Site visit audit report on compliance with HTA requirements

Nottingham University Hospitals NHS Trust

HTA licensing number 40017

Licensed for

- **<u>Procurement Activities</u>: donor characterisation (DC), organ characterisation (OC), preservation of an organ (P), making arrangements to transport an organ (T), 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

Wednesday 15 January 2014

Summary of Audit findings

Nottingham University Hospitals NHS Trust (the establishment) was found to have met all assessment criteria.

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	**DC, OC, P, T, R**
Adult Deceased	**OC, P, T**

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
Adult Living	**OC, P, T, I**
Adult Deceased	**OC, P, T, I**
Paediatric Deceased	**OC, P, T, I**

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

Background to the establishment and description of audit activities undertaken

The establishment carries out deceased donor kidney transplants in adult and paediatric patients. Paediatric transplant activity takes place at the establishment's Queen's campus and adult transplant activity at the City campus.

Living donor kidney retrievals from adults and transplants are also performed at the establishment. Living donor work up and organ retrieval surgery takes place at the establishment's City campus. The establishment also participates in paired and pooled transplants using organs from living donors which are sent onto other implanting centres. Retrievals also take place from living donors where the kidney is sent to another licensed establishment for use in a directed recipient. The establishment also receives directed organs for its recipients from other licensed establishments. Additionally, the establishment retrieves kidneys from altruistic living donors which again may be used at the establishment or sent onto other centres.

Tissue typing and cross matching are performed by an external laboratory with current CPA accreditation. Other characterisation tests such as additional histopathological tests and donor serology testing are performed by the establishment's pathology laboratory and hospital testing laboratory respectively, which also have current CPA accreditation.

The establishment is responsible for transporting organs to other recipient centres. Transport is undertaken by couriers working under a service level agreement with the establishment.

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.	The establishment is not responsible for obtaining information relating to a deceased donor. This will be carried out by the specialist nurse – organ donation (SN-OD) under NHSBT's licence.	**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. For deceased donor organs, characterisation is carried out at the retrieval centres by another licensed establishment. The establishment has adopted NOP001 which defines donor characterisation as specified in part A of the Annex to the Directive. This is followed when characterising living organ donors. The establishment has developed a series of living donor work up forms and living donor questionnaires to document the results of the mandatory donor characterisation assessments specified in NOP001. These questionnaires also include questions relating to previous or current IV drug use.	**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. For deceased donor organs additional characterisation tests will usually be arranged by the SN-OD under NHSBT's licence. These tests are performed at the retrieval centre. If necessary however, extra tests, most commonly histopathological analysis, may be undertaken at the establishment upon receipt of the organ. The establishment does not have access to 24 hour histopathology services and if necessary, implantation will not proceed until appropriate analysis can be undertaken. For living donor cases, if additional tests are required, these will be carried out at the establishment as part of the living donor work up. Living donor work up also includes questions on lifestyle and travel history. All donor characterisation assessments specified in part B of the Annex to the Directive are also listed in NOP001 which has been adopted by the establishment.	**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 has adopted NOP006 which stipulates that all documentation relating to the establishment's transplant activity will be stored for 30 years. Additionally the Trust is aware of and follows the guidance from the Department of Health which again stipulates that all records relating to transplantation should be maintained for 30 years. The establishment stamps all donor and recipient notes with a 'Retain for 30 years from last episode' notice so that notes which should be retained are identifiable to the Trust's record management department. The establishment stored copies of the HTA-A, HTA-B and copies of the deceased donor core donor data forms in a separate file in the transplant office.	**None**
CT5) Tests required for donor and organ characterisation are carried out by laboratories with CPA accreditation.	This criterion is fully met. The CPA accreditation status of all laboratories used by the establishment for donor and organ characterisation was reviewed during the audit. All laboratories had non-conditional accreditation.	**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. Once potential living donors have passed the initial high level suitability check they are called to attend the establishment so that the characterisation process can begin. Characterisation information for living kidney donors is gathered during donor work-up by the living donor coordinator and nephrologist. Donors seen by the transplant coordinator are interviewed and asked the mandatory donor medical history and lifestyle questions in addition to being scheduled for other characterisation assessments such as blood tests and scans. When all assessments have been completed the nephrologist reviews all of the donor characterisation information including the donor's medical history provided by their GP. The nephrologist discusses the risks of the procedure, life following living donation and any possible implications for life insurance which helps to ensure that living donors are fully informed of potential implications of donating a kidney. The donor will then undergo a surgical assessment by the retrieving surgeon during which donor kidney anatomy is reviewed and the risks associated with the procedure are discussed in more detail. Living donors are then discussed at multidisciplinary team (MDT) meetings which include the establishment's surgical staff, nephrologist and living donor coordinators. The living donor is then signed off at the MDT if they are a suitable donor. For deceased donor kidneys the establishment is alerted to a potential donor by NHSBT. The coordinator uses the donor's unique number and logs onto NHSBT's electronic offering system (EOS) to collect initial donor and organ characterisation information. The establishment uses EOS to collect characterisation information in all cases where a deceased donor kidney is being offered. Key characterisation information sufficient for a surgeon to accept or reject a kidney offer is transcribed onto a separate kidney offer form. The coordinator then calls the implanting surgeon to discuss the information. The implanting surgeon will then log onto EOS to review the core donor data including any updated information which has been entered.	**None**

	If accepted, the organ arrives at the establishment's renal ward where the receiving nurse will check the accompanying paperwork, donor details, courier driver details, time of arrival and ice levels within the organ box. Details of the checks are recorded on the recipient's care pathway document. Samples for tissue typing are removed and sent on to the tissue typing laboratory. The organ in the transport box is then closed and stored in a locked room until it is collected by the implanting surgeon and taken to theatres. In some cases, the transport company is instructed to go the laboratory and deliver the samples for tissue typing before delivering the organ to the establishment. The implanting surgeon reviews the core donor data from EOS, checks the paperwork accompanying the organ and signs the recipient pathway documents to record that the characterisation information has been reviewed and paperwork checked.	
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. When retrieving an organ from a living donor the establishment's surgical staff follow a WHO surgical safety checklist which in addition to checks ensuring that the donor is the correct person includes a check to ensure that consent is in place prior to surgery commencing.	**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 has adopted NOP004 which stipulates that all devices used must meet the requirements of The Medical Devices Regulations. The Trust's 'Procurement five year strategy' document also states that the Trust's procurement department operates within EU and UK law which include the Medical Devices Regulations.	**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. NOP004 states that reusable equipment must be subjected to a validated decontamination and sterilisation procedure. The audit team reviewed certificates demonstrating that the Trust's decontamination services department had been assessed and accredited as meeting the accreditation requirements for sterilisation processes. This accreditation is valid until December 2014.	**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. Live kidney donors are seen by the retrieving surgeon after surgery. The surgeon then reviews the donor six weeks post surgery. Living donor coordinators also follow up donors and monitor their progress following surgery. The donor is then seen at the establishment's renal clinic at three, six and twelve months post surgery. Following these assessment visits the donor is reviewed annually in the establishment's renal clinic. Donors can choose to have the annual reviews with a local clinician rather than returning to the establishment for follow up. If seeing a local clinician the establishment writes to the clinician with details of live donor follow up assessments. The establishment also writes to the donor's GP to alert them that they have been a live kidney donor. This letter includes details for the GP of the possible consequences of being a live kidney donor.	**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. Refer 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. Refer 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. During the audit a review of transplant related records was undertaken. As part of this exercise, HTA-A and HTA-B forms were reviewed and evidence was seen that the establishment is recording the details of perfusion fluid used.	**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 criterion is fully met. The establishment has adopted and adapted NOP003 which gives details on how to pack organs for transport. NOP003 has been adapted by the establishment to reflect the labels used locally at the establishment. The establishment has also developed an 'Export check list'. This document acts to prompt establishment staff to make various checks on transported organs including what paperwork should accompany the organ and labelling of the transport box. The checklist is used for all organs that are being sent outside of the establishment *i.e.* 'Exported', to other recipient centres.	**None**
TP2) The organ shipping container is suitable for transport of the specified organ.	This criterion is fully met. If sending organs to other implanting centres, the establishment uses NHSBT's kidney transport boxes which are suitable.	**None**
TP3) The organ shipping container used for transporting organs from the licensed premises is labelled with the information specified in paragraph 68 of the framework document, and there is an operating procedure in place to demonstrate how this requirement is complied with.	This criterion is fully met. Refer to criterion TP1	**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 criterion is fully met. A combination of NOP003 and the establishment's 'Export checklist' stipulate what documentation must be included when transporting an organ to another recipient centre.	**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 criterion is fully met. Organs from deceased donors are transported to the establishment using a dedicated courier with which the establishment has a service level agreement (SLA).. When sending organs to other recipient centres from the it is the responsibility of that other center to arrange the transport. The SLA details serious adverse event and reaction reporting requirements in addition to driver training, patient confidentiality, communication with the establishment and security and handling instructions.	**None**

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. The establishment has adopted and adapted NOP002 which contains details of the characterisation information that must be reviewed by the implanting surgeon prior to implanting the organ. The establishment's in house recipient pathway document also contains a field which must be signed by the implanting surgeon to record that they have reviewed the donor and organ characterisation information prior to surgery.	**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. Ice levels in the organ transport box are checked by the nurse receiving a deceased donor organ upon arrival at the establishment. As part of the benching process, prior to commencing the implantation of the organ, the surgeon also verifies that the organ has been correctly packed and has sufficient ice to preserve the organ	**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 surgeon will assess any risk associated with the organ against the benefit to the recipient including the risk to the recipient of not going ahead with the transplant. If necessary the establishment's surgical team have access to advice from virology or microbiology departments. If any risks have been identified the surgeon will discuss these with the recipient and document the conversation in the recipient's clinical notes.	**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 has adopted NOP006 which details the relevant timeframes for the return of the forms to NHSBT. Completed forms are given to the establishment's data analysts who return them to NHSBT. The analyst notes the dates on which they were sent to NHSBT on the form.	**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. Deceased donors are traceable by their NHSBT donor number, available in EOS. For living donors and living donor organs the establishment uses its standard three point identification system using name, date of birth and hospital number.	**None**

TC3) A record (date and time) of the transportation of organs arriving at and/or leaving the establishment is kept for 30 years as part of the traceability information.	This criterion is fully met. The establishment records receipt of an organ on its in house recipient pathway document which includes time of receipt and courier driver details. The establishment has developed a guidance document for ward staff to follow when receiving an organ. This includes the procedures for staff to follow such as checks on paperwork, ice levels and how to record time of receipt and driver details. This guidance document is currently only used by staff receiving organs for adult recipients at the establishment's City Campus. The establishment recently implemented an 'Import' form which is completed by the transplant coordinator when receiving an organ from outside the establishment.	**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.	This criterion is fully met. The establishment has developed an in-house serious adverse event and serious adverse reaction (SAEAR) procedural document. This local document (LOP001 – Management of Serious Adverse Event and Serious Adverse Reaction) details how SAEARs are managed at the establishment. Details of how to report a SAEAR to NHSBT and the timeframe for reporting are also included in LOP001. LOP001 also includes the standard text that should be included in letters referring living donors or recipients to other centers post retrieval or transplant. This helps to ensure that clinicians external to the establishment are made aware of the need to report SAEARs.	**None**

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.	This criterion is fully met. Refer to criterion S1.	**None**
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 criterion is fully met. The establishment's SLA with its transport company includes details of SAEARs reporting (see criterion TP5). The establishment has also informed the laboratories undertaking testing on its behalf of the need to report any serious adverse events to staff at the establishment upon discovery.	**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. New staff are trained in the processes around the establishment's transplant activity as part of an orientation process. In paediatrics, this training also extends to staff in the paediatric intensive care unit so that they are familiar with transplant related procedures. Nursing staff receive training in the establishment's internal transplant related documents such as the recipient pathway. All staff attend mandatory training such as health and safety and fire training. All staff receive annual mandatory appraisals. Surgical staff also receive annual appraisals and evidence of this was reviewed during the audit.	**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. Refer to criterion GN1.	**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 has adopted NOP005 'Activities to be performed under the guidance of a registered medical practitioner in deceased and living donation and transplantation' which describes how activities are performed under the advice and guidance of a registered medical practitioner. NOP005 is also appropriately referenced in other operating procedures when an activity is being described that must be carried out under the advice and guidance of a registered medical practitioner.	**None**

Advice

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

No.	Assessment Criterion	Advice
1.	CT2	The establishment has developed a series of living donor work up forms and living donor questionnaires to document the results of the mandatory donor characterisation assessments specified in part A of the Annex to the Directive. The licence holder is advised to append these documents to NOP001 to that they from part of the procedural document.
2.	CT4	The establishment stored copies of the HTA-A, HTA-B and copies of the deceased donor core donor data forms in a separate file in the transplant office. The licence holder is advised to amend NOP006 to include reference to this separate document archive so that it is clear that these too are covered by NOP006 and therefore must be kept for 30 years from the date of retrieval of an organ.
3.	R4	Where a live donor is being discharged by the establishment following donation, the establishment sends a letter to the donor's local clinician to alert them that their patient has been a live organ donor. The establishment is advised to amend this discharge letter so that it also includes a reminder notice to a local clinician of the requirement to alert the establishment should the donor present with any indication that may have consequences for the recipient, such as development of a malignancy or transmissible infection, or any event as a result of the retrieval surgery.
4.	TP4	The establishment has developed an 'Export check list'. This document acts to prompt establishment staff to make various checks on transported organs including what paperwork should accompany the organ and labelling of the transport box. The licence holder is advised to amend NOP006 to include reference to this checklist so that it may be included in the procedural document relating to transportation of organs.

5.	TC3	The establishment has developed a guidance document for ward staff to follow when receiving an organ which is used at the establishment's City campus. The licence holder is advised to share this guidance document with staff at the establishment's Queen's campus who also complete the same recipient pathway document when receiving an organ for a paediatric recipient.

Concluding comments

The establishment has adopted and adapted many of the national operating procedures (NOPs) to develop the necessary operating procedures that are required under the Regulations since the advent of licensing. The establishment has also introduced a number of supporting pathway documents, guidance documents and checklists to support the NOPs. Advice has been offered above regarding appending these additional procedural documents with the NOPs to further strengthen the establishment's governance procedures.

The establishment's proactive approach to the implementation of these procedural documents continues with advice and training given to staff who are expected to follow the procedures. Evidence was reviewed that staff had reviewed procedural documents that were relevant to their work and had signed a record sheet included with each procedure to demonstrate that they had read and understood the document.

The HTA has given advice to the establishment with respect to updating some of its procedural documents to include the supplementary, in house documentation developed by the establishment. Advice has also been given with regards to the referral letter that is sent to GPs of living donors.

The HTA has assessed the establishment as suitable to be licensed for the activities specified.

Report sent for factual accuracy: 13 February 2014

Report returned with comments: 21 February 2014

Final report issued: 19 March 2014

Appendix: Classification of the level of shortfall

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 donor or recipient.
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 donor or 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 donor or 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 donor or 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 audit.
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 audit 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 audit 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 audit
- a request for information that shows completion of actions
- monitoring of the action plan completion
- follow up at next desk-based or site-visit audit.

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