Inspection report on compliance with HTA licensing standards
Inspection date: **30 31 October 2024**

**Sunderland Royal Hospital**
HTA licensing number 12281

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**<br>**Sunderland Royal Hospital** | Licensed | Licensed | Licensed |
| **Mortuary** | *Carried out* | *Carried out* | *Carried out* |
| **Maternity** | - | *Carried out* | *Carried out* |
| **A&E** | - | *Carried out* | - |
| **Satellite site**<br>**South Tyneside District General Hospital** | 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 Sunderland Royal Hospital ('the establishment') had met the majority of the HTA's standards, three major and five 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 |
|---|---|---|
| **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. | Some of the establishment's Standard Operating Procedures (SOPs) require updating to ensure they include the full procedure and reflect practice:<br>• CP-MOR-SOP-005.UN Viewing of the deceased is not clear that the viewing log form stating three identifiers of the deceased is used to:<br>- prepare the body for viewing;<br>- check the identification of the deceased with the relatives when they attend for the viewing; and<br>- check the identification band on the body before the relatives view.<br>• CP-MOR-SOP-013.UN Samples taken at post mortem (PM) refers to the use of a PM book where specimens are recorded for cases at South Tyneside District General Hospital (STDGH). In practice, traceability and transfer records are scanned and saved electronically.<br>• CP-MOR-SOP-015.UN Baby deaths does not contain details of the process for transfer and return of babies/fetuses sent off site, including identification checks and the documentation required for transfer for coroner's cases and hospital cases (pre and post 24 weeks fetuses). In addition, where identification checks are referred to what the identifiers could be and what they are checked against is not always stated.<br>• CP-MOR-SOP-018.SR Mortuary procedures for portering and security staff states the porters or security staff collect a central swipe card to access the mortuary. This is incorrect as authorised staff have individual swipe access. | **Major** |
| **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 | The inspection team identified three discrepancies for three bodies during the body audit:<br>• The name of one body was spelt differently between mortuary paperwork and the identification bands. This had been identified by mortuary staff but documentation/records had not been fully updated.<br>• The name of one body had been incorrectly transposed in the mortuary register and this had not been identified during body check procedures.<br>• The unique mortuary register number for one body was not readable on the identification band.<br>*See advice item 4* | **Major** |
| **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 | <u>Sunderland Royal Hospital</u><br>The inspection team identified a small hatch door in the specimen cupboard in the PM room which does not lock and is not used by establishment staff. The door leads to an internal mortuary area, however is a means of access to the PM room which is not monitored.<br><u>South Tyneside District General Hospital</u><br>The automatic sliding door at the rear entrance to the mortuary does not completely close. The door has a key lock and the hook-lock mechanism can be seen even when locked. The gap and exposure of the lock mechanism compromises the security of the door.<br>*The establishment submitted sufficient evidence to address this shortfall before the report was finalised* | **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 | Tissue traceability audits for Sunderland Royal Hospital (SRH) mortuary are not up to date. However, the establishment stated they are already addressing this. In addition, these audits do not include tissue traceability records completed in the mortuary. Audits commence when specimens arrive at the laboratory of another linked licensed establishment. | **Minor** |
| **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>Sunderland Royal Hospital</u><br>Some areas require attention. The inspection team identified the following:<br>• The cupboard doors of the unit in the body store has minor damage exposing porous wood underneath.<br>• The seals around the hand wash sinks in the PM rooms have deteriorated and the adjacent wall areas are showing wear.<br>• The floor edging adjoining the walls in the PM rooms is coming away in some places.<br>• The edge of a shelf in the PM room has been covered with tape as there is underlying minor damage.<br>• The fridge door seals require cleaning or replacing.<br><u>South Tyneside District General Hospital</u><br>• The top of the unit in the fridge room has minor damage exposing porous wood underneath.<br>• The floor edging adjoining the fridges (in particular) in the body store is not completely sealed<br>Areas with damage or inadequate sealing mean they cannot be adequately cleaned and disinfected. | **Minor** |
| **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 | The establishment do not currently test the lower alarm trigger points for the body store fridges to provide assurance they will trigger should temperatures drop too low. | **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 items of equipment used to measure body size in the PM room have been repaired with tape, meaning they cannot be adequately cleaned or disinfected.<br>*The establishment submitted sufficient evidence to address this shortfall before the report was finalised* | **Minor** |
| c) The ventilation system provides the necessary ten air changes per hour and is checked and maintained at least annually | The last ventilation report for STDGH from November 2023 indicates the system does not meet the required standard for supply air change rates. Although action was taken to address this, the November 2024 report indicates the system still does not meet the required standard.<br>*See advice item 8* | **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. | C1(a) | The DI is advised to ensure references to seeking consent for adult consented PM examinations is removed from relevant Trust policies, mortuary SOPs and other documentation. |
| 2. | GQ1(a) | The DI is advised to inform the Trust that the following policies are past their review dates:<br>• Data Protection, Confidentilaity and Disclosure of Information (STS-IG3.DPC-V1 - Review date November 2022) |

| | | |
|---|---|---|
| | | • Management of Sudden Unexpected Death of a Child (CG0510 – Review date November 2023)<br>The mortuary manager is advised to include the normal fridge temperature ranges, alarm trigger points and time delay before the alarms will trigger in the relevant SOP. |
| 3. | GQ4(a) | The DI is advised to consider the benefits of using and storing mortuary records electronically as the majority of records are currently paper-based. |
| 4. | T1(c) | The mortuary manager is advised to:<br>• ensure that when bodies are admitted to the mortuary with more than one identification band, mortuary staff check all identification bands to ensure they are correct and match.<br>• look into alternative options for recording the unique identifier of a deceased on their identification band that will not wash off should these become wet. |
| 5. | PFE1(d) | The DI is advised to:<br>• use the mortuary security alarm that is already installed at SRH as another security measure and continue with the plans to include the mortuary garage area.<br>• continue with the plans to upgrade the PM room door from the body store to swipe card access at STDGH.<br>• change any security alarm or key pad door codes on a regular basis. |
| 6. | PFE1(e) | The DI is advised to ensure that the visitor logs for the mortuaries are fully completed for identification checks and exit times. |
| 7. | PFE1(a) | The mortuary manager is advised to investigate the cause of the patchy staining on the PM room floor under the dissection bench at SRH and explore options to address this. |
| 8. | PFE3(c) | The DI is advised to ensure that the ventilation system reports for both sites are made available to the mortuary manager in a timely manner. This will help ensure oversight of actions by the estates departments if any issues are identified and provide assurance that the systems are working to the required standard. |

## Background

Sunderland Royal 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 February 2022.

Since the previous inspection, South Tyneside District Hospital has become a satellite site under this licence. In addition, the decision has been taken by the establishment to not offer adult consented PM examinations at either site.

## 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 for the mortuary were reviewed. This included standard operating procedures, risk assessments, audits, incidents, meeting minutes, equipment servicing reports, and training and competency assessment documents. Consent seeking procedures and information for families giving consent for perinatal PM examinations 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, viewing rooms, PM rooms and the fridge storage area in the maternity unit at the hub site.

*Audit of records*

The inspection team undertook audits of traceability for nine bodies across both sites. This included eight adults from the hospital and community and one perinatal case. There were no bodies in long term storage at the time of the inspection. Traceability details were crosschecked between the identification bands on the bodies, information on the door of the body store, the body store whiteboard, the mortuary register and mortuary documentation. Three discrepancies were identified at the satellite site (see shortfall against standard T1(c)).

*Meetings with establishment staff*

The assessment team met with staff carrying out processes under the licence, including mortuary staff, quality manager, portering staff, pathologists, staff involved in the consent seeking process for perinatal PM examination, staff responsible for the removal of relevant material in the Emergency Department and the DI.

**Report sent to DI for factual accuracy: 22 November 2024**

**Report returned from DI: 06 December 2024**

**Final report issued: 19 December 2024**

**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: 4 March 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.