

Site visit inspection report on compliance with HTA minimum standards

CenoBiologics Ltd

HTA licensing number 22640

Licensed for the

- **processing, storage, distribution and import/export of human tissues and cells for human application under the Human Tissue (Quality and Safety for Human Application) Regulations 2007; and**
- **storage of relevant material which has come from a human body for use for a scheduled purpose**

4 November 2014

Summary of inspection findings

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

Although the HTA found that CenoBiologics Ltd (the establishment) had met the majority of the HTA standards, eight shortfalls were found in relation to Governance and Quality Systems. These relate to the establishment's approach to internal and independent audits, risk assessment, contingency planning and document control. The remaining shortfalls relate to the requirement for establishment's to submit appropriate validation data prior to processing a new tissue/cell type, and to the content of end user agreements and training records.

Particular examples of strengths and 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.

Licensable activities carried out by the establishment

'E' = Establishment is licensed to carry out this activity.

'TPA' = Third party agreement; the establishment is licensed for this activity but another establishment (unlicensed) carries out the activity on their behalf.

| Tissue type | Procurement | Processing | Testing | Storage | Distribution | Import | Export |
|-------------------------------|--------------------|-------------------|----------------|----------------|---------------------|---------------|---------------|
| Bone | | E | | E | | E | E |
| Acellular bone chip | | | | E | | E | E |
| DBM | | E | | E | | E | E |
| Other skeletal tissues | | | | E | | E | E |
| Heart valves | | | | E | | E | E |
| Blood vessels | | | | E | | E | E |
| Pericardium | | E | | E | | E | E |

Background to the establishment and description of inspection activities undertaken

This report refers to the activities carried out by CenoBiologics Ltd. The establishment has been licensed by the HTA since June 2012 and has been inspected on one previous occasion. At the time of the last inspection, the establishment was licensed for the storage and import/export of human tissues and cells under the Human Tissue (Quality and Safety for

Human Application) Regulations 2007, and for the storage of relevant material which has come from a human body for use for a scheduled purpose under the Human Tissue Act 2004. Since then, the establishment has applied for, and been granted, an extension to their licence such that it is now licenced for the additional activities of processing and distribution.

This report describes the establishment's second routine site visit inspection which took place on 4 November 2014. The inspection included interviews with key members of staff working under the licence, including the Medical Director, who is also the Designated Individual, one of the establishment's Production Managers, and a Production Operator. A review of documentation relevant to the establishment's activities and a visual inspection of the areas of the establishment where licensable activities are carried out were also conducted as part of the inspection.

In light of the changes made to the licence since the last site visit, the inspection focused primarily on the procedures and facilities that have been put in place to safeguard the tissues and cells during processing and whilst in storage. Processing of tissues takes place within a dedicated cleanroom facility according to documented procedures. Environmental monitoring takes place during processing, with preliminary microbiological analysis carried out on site. In the event that a positive culture is obtained during tissue processing, samples are sent to a third party for qualitative analysis. All products processed by the establishment are terminally sterilised by a third party and agreements are in place for this service. Freeze-dried, sterilised products are stored at room temperature in a specified, monitored room away from the processing suite. Frozen tissue is stored in the laboratory adjacent to the cleanroom in appropriately monitored and alarmed freezers.

During the inspection, consideration was also given to the establishment's import arrangements to ensure that they continue to meet the requirements of the legislation. In this regard, the establishment's procedures were largely unchanged from the last inspection, with all samples being imported from a single overseas tissue bank with whom the DI has a long standing professional relationship. More information about this aspect of the establishment's activities can be found in the previous inspection report. At the time of the inspection, the establishment was not distributing products within the EEA. Instead, all products were being exported outside of the EEA for distribution and end use. As a result, this aspect of the organisation's activities (i.e. distribution) was not reviewed during this inspection.

An audit of seven samples held in storage was performed. The samples chosen for the audit were reflective of the range of tissues handled by the establishment, and included heart valves, bone products and demineralised bone matrix. Storage locations were cross-checked with appropriate records and the donor files were reviewed to ensure that they contained all relevant documentation, including consent forms, serology and microbiology test results, and the results of environmental monitoring. No discrepancies were found.

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

Human Tissue (Quality and Safety for Human Application) Regulations 2007 Standards

Governance and Quality

| Standard | Inspection findings | Level of shortfall |
|---|--|--------------------|
| GQ1 All aspects of the establishment's work are supported by ratified documented policies and procedures as part of the overall governance process. | | |
| d) There is a document control system to ensure that changes to documents are reviewed, approved, dated and documented by an authorised person and only current documents are in use. | At the time of the inspection, a significant number of the establishment's controlled documents were past their specified 'review by' date. | Minor |
| GQ2 There is a documented system of quality management and audit. | | |
| b) There is an internal audit system for all licensable activities. | At the time of the inspection, an internal audit system encompassing the full range of licensable activities had not been implemented. Completed audits were restricted to the establishment's policies and procedures. As a result, documentation such as training records, batch processing records, and stock databases had not been appropriately reviewed. | Minor |
| c) An audit is conducted in an independent manner at least every two years to verify compliance with protocols and HTA standards, and any findings and corrective actions are documented. | Although the establishment is audited in relation to its ISO accreditation, an independent audit aimed at assessing compliance with HTA standards has not been conducted since the last inspection. | Minor |
| d) Processes affecting the quality and safety of tissues and / or cells are validated and undergo regular evaluation to ensure they continue to achieve the intended results. | Since the last inspection the establishment has applied for, and been granted, an extension to their licence to enable it to process and distribute tissues and cells for human application. Although the HTA has authorised a Preparation Process Dossier (PPD) in relation to this licence variation, the scope of the validation report that was submitted at the time does not encompass the range of tissue now being processed by the establishment. | Major |

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| GQ3 Staff are appropriately qualified and trained in techniques relevant to their work and are continuously updating their skills. | | |
| e) Personnel are trained in all tasks relevant to their work and their competence is recorded. | Although staff receive a range of training relevant to their roles within the organisation, the establishment does not have a consistent, robust approach to the recording of task-related competence. | Minor |
| GQ4 There is a systematic and planned approach to the management of records. | | |
| m) In the event of termination of activities of the establishment a contingency plan to ensure records of traceability are maintained for 10 or 30 years as required. | Although the establishment has an agreement in place with another HTA-licensed establishment to ensure that stored tissues and/or cells are transferred in the event of a termination of activities, comparable contingency arrangements are not in place to ensure relevant records are also maintained for the required timeframes. | Minor |
| GQ7 There are systems to ensure that all adverse events are investigated promptly. | | |
| g) Establishments distributing tissue and / or cells provide information to end users on how to report a serious adverse event or reaction and have agreements with them specifying that they will report these events or reactions. | The establishment's product information leaflets state that adverse outcomes potentially attributable to the products must be reported promptly. However, the requirement to report such events within 24 hours of discovery is not clearly documented. End user agreements and distribution agreements also lack this information. | Minor |
| GQ8 Risk assessments of the establishment's practices and processes are completed regularly and are recorded and monitored appropriately. | | |
| a) There are documented risk assessments for all practices and processes. | The establishment has performed a number of risk assessments in relation to the work being conducted under the authority of their | Minor |

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| b) Risk assessments are reviewed regularly, as a minimum annually or when any changes are made that may affect the quality and safety of tissues and cells. | HTA licence, including disease transmission and contamination of products during processing. However, risk assessments were not in place for the full range of licensable activities being carried out, such as the import, storage and distribution of tissue. Furthermore, the establishment's organisational and health and safety risk assessments were not controlled documents at the time of the inspection, thereby increasing the likelihood that they will not be reviewed at appropriate intervals. | |
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Advice

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

| No. | Standard | Advice |
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| 1. | GQ1b | The DI is advised to update the standard operating procedure (SOP) relating to microbiological monitoring to ensure that it captures the daily checks that are carried out on cultures. The SOP should make reference to the form that is completed, which itself should be a controlled document. |
| 2. | GQ8 | The DI is advised to formally risk assess the current storage arrangements for research tissue to ensure that existing control measures adequately mitigate the risk of cross-contamination of tissue samples. |
| 3. | PFE2b | The DI is advised to update the establishment's SOPs to clearly define the grade of the environment in which tissues and cells are processed. This will help ensure that the choice of environment is regularly reviewed and remains suitable for maintaining the critical quality and safety attributes of each product. |

Concluding comments

The HTA saw examples of good practice during the course of the inspection. In particular, the DI has continued to foster strong links with the establishment's overseas tissue supplier and is extremely knowledgeable about their consent, procurement and processing procedures. Detailed information is retained, or is directly accessible by the establishment, for all imported material and regular site visit audits of the supplier are carried out by the DI. This helps to ensure that imported material meets the quality and safety standards set out in the EU Tissues and Cells Directives. The organisation has also established strong links with local universities to support its research and development initiatives.

Eight areas of practice were identified during the inspection that require improvement, resulting in one major and seven minor shortfalls. These relate to certain aspects of the establishment's governance and quality systems, including risk assessment, training, audit, contingency planning, document control, and the validation of preparation processes. The HTA has also given advice to the Designated Individual in relation to a small number of practices and procedures view to helping the establishment further develop their working practices and governance systems.

The HTA requires that the Designated Individual addresses the shortfalls 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 shortfalls identified during the inspection.

Report sent to DI for factual accuracy: 28 November 2014

Report returned from DI: 2 December 2014

Final report issued: 11 December 2014

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.

Human Tissue (Quality and Safety for Human Application) Regulations 2007 Standards

Governance and Quality

| Standard |
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| GQ1 All aspects of the establishment's work are supported by ratified documented policies and procedures as part of the overall governance process. |
| a) There is an organisational chart clearly defining the lines of accountability and reporting relationships. |
| b) There are procedures for all licensable activities that ensure integrity of tissue and / or cells and minimise the risk of contamination. |
| c) There are regular governance meetings, for example health and safety, risk management and clinical governance committees, which are recorded by agendas and minutes. |
| d) There is a document control system to ensure that changes to documents are reviewed, approved, dated and documented by an authorised person and only current documents are in use. |
| g) There are procedures to ensure that an authorised person verifies that tissues and / or cells received by the establishment meet required specifications. |
| h) There are procedures for the management and quarantine of non-conforming consignments or those with incomplete test results, to ensure no risk of cross contamination. |
| i) There are procedures to ensure tissues and / or cells are not released from quarantine until verification has been completed and recorded. |
| j) There are procedures detailing the critical materials and reagents used and where applicable, materials and reagents meet the standards laid down by the European directives on medical devices and in vitro diagnostic medical devices. |
| k) There is a procedure for handling returned products. |
| l) There are procedures to ensure that in the event of termination of activities for whatever reason, stored tissues and / or cells are transferred to another licensed establishment or establishments. |
| m) The criteria for allocating tissues and / or cells to patients and health care institutions are documented and made available to these parties on request. |
| n) The establishment ensures imports from non EEA states meet the standards of quality and safety set out in Directions 003/2010. |
| o) There is a complaints system in place. |
| p) There are written agreements with third parties whenever an activity takes place that has the potential to influence the quality and safety of human tissues and / or cells. |
| q) There is a record of agreements established with third parties. |

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| r) Third party agreements specify the responsibilities of the third party and meet the requirements set out in Directions 003/2010. |
| s) Third party agreements specify that the third party will inform the establishment in the event of a serious adverse reaction or event. |
| t) There are procedures for the re-provision of service in an emergency. |
| GQ2 There is a documented system of quality management and audit. |
| a) There is a quality management system which ensures continuous and systematic improvement. |
| b) There is an internal audit system for all licensable activities. |
| c) An audit is conducted in an independent manner at least every two years to verify compliance with protocols and HTA standards, and any findings and corrective actions are documented. |
| d) Processes affecting the quality and safety of tissues and / or cells are validated and undergo regular evaluation to ensure they continue to achieve the intended results. |
| GQ3 Staff are appropriately qualified and trained in techniques relevant to their work and are continuously updating their skills. |
| a) There are clearly documented job descriptions for all staff. |
| b) There are orientation and induction programmes for new staff. |
| c) There are continuous professional development (CPD) plans for staff and attendance at training is recorded. |
| d) There is annual documented mandatory training (e.g. health and safety and fire). |
| e) Personnel are trained in all tasks relevant to their work and their competence is recorded. |
| f) There is a documented training programme that ensures that staff have adequate knowledge of the scientific and ethical principles relevant to their work, and the regulatory context. |
| g) There is a documented training programme that ensures that staff understand the organisational structure and the quality systems used within the establishment. |
| h) There is a system of staff appraisal. |
| i) Where appropriate, staff are registered with a professional or statutory body. |
| j) There are training and reference manuals available. |
| k) The establishment is sufficiently staffed to carry out its activities. |
| GQ4 There is a systematic and planned approach to the management of records. |
| a) There are procedures for the creation, identification, maintenance, access, amendment, retention and destruction of records. |
| b) There is a system for the regular audit of records and their content to check for completeness, legibility and accuracy and to resolve any discrepancies found. |
| c) Written records are legible and indelible. Records kept in other formats such as computerised |

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| records are stored on a validated system. |
| d) There is a system for back-up / recovery in the event of loss of computerised records. |
| e) The establishment keeps a register of the types and quantities of tissues and / or cells that are procured, tested, preserved, processed, stored and distributed or otherwise disposed of, and on the origin and destination of tissues and cells intended for human application. |
| f) There are procedures to ensure that donor documentation, as specified by Directions 003/2010, is collected and maintained. |
| g) There is a system to ensure records are secure and that donor confidentiality is maintained in accordance with Directions 003/2010. |
| h) Raw data which are critical to the safety and quality of tissues and cells are kept for 10 years after the use, expiry date or disposal of tissues and / or cells. |
| i) The minimum data to ensure traceability from donor to recipient as required by Directions 003/2010 are kept for 30 years after the use, expiry or disposal of tissues and / or cells. |
| j) Records are kept of products and material coming into contact with the tissues and / or cells. |
| k) There are documented agreements with end users to ensure they record and store the data required by Directions 003/2010. |
| l) The establishment records the acceptance or rejection of tissue and / or cells that it receives and in the case of rejection why this rejection occurred. |
| m) In the event of termination of activities of the establishment a contingency plan to ensure records of traceability are maintained for 10 or 30 years as required. |
| GQ6 A coding and records system facilitates traceability of tissues and / or cells, ensuring a robust audit trail. |
| a) There is a donor identification system which assigns a unique code to each donation and to each of the products associated with it. |
| b) An audit trail is maintained, which includes details of when the tissues and / or cells were acquired and from where, the uses to which the tissues and / or cells were put, when the tissues and / or cells were transferred elsewhere and to whom. |
| c) The establishment has procedures to ensure that tissues and / or cells imported, procured, processed, stored, distributed and exported are traceable from donor to recipient and vice versa. |
| GQ7 There are systems to ensure that all adverse events, reactions and/or incidents are investigated promptly. |
| a) There are procedures for the identification, reporting, investigation and recording of adverse events and reactions, including documentation of any corrective or preventative actions. |
| b) There is a system to receive and distribute national and local information (e.g. HTA regulatory alerts) and notify the HTA and other establishments as necessary of serious adverse events or reactions. |
| c) The responsibilities of personnel investigating adverse events and reactions are clearly defined. |
| d) There are procedures to identify and decide the fate of tissues and / or cells affected by an |

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| adverse event, reaction or deviation from the required quality and safety standards. |
| e) In the event of a recall, there are personnel authorised within the establishment to assess the need for a recall and if appropriate initiate and coordinate a recall. |
| f) There is an effective, documented recall procedure which includes a description of responsibilities and actions to be taken in the event of a recall including notification of the HTA and pre-defined times in which actions must be taken. |
| g) Establishments distributing tissue and / or cells provide information to end users on how to report a serious adverse event or reaction and have agreements with them specifying that they will report these events or reactions. |
| h) Establishments distributing tissues and / or cells have systems to receive notifications of serious adverse events and reactions from end users and notify the HTA. |
| GQ8 Risk assessments of the establishment's practices and processes are completed regularly and are recorded and monitored appropriately. |
| a) There are documented risk assessments for all practices and processes. |
| b) Risk assessments are reviewed regularly, as a minimum annually or when any changes are made that may affect the quality and safety of tissues and cells. |
| c) Staff can access risk assessments and are made aware of local hazards at training. |
| d) A documented risk assessment is carried out to decide the fate of any tissue and / or cells stored prior to the introduction of a new donor selection criteria or a new processing step, which enhances the quality and safety of tissue and / or cells. |

Premises, Facilities and Equipment

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| Standard |
| PFE1 The premises are fit for purpose. |
| a) A risk assessment has been carried out of the premises to ensure that they are fit for purpose. |
| b) There are procedures to review and maintain the safety of staff, visitors and patients. |
| c) The premises have sufficient space for procedures to be carried out safely and efficiently. |
| d) Where appropriate, there are procedures to ensure that the premises are of a standard that ensures the dignity of deceased persons. |
| e) There are procedures to ensure that the premises are secure and confidentiality is maintained. |
| f) There is access to a nominated, registered medical practitioner and / or a scientific advisor to provide advice and oversee the establishment's medical and scientific activities. |
| PFE2 Environmental controls are in place to avoid potential contamination. |
| a) Tissues and / or cells stored in quarantine are stored separately from tissue and / or cells that have been released from quarantine. |
| b) Where processing of tissues and / or cells involves exposure to the environment, it occurs in an appropriate, monitored environment as required by Directions 003/2010. |

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| c) There are procedures for cleaning and decontamination. |
| d) Staff are provided with appropriate protective clothing and equipment that minimise the risk of contamination of tissue and / or cells and the risk of infection to themselves. |
| PFE3 There are appropriate facilities for the storage of tissues and / or cells, consumables and records. |
| a) Tissues, cells, consumables and records are stored in secure environments and precautions are taken to minimise risk of damage, theft or contamination. |
| b) There are systems to deal with emergencies on a 24 hour basis. |
| c) Tissues and / or cells are stored in controlled, monitored and recorded conditions that maintain tissue and / or cell integrity. |
| d) There is a documented, specified maximum storage period for tissues and / or cells. |
| PFE4 Systems are in place to protect the quality and integrity of tissues and / or cells during transport and delivery to its destination. |
| a) There is a system to ensure tissue and / or cells are not distributed until they meet the standards laid down by Directions 003/2010. |
| b) There are procedures for the transport of tissues and / or cells which reflect identified risks associated with transport. |
| c) There is a system to ensure that traceability of tissues and / or cells is maintained during transport. |
| d) Records are kept of transportation and delivery. |
| e) Tissues and / or cells are packaged and transported in a manner and under conditions that minimise the risk of contamination and ensure their safety and quality. |
| f) There are third party agreements with courier or transport companies to ensure that any specific transport conditions required are maintained. |
| g) Critical transport conditions required to maintain the properties of tissue and / or cells are defined and documented. |
| h) Packaging and containers used for transportation are validated to ensure they are fit for purpose. |
| i) Primary packaging containing tissues and / or cells is labelled with the information required by Directions. |
| j) Shipping packaging containing tissues and / or cells is labelled with the information required by Directions. |
| PFE5 Equipment is appropriate for use, maintained, quality assured, validated and where appropriate monitored. |
| a) Critical equipment and technical devices are identified, validated, regularly inspected and records are maintained. |
| b) Critical equipment is maintained and serviced in accordance with the manufacturer's instructions. |
| c) Equipment affecting critical processes and storage parameters is identified and monitored to |

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| detect malfunctions and defects and procedures are in place to take any corrective actions. |
| d) New and repaired equipment is validated before use and this is documented. |
| e) There are documented agreements with maintenance companies. |
| f) Cleaning, disinfection and sanitation of critical equipment is performed regularly and this is recorded. |
| h) Users have access to instructions for equipment and receive training in the use of equipment and maintenance where appropriate. |
| i) Staff are aware of how to report an equipment problem. |
| j) For each critical process, the materials, equipment and personnel are identified and documented. |
| k) There are contingency plans for equipment failure. |

Disposal

| Standard |
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| D1 There is a clear and sensitive policy for disposing of tissues and / or cells. |
| a) The disposal policy complies with HTA's Codes of Practice. |
| b) The disposal procedure complies with Health and Safety recommendations. |
| c) There is a documented procedure on disposal which ensures that there is no cross contamination. |
| D2 The reasons for disposal and the methods used are carefully documented. |
| a) There is a procedure for tracking the disposal of tissue and / or cells that details the method and reason for disposal. |
| b) Disposal arrangements reflect (where applicable) the consent given for disposal. |

Human Tissue Act 2004 Standards

| Consent standards |
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| 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 |
| <ul style="list-style-type: none"> • 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

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| GQ3 Staff are appropriately qualified and trained in techniques relevant to their work and are continuously updating their skills |
| <ul style="list-style-type: none"> • 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 |
| <ul style="list-style-type: none"> • 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 |
| <ul style="list-style-type: none"> • 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 |
| <ul style="list-style-type: none"> • 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 |
| <ul style="list-style-type: none"> • 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 |
| <ul style="list-style-type: none"> • 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 |
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| PFE1 The premises are fit for purpose |
| <ul style="list-style-type: none"> • 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 |
| <ul style="list-style-type: none"> • 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. |
| <ul style="list-style-type: none"> • 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 |
| <ul style="list-style-type: none"> • 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 |
| <ul style="list-style-type: none"> • 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 (HA)

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 direct risk of causing harm to a recipient patient or to a living donor,

Or

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 number of 'major' shortfalls, none of which is critical on its own, but viewed cumulatively represent a systemic failure and therefore are considered 'critical'.

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.

A shortfall in the carrying out of licensable activities which poses an indirect risk to the safety of a donor or a recipient

or

A shortfall in the establishment's quality and safety procedures which poses an indirect risk to the safety of a donor or a recipient;

or

A shortfall which indicates a major deviation from the **Human Tissue (Quality and Safety for Human Application) Regulations 2007** or the **HTA Directions**;

or

A shortfall which indicates a breach in the relevant Codes of Practices, the HT Act and other relevant professional and statutory guidelines;

or

A shortfall which indicates a failure to carry out satisfactory procedures or a failure on the part of the designated individual to fulfil his or her legal duties;

or

A combination of several 'minor' shortfalls, none of which is major on its own, but which, viewed cumulatively, could constitute a major shortfall.

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 and, which can be addressed by further development by the establishment.

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 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.