Inspection report on compliance with HTA licensing standards
Inspection date: **22 and 26 September 2022**

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*	*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 six minor shortfalls were found against standards for Consent, Governance and quality systems and Premises, facilities and equipment. These related to competency assessment of those seeking consent, standard operating procedures, alarms on equipment and maintenance of the body storage area.

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

Minor Shortfalls

Standard	Inspection findings	Level of shortfall
C2 Staff involved in seeking consent receive training and support in the essential requirements of taking consent		
d) Competency is assessed and maintained	Whilst regular training and refresher training is provided to post mortem (PM) consent seekers and all consent forms are checked for accuracy of completion, there is no formal system in place to assess and record the competency of those seeking consent.	**Minor**
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.	Standard Operating Procedures (SOPs) do not always include sufficient detail of identification checks performed relating to traceability of bodies or describe current practice. These include but are not limited to: • IPS_Histo_LPM_01 Receipt of bodies – the SOP does not detail the identifiers of the deceased which should be recorded on identification bands in the rare event a body is received from ambulance staff. Furthermore, it does not detail how the regular condition checks of bodies are to be recorded. • IPS_Histo_LPM_03 Viewing during working hours – this SOP details that three identifiers of the deceased are checked against mortuary records when preparing a body for viewing, however, in practice, the establishment are using the identifiers provided by the family at the point of making a viewing request on a viewing form which would be the expectation to ensure the correct body is being prepared. To fully address this shortfall the establishment should review all SOPs relating to traceability of bodies to ensure they contain sufficient details of identification checks performed and are reflective of current practice.	**Minor**
GQ2 There is a documented system of audit		
a) There is a documented schedule of audits	The establishment complete weekly audits of traceability of bodies in storage, which include checking the condition of the deceased, however, these audits are not formally recorded.	**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, there are some areas of damage to walls in the body store exposing plaster and a radiator which is showing signs of rust. Furthermore, a wooden body measuring tool is in use. This means these areas would be difficult to effectively disinfect and decontaminate.	**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	Whilst the fridges in the mortuary and maternity department are monitored frequently and temperatures are recorded and analysed for trends, the inspection team identified the following: • the maternity unit is not connected to the remote fridge alarm system • the upper alarm trigger point for the mortuary fridges is currently set at 12 degrees Celsius. This may risk bodies being stored in suboptimal temperatures before an alarm would trigger.	**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	One mortuary hydraulic trolley has areas of rust which means it would be difficult to effectively disinfect and decontaminate.	**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)	Whilst it is verbally discussed with those giving consent that the body of the deceased is transferred to another licenced establishment for PM examination, the DI is advised to reference this in the information leaflets for relatives for adult and perinatal PM examination. This would ensure those giving consent have relevant information of the process to make informed decisions.
2.	GQ3(c)	The DI is advised to review how competency assessments of mortuary staff are recorded. Whilst competency assessment includes being assessed and observed completing specific tasks against SOPs, the system currently uses a combination of a tick box or comments section to indicate a staff member has been assessed. It is advisable to capture comments on competency for all tasks so it is clear what was observed and how this demonstrates the staff member is competent.
3.	GQ5(a)	The DI is advised to place visual Human Tissue Authority reportable incident (HTARI) guidance in the areas licensed activity takes place. This will assist staff working in such areas to understand the types of incidents which require reporting to the HTA. Detail 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.
4.	GQ6(b)	Whilst risk assessments have been completed against HTARI categories and control measures to mitigate risks have been identified and documented, the DI is advised to expand on the level of detail of the control measures. For example, where ‘staff training’ has been identified as a control measure, detail should be included of the frequency of any refresher training or competency assessment undertaken.
5.	T1(h)	The DI is advised to ensure the forms produced by the Coroner and brought by the Coroner’s contracted funeral director for transfer of deceased for PM examination are also signed and completed by mortuary staff. This would further evidence that transfers are completed using three points of identification of the deceased in an equivalent manner to routine release of the deceased.

6.	PFE1(e)	Whilst there are procedures in place to frequently monitor routine access to the mortuary and any unauthorised visitors are supervised, the DI is advised to introduce a visitor log for visitors to sign into and out of the department.

Background

Airedale General 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 May 2018.

Since the previous inspection, the following changes have been made to the licensing arrangements: the current Corporate Licence Holder contact (CLHc) was approved in 2020, the current DI was approved in 2022 and Persons Designated (PDs) were reviewed and updated in 2022.

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

Three standards (GQ1(b), T2(b) and PFE3(e)) out of the total 72 were not covered during the inspection. These standards 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 self-assessment document provided by the DI in advance of 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, including completed consent forms 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 in close proximity to the mortuary.

Audit of records
The inspection team undertook audits of traceability for four bodies in storage. This included bodies with same / similar names and a body housed in the temporary storage unit in the mortuary. 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 four cases. Information was crosschecked between consent forms, information on the laboratory database and tissue blocks and slides being stored. One case reviewed demonstrated disposal of tissue had been completed in line with the wishes of the family. The further three cases demonstrated they were being held with appropriate consent for a scheduled purpose. No discrepancies were identified.

Meetings with establishment staff
The inspection team met with staff carrying out processes under the licence, including the newly appointed mortuary manager, laboratory staff, a member of the portering staff, staff involved in the consent seeking process for adult and 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: 04 October 2022

Report returned from DI: 04 October 2022

Final report issued: 10 October 2022

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: 9 December 2022

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.