Site visit audit report on compliance with HTA requirements

Plymouth Hospitals NHS Trust

HTA licensing number 40055

Licensed for

- **<u>Procurement Activities</u>: donor characterisation (DC), organ characterisation (OC), preservation of an organ (P), retrieval of an organ (R)**

- **<u>Transplantation Activities</u>: organ characterisation (OC), preservation of an organ (P), making arrangements to transport an organ (T), implantation of an organ (I)**

Under the Human Tissue Quality and Safety of Human Organs Intended for Transplantation Regulations 2012

30 April 2013

Summary of Audit findings

The HTA found that NHS Trust (the establishment) had met the majority of the HTA assessment criteria.

One shortfall was found, in relation to having a documented procedure for reporting serious adverse events and reactions. The HTA have provided advice in relation to a number of other standards.

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

The HTA's regulatory requirements

The HTA shall ensure that licence holders are audited for the purposes of ensuring compliance with the licensing conditions in schedule 1 of The Quality and Safety of Organs Intended for Transplantation Regulations 2012 and any requirements imposed by directions made under these Regulations.

The assessment criteria reflect the requirements of the statutory conditions outlined in schedule 1 and the HTA's directions. They are designed to promote the safe use of human organs and ensure traceability is maintained between donor and recipient. The HTA audits establishments it licences against eight groups of assessment criteria:

- Donor characterisation and organ characterisation
- Retrieval of organs for transplantation
- Organ preservation
- Making arrangements to transport an organ
- Implantation
- Traceability
- Serious adverse events and serious adverse reactions
- General (apply to all licences)

Reports of HTA audits are published on the HTA's website.

Throughout the audit process, the HTA assesses the establishment against the assessment criteria. Where the HTA determines that an assessment criteria is not met, the level of the shortfall is classified as 'Critical', 'Major' or 'Minor' (see Appendix 1: Classification of the level of shortfall). Where HTA assessment criteria are fully met, but the HTA has identified an area of practice that could be further improved, advice is provided in this report.

Licensable activities carried out by the establishment – Procurement activities

Organ type	Kidney
Adult (living donor)	**DC, OC, P, R**

Procurement Activities: donor characterisation (DC), organ characterisation (OC), preservation of an organ (P), making arrangements to transport an organ (T), retrieval of an organ (R)

Licensable activities carried out by the establishment – Transplant activities

Organ type	Kidney (living and deceased)
Adult Recipients	**OC, P, I**

Transplantation Activities: organ characterisation (OC), preservation of an organ (P), making arrangements to transplant an organ (T), implantation of an organ (I)

Background to the establishment and description of inspection activities undertaken

The South West Transplant Centre (SWTC) is based at Derriford Hospital and provides adult kidney transplant services for Plymouth hospitals NHS Trust (the establishment).

The establishment runs a living kidney transplant programme and both procurement (nephrectomy) and transplant activities take place on the same site. The establishment also receives deceased donor organs for transplantation into adult recipients.

Living kidney donors are characterised at the establishment under the care of the live donor coordinator, consultant nephrologist and renal transplant surgeon. Tests required for donor / organ characterisation are carried out by Plymouth Hospital NHS trust laboratories.

Deceased donor organs are received for transplant at Derriford Hospital's histocompatibility and immunogenetics (H & I) laboratory.

The South West Transplant Centre also provides a local deceased donor kidney retrieval service upon request when the National Organ Retrieval Services team are not available. This activity currently occurs approximately twice a year. In such instances the donor and organ characterisation will take place under NHSBTs procurement licence and the retrieval, done by surgeons employed by Plymouth Hospitals NHS Trust, will be under HTA Licence 40055; Plymouth Hospitals NHS Trust.

Living donor nephrectomies are carried out from related and unrelated directed donors who have been assessed locally. The centre has also had a high proportion of altruistic donors who will also be assessed locally, but the donated organ may be allocated to a recipient for implantation at another transplant centre. The establishment also take part in the paired exchange scheme and most recently have been involved in a three-way exchange.

In 2011/12 the unit carried out 66 kidney transplants: 54 deceased donor organs; 7 living related donors and 5 living unrelated donors. The centre also carried out nephrectomies on two altruistic donors during 2011/12 and is currently assessing 14 further altruistic donors.

The establishment has adopted all the relevant National Operating Procedures (NOPs) and have adapted them to reflect local practice.

Compliance with HTA assessment criteria

Assessment Criteria	Audit findings	Level of shortfall
Donor Characterisation and Organ Characterisation		
CT1) Where a donor is deceased, a registered medical practitioner, or a person acting under the supervision of a registered medical practitioner, has endeavoured to obtain information from the relatives or other persons about the donor, and has explained the importance of swift transmission of information.	Deceased donor organs are received at the establishment for transplant, but information for this assessment criterion is obtained and transmitted under NHS Blood and Transplant's (NHSBT) licence. When local organ retrievals take place from deceased donors the donor and organ characterisation takes place under NHSBTs licence, as above.	**N/A**
CT2) Donors and organs are characterised before implantation by the collection of information specified in Part A of the Annex to the Directive.	This criterion is fully met. This criterion is applicable for living donors and organs and any subsequent tests conducted under this licence for deceased donor organs. All mandatory and complementary donor tests are carried out as part of living donor work up. The establishment has a document 'integrated care pathway for live kidney donor' that provides a record of discussions, risk factors and tests that have been carried out in order to assess the suitability of a living donor. All mandatory information is collected and documented.	**None**
CT3) Donors and organs are characterised before implantation by, where considered appropriate, the collection of information specified in Part B of the Annex to the Directive.	This criterion is fully met. Reference is made to CT2 above.	**None**
CT4) All information relating to donor and organ characterisation is kept for a period of 30 years from the date of retrieval of the organ and there is an operating procedure in place to demonstrate how this requirement is complied with.	This criterion is fully met. The establishment provided a copy of the Health Records Policy, which stated that the Trust adheres to the minimum retention periods set out in the Records Management NHS Code of Practice 2006 (part 2). This Code of Practice (Annex D1) states a retention period of 30 years for records relevant to organ transplantation should be kept for 30 years.	**None**

CT5) Tests required for donor and organ characterisation are carried out by laboratories with CPA accreditation.	This criterion is fully met. Donor and organ characterisation tests are carried out by the Trust's laboratories. The establishment confirmed that the H & I, microbiology / virology and biochemistry laboratories used for donor and organ characterisation of living donors are all CPA accredited. The Trust's histopathology laboratory is not currently CPA accredited. The establishment may utilise the services of the histopathology laboratory on rare occasions when biopsy material is processed as part of organ characterisation for living donors (this occurs once or twice a year). The establishment have reviewed the non compliances identified by CPA that resulted in the loss of accreditation and do not consider that the non compliances would impact on the quality of any results provided by this laboratory. On this basis, and also because the laboratory is not frequently used - the establishment advised they will continue to use this laboratory.	**None**

CT6) Information on organ and donor characterisation reaches the person who will be implanting an organ within a time period that would not compromise the quality and safety of the organ and there is an operating procedure in place to demonstrate how this requirement is complied with.	This criterion is fully met. Organ procurement and implantation are both carried out at the establishment. The Living Donor Coordinator is responsible for collecting information on donor and organ characterisation. This would be discussed with the nephrologist in the first instance, and then with the implanting surgeon. Any relevant test results and risk factors would be discussed at the multidisciplinary team (MDT) meeting. For deceased organ donation, a member of the recipient coordinator team will receive the initial organ offer from NHSBT and will access the donor and organ characterisation information via the electronic offering system (EOS). The recipient coordinator will then discuss the information with the implanting surgeon, who will make a decision whether or not to accept the organ. The nephrologist may also be contacted if there is a need to further discuss acceptance of the organ. The establishment has adopted the NOP 002 – Verification of donor identity, consent / authorisation and organ and donor characterisation in deceased and living donation and transplantation, and have adapted this to reflect current, local practice.	**None**

Assessment Criteria	Audit findings	Level of shortfall
Retrieval of Organs for transplantation		
R1) Procurement is only carried out after all the requirements relating to consent (or authorisation in Scotland) have been met.	This criterion is fully met. Living donors are consented by the consultant surgeon who will conduct the nephrectomy. Evidence of consent for living donors was seen in medical notes available during the site visit audit. The establishment also uses the World Health Organization (WHO) Surgical checklist to confirm consent prior to administering anaesthesia. When organs are retrieved locally on behalf of the NORS teams, consent will be the responsibility of specialist nurse – organ donation (SNOD) employed by NHSBT. The retrieving surgeon will check the appropriate consent is in place prior to commencement of retrieval.	**None**
R2) Material and equipment used in retrieval meets the requirements of The Medical Devices Regulations 2002 (SI 2002/618), where these apply, and there is an operating procedure in place to demonstrate how this requirement is complied with.	This criterion is fully met. The establishment provided the Trust Policy: Management and use of Medical Devices, which covers re-useable and disposal medical equipment. This policy states that only CE marked medical equipment will be purchased by the Trust and that all equipment will meet the requirements of the Medicines and Healthcare Products Regulatory Agency (MHRA). Reference is made to P1.	**None**
R3) Reusable instruments used in retrieval are subject to a validated cleaning and sterilisation procedure for removal of infectious agents, which is documented.	This criterion is fully met. All sterilisation of reusable medical equipment is carried out by Plymouth Hospitals NHS Trust Sterilisation and Disinfection unit. This unit has been assessed and certified as meeting the requirements of Directive 03/42/EEC Annex 5 (sterility aspects only). The audit team were provided with current UKAS certificates for the Sterilisation and Disinfection unit.	**None**

R4) Endeavours are made to follow-up a living donor for the purposes of identifying and managing any event potentially relating to the quality and safety of the donated organ and any serious adverse reaction in the living donor that may result from the donation.	This criterion is fully met. Living donors are extensively followed up and offered this service for life. Follow up will be frequent in the first twelve months and in accordance with the national guidelines. Follow up reports are submitted to NHSBT between one and ten years post donation When donors are discharged to primary care they are accompanied with a thorough discharge letter. All living donors will be encouraged to contact the South West Transplant Centre if they have any concerns. The HTA have provided advice in relation to this criterion.	**None**

Assessment Criteria	**Audit findings**	**Level of shortfall**
Organ preservation		
P1) Material and equipment used in organ preservation meet the requirements of The Medical Devices Regulations 2002 (SI 2002/618), where these apply, and there is an operating procedure in place to demonstrate how this requirement is complied with.	This criterion is fully met. The establishment provided the Trust Policy: Management and use of Medical Devices, which covers re-useable and disposal medical equipment. This policy states that only CE marked medical equipment will be purchased by the Trust and that all equipment will meet the requirements of the Medicines and Healthcare Products Regulatory Agency (MHRA). Reference is made to R2.	**None**
P2) Reusable instruments used in organ preservation are subject to a validated cleaning and sterilisation procedure for removal of infectious agents, which is documented.	This criterion is fully met. Reference is made to R3.	**None**
P3) Records of perfusion fluid coming into contact with organs are made on the appropriate HTA A and B forms.	This criterion is fully met. The establishment retains copies the HTA A and B forms on site. Evidence was provided to the audit team, that the establishment record the batch numbers and expiry dates of perfusion fluids.	**None**

Assessment Criteria	Audit findings	Level of Shortfall
Making arrangements to transport an organ		
TP1) The integrity of the organ is maintained during transport and the transport time is suitable to ensure the quality and safety of the organ, and there is an operating procedure in place to demonstrate how this requirement is complied with.	This assessment criterion is fully met. In living donors, SWTC staff would be responsible for packing of the kidney. The establishment have adapted NOP 003 – Packaging, labelling and transport of organs in deceased and living donation and transplantation. Transport of deceased organs will be the responsibility of NHSBT and packaging will be carried out by the specialist nurse organ donation in situations where a local retrieval takes place and the kidney is being transported to another transplant centre. Due to the geographical location of the SWTC it is unlikely that a deceased donor organ will be accepted for transplant, received at the centre and then, if deemed untransplantable, offered to another transplant centre. This has never happened to date, and the audit team were advised it would be very unlikely due to the prolonged cold ischaemic time associated with offering on an organ. The HTA has provided advice against this criterion.	**None**
TP2) The organ shipping container is suitable for transport of the specified organ.	This assessment criterion is fully met. The SWTC uses kidney boxes provided by NHSBT. These boxes are suitable for the transport of kidneys.	**None**
TP3) The organ shipping container used for transporting organs from the licensed premises is labeled with the information specified in paragraph 8(b) (i) to (iv) of the SI, and there is an operating procedure in place to demonstrate how this requirement is complied with.	This assessment criterion is fully met. The establishment have adapted NOP 003 – Packaging, labelling and transport of organs in deceased and living donation and transplantation. Labels are supplied by NHSBT and would be completed in accordance with the regulatory requirements.	**None**

TP4) Transported organs are accompanied by a report on the organ and donor characterisation, and there is an operating procedure in place to demonstrate how this requirement is complied with.	This assessment criterion is fully met. When living donor organs are transported for implant at another transplant centre all donor and organ characterisation information will have been shared and discussed with the implanting transplant team. The establishment have adapted NOP 003 – Packaging, labelling and transport of organs in deceased and living donation and transplantation	**None**
TP5) Arrangements are in place to ensure that any organisations transporting organs on behalf of the licence holder meet the requirements for transportation and serious adverse event and reaction reporting specified in the framework document.	This assessment criterion is not applicable. The SWTC will transport organs using NHSBT's transport provider. This provider has been advised of the requirements to report serious adverse events – but it is not the responsibility of the SWTC licence holder to ensure this.	**N/A**

Assessment Criteria	**Audit findings**	**Level of shortfall**
Implantation		
I1) The identification of the donor and the collection of the information in Annex A and B of the Directive are verified prior proceeding to implant an organ, and there is an operating procedure in place to demonstrate how this requirement is complied with.	This criterion is fully met. For living kidney implantation the surgeon will have had full access to all relevant information in advance of the transplant procedure. The establishment uses the WHO surgical checklist and will verify the donor identity and all relevant information in advance of anaesthetising the recipient. For implantation of kidneys from deceased donors the registrar will document details to be confirmed by the surgeon. The surgical team will check these details prior to implantation. The establishment has adopted the NOP 002 – Verification of donor ID, consent and donor characterisation.	**None**

I2) Compliance with the conditions of preservation and transport outlined in the framework document are verified prior to proceeding to implant an organ.	This criterion is fully met. The establishment have adapted the NOP 003 Packaging, labelling and transport of organs in deceased and living donation and transplantation. There is a newly implemented log book to record details of the organ information upon its arrival at theatres. The implanting surgeon will also check the condition of the organ prior to implantation as standard practice. See advice under TP1	**None**
I3) Where any of the information specified in Annex A of the Directive is not available; a risk-benefit analysis is conducted to determine whether the expected benefits for the recipient of the organ outweigh the risks posed by the lack of any information.	This criterion is fully met. The audit team were advised that a risk benefit analysis would be documented in the patients' medical notes when conducted.	**None**

Assessment Criteria	**Audit findings**	**Level of shortfall**
Traceability – (*these criteria apply to all licensed activities*)		
TC1) The data required to ensure traceability of organs are recorded using the HTA A and B forms, which are returned to NHSBT within 7 days, and there is an operating procedure in place to demonstrate how this requirement is complied with.	This criterion is fully met. The establishment return the forms to NHSBT on the next working day. The establishment has adopted the NOP 006 – Transfer and storage of donor and organ characterisation information and traceability data, to reflect their own local practice.	**None**
TC2) There is an identification system for donor and recipient to identify each donation and each of the organs and recipients associated with it.	This criterion is fully met. All donors and recipients are identified using unique identifiers, including NHS numbers. There may be situations where more than one organ is received at the H & I laboratory at one time. In such situations the laboratory staff use a priority system to process any associated tissue typing samples, and organs are physically separated on different work benches.	**None**

TC3) A record (date and time) of the transportation of organs arriving at/or leaving the establishment is kept for 30 years as part of the traceability information.	This assessment criterion is fully met. Deceased organs are received at the SWTC tissue typing laboratory, which is on the Derriford hospital site. During office hours a member of the laboratory staff will record the time of arrival on the kidney donor crossmatch form. Outside of office hours the organs are received at the laboratory reception, which is staffed 24 hours a day. In such situations the reception staff will contact the on call tissue typer to let them know an organ has been received. The audit team highlighted that when organs were received out of hours the time of receipt was not recorded until collected by the tissue typer on call. During our time on site the establishment produced a new procedure – Receipt of tissue typing samples out of hours (WAF 0292). This document included the requirement for reception staff to record the time the organ had arrived and immediately contact the appropriate staff member. Reception staff should now be made aware of the new document and procedure. When organs from living donors leave the establishment (altruistic or paired pooled donations) SWTC uses the NHSBT transport form to record the time / date the organ has left the premises. A copy of this form is kept locally.	**None**

Assessment Criteria	**Audit findings**	**Level of shortfall**
Serious adverse events and reactions (SAEARs) – (*these criteria apply to all licensed activities*)		
S1) Operating procedures are in place for the management of a serious adverse event or a serious adverse reaction.	There is a minor shortfall against this assessment criterion. The establishment has a well developed reporting procedure for Trust incidents. The establishment also have experience of reporting to NHSBT in relation to a serious adverse reaction that occurred prior to the implementation of the legislation. However, there is currently no written procedure detailing how and when to report to NHSBT and have not adopted the SOP 3888/1 – Reporting an organ donation or transplantation incident to NHSBT, produced by NHSBT.	**Minor**

S2) Serious adverse events and reactions are reported to NHSBT within 24 hours of discovery, a follow-up report is provided within 90 days, and there is an operating procedure in place to demonstrate how this requirement is complied with.	The establishment's staff were aware of the requirement to report any adverse incidents via the NHSBT portal and some did have experience of doing this prior to the implementation of the new portal. However, SWTC may benefit from raising staff awareness in relation to identifying and reporting serious adverse events and reactions (SAEARs) and the mandatory time frames associated with reporting. See advice in relation to this assessment criterion.	
S3) Third parties, such as those undertaking testing or transportation, are instructed to report any serious adverse events and reactions to the licence holder within 24 hours of discovery.	This assessment criterion is fully met. There are no third parties carrying out testing under this licence. Any transport is carried out under NHSBT's licence – and providers have been made aware of the requirement to report any serious adverse events. The establishment uses the Trust's own laboratories to carry out any required donor and organ characterisation tests. Any serious adverse events related to these tests would be reported via the Trusts incident reporting system.	**None**

Assessment Criteria	**Audit findings**	**Level of shortfall**
General – (*these criteria apply to all licensed activities*)		
GN1) Healthcare personnel directly involved in the chain from donation to the transplantation or disposal of an organ are competent and suitably qualified or trained to perform their tasks.	This criterion is fully met. Examples of training and qualification documents were provided during the audit. The competence of all staff is assessed by the appraisal process. Nursing staff involved in donation and transplantation hold personal professional development portfolios as evidence of training and competency.	**None**
GN2) Healthcare personnel directly involved in the chain from donation to the transplantation or disposal of an organ are provided with the training necessary to perform their tasks.	This criterion is fully met. Staff are provided with training required to perform their tasks. Nursing staff involved in transplantation are required to complete renal transplant training, evidence of which was seen during the audit.	**None**

GN3) Medical activities are performed under the advice and guidance of a registered medical practitioner, and there are operating procedures in place to demonstrate this.	This criterion is fully met. The establishment provides a consultant-led service for transplantation where all relevant medical activities are performed under the guidance of the consultant surgeon or physician. The trust has not adopted NOP 005 Activities to be performed under the guidance of a registered medical practitioner in deceased and living donation and transplantation. The audit team considered that the requirements to have a documented procedure for this assessment criterion were fulfilled by the references to activities that must be carried out under supervision in the other written documents that the establishment have in place.	**None**

Advice

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

No.	Assessment Criterion	Advice
1.	R4	The HTA advises that the discharge letter should emphasise that in the event that the donor develops any transmissible disease that was unknown at time of donation and may have the potential to affect the recipient, then this should be reported to the transplant team.
2.	TP1	The HTA advises that it is good practice to have a documented receipt procedure when organs are received at SWTC for transplant. This may include a written checklist for levels of melting water ice / integrity of packing etc.
3.	S2	The HTA advises the establishment to provide staff with training in relation to identification and management of serious adverse events and reactions. The HTA also advises that laboratory staff are included in the training sessions or provided with information to allow them to identify potential serious adverse events that may occur in relation to donor and organ characterisation tests. The establishment may find the following document useful when providing this training: 'Serious adverse event and reaction reporting for organs intended for transplantation – guidance for licence holders'.

Concluding comments

The HTA audit team would like to thank the staff at Derriford Hospital for their positive approach to the audit and their openness during discussions, providing the audit team with a detailed overview of activities carried out under the HTA licence.

The audit team observed a number of examples of good practice.

There was good communication between staff members whose interactions during our time on site indicated a strong working relationship across different disciplines.

There was also evidence of good governance in place and staff members were aware of the requirements of the legislation. The audit team thought the teams proactive approach to dealing with incidents was worthy of comment. The team has introduced a standard practice of sampling and culturing the perfusion fluid of all deceased organs, in response to a significant historical incident. They have also proactively sought to have an external audit conducted – this was before the implantation of the legislation – for the purpose of identifying any areas of improvement to practice.

Finally, the audit team wanted to acknowledge the newly implemented living donor assessment form, which is to be used to document all the mandatory and complementary donor and organ characterisation information required by the Regulations. This form was extremely comprehensive and contained all relevant information.

The HTA requires that the establishment 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 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 audit and subject to completion of the existing action plan.

Report sent for factual accuracy: 23 May 2013

Report returned with comments: 19 June 2013

Final report issued: 21 June 2013

Based on information provided, the HTA is satisfied that the establishment has completed the agreed actions in the CAPA plan and in doing so has taken sufficient action to correct all shortfalls addressed in the Inspection Report.

Date: October 2013

Appendix: Classification of the level of shortfall (HA)

Where the HTA determines that an assessment criterion 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 assessment criterion, 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 the quality of an organ intended for transplantation or 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:
(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 quality and safety of an organ intended for transplantation or which poses an indirect risk to the safety of a recipient
or
A shortfall in the establishment's quality and safety procedures which poses an indirect risk to the quality and safety of an organ intended for transplantation or which poses an indirect risk to the safety of a recipient;
or
A shortfall which indicates a major deviation from the **Human Tissue (The Quality and Safety of Organs Intended for Transplantation) Regulations 2012** or the **Documentary Framework for the Quality and Safety of Organs Intended for Transplantation**;
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 quality and safety of an organ intended for transplantation or the safety of a recipient;

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 audit 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.