Inspection report on compliance with HTA licensing standards
Inspection date: **11 September 2024**

British American Tobacco Group Research and Development Centre
HTA licensing number 12514

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	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
British American Tobacco Group Research and Development Centre	Licensed	Not 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.

The British American Tobacco Group Research and Development Centre (‘the establishment’) was found to have met all of the HTA’s standards.

Advice

The HTA advises the DI to consider the following to further improve practices:

Number	Standard	Advice
1.	GQ1(a)	The tracking spreadsheet has columns to allow for disposal of a sample to be documented; however, the establishment's procedure named, 'Order, receipt, storage, tracking and disposal of biological samples' states that only the date of disposal must be recorded. The DI should review the standard operating procedure (SOP) to ensure that it also includes the requirement for the date, reason and method of disposal to be documented.
2.	GQ1(a)	The DI should consider including procedural steps relevant to transportation of human tissue to existing procedures, so that should licensable activities re-commence and if human tissue is transported externally, staff are aware of the steps to follow.
3.	GQ2(a)	The establishment plans to carry out an audit in 2025 to review their state of readiness should activities re-commence in the future. Although the establishment has not stored human tissue since 2020, the DI should consider carrying out an annual audit of compliance with HTA standards to ensure that they continue to be met.
4.	GQ5(a)	The establishment has a documented procedure that covers the reporting of adverse events and their management to resolution. To further strengthen incident reporting, the DI is advised to consider adding examples of reportable incidents to the incident reporting procedure.

5.	GQ6(a)	Although the establishment had sufficient control measures against each of the risks documented in their risk assessment, the DI is advised to consider whether the measures are detailed enough to provide assurance that risks are controlled.
6.	PFE2(d)	The establishment has a procedure called ‘Cryogenic Storage in Liquid Nitrogen’ which provides steps to manage a failure in the liquid nitrogen storage tank. As the establishment may also store at -80 degrees Celsius, the DI should consider developing an equivalent documented procedure for these conditions.

Background

The establishment specialises in innovation technologies. The establishment has not stored or used human tissue under their licence since 2020. The last inspection took place in 2016.

Description of inspection activities undertaken

The HTA’s regulatory requirements are set out in Appendix 1. The Regulation Manager covered the following areas during the inspection:

Standards assessed against during inspection

Of the 47 HTA standards, 46 standards were assessed (standards published 3 April 2017). PFE2(b) is not applicable as the establishment does not intend to store material from the deceased.

Review of governance documentation

A number of documents were reviewed during the assessment which included, but were not limited to, standard operating procedures for licensable activities, key policies, traceability audits, meeting minutes, staff training records, temperature monitoring data and incident reports.

Visual inspection

There was no visual inspection of the premises; however, a meeting took place with relevant staff members to discuss the PFE standards. There has been no storage of human tissue at the establishment since 2020.

Audit of records

The last audit was performed in 2020 when licensable activities were being undertaken. There has been no audits since as no storage of human tissue has taken place.

Meetings with establishment staff

A roundtable discussion was carried out with establishment staff which included the DI, Person Designated (PD) and Quality Manager.

Report sent to DI for factual accuracy: 4 October 2024

Report returned from DI: 29 November 2024 (with comments)

Final report issued: 29 November 2024

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 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 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.