Inspection report on compliance with HTA licensing standards
Inspection date: **9 April 2025**

BBI Solutions OEM Limited
HTA licensing number 12443

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
BBI Solutions OEM Limited	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.

Although BBI Solutions OEM Limited ('the establishment') was found to have met the majority of the HTA's standards, two minor shortfalls were identified against Consent and Premises, facilities and equipment standards; these were in relation to the the lack of a documented consent procedure for the blood donation programme and contingency plan in the event of freezer failure.

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
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		
a)Consent procedures are documented and these, along with any associated documents, comply with the HT Act and the HTA's Codes of Practice	The establishment has a blood donation programme for staff to donate their blood for research purposes. Donor consent was last obtained in 2021 and there has been no further recruitment into the programme. Although the establishment has a consent procedure, this does not set out the consent process for the blood donation programme. *"The establishment submitted sufficient evidence to address this shortfall before the report was finalised."*	**Minor**

PFE2 There are appropriate facilities for the storage of bodies and human tissue		
d) There are documented contingency plans in place in case of failure in storage area	There was no documented plan or associated procedures for the management of a storage failure.	**Minor**

Advice

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

Number	Standard	Advice
1.	C2(c)	There have been no consent-seeking activities since 2021 and, at present, it would be the DI's responsibility to seek consent from volunteers recruited to the blood donation programme. As there are plans to extend the number of staff involved in seeking consent, the DI should consider introducing a regular cycle of refresher training particularly if recruitment of donors is infrequent. This may help to ensure that staff maintain competence in seeking consent.
2.	GQ4(b)	Consent forms are stored securely in a locked cabinet. The DI may wish to consider digitising the consent forms to ensure they are backed-up and recoverable in the event of loss of, or damage to, physical records.
3.	GQ6(a)	The establishment has a range of risk assessments in place. The DI should consider including references to key standard operating procedures (SOPs) within risk assessment control measures. This may help staff to identify documents and procedures that are relevant in mitigating identified risks.

Background

The establishment is private company which specialises in the development of reagents and immunoassays. Human tissue samples are purchased from third party suppliers under appropriate agreements that stipulate consent for research is in place. At the time of the inspection, the establishment also stored urine collected from two patients with consent for research. This work was being undertaken under the governance of a project-specific ethical approval from a recognised Research Ethics Committee. The establishment also regularly collects and stores blood from six healthy volunteers who are staff members, who have given their consent for their samples to be used for research. The establishment stores material from deceased donors.

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

All 47 HTA standards were assessed (standards published 3 April 2017).

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, policies, traceability audits, meeting minutes, staff training records, incident reports, maintenance/service records and agreements with suppliers of human tissue.

Visual inspection

There was no visual inspection of the premises; however, a meeting took place with relevant staff members to discuss the PFE standards which included security arrangements, storage conditions, equipment maintenance, contingency plans and cleaning and decontamination procedures.

Audit of records

No traceability audit was carried out; however, a review of recently conducted audits was undertaken as part of the assessment.

Meetings with establishment staff

A roundtable discussion was carried out with establishment staff which included the DI, Corporate Licence Holder contact (CLHc) and Stores and Procurement Leads.

Report sent to DI for factual accuracy: 6 May 2025

Report returned from DI: 9 May (with comments)

Final report issued: 6 June 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 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.