and human tissue.		
c) Storage for long-term storage of bodies and bariatric bodies is sufficient to meet needs	There were no bariatric-sized freezers and no formal contingency plan in place if one was required.	**Minor**
e) Fridge and freezer units are alarmed and the alarms are tested regularly to ensure that they trigger when temperatures go out of upper or lower set range	Whilst fridge and freezer units were alarmed, there was no evidence of formal testing of the fridge and freezer temperature alarms to ensure out of hour call-out procedures work and are followed.	**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 practices:

Number	Standard	Advice
1.	C1(c)	There are a number of documents relating to consent seeking for post mortem which repeats details of the process. The DI is advised to review all consent documentation and consider amalgamating them. The DI is further advised to make it clear in these documents that adult consented post-mortem examinations do not take place at the establishment.
2.	GQ1(h)	The DI is advised to review the HTA meetings to ensure all PDs on the licence have the opportunity to

		attend and/or receive meeting minutes.
3.	GQ2(a)	Audits have been conducted against the old HTA licensing standards. The DI is advised to update the audit template to include the most up-to-date HTA Post-mortem examination standards, which were published in 2017.
4.	PFE1(a)	The DI is advised to review the cleaning methods of the flooring in the mortuary body store units to ensure it is suitable for the embossed metal surface.
5.	PFE3(a)	The DI is advised to monitor the minor rusting on the mortuary trollies to ensure that they do not deteriorate further, inhibiting effective cleaning and decontamination.
6.	PFE3(d)	The DI is advised to continue the work to evaluate the implementation of lone worker alarms to ensure risks to staff working alone have been fully mitigated.

Background

Royal Albert Edward Infirmary has been licensed by the HTA since May 2007. This was the third inspection of the establishment; the most recent previous inspection took place in July 2018.

Since the previous inspection there have been no significant changes to the licensing 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 27 September 2022).

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, cleaning records for the mortuary, records of servicing of equipment, audits, risk assessments, meeting minutes, reported incidents and training records for staff.

Visual inspection
The inspection included a visual assessment of mortuary fridge room, post mortem room, tissue storage areas and the viewing facilities. The inspection team observed the processes for admission, release and viewing of bodies within the mortuary.

Audit of records
Audits were conducted for three bodies from refrigerated storage. Identification details on bodies were crosschecked against the information recorded in the mortuary register and associated paperwork. No discrepancies were identified.

Audits of traceability were conducted for tissue blocks and slides retained following coronial post mortem examinations. These included audits of the consent documentation for the retention or disposal of these tissues. No discrepancies were identified, however delays in contacting the Coroner's office were identified. *See shortfall T2(b).*

Meetings with establishment staff
Staff carrying out processes under the licence were interviewed including the DI, Senior APT, Mortuary Porter Supervisor, Pathologist and Bereavement Midwife.

Report sent to DI for factual accuracy: 25 July 2023

Report returned from DI: 26 July 2023

Final report issued: 28 July 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: 9 April 2024

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.