Inspection report on compliance with HTA licensing standards
Inspection date: **24 and 27 July 2023**

York Hospital

HTA licensing number 12093

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 **York Hospital**	Licensed	Licensed	Licensed
Mortuary	*Carried out*	*Carried out*	*Carried out*
Pathology Laboratory	-	-	*Carried out*
A&E	-	*Carried out*	-
Satellite site **Scarborough Hospital**	Not licensed	Licensed	Licensed
Mortuary	-	*Carried out*	*Carried out*

A&E	-	*Carried out*	-
Satellite site **Hull Royal Infirmary**	Not licensed	Licensed	Licensed
Pathology Laboratory	-	-	*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 York Hospital ('the establishment') had met the majority of the HTA's standards, six major and four minor shortfalls were found against standards for Consent, Governance and quality systems, Traceability and Premises, facilities and equipment. These related to standard operating procedures (SOPs), audits of security, staff competency assessments, incident reporting, identification procedures for viewing undertaken out-of-hours at the satellite site, fridge and freezer alarm testing and monitoring, the consent policy and maintenance of the external area at the satellite site.

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.	SOPs did not always include sufficient detail of procedures or reflect current practice. These include but are not limited to: • The SOPs in use for portering staff did not include detail of incident reporting, including incidents that should be reported to the HTA, security procedures in the mortuaries or fully detail the procedure for transfer of bariatric bodies at the satellite site. • Whilst there is a Trust policy in place for lone working, there is no mortuary specific SOP. • The SOP for transfer of tissue and organs did not include reference to the tissue / organ receipt form in use or detail the procedure undertaken to ensure arrival of tissue and organs at the referral center when the receipt form is not returned. • The SOP for the handling of SUDIC specimens did not detail the number and types of identifiers samples are labelled with or the checks undertaken to ensure correct samples are sent away for testing. To fully address this shortfall the establishment should review all SOPs to ensure they contain sufficient detail, are reflective of current practice and cover all mortuary and laboratory procedures relevant to licensed activity.	**Major**

GQ2 There is a documented system of audit		
a) There is a documented schedule of audits	Whilst the premises are secure and there are systems in place to prevent unauthorised access, security audits of access and review of CCTV have not been undertaken. (see *Advice* item 9)	**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	Porters undertaking mortuary duties at the satellite site, Scarborough Hospital, had not been assessed as competent in the following key procedures: • Out-of-hours viewing of the deceased. • Transfer of bariatric bodies to the mortuary using the 'X-Cube' bariatric transfer system. This poses risks to the viewing of the wrong body and to transfers of bariatric bodies being undertaken in a manner that could compromise dignity of the deceased.	**Major**
T1 A coding and records system facilitates traceability of bodies and human tissue, ensuring a robust audit trail		
a) Bodies are tagged/labelled upon arrival at the mortuary	During the review of the establishment's incident log, the inspection team identified that 12 incidents had been reported in the previous year of bodies arriving to the mortuary from hospital wards unlabelled. This poses both a risk of misidentification of bodies in the mortuary and raises concerns about accuracy of patient identifiers more generally at ward level. Preventative actions implemented at ward level do not appear sufficient in mitigating risk of reoccurrence.	**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	Whilst there was a form in place to cross-check three points of identification on the body to information provided by visitors at the time of arrival, porters undertaking this procedure out-of-hours at the satellite site are initially only provided with the name of the deceased by the site manager to prepare the body for the viewing. This poses the risk viewing of the wrong body. (see *Shortfall* against HTA standard GQ3(c)).	**Major**
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	Whilst the alarms of fridge and freezer units at both the hub and satellite site are regularly challenged in hours, the out-of-hours procedures were not challenged to ensure they would work as expected.	**Major (cumulative)**
f) Temperatures of fridges and freezers are monitored on a regular basis	Temperature monitoring of fridge and freezer units was not undertaken during weekends and bank holidays at the satellite site, Scarborough Hospital mortuary. (see *Advice* item 6)	

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		
a) There is a documented policy which governs consent for post-mortem examination and the retention of tissue and which reflects the requirements of the HT Act and the HTA's Codes of Practice	The policy which governs consent for post mortem (PM) examination did not include detail that consent can be given by the person in life or by a nominated representative following death. Furthermore, it did not detail that staff not trained in the consent seeking process must be accompanied by a trained individual.	**Minor**
GQ5 There are systems to ensure that all untoward incidents are investigated promptly		
a) Staff know how to identify and report incidents, including those that must be reported to the HTA	Whilst staff know how to identify and report incidents, some incidents falling within the HTA reportable incident (HTARI) categories had not been reported to the HTA as the establishment had determined them to be a near miss. (see *Advice* item 5)	**Minor**
GQ6 Risk assessments of the establishment's practices and processes are completed regularly, recorded and monitored		
a) All procedures related to the licensed activities (as outlined in standard GQ1) are risk assessed on a regular basis	Whilst mitigations were in place to prevent a release of the wrong body, and the establishment have risk assessments which cover misidentification of body incidents, the risk of release of the wrong body was not included in these assessments.	**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	Whilst the mortuaries were clean and well maintained, the outside corridor used for transfer of bodies from the hospital to the mortuary at the satellite site, Scarborough Hospital, was reported to have poor lighting when transfer of bodies occurs out of hours.	**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(c)	The DI is advised to include reference in the adult PM information leaflet that material retained at PM examination may be disposed of if not collected within a specified timeframe where a request for return at a later date has been made. Whilst the consent form used for perinatal PM includes detail of how families can change their mind or withdraw their consent to PM examination, the DI is advised to reference this in the perinatal PM information leaflet also.
2.	C1(g)	The DI is advised to ensure the adult consent form in use is the version agreed from findings at a previous inspection.
3.	GQ1(g)	The DI is advised to invite the newly appointed Persons Designated (PD) from the laboratory at the Hull satellite site to HTA meetings.
4.	GQ2(c)	The DI is advised to align the PM tissue audit processes across the laboratories for consistency.
5.	GQ5(a)	The DI is advised to place visual HTARI guidance in the areas in which licensed activity takes place.

		This will assist staff working in such areas to understand the types of incidents which require reporting to the HTA. Details of who should be informed of an incident within the establishment both in, and out-of-hours so timely HTARI reporting can be completed should also be included. The DI is also advised to review the HTARI SOP to ensure links to the HTA website are working and that the information provided on HTARI categories reflects the latest guidance form the HTA.
6.	GQ6(c)	Plans to relocate and upgrade the mortuary at the satellite site, Scarborough Hospital are currently in progress due to the size and age of the equipment and premises. The DI is advised to continue to have oversight of these plans to ensure the mortuary facilities continue to be fit for purpose in the long term. Furthermore, the DI is advised to continue with the plans to employ an additional staff member this year at this site. A review of progress and outcome will be undertaken as part of the next routine inspection.
7.	T1(a)	The DI is advised to liaise with local police forces to improve the system for the labelling of bodies at the place of death prior to admission to the mortuary. This may ensure the number and types of identifiers used on identification bands is consistent.
8.	T1(b)	The mortuaries were heavily reliant on paper-based tracking systems for the deceased. Due to the number and location of body storage areas the DI is advised to consider an electronic mortuary tracking system so staff can manage traceability of the deceased and their associated records more effectively.
9.	PFE1(e)	The DI is advised to consider the following to improve security measures in the mortuaries: • The inclusion of CCTV in the body storage area at the hub site which can be reviewed should any incidents occur out-of-hours. • That all visitors to the satellite site sign into the visitor log (as per the hub site) so this can be reviewed as part of the security audit process. • That doors reliant on the use of manual locks be reviewed and alternative security measures considered to prevent unauthorised access to secure areas should the manual locks not be deployed.
10.	PFE3(f)	The DI is advised to regularly monitor and maintain the condition of hydraulic body trolleys in use in the mortuaries and the body storage unit doors at the satellite site as they were starting to show signs of

		rusting and minor damage. Furthermore, the DI is advised to remove PM room equipment at the satellite site that is no longer in use.

Background

York Hospital has been licensed by the HTA since June 2007. This was the fourth inspection of the establishment; the most recent previous inspection took place in April 2019.

Since the previous inspection, there has been a change of DI in December 2019, with the current DI in post since May 2023. A change to the Corporate Licence Holder contact took place in May 2023. The activity of 'making of a PM examination' was removed from the licence at the satellite site, Scarborough Hospital in September 2020 and an addition of a satellite site 'Hull Royal Infirmary pathology laboratory' took place in July 2023.

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 policies and procedural documents relating to licensed activities. This included cleaning records for the mortuary and PM room, records of servicing of equipment, fridge and freezer alarm testing records, ventilation reports, body and tissue traceability audits, risk assessments, meeting minutes, temperature monitoring for the storage units, reported incidents, and staff training and competency records. Consent seeking policies and procedures, information for relatives giving consent and consent forms in use for both adult and perinatal PM examination were also reviewed.

Visual inspection
The inspection team undertook a visual inspection of the premises at the hub and satellite sites. This included the mortuary body storage areas, the PM rooms and viewing rooms. The areas for the storage of relevant material held within the pathology departments was also reviewed.

Audit of records
The inspection team undertook audits of traceability for five bodies in storage at the hub site and four bodies in storage at the satellite site. This included a body stored longer term and a perinatal body. Traceability details were cross-checked between the identification bands on the body, information on the door of the storage units, the mortuary register, and associated paperwork. Two minor discrepancies were identified at the hub site; however, these were rectified at the time of the inspection.

Audits were conducted of tissue taken at PM examination for six cases at the hub site and five cases at the satellite site. Information was crosschecked between the mortuary traceability documentation, Coroner's paperwork, family wishes forms, the electronic databases and the tissue blocks and slides being stored. No discrepancies were identified.

Meetings with establishment staff
The inspection team met with staff carrying out processes under the licence, including mortuary staff, members of the portering teams, members of the laboratory staff, a pathologist, staff involved in the consent seeking process for adult and perinatal PM examination, a member of the team from the Emergency Department undertaking removal of relevant material for SUDIC purposes and the DI.

Report sent to DI for factual accuracy: 30 August 2023

Report returned from DI: 13 September 2023

Final report issued: 20 September 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: 19 June 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.