Inspection report on compliance with HTA licensing standards
Inspection date: **24/04/2025**

Northampton General Hospital

HTA licensing number 12253

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 **Northampton General Hospital**	Licensed	Licensed	Licensed
Mortuary	*Carried out*	*Carried out*	*Carried out*
Pathology lab	-	-	*Carried out*
Maternity	-	-	*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 Northampton General Hospital ('the establishment') had met the majority of the HTA's standards, eight major and four minor shortfalls were found against standards for Governance and quality systems, Traceability and Premises, facilities and equipment.

Three of the shortfalls relate to findings from the last inspection. A similar issue was identified in three of the Major shortfalls (standards GQ6(b), PFE2(c) and (e) that were found in the previous inspection carried out in October 2022.

This was acknowledged by the establishment and progress will be monitored through an agreed corrective action plan.

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.

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 Standard Operating Procedures (SOPs) lack detail and are not consistently reflective of best practice and the practices staff use. This includes the SOPs for: • Admission of deceased • Viewing of deceased • Release of deceased • Risk management and incident reporting • High Risk Post mortems (PMs) This is not an exhaustive list of the SOPs requiring amendment. To fully address this shortfall, the establishment should review all SOPs to ensure they are accurate and contain sufficient detail to reflect current practice.	**Major (cumulative)**
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.	Whilst most SOPs have been reviewed regularly, some SOPs have not been reviewed in line with the documented review date. This includes SOPs for: - Tissue retrieval - High Risk PMs - Body status checks - Admissions to the mortuary This poses the risk of staff following processes which are no longer in place.	
GQ2 There is a documented system of audit		

a) There is a documented schedule of audits	A security audit is scheduled to be undertaken once a month. However, at the time of the inspection, there were no records available to review indicating an audit of the CCTV feed against swipe card access logs had been carried out for at least three months.	**Major**
GQ3 Staff are appropriately qualified and trained in techniques relevant to their work and demonstrate competence in key tasks		
a) All staff who are involved in mortuary duties are appropriately trained/qualified or supervised	The inspection team are not assured all staff who undertake licensed activity are appropriately trained. There were no records available to review showing that mortuary staff had received role specific assessments from the establishment. This poses a risk of a serious incident occurring	**Major (cumulative)**
c) Staff are assessed as competent for the tasks they perform	The inspection team are not assured all staff who undertake licensed activity have undertaken a competency assessment. Mortuary staff competency records were incomplete and did not reflect staff had been assessed as competent to undertake all mortuary tasks. This poses the risk of a serious incident occurring. *(See advice item one below)*	
GQ6 Risk assessments of the establishment's practices and processes are completed regularly, recorded and monitored		

b) Risk assessments include how to mitigate the identified risks. This includes actions that need to be taken, who is responsible for each action, deadlines for completing actions and confirmation that actions have been completed	Some risk assessments lack detail of the mitigating controls used by staff. This includes risk assessments for: • Lone working in the mortuary • Release of bodies • Post Mortem Examinations This is not an exhaustive list of the risk assessments requiring amendment. To fully address this shortfall, the establishment should review all risk assessments to ensure they are accurate and contain sufficient detail to reflect current practice. *(See advice item two below)*	**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 three identifiers that are obtained from family members when organising a viewing are checked against written records. However, the inspection team were not assured that this information was checked against the wristbands on the body prior to the family being shown into the viewing room. This poses the risk of the viewing of the wrong body.	**Major (cumulative)**

g) Organs or tissue taken during post-mortem examination are fully traceable, including blocks and slides (including police holdings).	During the inspection, cases were identified where the number of blocks and slides taken had not been recorded onto the paper record card before being scanned into the laboratory information management system (LIMS) as per the SOP. For one case there was no record on the LIMS of tissue received, however, blocks and slides had been created and stored. This poses the risk of a loss of tissue traceability and the retention of tissue against the wishes of the family.	
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	There are some areas of damage to the fabric of the building: • There is damage to the floor seals in the PM suite and body store • There is breach in the seal between the base of the PM tables and the floor • The door frames have sustained damage leading to some areas of exposed wood • There is an area of exposed plaster in the PM suite This may prevent effective decontamination. Furthermore, whilst the PM suite had recently been cleaned there was some residual debris in the floor drainage holes. *The establishment submitted sufficient evidence to address this shortfall before the report was finalised.*	**Major**
PFE2 There are appropriate facilities for the storage of bodies and human tissue.		

c) Storage for long-term storage and bariatric bodies is sufficient to meet needs.	There is insufficient freezer storage capacity to meet establishment needs. During the body audit there were bodies held in refrigerated storage for longer than the HTA's recommended 30 days. There are five freezer spaces available and none of these are suitable for the storage of bariatric bodies.	**Major**
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 fridge used for the storage of pregnancy losses on the Maternity unit is not connected to a remote temperature monitoring system. Whilst the fridge does have an audible local alarm, due its location it would not be heard by staff out of hours (OOH). Furthermore, whilst there is regular temperature monitoring in place, there is no regular alarm testing of the upper and lower set range on maternity, and the lower set range in the mortuary. Additionally, Out of Hours (OOH) alarm testing is not carried out in the mortuary. This poses the risk of accidental damage to a body.	**Major**

Minor Shortfalls

Standard	Inspection findings	Level of shortfall
GQ1 All aspects of the establishment's work are governed by documented policies and procedures		
h) Matters relating to HTA-licensed activities are discussed at regular governance meetings involving establishment staff	There is regular communication between mortuary staff and staff undertaking licensed activity in areas outside the mortuary. However, there were no records available to review indicating regular formal governance meetings were undertaken.	**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, the inspection team identified several near misses which met the threshold for reporting to the HTA which had not been reported.	**Minor**
PFE2 There are appropriate facilities for the storage of bodies and human tissue.		
i) There are documented contingency plans in place should there be a power failure or insufficient numbers of refrigerated storage spaces during peak periods	Whilst there are contingency plans in place detailing actions to be taken in the event of a power failure or insufficient storage spaces. There were no documents available for review relating to contingency planning in the event of the need for a bariatric body to be transferred into long term (frozen) storage.	**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	There was moderate rusting to three hydraulic trolleys used to transfer the deceased. This poses a risk of ineffective cleaning and decontamination.	**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.	GQ3(c)	The DI is advised to document the method used to assess the competency of staff undertaking activities under the licence.

2.	GQ6(b)	Whilst high risk PM examinations are not routinely undertaken, the DI is advised to risk assess if the current face masks in use provide suitable protection for staff in the event of the discovery of an undiagnosed airborne pathogen.
3.	PFE1(d)(e)	The DI is advised to review the time it takes for the main door to the mortuary to close to ensure any risk of tailgating or unauthorised access is mitigated. Furthermore, the DI is advised to consider the introduction of a “man down” alarm for staff to use when lone working.
4.	PFE3(f)	The systems and equipment within the mortuary are subject to regular testing and servicing however records are not kept within the mortuary and are only available upon request. The DI is advised to request copies of all maintenance, servicing and repair reports so that they are easily accessible to mortuary staff for review and monitoring purposes.

Background

Northampton General Hospital has been licensed by the HTA since 2007. This was the fourth inspection of the establishment and the first inspection using the unannounced methodology. The most recent previous inspection took place in October 2022.
Since the previous inspection, there have been no significant changes to the licensed activity within the establishment. However, there has been a change to the licensed personnel with a change to the Corporate Licence Holder contact (CLHc) in October 2024.
Offsite building work is currently being undertaken to enable county wide mortuary services to be merged and operate from a single 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 documents provided by the DI after the inspection. Policies and procedural documents relating to licensed activities were reviewed. Traceability audits, risk assessments, staff training and competency records, staff annual appraisals, meeting minutes, cleaning logs and schedules, maintenance records, incidents, consent seeking procedures, and information for relatives giving consent was also reviewed.

Visual inspection
The inspection team undertook a visual inspection of the premises which included the PM suite, mortuary body storage area and viewing room. The area within the maternity department for the storage of bodies was inspected as well as the storage arrangements for relevant material held within the pathology department.

Audit of records
The inspection team undertook audits of traceability for five bodies in storage and witnessed the release of three bodies into the care of Funeral Directors. Traceability details were crosschecked between the identification band on the body, the mortuary register, the electronic mortuary database, and associated paperwork. No discrepancies were identified.
Audits were conducted of tissue taken at PM examination for nine cases. Information was crosschecked between consent forms, information on the laboratory database and tissue blocks and slides being stored. Discrepancies were identified in the record keeping of six cases. Refer to shortfall T1(g) above.

Meetings with establishment staff
The inspection team met with staff carrying out processes under the licence, including the lead APT, Pathology Systems Manager, laboratory staff, portering staff, a Pathologist, staff involved in the consent seeking process for adult and perinatal PM examination, and the DI.

Report sent to DI for factual accuracy: 22 May 2025

Report returned from DI: 02 June 2025

Final report issued: 02 June 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.