Inspection report on compliance with HTA licensing standards
Inspection date: **14 February 2024**

North Tyneside General Hospital

HTA licensing number 12261

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 **North Tyneside General Hospital**	Licensed	Licensed	Licensed
Mortuary	*Carried out*	*Carried out*	*Carried out*
Pathology lab	-	-	*Carried out*
Satellite **Northumbria Specialist Care Hospital**	Not licensed	Licensed	Licensed
Mortuary	-	*Carried out*	*Carried out*

A&E	-	*Carried out*	-
Maternity	-	*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 North Tyneside General Hospital ('the establishment') had met the majority of the HTA's standards, one major and six minor shortfalls were found against standards for Consent, Governance and quality systems 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 Standard Operating Procedures (SOPs) lack detail and have not been updated to reflect current practices, for example; ○ The reception and storage of bodies SOP does not detail the electronic register that is in use. ○ The viewing SOP does not detail the final identification check that takes place after the family has arrived to visit the deceased. ○ The release SOP does not detail the identification checks that take place when bodies are transferred between hospital sites. ○ The long term storage of bodies SOP does not detail the condition checking processes that are in place. ○ The body store shortage SOP does not detail contingencies in place if freezer or bariatric storage capacity is reached. ○ The SOP for post mortem (PM) examinations with high risk infection hazards lacks detail. Whilst some SOPs detail that staff must use three points of identification of the deceased during identification procedures, some SOPs were not fully clear that it is three identifiers on the body that must be used to match against documentation in the relevant procedure. SOPs for mortuary activities are overarching across sites however there are some site specific procedures that are not documented. To fully address this shortfall the establishment should review all documents to ensure that they are reflective of current practice at each of the sites they cover.	**Major**

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		
b) There is a documented standard operating procedure (SOP) detailing the consent process	The SOP for gaining consent for perinatal PM examinations is overdue review. The SOP for the storage and disposal of tissue retained at PM examination references next of kin throughout. This implies that consent could be obtained from someone other than the person ranked highest in the hierarchy of qualifying relationships, however the inspectors found no evidence of this.	**Minor**
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	The establishment do not conduct audits of PM tissue being stored in the block and slide archive.	**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	Competency assessments do not include PM examination techniques such as evisceration. Not all porters have been trained on the equipment that is used to transfer bariatric patients to the mortuary.	**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	The SOP for the reporting incidents does not provide enough detail to ensure that staff are fully aware of what needs to be reported to the HTA. During the inspection two incidents were identified as potential near-miss HTARIs however these had not been reported to the HTA.	**Minor**
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	Lone working at the satellite site is commonplace and although this has been risk assessed, there are few formalised arrangements for staff in place to mitigate the risks identified. Lone working has the potential for greater risks to staff and the dignity of the deceased and more careful management and oversight is required.	**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.	There are some areas of the PM room and fridge room floor that are cracked and require repair. There are some areas of rusting on the bottom of the fridges that require maintenance. There are sticky black marks on the fridge doors which have been caused by labels that require cleaning.	**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.	GQ1(a)	There are two separate SOPs in place for PM and reconstruction of a body. As this is one procedure the DI is advised to combine the two SOPs so that the procedure is documented from start to finish.
2.	GQ1(e)	The establishment only redistribute SOPs after changes have been made. The DI is advised to redistribute SOPs after review even when there are no changes made as part of refresher training.
3.	GQ2(c)	There are two separate security audits, one that covers the review of swipe card access and one that covers CCTV review. The DI is advised to combine the two audits to ensure that everyone entering the mortuary has legitimate right of access and to fully scrutinise the purpose, frequency and duration of access.
4.	GQ6(a)	The risk assessment for PM details that serology is taken on high risk cases, however it was determined that this is not commonplace, and would not occur unless necessary and appropriate consent was obtained. The DI is therefore advised to remove reference to this in the document.
5.	T1(c)	The DI is advised to review and update the viewing form checklist to include written confirmation of the three-point identification check that is completed at the point of arrival of visitors and prior to the viewing. This will act as a reminder to staff, and well as ensuring a complete and auditable procedure.
6.	PFE2(e)	The fridge and freezer units are temperature monitored, alarmed and temperature is reviewed for trends. The alarm is triggered if the temperature increases over 10 degrees Celsius. The DI is advised to review this temperature to ensure that the condition of bodies is appropriately preserved should there be an issue.

Background

North Tyneside General Hospital has been licensed by the HTA since August 2007. This was the fourth inspection of the establishment; the most recent previous inspection took place in March 2018.

Since the previous inspection, there have been significant changes to the licence arrangements including a change to the Designated Individual (DI) in 2022. Furthermore, the satellite licence for Hexham General Hospital was revoked in 2019 after licenced activities were ceased.

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 and Quality Manager. Policies and procedural documents relating to licensed activities 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 adult and perinatal PM's were also reviewed.

Visual inspection
The inspection team undertook a site visit inspection which included the mortuary body storage areas, PM room and histopathology storage areas at the hub site and the mortuary body storage area at the satellite site.

Audit of records
At the hub site, the inspection team undertook traceability audits for four bodies in storage including one body that was stored in the freezer. Traceability details were crosschecked between the identification bands on the body and information on the electronic and paper records. No discrepancies were identified.

At the satellite site, the inspection team undertook traceability audits for three bodies in storage. Traceability details were crosschecked between the identification bands on the body and information on the electronic and paper records. No discrepancies were identified.

Audits were conducted of stored tissue taken at PM examination for four cases. Information was crosschecked between the mortuary documentation, Coroner's paperwork, family wishes forms, the mortuary electronic database, and tissue being stored. No discrepancies were identified.

Meetings with establishment staff
The assessment team met with staff carrying out activities under the licence, including the Cellular Pathology and Mortuary Manager, Quality Manager, Quality Lead, Senior APT, Trainee APT, Porters at both sites, a paediatric emergency lead and A&E consultant, and a Consultant Histopathologist who is the establishment's DI.

Report sent to DI for factual accuracy: 5 March 2024

Report returned from DI: 13 March 2024

Final report issued: 20 March 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.