Site visit inspection report on compliance with HTA licensing standards
Inspection date: **10 to 12 December 2019**

Royal Victoria Infirmary
HTA licensing number 11122

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

Licensable activities carried out by the establishment

Licensed activities

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

'E*' = Establishment is licensed to carry out this activity but is not currently carrying it out.

'TPA' = Third party agreement; the establishment is licensed for this activity but another establishment (not licensed by the HTA) carries out the activity on their behalf.

Site	Procurement	Processing	Testing	Storage	Distribution	Import	Export
Royal Victoria Infirmary	E	E	E	E	E		E
Freeman Hospital	E		E	E	E		
Newcastle Bio-Manufacturing Facility		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; Bone				Authorised	Authorised		
Musculoskeletal, Bone; Bone Struts				Authorised	Authorised		
Musculoskeletal, Tendon & Ligament; Tendon				Authorised	Authorised		
Progenitor Cell, Hematopoietic, PBSC; PBSC	Authorised	Authorised	Authorised	Authorised	Authorised		
Progenitor Cell, Hematopoietic, Bone Marrow; Bone Marrow	Authorised	Authorised	Authorised	Authorised	Authorised		
Mature Cell, MNC; DLI	Authorised	Authorised	Authorised	Authorised	Authorised		
Progenitor Cell, Hematopoietic, Cord Blood; Cord Blood	Authorised	Authorised	Authorised	Authorised	Authorised		
Cardiovascular, Valves; Heart				Authorised	Authorised		

Valves							
Cardiovascular, Valves; Pulmonary Patches				Authorised	Authorised		
Cardiovascular, vessels; Conduits				Authorised	Authorised		
Cardiovascular, vessels; Others				Authorised	Authorised		
Other; Limbal Stem Cells (ATMP)	Authorised	Authorised	Authorised	Authorised			
Membrane, Amniotic: Amniotic Membrane				Authorised			
Mature Cell, Pancreatic Islets; Pancreatic Islets	Authorised*	Authorised*	Authorised*				
Mature Cell, MNC; PBMC	Authorised	Authorised	Authorised	Authorised	Authorised		Authorised
Other; Tumour (ATMP)	Authorised		Authorised				
Other; hESCs				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 the Royal Victoria Infirmary (the establishment) had met the majority of the HTA's standards, five major and five minor shortfalls were found against standards for Consent, Governance and Quality, Premises, Facilities and Equipment, and Disposal.

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.		
g) There are procedures to ensure that an authorised person verifies that tissues and / or cells received by the establishment meet required specifications.	A review of products stored in the orthopaedic bone bank freezer identified that products purchased by the establishment for end use were labelled with a three year expiry date and require storage at temperatures below -40°C. The establishment's bone storage freezer operates at between -20°C to -40°C. Between these temperatures, the tissue being stored by the establishment would usually be assigned a six month expiry date as opposed to the incorrect three year date which was found. The establishment does not have a procedure to verify that tissue being supplied to it has both the relevant storage temperature requirements and expiry dates applied to it. A review of the product log book identified that current stock was recorded as having a three year expiry date, while other historical records indicated a six month expiry date had been applied to previously supplied tissue. Subsequent to the inspection the establishment undertook a 12 month inventory check and were able to identify all products where an incorrect three year expiry date had been applied, rather than the expected six month expiry. No products were released and used beyond six months. The establishment has contacted the supplier and confirmed that all future products will have a six month expiry date applied.	**Major**

GQ2 There is a documented system of quality management and audit.		
b) There is an internal audit system for all licensable activities.	During the previous inspection it was identified that 'Internal audits are conducted for some of the activities undertaken by the establishment. For activities such as storage of heart valves or bone, there is an inventory check however, this is not documented and no further audits are conducted.' The establishment has expanded the scope of its internal audits. However, they do not cover all licensable activities and remain insufficient to provide an assurance that activities are undertaken as expected.	**Major**
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.	During the previous inspection it was identified that 'The independent audits for some activities are limited to a desk based audit assessment. This does not fulfil the requirements of this standard since not all the relevant standards applicable to this licence have been assessed.' During this inspection, it was found that a number of external organisations have conducted audits of specific activities at the RVI. However, these audits did not cover all activities at the establishment and did not verify compliance with the establishment's protocols and the HTA standards.	**Major**

GQ5 There are documented procedures for donor selection and exclusion, including donor criteria.		
b) The testing of donors by the establishment or a third party on behalf of the establishment is carried out in accordance with the requirements of Directions 002/2018.	During the previous inspection, issues associated with the serology testing of cadaveric liver donors were identified. Where vessels are being stored for more than 48 hours for use in a patient other than the recipient of the associated liver, donor serology testing of the donor's blood sample must be performed in accordance with the requirements of the Human Tissue (Quality and Safety for Human Application) Regulations 2007 (the Regulations). The establishment testing of a donor blood sample does not include the full panel of tests required by Directions 003/2010. During this inspection it was identified that this shortfall had not been addressed. In addition, a review of donor documentation identified that for patients undergoing a procedure specifically to harvest cells for Donor Lymphocyte Infusion (DLI), the blood sample which is taken for mandatory serological testing was not being taken at the correct time point as specified in Directions 002/2018. During a review of donor mandatory serological testing records, an allogenic bone marrow donor was identified who had a testing blood sample taken for an HTLV serology test more than 30 days prior to the day of the bone marrow collection procedure. This test has therefore not been undertaken at the correct time point specified in Directions 002/2018, and this non-compliance was not identified by existing establishment procedures.	**Major (cumulative)**

<table>
<tr><th colspan="3">GQ8 Risk assessments of the establishment’s practices and processes are completed regularly and are recorded and monitored appropriately.</th></tr>
<tr><td>a) There are documented risk assessments for all practices and processes.</td><td rowspan="5">During the previous inspection it was noted that ‘The establishment has in place risk assessments; however, these were limited in scope and do not fully capture all the risks associated with activities that may affect the quality and safety of tissues and cells.’

This inspection identified that there continues to be a lack of suitable risk assessments covering the establishment’s licensable activities. Areas and activities where risk assessments were not available or suitable include, but are not limited to, those:
related to the storage of amniotic membrane, heart valves, and orthopaedic products;
for potential storage freezer failure;
for the premises where storage of amniotic membrane, heart valves and orthopaedic bone products is undertaken; and
for academic staff accessing the freezer where amniotic membrane is stored.
In addition, staff in several areas where licensable activity is undertaken indicated that they were unaware if risk assessments were available.</td><td rowspan="5">Major (cumulative)</td></tr>
<tr><td>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.</td></tr>
<tr><td>c) Staff can access risk assessments and are made aware of local hazards at training.</td></tr>
<tr><td>PFE1 The premises are fit for purpose.</td></tr>
<tr><td>a) A risk assessment has been carried out of the premises to ensure that they are fit for purpose.</td></tr>
</table>

Minor 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.		
b) There are procedures for all licensable activities that ensure integrity of tissue and / or cells and minimise the risk of contamination.	Although the establishment utilises a commercially available document control system, it was identified that heart valve and orthopaedic bone bank staff developed procedures that were not controlled through this system and were not reviewed by the Quality Manager. Additionally, establishment staff were able to describe a number of processes where there were no corresponding, documented procedures in place to help assure the DI that staff undertake the activity as expected. These processes included, but were not limited to, the procedures for: • transferring product from the bone bank freezer at the Freeman Hospital to the contingency freezer at RVI; • cleaning the freezer at the Heart Valve bank; • training and assessing competency of staff at the bone bank and heart valve bank; • documenting receipt of product into the bone bank; • undertaking a human tissue audit (bone bank); and • disposing of unused product from the bone bank should any released tissue be returned from theatre.	**Minor**
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.		

GQ5 There are documented procedures for donor selection and exclusion, including donor criteria.		
a) Donors are selected either by the establishment or the third party acting on its behalf in accordance with the criteria required by Directions 002/2018.	The establishment's donor selection questionnaires for allogeneic PBSC or bone marrow donors do not ask about the possible ingestion of, or exposure to, a substance (such as cyanide, lead, mercury) that may be transmitted to recipients in a dose that could endanger their health, or give consideration to the possibility the donor may have undergone transplantation with xenografts. These donor exclusion criteria are set out in Annex A of the HTA's Guide to Quality and Safety Assurance for Human Tissues and Cells for Patient Treatment.	**Minor**

GQ6 A coding and records system facilitates traceability of bodies, body parts, tissues and cells, ensuring a robust audit trail.		
d) The requirements of the Single European Code are adhered to as set out in Directions 002/2018.	The establishment does not consistently record the Single European Code (SEC) for products used in heart valve transplantation, as required by Directions 002/2018. The establishment procures starting material for a number of external Advanced Therapy Medicinal Product (ATMP) clinical trials. Four of the nine ATMP starting material procurements that were reviewed, comprising material for three different studies being sent to two different organisations, were not labelled with the SEC-donation identification sequence (SEC-DI), as required by Directions 002/2018. It was noted however that for one of these three studies, more recently procured starting material had been allocated an appropriate SEC-DI.	**Minor**

PFE3 There are appropriate facilities for the storage of bodies, body parts, tissues, 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.	The cold room where several of the serology testing kits are stored was monitored. However, the temperature monitoring probes had not been re-calibrated and were beyond their required re-calibration date.	**Minor**

PFE4 Systems are in place to protect the quality and integrity of bodies, body parts, tissues and cells during transport and delivery to a destination.		
g) Critical transport conditions required to maintain the properties of tissue and / or cells are defined and documented.	Procured stem cell products are transferred for processing in ambient temperature transport boxes. The boxes in use during the inspection had been purchased and validated in February 2014. The validation exercise that was undertaken did not define any critical transport conditions that are required to be maintained. There is no ongoing revalidation of the transport boxes to ensure they remain suitable for use. Cryopreserved product may be transported in Liquid Nitrogen (LN2) dry shippers. While the inspection team were informed that the shippers had been validated, there was no documentation available to provide evidence of the validation.	**Minor**
h) Packaging and containers used for transportation are validated to ensure they are fit for purpose.		

The HTA requires the DI to submit a completed corrective and preventative action (CAPA) plan setting out how the shortfalls will be addressed, within 14 days of receipt of the final report (refer to Appendix 2 for recommended timeframes within which to complete actions). The HTA will then inform the establishment of the evidence required to demonstrate that the actions agreed in the plan have been completed.

Advice

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

Number	Standard	Advice
1.	GQ1c	The DI is advised to include staff from the testing laboratory at the establishment governance meetings where HTA related activities are discussed.
2.	GQ1l	The establishment stores a large number of haematopoietic stem cells (HSCs) and have identified difficulties in locating sufficient alternative storage in the event that it terminates undertaking this activity. Staff have proposed potential options to address this eventuality should it occur and the DI is advised to document these options should they be required.
3.	GQ3f	Since the last inspection there has been a change in staff undertaking some of the activities under the licence, including PDs overseeing several of the activities across different areas under the licence. The DI is advised to review systems for training staff, to help provide him with assurance that all staff are appropriately trained in a timely and consistent manner across the different activities.
4.	GQ3k	The establishment is adequately staffed to carry out the licensable processes. However, in light of the future planned expansion of activities, the DI is advised to review the allocation of staff involved in a quality and governance role to help assure himself that they have sufficient time to provide the required oversight, on his behalf, of all the establishment's licensable activities.
5.	GQ7a	The incident reporting system at the testing laboratory does not directly notify the DI of potential serious adverse events and adverse reactions (SAEARs), or near misses. The DI is advised to appoint a Person Designated (PD) in the testing laboratory to act as a point of contact and who would be able to report and investigate SAEARs, providing an assurance that all incidents are reported to the DI.
6.	PFE3a	Amniotic membrane is stored on a designated shelf within a freezer shared with academic staff. While the freezer is within a restricted access area it was kept unlocked. The DI is advised to implement a process

		where the freezer is kept locked, and to consider any risks to the stored tissue that may arise through sharing the freezer with academic colleagues working under another HTA licence.
7.	PFE3a	During the previous inspection a shortfall against standard PFE3a, related to downloading and retaining temperature monitoring records for the storage of the anticoagulant ACD-A, was identified. While the establishment has implemented a procedure for the data to be downloaded and archived, this was undertaken by a single member of staff. During the inspection the staff member was unavailable and the data could not be located or provided to the inspection team, although it was provided to the HTA post inspection. The DI is advised to develop procedures to provide an assurance that there is contingency for staff during absences, and that data is stored in an identifiable location that can be easily accessed.

Background

The Royal Victoria Infirmary has been licensed by the HTA since April 2008. This was the seventh site visit inspection of the establishment; the most recent previous inspection took place in November 2017. Licensable activities take place at The Royal Victoria Infirmary ('the hub') and two satellite sites (the Freeman Hospital and the Newcastle Bio-Manufacturing Facility).

The establishment undertakes the following activities:

- Procurement, testing, processing, storage, and distribution of HSCs:
    - Peripheral Blood Stem Cells (PBSC) for pediatric patients are procured at the RVI and procurement of adult PBSC and Donor Lymphocyte Infusions (DLI) is undertaken at the Freeman Hospital.
    - Procurement of adult bone marrow occurs infrequently and is undertaken at the RVI.
    - Procurement, at the Freeman Hospital, of directed umbilical cord blood towards a named patient undergoing treatment at Newcastle upon Tyne Hospitals NHS Foundation Trust for hematological or immunological disease. On occasion, the unit may be stored for potential use by future affected family members.

- HSCs are processed and stored at the RVI.
- Testing for all HSC is undertaken at the testing laboratory at the Freeman Hospital.

Products may undergo processing to isolate specific cell populations for therapeutic treatment under HTA authorised Process Preparation Dossiers (PPDs), and/or may be cryopreserved and stored for later use;

- Procurement of peripheral blood mononuclear cells (PBMC) and tumour tissue as the starting material for the manufacture of ATMPs to be used in a clinical trial, also takes place at the RVI. Tissues and cells are procured, tested, and processed (if applicable to the specific study) before being sent to a collaborating establishment for the production into an ATMP. Only procurement, donor testing, and occasional PBMC storage, take place under the establishment's HTA licence. All other activities are regulated by the Medicines and Healthcare products Regulatory Agency (MHRA);

- Procurement of autologous limbal cells as the starting material for the manufacture of ATMPs also takes place at the RVI. The RVI undertake this process both through the production of the final ATMP product using an internal process, and through the use of a commercial company to produce the final ATMP. Only procurement and testing take place under the establishment's HTA licence. All other activities are regulated by the MHRA;

- Femoral heads and struts are stored for end use by the establishment. The products are supplied to the Freeman Hospital by another HTA licensed establishment;

- Heart valves are stored for end use by the establishment. The products are supplied to the Freeman Hospital by another HTA licensed establishment;

- Storage, testing and distribution of iliac vessels which are initially received for solid organ transplant at the Freeman Hospital. If the vessels are not used with the organ, the vessels may be stored for up to 14 days and used for another organ recipient. At the time of the inspection, no iliac vessels were being stored;

- Storage of amniotic membrane, supplied by another HTA licensed establishment, for use in the processing of limbal stem cells for

culture into autologous limbal stem cells for transplantation (ATMP); and

- Storage of human embryonic stem cells (hESCs) for therapeutic use. This activity takes place at the Newcastle Bio-Manufacturing Facility. No additional hESC have been stored at this satellite site since the previous two inspections, and establishment staff have not accessed the tissue since the last inspection. As a result the storage of this material was not reviewed during this inspection.

During the last inspection the HTA identified five minor shortfalls in relation to Governance and Quality Systems as well as Premises, Facilities and Equipment. These were related to the scope of internal and independent audits; the limited scope of the establishment's risk assessments; the testing of vessels, and the storage of reagents at the appropriate temperature. During the current inspection it was confirmed that only one of the previously identified shortfalls has been sufficiently addressed to allow the closure of its associated CAPA actions, and in several cases, additional non-compliances against the relevant standard were identified. Therefore, the four remaining open shortfalls will be included with, and managed as part of, the corrective and preventative action (CAPA) plan for this inspection. The shortfalls will remain open from the previous inspection until the corresponding shortfall from the current inspection has been sufficiently addressed.

Since the previous inspection the Royal Victoria Infirmary has removed the licensable activity of 'storage of relevant material which has come from a human body for use for a scheduled purpose' under the Human Tissue Act 2004, on the advice of the previous HTA inspection team. In addition, a number of Persons Designate have retired from their posts, and been replaced by new members of staff.

The establishment is proposing to implement several new processes in the near future, and have submitted a number of PPDs to the HTA for review. These proposed processes were discussed during the site visit, and areas where the activity will be undertaken were visited. Discussions related to these proposed processes will continue as part of the formal HTA PPD assessment process, which is separate to this inspection. Once the preparation processes have been authorised for use the final procedures, and associated facilities and equipment, will be formally assessed and reviewed during future inspections.

Description of inspection activities undertaken

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

Standards assessed against during inspection

There are 121 standards in the Human Application sector of which 114 were assessed. Standards C1b, C2b, GQ1f, GQ1n, and PFE1d were not applicable and standards C2a and C3b were reviewed at the last inspection and not assessed on this occasion.

Review of governance documentation

The inspection team undertook a review of documentation relevant to the establishment's licensable activities. Documentation reviewed included policies and procedural documents relating to licensed activities, donor information sheets, medical history questionnaires, consent documentation, agreements with third parties, shipping and receipt records, donor-related records including records of procurement and donor testing, contracts relating to equipment servicing and servicing records, environmental monitoring records, temperature monitoring records relating to tissue, cell and consumables storage, minutes of governance meetings, incident logs, adverse events, audits, risk assessments and training records for establishment staff.

Visual inspection

The inspection team undertook a visual inspection of areas where licensable activity is undertaken. This included areas where tissues and cells are received or procured (e.g. the apheresis suite and theatre areas) at the hub and satellite sites, the storage areas at the hub and satellite sites (e.g. vapour phase LN2 storage, freezer storage, and ambient storage areas), the processing laboratory and clean room areas at the hub and satellite facilities, the serological testing laboratory and the flow cytometry facility. The storage area for the hESCs was not inspected on this occasion.

Audit of records

All records associated with a range of samples were audited. Where relevant, the records audited included product receipt and shipping records, procurement records, evidence of donor consent and donor testing results, processing records and associated environmental monitoring records, storage and eventual release documentation, theatre logs and patient records. Where products were present at the establishment their physical storage location was compared against electronic and / or paper inventories.

Documentation related to the following products was assessed:

- one amniotic membrane;
- two records for autologous limbal stem cell transplantations (comprising one product for ATMP production at RVI and one product transported elsewhere for ATMP production);
- nine sample sets for PBMC and / or tumour cell ATMP (comprising tissue and cells for five clinical protocols with four different clinical partners);
- two iliac vessel transplantations;
- one tendon;
- seven femoral heads (comprising three femoral heads in storage, two femoral heads released for use at the Freeman Hospital and two released for use at the RVI);
- two bone marrow products (comprising one allogeneic and one autologous);
- three autologous PBSC products (comprising adult and paediatric products);
- two DLI transplantations; and
- one cardiac valve and one pulmonary patch vessel.

Issues were identified related to the use of the SEC and to expiry dates for femoral heads stored in the bone bank freezer.

Meetings with establishment staff
Discussions were held with the DI and Quality Manager for the establishment. Round table discussions were held with key staff involved in:

- processes related to the procurement, processing and release of starting material for ATMP production, including limbal stem cells and PBMCs / tissue for external clinical studies;
- the apheresis and bone marrow collection process, both for adult and paediatric patients;
- receipt, storage and release of iliac vessels;
- receipt, storage and release of heart valves;
- receipt, storage and release of femoral heads and other bone products;
- processing, storage and release of stem cell products;
- quality management systems;
- serological and infectious disease marker assessment;
- flow cytometric analysis of products;
- maintenance and management of the clean room facilities at the hub and satellite; and
- the development of three new processes submitted to the HTA as PPDs.

Report sent to DI for factual accuracy: 14 January 2020

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

Final report issued: 12 February 2020

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 (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 Human Tissue Act 2004, Human Tissue (Quality and Safety for Human Application) Regulations 2007, 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 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 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 site-visit inspection
- a request for information that shows completion of actions
- monitoring of the action plan completion
- follow up at next routine site-visit inspection.

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