Inspection report on compliance with HTA licensing standards
Inspection date: **03 September 2025**

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
Southend Hospital	Licensed	Licensed	Licensed
Mortuary	*Carried out*	*Carried out*	*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 Southend Hospital ('the establishment') had met the majority of the HTA's standards one major and three minor shortfalls were found against standards for 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
PFE1 The premises are secure and well maintained and safeguard the dignity of the deceased and the integrity of human tissue.		
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)	Whilst access to the mortuary storage area is audited using CCTV monitoring, the designated individual and mortuary manager only receives a summary of compliance from the security team. Assurance is not obtained that the processes audited are in line with documented procedure, which poses a risk that deviations from security processes are not identified. Further, the sample size and pre-selected timeframe, limits the ability to detect unauthorised or inappropriate access. As a result, the establishment cannot effectively monitor access patterns or identify suspicious activities.	**Major**

Minor Shortfalls

Standard	Inspection findings	Level of shortfall
GQ2 There is a documented system of audit		
c) Regular audits are carried out of tissue being stored so that staff are fully aware of what is held and why and to enable timely disposal of tissue where consent has not been given for continued retention	Regular audits are carried out on tissue for open coronial cases to ensure disposal or retention is in line with families wishes. However, once the families wish has been completed, no further audits take place to ensure consent is still recorded for its continued retention.	**Minor**

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	All staff are assessed as competent as part of their initial training, and then at regular intervals. Staff were unable to provide evidence that these ongoing competency assessments extended to porter staff that completed regulated activity within the mortuary.	**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 inspection team noted that the external mortuary condenser units had no mechanism to protect against unauthorised access to the on/off switches. As these are in a public area it increases the risk of the fridges being inadvertently turned off, without oversight of the mortuary staff. Further, the inspection team noted that condemned hospital equipment was stored against these units, posing a risk to the inefficient working of the refrigeration units. *Staff took immediate actions to rectify this before the inspection team left the site.*	**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)	Training for taking post mortem consent is currently open for all establishment staff to complete. The DI is advised to have a core team of consent takers and differentiate between those individuals that has taken the training for interest, and those that would be contacted to take post mortem consent.
2.	GQ2 (c)	Tissue is disposed if family wishes are not received within six months of the end of the coroner's authorisation. The DI is advised to align this with HTA guidance of three months, to mitigate the risk of tissue being retained without valid consent.
3.	GQ3 (c)	The DI and mortuary manager are advised to progress plans for peer competency assessments for mortuary management staff.
4.	GQ6 (c)	The DI is advised to risk assess the current route of transfer between the ward and mortuary, to ensure suitable mitigations of oversight of activity.
5.	PFE1 (a)	The area currently designated for funeral service collections currently has a large amount of debris and storage of condemned hospital equipment. The DI is advised to progress plans to use the new collection area for all collections when the refurbishment is complete and include these hazards in mortuary risk assessments.

Background

Southend Hospital has been licensed by the HTA since May 2007. This was the fourth inspection of the establishment; the most recent previous inspection took place in July 2022.

Since the last inspection, the establishment has undergone a full refurbishment of the mortuary premises and facilities. At the time of the site visit the mortuary was in the final stages of refurbishment and provided a limited service of storage within their recently upgraded contingency storage area. Viewings and post mortems were transferred to surrounding, licensed establishments. Since the last inspection there has also been a new corporate licence holder contact, appointed in July 2024.

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.
69 out of the 72 HTA licensed standards were covered during the inspection. Standards PFE1 (b), PFE3 (c), and PFE3 (e) were not applicable as the establishment did not have a functioning postmortem facility.

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, 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 mortuary body and tissue storage areas. This included observation of the processes for admission and release of bodies within the mortuary.

The inspection team also visited the new mortuary building, which was in the final stages of refurbishment. This was in an advisory capacity and did not form part of this regulatory assessment.

Audit of records
Audits were conducted for five 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 six coroners consented cases. These included audits of the consent documentation for the retention of these tissues. One transcription discrepancy was identified. This was not sufficient to amount to a shortfall, but oral advice was given to the establishment at the time of the inspection.

Meetings with establishment staff
Staff carrying out processes under the licence were interviewed including the DI, Mortuary Manager, APT, Pathologist, Histopathology

Manager, and Bereavement Midwife.

Feedback was provided on 18 September 2025 to the DI, Chief Medical Officer (CLHc), Mortuary Manager, Specialist Lead Nurse, Divisional Director, Risk & Compliance Manager, Deputy Director of Nursing, and Anatomical Pathology Technologists.

Report sent to DI for factual accuracy: 15 October 2025

Report returned from DI: 17 October 2025

Final report issued: 17 October 2025

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.