Inspection report on compliance with HTA licensing standards
Inspection date: **17 September 2025**

TJ Smith and Nephew
HTA licensing number 12663

Licensed under the Human Tissue Act 2004

Licensed activities

Area	Carrying out of an anatomical 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 a body of a deceased person or relevant material which has come from a human body for use for a scheduled purpose	Storage of an anatomical specimen
TJ Smith and Nephew	Not licensed	Not licensed	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 the HTA found that TJ Smith and Nephew (‘the establishment’) had met the most of the HTA’s standards, however, one minor shortfall was identified against Governance and quality systems standards. This was in relation to a lack of documented risk assessments that cover risks to cadaveric parts in storage areas and when left out during thawing in preparation for courses.

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 shortfall identified during the inspection.

Compliance with HTA standards

Standard	Inspection findings	Level of shortfall
GQ6 Risk assessments of the establishment's practices and processes are completed regularly, recorded and monitored.		
a) There are documented risk assessments for all practices and processes requiring compliance with the HT Act and the HTA's Codes of Practice.	There was no documented risk assessment relating to the practice of leaving out cadaveric parts in the specimen preparation room during thawing in preparation for courses. In addition, there was no documented risk assessment to cover the security risks to cadaveric parts in the storage areas. For context, the establishment has appropriate restricted security and access control leading from the internal laboratory area to the specimen preparation room. The specimen preparation room leads into an unlocked refrigerated area and then freezer storage. The specimen preparation room is used to thaw cadaveric material for up to four days (including out-of-hours). There is emergency access door leading from the specimen preparation room to the outside of the building.	**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 practices:

Number	Standard	Advice
1.	GQ2(a)	On review of a recently-completed audit, some documented observations required clarification. The DI is advised to ensure that recorded notes are as clear as they can be.
2.	GQ3(a)	All staff must be trained and competent in tasks relevant to their job roles before working under the licence and are also required to be observed undertaking activities. To strengthen the approach, the DI should consider having a documented competency framework which serves as evidence that a staff member has gained competence in carrying out a specific task.
3.	GQ5(a)	The establishment has a standard operating procedure that deals with adverse events, which includes some examples of the types of incidents that would need to be reported internally. To widen staff awareness, the DI should consider including the broader range of adverse events that are included in the HTA's Anatomy standards and guidance document.
4.	GQ6(a)	Although the establishment has agreements in place with suppliers to confirm that valid and appropriate consent is in place for the use of the cadaveric specimens, the DI should consider documenting an assessment of the risks of receiving and/or storing specimens without valid and appropriate consent.

Background

The establishment has been licensed by the HTA since 2017. This was the second inspection of the establishment; the most recent previous inspection took place in December 2021.

The establishment purchases cadaveric material from outside of the UK. The material is stored and used in surgical training for clinicians intending to use the establishment's medical devices in patient care. All material is fully consented to for use in education and training. Once the material has been used it will be disposed of sensitively.

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

Out of the total 47 standards, 39 were assessed. C1(a),(b),(d), (e), (f) and C2(a), (b) and (c) were not applicable as the establishment is not involved in seeking consent.

Review of governance documentation

During the inspection, policies and procedural documents relating to licensed activities, cleaning records for the storage areas, records of servicing, internal audits, meeting minutes, risk assessments, temperature logs for the storage units, reported incidents and staff training records were reviewed.

Visual inspection

The visual inspection comprised of review of the fridge and freezer where cadaveric parts are stored, the specimen preparation room, the surgical training area and included a on-site review of the receipt procedure for specimens.

Audit of records

An audit trail of records and cadaveric parts in storage was undertaken.

A 'forward' audit of three used cadaveric parts was undertaken by identifying the parts from the inventory and tracing these to their respective storage locations. Two of the three parts had been used in surgical training and then disposed of, with smaller parts retained

for re-use. These were successfully located in storage. A review of the disposal records for the original part that had been disposed of was also undertaken. There were no discrepancies identified.

A ‘reverse’ audit of three unused cadaveric parts in storage was undertaken by identifying the parts in storage and tracing these to the inventory. There were no discrepancies identified.

Meetings with establishment staff

The inspection involved meeting with staff carrying out processes under the licence, including the DI, EU Director for Regulatory Affairs and the Global Facilities Director.

Report sent to DI for factual accuracy: 8 October 2025

Report returned from DI: 20 October 2025

Final report issued: 21 October 2025

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 December 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.