Inspection report on compliance with HTA licensing standards
Inspection date: **27 October 2025**

Digital Autopsy UK

HTA licensing number 12813

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 Digital Autopsy UK	Licensed	Not licensed	Not licensed
CT Scanning Facility	*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 Digital Autopsy UK ('the establishment') had met the majority of the HTA's standards, six major and five minor shortfalls were found against standards for Governance and quality systems, Traceability 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		
h) Matters relating to HTA-licensed activities are discussed at regular governance meetings involving establishment staff	There were no records available to review indicating regular governance meetings to discuss matters relating to HTA business are carried out.	**Major**
GQ2 There is a documented system of audit		
a) There is a documented schedule of audits	There were no records available to review indicating there is a schedule of audits. *The establishment submitted sufficient evidence to address this shortfall before the report was finalised.*	**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 activity under the licence have received regular refresher training for all activities relevant for their role. *The establishment submitted sufficient evidence to address this shortfall before the report was finalised.*	**Major (cumulative)**
c) Staff are assessed as competent for the tasks they perform	The inspection team are not assured all staff who undertake activity under the licence have undertaken a regular competency assessment for all activities relevant for their role.	
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	There was no document available to review indicating the risk of the scanning of the wrong body had been assessed. *The establishment submitted sufficient evidence to address this shortfall before the report was finalised.*	**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	Whilst three identifiers on the body are checked against the transfer paperwork and Coronial instruction, the inspection team were not assured all ID bands present on the body were checked. *The establishment submitted sufficient evidence to address this shortfall before the report was finalised.*	**Major**
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	Staff do not undertake regular documented audits of CCTV recordings against mortuary access via key fob and physical keys. *The establishment submitted sufficient evidence to address this shortfall before the report was finalised.*	**Major**

Minor Shortfalls

Standard	Inspection findings	Level of shortfall
GQ1 All aspects of the establishment's work are governed by documented policies and procedures		
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	Although SOPs are reviewed regularly and there is a collaborative approach to authorship, the documented author and authoriser is the same person for some of the SOPs. *The establishment submitted sufficient evidence to address this shortfall before the report was finalised.*	**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 were not assured staff knew the type of incidents that would need to be reported to the HTA. *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	There are some areas of damage to the fabric of the building: • The door frames have sustained damage leading to some areas of exposed wood • There are some areas of exposed plaster in the scanning room. • A metal cupboard used for storing equipment in the scanning room had significant areas of corrosion. This poses the risk of ineffective cleaning and decontamination.	**Minor**
b) There is demarcation of clean, dirty and transitional areas of the mortuary, which is observed by staff and visitors	Whilst signage was displayed in most areas of the scanning facility, there was no signage between the reception area for bodies and the scanning room to indicate staff were entering a “dirty” area. *The establishment submitted sufficient evidence to address this shortfall before the report was finalised.*	**Minor**
PFE3 Equipment is appropriate for use, maintained, validated and where appropriate monitored		
d) Staff have access to necessary PPE	Whilst face masks are available for staff to use when carrying out invasive procedures, there is no record to demonstrate that staff have received face fit testing for use of this personal protective equipment.	**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.	PFE3(e)	Whilst bodies are scanned through body bags, there are some areas of wear to the cushioned cover on the scanning table. This should be monitored and rectified as any further deterioration could pose the risk of ineffective decontamination.
2.	GQ1(c)	The DI is advised to risk assess the use of CCTV in the scanning room and adjacent office to ensure there are suitable mitigations in place to maintain the dignity of the deceased and prevent any oversight of information by non establishment staff.

Background
Digital Autopsy UK has been licensed by the HTA since September 2025.This was the first inspection of the establishment; the establishment undertakes non invasive CT scanning and minimally invasive post mortem procedures including Aortic Angiography.

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
43 of the 72 HTA licensing standards were covered during the inspection (standards published 3 April 2017), this is because the establishment does not store bodies, remove, store or dispose of tissue or obtain consent.

Review of governance documentation
The inspection included a review of the establishment's governance documentation relating to licensed activities. This included policies and procedural documents relating to licensed activities, cleaning records for the mortuary, records of servicing, audits, risk assessments, meeting minutes, reported incidents and training records for mortuary staff.

Visual inspection
The inspection included a visual assessment of the establishment including body reception area and scanning suite. The inspection team observed the processes for admission and release of bodies from the scanning unit.

Audit of records
Audits were conducted onsite of four bodies transferred from third party establishments, identification details on bodies were crosschecked against the information recorded on the electronic system and associated transfer paperwork. No discrepancies were identified.

Meetings with establishment staff
Staff carrying out processes under the licence were interviewed including the DI, Radiographer and radiography assistant.

Report sent to DI for factual accuracy: 21 November 2025

Report returned from DI: 05 December 2025

Final report issued: 11 December 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.