Inspection report on compliance with HTA licensing standards
Inspection date: **18 May 2023**

Doncaster Royal Infirmary
HTA licensing number 12268

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 Doncaster Royal Infirmary	Licensed	Licensed	Licensed
Mortuary	*Carried out*	*Carried out*	*Carried out*
Pathology lab	-	-	*Carried out*
A&E	-	*Carried out*	-
Satellite site Bassetlaw Hospital	Licensed	Licensed	Licensed
Mortuary (satellite site)	-	*Carried out*	*Carried out*

Summary of inspection findings

This was a targeted unannounced site visit inspection. The Designated Individual (DI) was not available during this visit. Assessment of suitability of the DI and the Licence Holder (LH) in accordance with the requirements of the legislation will be carried out at the next routine inspection.

The targeted unannounced site visit of Doncaster Royal Infirmary ('the establishment') found two minor shortfalls against standards for Governance and quality systems and Premises, facilities and equipment. These related to condition monitoring and recording of information on condition of bodies in storage and shrouding practices.

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
GQ1 All aspects of the establishment's work are governed by documented policies and procedures		
c) Procedures on body storage prevent practices that disregard the dignity of the deceased	At the time of the inspection, two bodies were still in refrigerated storage after 30 days. One of the bodies was deteriorated. It was explained to the inspection team that the body had arrived in a deteriorated condition. This could not be verified as the establishment do not have a formalised process in place to routinely record the condition of bodies upon arrival or monitor and record the condition of bodies at regular intervals whilst in refrigerated storage. Furthermore, the establishment does not have a formalised process for expediting release of long-term bodies from the mortuary or when consideration to move bodies to frozen storage should be given.	**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 occasions where bodies were not effectively shrouded whilst in storage. Furthermore, whilst there is a requirement for the mortuary to remove clothing / shrouding for those bodies sent to a different facility for post mortem scanning and for bodies undergoing post mortem examination, some bodies had not been fully re-shrouded inside the body bags following these procedures being undertaken.	**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(b)	The mortuary is heavily reliant on paper-based tracking systems for the deceased. Due to the number and location of body storage areas and the frequent movement of bodies into and out of the department for post mortem scanning purposes, the DI is advised to expedite progression of the electronic mortuary tracking system so staff are able to manage traceability of the deceased and their associated records more effectively.
2.	T1(c)	Whilst all bodies were labelled with a minimum of three points of identification either on identification bands or on information attached to the body, the DI is advised to ensure that where relevant, date of birth is used rather than age as this is not considered a robust identifier.

3.	PFE3(a)	Whilst the inspection did not focus on this standard, the DI is advised to assess the condition of the base of the refrigerated units as they are showing signs of extensive rusting. This would be identified as a shortfall at the next routine inspection if not addressed.

Background

Doncaster Royal Infirmary has been licensed by the HTA since May 2007. The most recent previous inspection took place in July 2018. Since the previous inspection, an extension to the premises took place in June 2020 to increase fridge capacity by a further 84 spaces, and in May 2022 there was a further extension to premises with the procurement of a freezer unit for 14 bodies. A change to the role of DI took place in July 2019.

A decision to undertake an unannounced visit was made by the HTA's Director of Regulation at a Regulatory Decision-Making meeting on 19 April 2023. This followed concerns relating to body storage and conditions that may impact dignity of the deceased. Accordingly, this inspection focussed on the following standards: GQ1(c), T1(a), T2(b), T1(c), T1(d), T1(f), PFE2(a), PFE2(b), PFE2(c), PFE2(d), PFE2(e), PFE2(f), PFE2(g), and PFE2(h).

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:

Review of governance documentation

A review of governance documents was not undertaken as part of this inspection. A full review of governance documentation will be undertaken at the next routine inspection to be scheduled.

Visual inspection

The inspection team undertook a visual inspection of the premises which included the body storage areas and the PM room. The PM room is currently undergoing an extensive refurbishment. It was evident this refurbishment has impacted on the ability of staff to access washing facilities for bodies requiring thorough cleaning or decontamination. Staff list any deceased requiring attention upon

arrival and take intermediate actions to address condition until they can gain access to the PM room washing facilities in the restricted times available. The work in this area is due to be finished in the next six weeks.

Audit of records
The inspection team undertook audits of traceability for six bodies in storage. This included a body in long term storage, and the two bodies still in refrigerated storage over 30 days. Traceability details were crosschecked between the identification band on the body, information on the door of the storage unit, the mortuary whiteboards, the mortuary register and associated paperwork. Whilst no discrepancies were identified one body was found to have been labelled with an age rather than a date of birth which is not considered a robust identifier.

Meetings with establishment staff
The inspection team met with staff carrying out processes under the licence at the hub site. This included the mortuary manager and mortuary staff.

Report sent to DI for factual accuracy: 06 June 2023

Report returned from DI: 16 June 2023

Final report issued: 19 June 2023

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: 8 August 2023

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.