Inspection report on compliance with HTA licensing standards
Inspection date: **14 May 2025**

Edge Medical Ltd

HTA licensing number 22646

Licensed under the Human Tissue (Quality and Safety for Human Application) Regulations 2007 (as amended)

Licensable activities carried out by the establishment

'E' = Establishment is licensed to carry out this activity and is currently carrying it out.

Site	Procurement	Processing	Testing	Storage	Distribution	Import	Export
Edge Medical Ltd				E	E	E	E

Tissue types authorised for licensed activities

Authorised = Establishment is authorised to carry out this activity and is currently carrying it out.
Authorised* = Establishment is authorised to carry out this activity but is not currently carrying it out.

Tissue Category; Tissue Type	Procurement	Processing	Testing	Storage	Distribution	Import	Export
Musculoskeletal Bone; Acellular				Authorised	Authorised	Authorised	Authorised

Bone							
Musculoskeletal Bone; Bone				Authorised	Authorised	Authorised	Authorised
Musculoskeletal Bone; Bone Struts				Authorised*	Authorised*	Authorised*	
Musculoskeletal Bone; Cancellous Bone Particles				Authorised	Authorised	Authorised	
Musculoskeletal, Cartilage; Cartilage				Authorised*	Authorised*	Authorised*	
Musculoskeletal, Bone; DBM				Authorised	Authorised	Authorised	
Musculoskeletal, Bone; DBM Putty				Authorised	Authorised	Authorised	
Membrane, Fascia Lata; Fascia Lata				Authorised*	Authorised*	Authorised*	
Musculoskeletal, Tendon & Ligament; Menisci				Authorised	Authorised	Authorised	
Musculoskeletal, Tendon & Ligament; Tendon				Authorised	Authorised	Authorised	Authorised*

Skin; Skin				Authorised*	Authorised*	Authorised*	Authorised*

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 Edge Medical Ltd (the establishment) had met the majority of the HTA's standards that were assessed during the inspection, one major and seven minor shortfalls were found against standards for Governance and Quality, and Premises, Facilities and Equipment.

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

Major Shortfalls

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.		
n) The establishment ensures imports from third countries meet the standards of quality and safety set out in Directions 001/2021.	During the inspection it was identified that the establishment had imported several products from a donor with a history of malignant disease despite this being an exclusion criterion. None of the products from the affected batch had been released to end users and immediate action was taken to prevent the release of all products from the third country supplier (3CS). In addition, although the establishment undertakes audits of its 3CSs these were limited in scope and did not include the information reviewed to provide assurance that imports from third country suppliers continue to meet the standards of quality and safety set out in Directions 001/2021. During the inspection the establishment was asked to provide additional information about donor selection for two of its three 3CSs. The DI was unable to provide all the requested information, either during or post-inspection.	**Major**

Minor Shortfalls

GQ1 All aspects of the establishment's work are supported by ratified documented policies and procedures as part of the overall governance process.		
b) There are procedures for all licensable activities that ensure integrity of tissue and / or cells and minimise the risk of contamination	The establishment's standard operating procedure (SOP) for receipt and compliance of imported tissue products does not reflect current practice of checking the temperature of the tissues on receipt and taking photographs of the tissue product identifier to cross-check against the paperwork. In addition, an example where a tissue product was returned by the end user was seen during the inspection. However, the establishment does not have a procedure for the handling of returned of tissue products. Finally, examples were seen where standard operating procedures and documents were overdue for review**.**	**Minor**
GQ2 There is a documented system of quality management and audit.		
b) There is an internal audit system for all licensable activities.	The establishment's internal audits are limited to SOPs and do not cover the full range of activities carried out by the establishment under its licence.	**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 an independent audit has been carried out since the last inspection, this did not include a review of primary and traceability records, including batch processing records for each of the tissue types imported to ensure that the products supplied by the 3CSs meet the requirements of the Human Tissue (Quality and Safety for Human Application) Regulations 2007 (as amended). Therefore, the scope of the independent audit was not sufficient to provide assurance of compliance with applicable HTA standards relating to the full range of activities being carried out under the licence.	**Minor**
GQ3 Staff are appropriately qualified and trained in techniques relevant to their work and are continuously updating their skills.		
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.	Although the establishment undertakes training for new and existing members of staff that includes the tissue products and HTA activities that the establishment is licensed for, this is not documented.	**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 scope of the risk assessments is limited and does not cover all the control measures in place which help to mitigate identified risks to the quality and safety of the tissues.	**Minor**

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.	There is no annual review of the risk assessments for all practices and processes relating to licensable activities.	**Minor**

Standard	**Inspection findings**	**Level of shortfall**
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.	The establishment uses temperature probes to check the temperature of frozen tissue and cell products on receipt or when they are returned by an end-user. The establishment also uses probes to monitor the temperature of the area used to store products at ambient temperatures and the -80°C storage freezer. The establishment was unable to provide the most recent calibration certificates for any of the probes being used.	**Minor**
b) Critical equipment is maintained and serviced in accordance with the manufacturer's instructions.		

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.

DI and CLH/LH suitability

The major shortfall above relates to the import of tissue products from a donor that did not meet UK requirements. The DI and CLH were asked to provide additional information in relation to donor selection and calibration of the probes used for temperature monitoring both during and after the inspection. Despite the establishment's assurances they were not able to provide all the information requested. At the time of writing the report this information was not forthcoming. Furthermore, the establishment could not provide any assurance that as part of the audits undertaken a selection of records for each of the products imported were reviewed, including records relating to:

- Donor consent and selection;
- Mandatory serology testing;
- Processing records and environmental monitoring data; and
- Sign-off of the tissue products by the manufacturer as being suitable for release.

At the time of writing this report the establishment was not able to provide all the information requested. In light of this the HTA will review the suitability of the DI and CLH as the corrective actions are undertaken to address the shortfalls identified during the inspection.

Advice

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

Number	Standard	Advice
1.	GQ2b/ GQ2c	The DI is advised to ensure that the documentation and records reviewed as part of internal and independent audits are recorded within audit reports.
2.	GQ4b	A couple of minor discrepancies were identified during the review of the establishment's records. For one imported tissue product, the unique identifier was logged within the paper log but not the

		electronic traceability spreadsheet. For another product, the expiry date was inputted incorrectly on the traceability spreadsheet. The DI is advised to review the establishment's approach to the audit of records to ensure that they are sufficiently robust to identify issues of this kind and that they result in appropriate corrective and preventative actions being taken.
3.	GQ7a	The DI is advised to nominate a Person Designated to report serious adverse events and reactions (SAEARs) in his absence.
4.	GQ7a	The establishment's SOP on SAEARs reporting includes incorrect information about reporting SAEARs via the HTA portal. The DI is advised to review this SOP and ensure it includes up-to date references and contact information so that staff are able to report SAEARs. The DI is also advised not to share individual login details within the SOP.
5.	PFE1a	The establishment's premises risk assessment has the incorrect temperature range for the -80°C freezer. The DI is advised to review the establishment's documentation and ensure the documented alarms limits are aligned with the set temperature limits of the -80°C freezer.
6.	PFE1f	The establishment has access to a medical advisor to provide advice and review records, if required. The DI is advised to consider formalising these arrangements in an agreement.
7.	PFE5b	In addressing the shortfall against PFE5b, the DI is strongly advised to ensure copies of the calibration certificates are readily accessible along with the calibration and maintenance requirements for each of the temperature probes. The DI is also advised to assign unique identifiers to both of the temperature probes used during the receipting of frozen products.

8.	N/A	The DI is advised to review the establishment's documentation to ensure it includes up-to-date references to the Human Tissue (Quality and Safety for Human Application) Regulations 2007 (as amended), which is the legislation that the establishment is working under.

Background

Edge Medical Ltd is licensed for the import, storage and distribution of various bone products, demineralised bone matrix (DBM), DBM Putty and tendon, as set out above. In addition, the establishment is licensed to import, store and distribute bone struts, cartilage, fascia lata, menisci and skin, but is not currently undertaking these activities. Edge Medical Ltd is also licensed to export acellular bone, tendon and skin, but it has only exported bone products since the previous inspection.

The establishment has been licensed by the HTA since August 2013. This was the establishment's sixth inspection; the last inspection took place in April 2023. Since the previous inspection a new 3CS was added and there has been a change to the CLHc.

Description of inspection activities undertaken

The HTA's regulatory requirements are set out in Appendix 1. The following areas were covered during the inspection:

Review of governance documentation

A review of a selection of documentation relevant to the establishment's licensable activities and quality management system was undertaken, including a review of policies and procedural documents, temperature monitoring records, audits, agreements, risk assessments, and staff training records. There were no incidents recorded by the establishment since the previous inspection.

Visual inspection

A review of the facilities was conducted at the establishment, including areas where receipt, storage and packing of the tissue products take place.

Audit of records
Representative records associated with each product were reviewed. These included:

- The processing records of four imported bone products. These records included documents relating to donor consent and selection, procurement dates and times, mandatory serology testing, terminal sterilisation or sterilisation with super-critical CO_2, and the review of donor eligibility. A discrepancy was noted during the review of the donor selection records of one of the bone products (Shortfall against standard GQ1(n)).
- A traceability audit of the whole stock from one of the 3CS consisting of 34 bone products was also reviewed against the electronic records. These were placed in quarantine as they related to the shortfall against GQ1(n).
- A traceability audit of six bone products stored at ambient temperature and deemed suitable for release to end-users, cross-checked against the electronic records. The expiry date for one of the products that had been returned from an end user was not inputted correctly within the electronic inventory. For another bone product the traceability information was recorded in the paper records, but not within the electronic inventory (Advice item, GQ4(b)). No other discrepancies were noted.
- A traceability audit of two bone products and a skin product in quarantine at ambient temperature, as well as a tendon product and bone product in -80°C storage was also reviewed against the electronic records. No discrepancies were noted.

Meetings with establishment staff
Discussions were held with the establishment's CLH and a number of staff carrying out processes under the licence.

Report sent to DI for factual accuracy: 2025 – 07 – 21

Report returned from DI: No factual accuracy or request for redaction comments were made by the DI

Final report issued: 2025 – 08 – 08

Appendix 1: The HTA's regulatory requirements

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

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.

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.

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, Human Tissue (Quality and Safety for Human Application) Regulations 2007 (as amended), 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 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:

   - 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.

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 (as amended) or the HTA Directions;

or

A shortfall which indicates a failure to carry out satisfactory procedures for the release of tissues and cells 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 by adversely affecting the quality and safety of the tissues and cells.

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 on-site 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.

Appendix 3: 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 (as amended)

Governance and Quality

Standard
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.
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 third countries meet the standards of quality and safety set out in Directions 001/2021.
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.
r) Third party agreements specify the responsibilities of the third party and meet the requirements set out in Directions 001/2021.
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.
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.
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 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 001/2021, is collected and maintained.
g) There is a system to ensure records are secure and that donor confidentiality is maintained in accordance with Directions 001/2021.
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 001/2021 are kept for 30 years after the use, expiry or disposal of tissues and / or cells.
k) There are documented agreements with end users to ensure they record and store the data required by Directions 001/2021.
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 is in place to ensure raw data and records of traceability are maintained for 10 or 30 years respectively, 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 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

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.
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.
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 001/2021.
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 001/2021.
j) Shipping packaging containing tissues and / or cells is labelled with the information required by Directions 001/2021.
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 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
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.