Inspection report on compliance with HTA licensing standards
Inspection date: **09 April 2025**

Airedale General Hospital

HTA licensing number 12138

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 **Airedale General Hospital**	Not licensed	Licensed	Licensed
Mortuary	-	-	*Carried out*
Pathology lab	-	-	*Carried out*
Maternity	-	*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 Airedale General Hospital ('the establishment') had met the majority of the HTA's standards, three major and three 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
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	Whilst there is guidance in place for staff to follow when seeking consent for adult and perinatal post mortem examinations (PMs), it does not detail the length of time given to those giving consent to change their mind. Furthermore, the SOPs have not received a documented review within the expected establishment timeframe. *The establishment submitted sufficient evidence to address this shortfall before the report was finalised.*	**Major (cumulative)**

c) There is written information for those giving consent, which reflects the requirements of the HT Act and the HTA's codes of practice	Whilst there is written information available for those giving consent, the documents have not received a documented review within the timeframe expected by the establishment. *The establishment submitted sufficient evidence to address this shortfall before the report was finalised.*	
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 unauthorised access and ensure oversight of visitors and contractors who have a legitimate right of access	The door between the viewing room and the body store cannot be effectively secured. This poses the risk of unauthorised access to the body store by visitors to the mortuary.	**Major**
PFE2 There are appropriate facilities for the storage of bodies and human tissue.		
d) Fridge and freezer units are in good working condition and well maintained	Whilst fridge and freezer units are subject to regular maintenance, some of the fridge door seals were coming away from the fridge doors. *The establishment submitted sufficient evidence to address this shortfall before the report was finalised.*	**Major (cumulative)**
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 bodies in maternity is not attached to the central alarm system. Whilst the fridge does have an audible local alarm, it would not be heard by staff working outside the room where the fridge is located. This poses the risk of accidental damage to a body.	

Minor 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.	Whilst most of the SOPs had been reviewed and were reflective of staff practice and HTA guidance. The SOP relating to the reporting of incidents had not received a documented review since 2023 and was not reflective of the HTA guidance updated in March 2024. *The establishment submitted sufficient evidence to address this shortfall before the report was finalised.*	**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 premises were clean at the time of the inspection, the non porous cladding on a door in the body store was peeling exposing the wood beneath. Furthermore, a wooden tray was being used as a shelf. This means these areas would be difficult to effectively disinfect and decontaminate. *The establishment submitted sufficient evidence to address this shortfall before the report was finalised.*	**Minor**
PFE2 There are appropriate facilities for the storage of bodies and human tissue.		

g) Bodies are shrouded or in body bags whilst in storage	The Inspection team identified some bodies where there was insufficient shrouding and bodies were not fully covered whilst in storage *The establishment submitted sufficient evidence to address this shortfall before the report was finalised.*	**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 liaise with the third party responsible for the production and governance of the referral document for perinatal PMs. The document currently states “July 2013” which suggests this was the last review date.
2.	GQ4(a)	The DI is advised to continue with existing plans to transfer governance documents to the newly purchased electronic record keeping system, as this will support the oversight of documents for review.
3.	GQ5(a)	The DI is advised to expand the current guidance regarding HTA reportable incidents given to Porters to include all reportable incidents relevant to their role.
4.	PFE2(a)	The DI is advised to undertake a review of the storage arrangements on Maternity to ascertain if the current fridge is a suitable size for the storage of pregnancy losses of all gestations.

5.	PFE2(e)	The DI is advised to add alarm testing of fridges out of hours to the existing fridge temperature testing schedule to ensure the system works as expected during times when the mortuary is closed.

Background

Airedale General Hospital has been licensed by the HTA since May 2007. This was the fifth inspection of the establishment and the first inspection using the unannounced methodology. The most recent previous inspection took place in September 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 December 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 of the 72 HTA licensing standards were covered during the inspection (standards published 3 April 2017), GQ1(b), T2(b) and PFE3(e) were not applicable. The establishment does not undertake PM examination and are only holding historical PM tissue with consent for storage for a scheduled purpose. This means the establishment have no ongoing interaction with the coroner's office.

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, 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 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 four bodies in storage. Traceability details were crosschecked between the identification band on the body, information on the mortuary whiteboard, the mortuary register, the electronic mortuary database, and associated paperwork. No discrepancies were identified.
Audits were conducted of historical tissue taken at PM examination for one case. Information was crosschecked between consent forms, information on the laboratory database and 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 the mortuary manager, mortuary assistant, laboratory staff, a member of the portering staff, staff involved in the consent seeking process for adult and perinatal PM examination, and the DI.

Report sent to DI for factual accuracy: 29/04/2025

Report returned from DI: 16/05/2025

Final report issued: 16/05/2025

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.