

Southend Hospital
 HTA licensing number 11068

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 Southend Hospital	Licensed	Licensed	Licensed
Mortuary	<i>Carried out</i>	<i>Carried out</i>	<i>Carried out</i>
A&E	-	<i>Carried out</i>	-

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 Southend Hospital ('the establishment') had met the majority of the HTA's standards, three major and

one minor shortfall were found against standards for governance, premises, facilities and equipment.

Concerns were discussed with the establishment as part of this inspection and the current DI has provided assurance that key personnel have been appointed to manage the activities under the licence and that the establishment is committed to meeting the regulatory requirements. Based on this assurance, 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. However, in light of the establishment's lack of progress with addressing shortfalls from the previous inspection, the HTA will consider the need for regulatory action if appropriate action is not taken to meet the regulatory requirements in accordance with the timeframes detailed in Appendix 2.

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		
c) Procedures on body storage prevent practices that disregard the dignity of the deceased	<p>Although a rare occurrence, bodies have been left unrefrigerated within the PM room for a significant time prior to PM examination. This could pose a risk to dignity.</p> <p>The establishment provided sufficient assurances to address this shortfall before the report was finalised.</p>	Major
PFE1 The premises are secure and well maintained and safeguard the dignity of the deceased and the integrity of human tissue.		

<p>a) The premises are clean and well maintained</p>	<p>This shortfall relates to findings from the last inspection. Although significant improvements have been made to the premises, the HTA is concerned that adequate steps were not taken to fully address the previous findings in the intervening period and to embed suitable practices at the establishment.</p> <p>Although the mortuary premises are subject to regular cleaning, the age and subsequent deterioration of some areas means that they cannot be maintained, cleaned and decontaminated effectively.</p> <p>Examples include:</p> <ul style="list-style-type: none"> • Fridge floors and racking are old and cannot be sufficiently cleaned. • Service contracts are unavailable due to the age of the fridges. • The freezer unit has been condemned. • Mortuary trolleys are showing significant signs of rust. • Post mortem room and viewing room doors are made of a porous material. • The service tunnel flooring between the mortuary and body store has stagnant and pooled water as a result of leaks from the building service systems. 	<p>Major</p>
<p>PFE2 There are appropriate facilities for the storage of bodies and human tissue.</p>		
<p>a) Storage arrangements ensure the dignity of the deceased</p>	<p>Transfer of the deceased between body storage areas is commonplace. Current arrangements do not ensure the dignity of the deceased is being maintained due to these internal transfers being in public view.</p>	<p>Major</p>

Minor Shortfalls

Standard	Inspection findings	Level of shortfall
PFE2 There are appropriate facilities for the storage of bodies and human tissue.		
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	<p>The inspection team identified two single unit fridges within the mortuary used for storing relevant material.</p> <p>Whilst there was temperature monitoring in place, and one had an audible alarm, these were not connected to any alarm systems.</p>	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(a)	The DI is advised to review the adult consent policy to ensure families are able to contact hospital staff out of working hours if they were to change their mind during the 24 hour cooling-off period.

2.	C1(e)	The establishment gives the option to families for retention of PM material for research. Currently the establishment does not conduct research. The DI is advised to consider providing this information to families to set expectations and ensure that informed consent is obtained.
3.	C2(a)	Whilst all relevant staff were trained on the HTA requirements for taking consent, the DI is advised to reinstate a routine training schedule which has been disrupted during the COVID pandemic.

Background

Southend 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.

Southend Hospital has been licensed by the HTA since 10 May 2007. This was the third inspection of the establishment; the most recent previous inspection took place in September 2017. There has been a change of DI since the last inspection.

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 mortuary, records of servicing of equipment, ventilation reports, audits, risk assessments, meeting minutes, reported incidents and training records for both the mortuary staff and porters.

Visual inspection

The inspection included a visual assessment of the three mortuary body storage areas, PM room, viewing room and tissue storage areas. The inspection teams 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 electronic register and associated paperwork. No discrepancies were identified.

Audits of traceability were conducted for tissue blocks and slides from four coroners consented cases. These included audits of the consent documentation for the retention of these tissues. No discrepancies were identified.

Meetings with establishment staff

Staff carrying out processes under the licence were interviewed including the DI, mortuary manager, APT, pathologist, mortuary porter, and bereavement midwife.

Report sent to DI for factual accuracy: 29 July 2022

Report returned from DI: 06 August 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: 29 December 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.