Site visit inspection report on compliance with HTA licensing standards
Inspection date: **10 December 2019**

# Thinktank Birmingham Science Museum

HTA licensing number 12207

Licensed under the Human Tissue Act 2004

**Licensed activities**

| Area | Storage of relevant material which has come from a human body for use for a scheduled purpose | Use, for the purpose of public display, of the body of a deceased person, or relevant material which has come from the body of a deceased person |
|---|---|---|
| **Thinktank Birmingham Science Museum** | Licensed | Licensed |

**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 Thinktank Birmingham Science Museum (the establishment) had met the majority of the HTA's standards, four minor shortfalls were found against standards for Governance and Quality.

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** | | |
| d) Policies and procedures are reviewed regularly and are version controlled. | Polices and standard operating procedures (SOPs) relating to licensed activities are not reviewed regularly. | **Minor** |
| **GQ3 Staff are appropriately qualified and trained in techniques relevant to their work and demonstrate competence in key tasks** | | |
| b) There is documented induction and training for staff, which includes the handling of human remains; attendance at training is recorded. | The induction and training programme for staff does not include information on the appropriate handling of human remains in accordance with the requirements of the Human Tissue Act 2004 (the HT Act), HTA licensing standards and codes of practice. | **Minor** |
| **GQ4 There is a systematic and planned approach to the management of records** | | |
| a) There are suitable systems for the creation, review, amendment, retention and destruction of records. | The establishment does not have a system or a policy for how records should be managed, including how often documents should be reviewed. | **Minor** |

| GQ6 Risks associated with the establishment's practices and processes in relation to the storage and display of human material are assessed and monitored | | |
|---|---|---|
| c) Risk assessments are reviewed regularly | Risk assessments relating to licensed activities are not reviewed regularly. | **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. | GQ1(c) | The DI is advised to include matters relating to the HTA licence and compliance with the licensing standards as part of the agenda for one of the museum's governance meetings.<br>The DI is also advised to maintain regular contact with the licensed establishment from which the exhibit is loaned. This will ensure continued awareness of the responsibilities of each establishment in relation to the exhibit. |
| 2. | GQ2(a) | The DI is advised to ensure that audits are performed as scheduled and corrective actions are taken to address audit findings. |
| 3. | GQ4(b) | The DI is advised to remove the consent form from the exhibition display. Whilst the establishment provided information showing that the donor's family expressed their wishes for the donor to be acknowledged as part of the display, the consent form includes some sensitive identifying information of the donor and a family member. |

| | | |
|---|---|---|
| 4. | T1(a) | The DI is advised to label the exhibit mounting case with a unique museum artefact number. This will help to ensure that traceability is maintained if the item is moved to the licensed contingency storage site or returned to the establishment of origin. |
| 5. | PFE1(a) | The DI is advised to strengthen systems to inform visitors that some exhibitions include material of human origin. This will help to ensure that visitors can make an informed choice of whether they enter these exhibition areas. |
| 6. | PFE2(b) | The DI is advised to manually challenge the storage monitoring alarm in the exhibit display case. This would help to assure the DI that the alarm functions as expected in the event of a deviation from optimal storage conditions. |
| 7. | PFE2(c) | The DI is advised to develop a system to manage any changes in the fluid level in the mounting case of the exhibit. |

**Background**

Thinktank Birmingham Science Museum has been licensed by the HTA since June 2007. This was the second site visit inspection of the establishment; the most recent previous inspection took place in July 2013.

Since the previous inspection, there has been a change of DI. The current DI has been in post since September 2019. There have been no significant changes to the licence arrangements or the activities carried out under the licence.

At the time of the inspection only one item of relevant material was on public display. This exhibit is on long-term loan from another HTA licensed establishment and was loaned to the museum in 2001. The exhibit is an ‘existing holding’ and so is exempt from the consent requirements of the HT Act.

**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*
Standards C1, C2, T2(b) and PFE2(a) were not assessed during the inspection as they are not applicable to the licensed activity undertaken. The remaining 29 HTA licensing standards were assessed during the inspection (standards published 3 April 2017).

*Review of governance documentation*
The inspection team reviewed policies and procedural documents relating to licensed activities, temperature monitoring for the exhibition display unit, audits, risk assessments, and staff training records.

*Visual inspection*
The inspection team completed a visual inspection of the area where the exhibit is displayed and the museum entrance area where the HTA licence is displayed.

*Audit of records*
The location and type of item held was audited against records on the museum database (see Advice, item 4).

*Meetings with establishment staff*
The inspection included a meeting with the DI and a roundtable discussion with staff carrying out procedures related to licensed activities.

**Report sent to DI for factual accuracy: 23 December 2019**

**Report returned from DI: 09 January 2020**

**Final report issued: 13 January 2020**

**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 site visit 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 site visit.

   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 the 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 site visit inspection
- a request for information that shows completion of actions
- monitoring of the action plan completion
- follow up at next routine site visit inspection.

After an assessment of the proposed action plan establishments will be notified of the follow-up approach the HTA will take.