Inspection report on compliance with HTA licensing standards
Inspection date: **28, 29 and 30 October 2025**

University Hospitals Birmingham
Heartlands Hospital
HTA licensing number 12366

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 **Heartlands Hospital**	Licensed	Licensed	Licensed
Mortuary	*Carried out*	*Carried out*	*Carried out*
Pathology lab	-	-	*Carried out*
Maternity	-	-	*Carried out*
Satellite site **Solihull Hospital**	Not licensed	Not licensed	Licensed

Mortuary (satellite site)	-	-	*Carried out*
Satellite site **Good Hope Hospital**	Not licensed	Licensed	Licensed
Mortuary (satellite site)	-	-	*Carried out*
Maternity	-	-	*Carried out*
Satellite site **Queen Elizabeth Hospital**	Licensed	Licensed	Licensed
Mortuary (satellite site)	*Carried out*	*Carried out*	*Carried out*
Pathology lab	-	-	*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 Heartlands Hospital ('the establishment') had met the majority of the HTA's standards, nineteen major and seven minor shortfalls were found against standards for Consent, Governance and quality systems, Traceability and Premises, facilities and equipment.

Two of the identified shortfalls (C2 d and GQ3 a) pertain to findings from the previous inspection conducted in March 2023. Additionally, five of the identified shortfalls (GQ1a, T1c, T2a, GQ1h, and PFE1e) relate to findings from the previous inspection carried out at the recently added satellite site, Queen Elizabeth Hospital, in October 2022. During the inspection feedback meeting,

the HTA raised concerns that sufficient action had not been taken to adequately address this finding, and that effective, fully embedded procedures had not been implemented during the intervening period. 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.

Compliance with HTA standards

Major shortfalls

Standard	Inspection findings	Level of shortfall
C2 Staff involved in seeking consent receive training and support in the essential requirements of taking consent		
b) Records demonstrate up-to-date staff training	• Although staff receive initial consent training and whilst staff confirmed that hospital consented post-mortems are only undertaken rarely, the establishment was unable to provide evidence that this training is kept up to date or refreshed. • The inspection team also found that there are currently no competency assessments in place for staff involved in seeking consent. *This shortfall was also identified during the previous inspection in 2023.*	**Major** **Cumulative**
d) Competency is assessed and maintained		

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.	The inspection team was not assured there was written guidance in place for all mortuary procedures. No documents were available for review pertaining to: • Lone working in the mortuary • Transfer of bodies internally, for example, for CT scanning • Transfer of bodies and tissue (including blocks and slides) off site or to other establishments • Access to the mortuary by non-mortuary staff, contractors and visitors • Contingency storage arrangements The inspection team was not assured that sufficient written guidance was in place for the following mortuary activities: • The Security SOP does not provide written guidance on how the security audit must be conducted or how frequently it should take place. • The Viewing Procedure SOP does not provide sufficient written guidance to instruct staff to check a minimum of three identifiers on the deceased against details provided by family members when they attend the mortuary for a viewing. Additionally, it does not include specific steps for transferring patients from the body store to the viewing room at Good Hope Hospital, a process that requires moving patients between two trolleys due to misaligned floors. *See also shortfall T1 c and GQ6 a.* This list is not exhaustive. To fully address this shortfall, the establishment should undertake a full review of all SOPs relating to mortuary activities to	**Major**

	ensure that they are accurate, reflect current practice, and provide sufficient procedural detail.	
h) Matters relating to HTA-licensed activities are discussed at regular governance meetings involving establishment staff	While mortuary meetings are held, there are currently no HTA specific meetings that involve the Designated Individual (DI) and all staff groups engaged in licensed activities, such as PDs. Consequently, the DI's oversight is limited, with reliance placed on staff to raise issues and concerns, rather than this being reinforced through regular meetings that would support comprehensive oversight.	**Major**

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 inspection team was not assured that tissue audits include a sufficient sample size to enable the establishment to identify non-conformances and ensure all required follow-up actions are completed in a timely manner. At present, audits are conducted annually, cover only five cases, and do not include a sample of historical cases dating back to the implementation of the Human Tissue Act. Despite the small sample size, the most recent tissue audit identified several delays in the disposal process. As a result, current tissue audits do not provide staff with a comprehensive understanding of long-term tissue retention, hindering the timely disposal of tissue where consent for continued retention has not been provided. *See also shortfalls under the T1 and T2 standards.*	**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	• Significant gaps in training were identified among staff carrying out licensed activities. Members of the Site Team, responsible for out-of-hours viewings and releases, had not received the necessary training. The inspection team instructed that they cease these duties until training is completed. This poses a serious risk, such as the viewing or release of the wrong body. *This shortfall was also identified during the previous inspection in 2023.* *The establishment submitted sufficient evidence to address this shortfall prior to the publication of the report.* • Although initial training is provided, there is no documented refresher training for staff undertaking releases from Maternity directly to funeral directors. This poses a risk of the release of the wrong body. • The Viewing risk assessment states that laboratory staff can provide additional assistance and support for the transfer of bariatric deceased patients. However, the inspection team was not provided with documentation verifying that these staff members have undergone appropriate training for this activity.	**Major**

c) Staff are assessed as competent for the tasks they perform	• Significant gaps in the assessment of competency were identified among staff carrying out licensed activities. Members of the Site Team, responsible for out-of-hours viewings and releases, had not undergone any competency assessments. This poses a serious risk, such as the viewing or release of the wrong body. *The establishment submitted sufficient evidence to address this shortfall before the publication of the report.* • Although relevant documentation was provided, interviews with Porters across all four sites revealed inconsistent knowledge regarding competency assessments. Some Porters reported that competency assessments are undertaken; others stated that they are completed online, while some indicated that such assessments are not conducted. • Although initial training is provided, there are no documented competency records for staff undertaking releases from Maternity directly to funeral directors. • The Viewing risk assessment states that laboratory can provide additional assistance and support for the transfer of bariatric deceased patients. However, the inspection team was not supplied with documentation verifying that these staff members have undertaken competency assessments for this activity. • Although APTs are trained, competency records for post-mortem reconstruction work are outdated due to the limited number of post mortem examinations in recent years.	**Major**

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 an accidental damage to a body incident, that met the threshold for reporting to the HTA but had not been reported.	**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.	Although a viewing SOP is in place, it does not instruct staff to check a minimum of three identifiers on the deceased against details provided by family members when they attend the mortuary for a viewing. Instead, the SOP assigns responsibility to the nurse to provide these three identifiers to the family to confirm the deceased's identity. *See also shortfall GQ1 a.*	**Major**
g) Organs or tissue taken during post-mortem examination are fully traceable, including blocks and slides (including police holdings).	Whilst work has already been undertaken to improve systems, the establishment currently does not have a robust system in place to ensure full traceability of all tissue samples taken during post mortem examinations. The current tissue management system does not support full traceability, is limited in functionality, and contains several inaccuracies. Additionally, the laboratory and mortuary operate separate systems that do not facilitate the sharing of information, including disposal statuses for blocks and slides. This lack of comprehensive and accurate record-keeping poses a risk to the effective traceability of retained tissue. *See also shortfalls under the T2 and GQ2 c standards.* *See advice item 1.*	**Major**

T2 Disposal of tissue is carried out in an appropriate manner and in line with the HTA's codes of practice.

a) Tissue is disposed of as soon as reasonably possible once it is no longer needed, such as when the coroner's or police authority over its retention ends or the consented post-mortem examination process is complete	The inspection team identified several non-conformities during the onsite tissue audit. In addition, thirty-five cases of wet tissue were found that were not held under coronal instruction, and for which family wishes were unknown or consent for storage had not been obtained. As a result, tissue blocks, slides, and wet tissue are retained without valid consent or are not being disposed of as soon as reasonably possible. The inspection team noted that the DI does not have comprehensive oversight of what tissue is being retained, or the associated consent required for its lawful retention or disposal. *See also shortfalls under the T1 and T2 standards.*	**Major**
b) There are effective systems for communicating with the Coroner's Office, which ensure tissue is not kept for longer than necessary	During the site visit, two cases were noted to have remained open awaiting the coroner's inquest conclusion, without timely follow-up. When staff contacted the coroner at the inspection team's request, it was confirmed that the inquests had already concluded and that the associated tissue could have been disposed of. Therefore, although improvement initiatives have commenced, there is not an effective system in place to communicate with the Coroner's Office to prevent tissue from being retained longer than necessary. *See also shortfalls under the T1, T2 and GQ2 c standards.*	**Major**
c) Disposal is in line with the wishes of the deceased's family	The inspection team identified several cases where tissue had not been disposed of in accordance with the wishes of the deceased's family. *See also shortfalls under the T1, T2 and GQ2 c standards.*	**Major**

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	Multiple areas were identified as requiring maintenance: • Damage to door frames exposing porous surfaces was observed across all four sites. In addition, visible wall damage was found to be exposing plaster in the body store at Heartlands Hospital, with similar damage noted in both the post-mortem room and body store at Queen Elizabeth Hospital. These exposed, porous surfaces present a significant risk to effective cleaning and decontamination. • Evidence of mould and fungal growth was observed on fridge seals at Queen Elizabeth Hospital and Solihull Hospital, indicating the need for a comprehensive deep clean. • Significant damage was observed on the interior side panel of multiple fridges at Queen Elizabeth Hospital. • The fridge floor at Good Hope Hospital was observed to be contaminated and in need of a deep clean. • Multiple drains in the body store at Good Hope Hospital were observed to be contaminated and in need of a deep clean. • Rust was observed on two cabinets, a set of steps, and a trolley in the body store at Heartlands Hospital. Rust was also observed on the wheels of three storage trolleys in the body store at Good Hope Hospital. • Two electrical sockets with damaged covers were identified in the body store Queen Elizabeth Hospital. • Damage was observed to the step-over barrier between the changing room and the post-mortem room at Heartlands Hospital. • A damaged cover was identified behind the sink in the body store at Heartlands Hospital. • Damage was observed to the floor in the shower room at Heartlands Hospital.	**Major**

	• Significant damage was observed to a plastic corner trim at Good Hope Hospital. • Although unoccupied during the inspection, the external freezer unit at Queen Elizabeth Hospital was observed to have a heavy buildup of ice and required a full defrost. *Please also see shortfall PFE2 a.* *See advice item 2.*	
d) The premises are secure (for example there is controlled access to the body storage area(s) and PM room and the use of CCTV to monitor access)	• Although self-identified prior to the inspection, at the time of the site visit, none of the four sites had adequate CCTV coverage to monitor access during or outside of working hours, including all external storage units. The inspection team was provided with evidence that CCTV installation across all sites is scheduled and awaiting imminent completion. • The refrigeration plant equipment for the external fridge unit at Queen Elizabeth Hospital is situated in an unsecured external area, and the power switches for this equipment are not fitted with tamperproof mechanisms.	**Major**

e) Security arrangements protect against unauthorized access and ensure oversight of visitors and contractors who have a legitimate right of access	• Although security audits are undertaken, they are not conducted regularly and do not include a sufficient sample size to reflect activity across all four sites. Additionally, the security audit process lacks sufficient written guidance. In its current form, security audits are limited in their effectiveness for reviewing and managing access. As a result, the establishment cannot be assured that individuals accessing the mortuary or contingency storage areas do so for legitimate purposes, nor can it scrutinise the purpose, frequency, duration, or unusual patterns of access that may require immediate investigation. • Security arrangements at Heartlands Hospital do not adequately prevent unauthorised access to restricted areas of the mortuary. The door from the body store leading to the viewing waiting area is not always locked when families or visitors are admitted to the mortuary. Furthermore, this door does not fully engage when closed and was observed during the inspection to remain consistently ajar throughout the day. If opened, this door provides direct access to the body store, which presents a significant security risk. • Security arrangements at Queen Elizabeth Hospital were found to be inadequate in preventing unauthorised access to the mortuary. The entrance door to the viewing waiting area had no access control mechanisms in place. The inspection team was informed that laboratory staff, whose department is located on the floor above the mortuary, routinely access the viewing waiting area to use the toilet facilities. The inspection team raised concerns about inadequate security in this area, including the absence of CCTV and any form of door access control to restrict or monitor entry. This creates a risk that non-mortuary staff could inadvertently enter during a viewing or at any time, and fails to ensure that access to the mortuary is effectively controlled. *See also shortfall PFE1 d.*	**Major**

	• The Medical Examiners' entrance door at Good Hope Hospital was found to be inadequate in preventing unauthorised access to the mortuary. The door-closing mechanism was observed to be ineffective, resulting in the door remaining ajar for extended periods during the inspection. This presents a security risk and does not provide assurance that access to the mortuary is appropriately controlled.	

PFE2 There are appropriate facilities for the storage of bodies and human tissue.		
a) Storage arrangements ensure the dignity of the deceased	• With regard to the external freezer unit located in the loading bay at Queen Elizabeth Hospital, the inspection team was not assured that its location and access arrangements adequately safeguard the dignity of the deceased. Under the current setup, the use of this area for body storage is considered unsuitable. The inspection team instructed that use of this freezer unit must stop until adequate measures are in place to address this shortfall. *See also shortfall PFE1 d* • At Heartlands Hospital, the family viewing entrance door, and at Good Hope Hospital, the funeral directors' entrance doors, contain large clear glass panels. Due to the building layouts, mortuary staff working in the body store area must open these doors when meeting families or visitors. This creates a direct line of sight into the body store, risking inadvertent observation of mortuary activities and compromising the dignity of the deceased. *The establishment submitted sufficient evidence to address this shortfall prior to the publication of the report.*	**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	• Whilst mortuary fridge and freezer alarms are tested, current tests do not include the lower set point range. • While monitoring is in place for the Maternity fridges at Heartlands Hospital and Good Hope Hospital, staff indicated during the onsite visit that the units are not routinely tested to verify they trigger when temperatures exceed the upper or lower set set range.	**Major**

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	• At Good Hope Hospital, one mortuary trolley was found to have defective brakes, while the second and only operational trolley had a failing battery and required maintenance. During the onsite body audit, this trolley failed mid-lift, leaving no functional trolleys available at Good Hope Hospital. This presents a significant manual handling and health and safety risk and compromises the ability to safely transfer deceased patients or perform condition checks. • A wooden baby cot was located on the floor of the body store at Good Hope Hospital. Its porous material, combined with its location in the body store, presents a significant risk to effective cleaning and decontamination. *See advice item 6.* • Wooden door wedges were found in use across all sites. The exposed, porous material of these items presents a significant risk to effective cleaning and decontamination.	**Major**
c) The ventilation system provides the necessary ten air changes per hour and is checked and maintained at least annually	While the ventilation reports indicate that annual testing is conducted, the inspection team has not been provided with a report for Queen Elizabeth Hospital confirming that the ventilation system meets the required ten air changes per hour.	**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		
d) Information contains clear guidance on options for how tissue may be handled after the post-mortem examination (for example, repatriated with the body, returned to the family for burial/cremation, disposed of or stored for future use), and what steps will be taken if no decision is made by the relatives	• During the inspection, it was confirmed that research is not routinely undertaken, despite this option being offered to families on the consent form. Consequently, families who select research are unaware that tissue may not be used for this purpose and could instead be stored without use or disposed of. This creates a risk that consent is provided without families being fully informed. *See advice item 3.* • The inspection team noted concerns regarding the written structure of Section Four in the post-mortem examination consent form for babies and children. In its current format, this section combines two scheduled purposes, teaching and research, into a single consent option. As a result, families wishing to consent to only one of these specific uses are unable to do so without also consenting to all listed purposes. This limits families' ability to make specific decisions about the retention and use of tissue.	**Minor**
GQ2 There is a documented system of audit		

a) There is a documented schedule of audits	• Although a mortuary audit schedule was provided, it lacked sufficient detail. The current audit schedule does not outline the required frequency of audits throughout the year. • The establishments' audit templates lack sufficient guidance on sample size and frequency within the instructions section.	**Minor**

GQ4 There is a systematic and planned approach to the management of records		
b) There are documented SOPs for record management which include how errors in written records should be corrected	The inspection team were not provided evidence to confirm there are documented SOPs for record management which include how errors in written records should be corrected.	**Minor**

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	Not all procedures related to the licensed activities are risk assessed: These include but are not limited to: • Incident leading to the temporary unplanned closure of a mortuary resulting in an inability to deliver services. • Loss, disposal or retention of a whole fetus or fetal tissue against the express wishes of the family. • Contingency storage arrangements. • Transfer of bodies and tissue (including blocks and slides) off site or to other establishments. • The process of transferring patients from the body store to the viewing room at Good Hope Hospital, which requires moving patients between two trolleys due to misaligned floors. *See also shortfall GQ1 a.* To fully address this shortfall, the establishment should undertake a full review of risk assessments relating to mortuary activities.	**Minor**

PFE1 The premises are secure and well maintained and safeguard the dignity of the deceased and the integrity of human tissue.		
b) There is demarcation of clean, dirty and transitional areas of the mortuary, which is observed by staff and visitors	At Heartlands Hospital and Queen Elizabeth Hospital, there was no demarcation of clean, dirty, or transitional areas between the post mortem room and the body store. *The establishment submitted sufficient evidence to address this shortfall prior to the publication of the report.*	**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	Although capacity is managed across the Trust and overseen by the Mortuary team, documented contingency plans were not available to confirm the measures in place to address periods of insufficient refrigerated storage during peak times or in the event of a power failure. *See also shortfall GQ1 a*	**Minor**

PFE3 Equipment is appropriate for use, maintained, validated and where appropriate monitored		
f) Key items of equipment, including fridges/freezers, trolleys and post mortem tables (if downdraught) are subject to regular maintenance and records are kept	The inspection team was not provided with servicing records for mortuary autopsy saws.	**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.	T1 g	The DI is advised to consolidate all post-mortem tissue onto a single site to strengthen traceability, record management, and oversight. In addition, the DI is advised to consider moving post-mortem activities to one site, given the current volume of post mortem work undertaken. This may support and provide operational efficiency.

2.	PFE1 a	The DI is advised to assess the suitability and safety of the following items and areas: • The stand-alone shower pod at Heartlands Hospital. • The rubber boots used for post mortems at Queen Elizabeth Hospital. • The non-adjustable post-mortem tables at Heartlands Hospital.
3.	C1 d	The DI is advised to review and update the consent form. Staff reported that they could not recall the last instance in which tissue consented for research was used for that purpose. This option should therefore be removed or amended. If amended, the DI should specify the period for which tissue will be retained before disposal to ensure that families receive accurate information at the time consent is sought. Please refer to your post mortem examination consent form for babies and children, which sets out this additional information.
4.	GQ1 g	The DI is advised to conduct regular visits to all sites and areas under the HTA licence. It was confirmed that the DI has not yet visited the mortuary at Queen Elizabeth Hospital, a recent addition to the licence in August 2025, and has rarely visited Good Hope Hospital or Solihull Hospital. Consequently, oversight is limited, instead relying on reassurance rather than direct assurance.
5.	PFE1 e	The DI is advised to implement a regular schedule for changing the keycode to the viewing area at Solihull Hospital, as it was identified that it has not been updated for an extended period.
6.	PFE3 a	The DI is advised to assess the necessity of items of equipment in the corridor to the Medical Examiner's Office at Good Hope Hospital.
7.	T1 b	The DI is advised to reassess the process for storing patient paperwork in the external fridge at Queen Elizabeth Hospital. Relocating these records to the mortuary with all other patient paperwork will ensure a single, consistent process and location for all patients.

Background

Heartlands Hospital has been licensed by the HTA since 2008. This was the fifth inspection of the establishment; the most recent previous inspection took place in March 2023. Since the previous inspection, the licence has been amended to include a satellite site at Queen Elizabeth Hospital.

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 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 of equipment, ventilation reports, audits, risk assessments, meeting minutes, reported incidents and training records for staff.

Visual inspection

The inspection team conducted an unannounced visual inspection of the hub and satellite premises, including the mortuary body storage areas, post-mortem rooms, and viewing suites. The team also observed the release process at two sites.

Audit of records

Audits were conducted on seventeen bodies from refrigerated and frozen storage across all four sites. Identification details on the bodies were cross-checked against the mortuary electronic register and associated paperwork, with no discrepancies identified. Audits of tissue traceability were also carried out for eleven histology cases; the inspection team identified five discrepancies and noted further queries relating to two additional cases.

Meetings with establishment staff

The inspection team met with staff carrying out activities under the licence, including the Mortuary Manager, Deputy Mortuary

manager, a Bereavement Midwife, a Consent Seeker, Porters across all four sites, a Pathologist and the Designated Individual.

Report sent to DI for factual accuracy: 01/12/2025

Report returned from DI: 08/12/2025

Final report issued: 08/12/2025

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.