Site visit inspection report on compliance with HTA minimum standards

Defence Science and Technology Laboratory

HTA licensing number 12440

Licensed under the Human Tissue Act 2004 for the

- **storage of relevant material which has come from a human body for use for a scheduled purpose**

11 December 2014

Summary of inspection findings

The HTA found the Designated Individual, the Licence Holder, the premises and the practices to be suitable in accordance with the requirements of the legislation.

Although the HTA found that Defence Science and Technology Laboratory had met the majority of the HTA standards, a minor shortfall was identified in relation to risk assessments (Governance and Quality Systems standard, GQ8)

Particular examples of good practice are included in the concluding comments section of the report.

The HTA's regulatory requirements

The HTA must assure itself that the Designated Individual, Licence Holder, premises and practices are suitable.

The statutory duties of the Designated Individual 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.

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. The HTA inspects the establishments it licences against four groups of standards:

- consent
- governance and quality systems
- premises facilities and equipment
- disposal.

This is an exception-based report: only those standards that have been assessed as not met are included. Where the HTA determines that a standard is not met, 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 given to the DI.

Reports of HTA inspections carried out from 1 November 2010 are published on the HTA's website.

Background to the establishment and description of inspection activities undertaken

The Defence Science and Technology Laboratory (Dstl) is an agency of the UK Ministry of Defence and provides science- and engineering-based products, services and expertise on defence and security issues. Dstl is comprised of 11 Departments. The Designated Individual (DI) is the Department Manager of the Department of Biomedical Sciences, which provides integrated research, development and advice on the biological effect of insults on the human body and how these effects can be mitigated through the application of cutting edge science and technology.

HTA-licensed activities take place within three of the departments: the Biomedical Sciences, Physical Sciences and Detection Departments. There are five Persons Designated (PDs): two in Biomedical Sciences, two in Detection and one in Physical Sciences. The DI holds meetings with them every six months to discuss updates on the HTA-related work in their areas.

The human tissue stored at Dstl includes blood, urine, skin, buccal and nasal swabs. Skin is received from a third party and there is a contract and material transfer agreement in place. The contract includes a consent letter written by Dstl to be provided to tissue donors. The rest of the tissue samples are procured from volunteers.

Volunteers from within Dstl are recruited using a well-established and documented system. Volunteers are recruited to the Clinical Laboratory and samples are taken in the presence of two competent and authorised staff who ensure that volunteers are provided with appropriate information to give informed consent. Consent documentation is stored in the Clinical Laboratory as a paper copy and as a scanned copy. Volunteer donated samples are then de-identified before being provided to researchers and the traceability of samples, including their use, storage and disposal, is recorded in a database. A unique identifier is assigned to each sample.

Human tissue is stored in five individual buildings, within the Biomedical Sciences, Physical Sciences and Detection Departments. Two of the buildings were visited during the inspection; one containing Biomedical Sciences and one containing research that is part of the Detection Department. The other three buildings were not visited due to the live status of the category 3 facility, the lack of staff availability at the Physical Sciences Department and the fact that there are no samples currently stored in the second Detection Department building.

In the areas visited, the storage facilities are located in secure areas with restricted access. The freezers (1x -30°C, 1 x -40°C and 1 x -80°C) are fitted with local alarms but are not linked to the Dstl external alarm system. The freezers have max/min thermometers attached and are monitored manually on a regular basis during the working week (Mon to Fri). A sheet to record the temperatures is stored next to each freezer with space for the expected operating range.

A database is used to track the samples between receipt and disposal. The following details are recorded: date of consent / supply; research project id; work / storage location; any sample splitting; disposal date / method. Researchers record their use / disposal of samples in laboratory notebooks and regularly update the database. The disposal of human tissue as waste is carried out by incineration on site. To aid full traceability, the researcher receives a confirmation of incineration with a reference number which links the sample to an incinerator.

The establishment has been licensed by the HTA since March 2007. This was the first routine site visit inspection carried out on this establishment. The inspection included an introduction to the work of Dstl given by the DI, a visual inspection of some of the storage areas and the clinical laboratory where samples are procured from volunteers, a review of documentation and meetings with establishment staff. The inspection team conducted interviews with the DI, a PD, a Consent Witness, a Quality Assurance representative and a Researcher.

A traceability audit was conducted on five samples. The identity and storage location of each item was cross-referenced with the Dstl database. Two of the samples were traced back from their storage location to consent records. Traceability was maintained, however, there was a minor inconsistency between the use of ‘date of supply’ and ‘date consented’ on the sample label and the database for two of the samples that were audited.

Inspection findings

The HTA found the Designated Individual and the Licence Holder to be suitable in accordance with the requirements of the legislation.

Compliance with HTA standards

Governance and Quality

Standard	Inspection findings	Level of shortfall
GQ8 Risk assessments of the establishment's practices and processes are completed regularly and are recorded and monitored appropriately.	The establishment has risk assessments that cover health and safety. However, appropriate safeguards should be in place to maintain the integrity and traceability of tissue obtained from consented volunteers. Risk assessments should also include risks specific to human tissue (for example, loss of traceability, freezer failure, etc.) and the procedures in place to mitigate such risks should be documented. See Advice, item 4.	**Minor**

Advice

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

No.	Standard	Advice
1.	GQ1	The establishment holds HTA committee meetings every 6 months. At these meetings PDs are expected to report on governance issues in their own areas. The DI is advised to strengthen the agenda so that all licensed activities are discussed at these meetings and the reports from PDs are consistent.
2.	GQ2	PDs conduct quarterly audits of HTA material in their own area using an audit checklist. The findings of these audits are stored on the computer, accessible to the DI, and discussed at the 6-monthly Dstl HTA Committee meetings attended by the DI and all PDs. At least one Dstl SOP states that an annual QA audit of HTA activities should be carried out. The DI should ensure that this separate QA audit takes place as planned.
3.	GQ6	There was a minor discrepancy found between the date labelled on samples and the date in the Dstl database. It is likely that this is due to a single column being used to record either date of supply or date of consent. Since these dates can differ, and to avoid confusion, the establishment is advised to include separate columns for date of supply and date of consent within the database.
4.	PFE3	The inspection team identified inconsistencies in relation to how each department approached temperature monitoring of their fridges and/or freezers. The temperature monitoring of freezers in two of the laboratories inspected was carried out only during the working week and the max/min thermometers were

		not appropriately calibrated. The DI should ensure that all human tissue is stored in a suitable environment and that precautions are taken to minimise the risk of damage to samples due to freezer failure. This could include reviewing the SOPs relevant to temperature monitoring of equipment, reviewing the adherence of individual teams to following the SOPs and a consideration of storing all HTA relevant material in freezers linked to an external alarm system.

Concluding comments

There were a number of areas of good practice observed during the inspection. The area of consent is covered in a detailed and comprehensive manner. For example the establishment keeps a tally of the volume donated by each individual to avoid over donation and each project requiring volunteers must be agreed by the Dstl Chief Medical Director and copied to the DI. The traceability of material via the database is good and has recently been improved by the use of additional lines when a sample is split. Problems with the previous version of the database were noted and acted upon. The DI pays careful attention to the appointment of PDs and the areas that they cover to ensure he is well supported by them.

There are a number of areas of practice that require improvement, including one minor shortfall. The HTA has given advice to the Designated Individual with respect to Governance and Quality Systems and Premises, Facilities and Equipment.

The HTA requires that the Designated Individual addresses the shortfall by submitting a completed corrective and preventative action (CAPA) plan 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.

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.

Report sent to DI for factual accuracy: 06 January 2015

Report returned from DI: 29 January 2015

Final report issued: 03 February 2015

Inspection CAPA Plan Closure Statement:

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: 26 May 2015

Appendix 1: HTA standards

The HTA standards applicable to this establishment are shown below; those not assessed during the inspection are shown in grey text. Individual standards which are not applicable to this establishment have been excluded.

Consent standards
C1 Consent is obtained in accordance with the requirements of the Human Tissue Act 2004 (HT Act) and as set out in the code of practice
• Consent forms comply with the HTA's Code of Practice • Consent forms are in records and are made accessible to those using or releasing relevant material for a scheduled purpose • If the establishment obtains consent, a process is in place for acquiring consent in accordance with the requirements of the HT Act 2004 and the HTA's Codes of Practice • Where applicable, there are agreements with third parties to ensure that consent is obtained in accordance with the requirements of the HT Act 2004 and the HTA's Codes of Practice • Consent procedures have been ethically approved
C2 Information about the consent process is provided and in a variety of formats
• Standard operating procedures (SOPs) detail the procedure for providing information on consent • Agreements with third parties contain appropriate information • Independent interpreters are available when appropriate • Information is available in suitable formats, appropriate to the situation • Consent procedures have been ethically approved
C3 Staff involved in seeking consent receive training and support in the implications and essential requirements of taking consent
• Standard operating procedures (SOPs) detail the consent process • Evidence of suitable training of staff involved in seeking consent • Records demonstrate up-to-date staff training • Competency is assessed and maintained

Governance and quality system standards
GQ1 All aspects of the establishments work are supported by ratified documented policies and procedures as part of the overall governance process
• Policies and procedures are in place, covering all activities related to the storage of relevant material for research in connection with disorders, or the functioning, of the human body • Appropriate risk management systems are in place • Regular governance meetings are held; for example, health and safety and risk management

committees, agendas and minutes

- Complaints system

GQ2 There is a documented system of quality management and audit

- A document control system, covering all documented policies and standard operating procedures (SOPs).
- Schedule of audits
- Change control mechanisms for the implementation of new operational procedures

GQ3 Staff are appropriately qualified and trained in techniques relevant to their work and are continuously updating their skills

- Qualifications of staff and training are recorded, records showing attendance at training
- Orientation and induction programmes
- Documented training programme, (e.g. health and safety, fire, risk management, infection control), including developmental training
- Training and reference manuals
- Staff appraisal / review records and personal development plans are in place

GQ4 There is a systematic and planned approach to the management of records

- Documented procedures for the creation, amendment, retention and destruction of records
- Regular audit of record content to check for completeness, legibility and accuracy
- Back-up / recovery facility in the event of loss of records
- Systems ensure data protection, confidentiality and public disclosure (whistle-blowing)

GQ5 There are documented procedures for distribution of body parts, tissues or cells

- A process is in place to review the release of relevant material to other organisations
- An agreement is in place between the establishment and the organisation to whom relevant material is supplied regarding the tracking and use of material and eventual disposal or return

GQ6 A coding and records system facilitates traceability of bodies, body parts, tissues and cells, ensuring a robust audit trail

- There is an identification system which assigns a unique code to each donation and to each of the products associated with it
- An audit trail is maintained, which includes details of when and where the relevant material was acquired, the consent obtained, the uses to which the material was put, when the material was transferred and to whom

GQ7 There are systems to ensure that all adverse events are investigated promptly
• Corrective and preventive actions are taken where necessary and improvements in practice are made • System to receive and distribute national and local information (e.g. HTA communications)
GQ8 Risk assessments of the establishment's practices and processes are completed regularly and are recorded and monitored appropriately
• Documented risk assessments for all practices and processes • Risk assessments are reviewed when appropriate • Staff can access risk assessments and are made aware of local hazards at training

Premises, facilities and equipment standards
PFE1 The premises are fit for purpose
• A risk assessment has been carried out of the premises to ensure that they are appropriate for the purpose • Policies in place to review and maintain the safety of staff, authorised visitors and students • The premises have sufficient space for procedures to be carried out safely and efficiently • Policies are in place to ensure that the premises are secure and confidentiality is maintained
PFE 2 Environmental controls are in place to avoid potential contamination
• Documented cleaning and decontamination procedures • Staff are provided with appropriate protective equipment and facilities that minimise risks from contamination • Appropriate health and safety controls are in place
PFE3 There are appropriate facilities for the storage of bodies, body parts, tissues and cells, consumables and records.
• Relevant material, consumables and records are stored in suitable secure environments and precautions are taken to minimise risk of damage, theft or contamination • Contingency plans are in place in case of failure in storage area • Critical storage conditions are monitored and recorded • System to deal with emergencies on 24 hour basis • Records indicating where the material is stored in the premises

PFE 4 Systems are in place to protect the quality and integrity of bodies, body parts, tissues and cells during transport and delivery to a destination

- Documented policies and procedures for the appropriate transport of relevant material, including a risk assessment of transportation
- A system is in place to ensure that traceability of relevant material is maintained during transport
- Records of transportation and delivery
- Records are kept of any agreements with recipients of relevant material
- Records are kept of any agreements with courier or transport companies

PFE5 Equipment is appropriate for use, maintained, quality assured, validated and where appropriate monitored

- Records of calibration, validation and maintenance, including any agreements with maintenance companies
- Users have access to instructions for equipment and receive training in use and maintenance where appropriate
- Staff aware of how to report an equipment problem
- Contingency plan for equipment failure

Disposal Standards

D1 There is a clear and sensitive policy for disposing of human organs and tissue

- Documented disposal policy
- Policy is made available to the public
- Compliance with health and safety recommendations

D2 The reason for disposal and the methods used are carefully documented

- Standard operating procedures (SOPs) for tracking the disposal of relevant material detail the method and reason for disposal
- Where applicable, disposal arrangements reflect specified wishes

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 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 Human Tissue Act 2004 (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:

   (1) A notice of proposal being issued to revoke the licence

   (2) 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.

   (3) A notice of suspension of licensable activities

   (4) Additional conditions being proposed

   (5) 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 CoPs, 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 or 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 both the draft and final inspection report. You 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 desk-based or site-visit inspection.

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