Site visit audit report on compliance with HTA requirements

University Hospitals of South Manchester NHS Foundation Trust

HTA licensing number 40053

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

24 July 2013

Summary of Audit findings

The HTA found that University Hospitals of South Manchester NHS Foundation Trust (the establishment) had 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 standards:

- 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	
Heart	**OC, P, T, R**
Lung	**OC, P, T, 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	
Heart	**OC, P, T, I**
Lung	**OC, P, T, 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 audit activities undertaken

The establishment carries out adult only, deceased donor, heart and lung transplantation. Approximately 22 heart transplants are carried out annually, and 26 lung transplants.

In addition, the establishment supplies a cardiothoracic National Organ Retrieval Service (NORS) team which is called to carry out organ retrievals in the local area approximately 90 times per year. In approximately half of the call-outs withdrawal of the retrieval team occurs when death in deceased cardiac death donors does not occur within the required timescales, therefore not allowing retrieval of lungs to be undertaken.

Organs are primarily retrieved for use in implantation operations at the establishment, but the NORS team also retrieves for implant at other centres throughout the UK. Similarly, the establishment implants organs retrieved by NORS teams from other establishments elsewhere in the country.

The NORS team consists of one or two surgeons, a scrub nurse and a specialist nurse – organ retrieval (SN-OR). The complete team attends most retrievals but in many cases only a surgeon and SN-OR attend initially in advance of the rest of the team, to carry out early donor management as part of the “Scout” project in an effort to improve the quality of the organs retrieved.

The retrieval team follow the University Hospitals of South Manchester NHS Foundation Trust Transplant Retrieval protocol (Retrieval protocol) and National Organ Retrieval protocol. The Retrieval protocol details the responsibilities of the various members of the team and outlines procedures to be followed by individual team members.

The NORS team are transported to the donor hospital by a contracted transport provider, which also provides transport for teams returning from a retrieval hospital accompanying organs for implant and also organs from retrievals carried out by other teams elsewhere in the country.

Organs are transported to the establishment’s dedicated transplant unit, where the driver has access via a secure swipe card system. Organs are delivered direct to theatres, either by the driver or one of the accompanying surgical retrieval team members and are then passed to the recipient transplant coordinator or a member of the surgical implanting team.

During the journey to the hospital, communication with the driver is updated periodically so that the implanting surgical team can prepare the recipient in order that implantation can be carried out with the minimum of delay.

Implantation of organs takes place within a dedicated transplant theatre, and patients are then transferred to the adjacent Intensive Care Unit for initial post-operative care. In advance of implantation, the transplant coordinator or scrub nurse checks the documentation accompanying the organ for identification details and donor blood group and sends blood, lymph and spleen samples to CPA accredited laboratories in a neighbouring NHS Trust for confirmatory microbiology, virology and immunology testing. The results, when received, are used to inform the recipient’s post-transplant therapy.

The establishment has an Ex Vivo Lung Perfusion (EVLP) machine which it is using as part of an on-going trial to determine the benefits of EVLP in improving function in lungs intended for transplant.

This routine audit was the first audit of the establishment’s activity. It comprised a tour of the “organ pathway” and round table discussions with key staff involved in retrieval and implantation. A review of quality documentation, patient files and traceability and transport records was also carried out.

As part of this, donor files and corresponding recipient medical notes were reviewed for donor / organ characterisation information and any documented clinical risk / benefit analyses. Files and notes were reviewed for two heart transplant recipients, two lung transplant recipients and two double lung transplant recipients.

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 is applicable for living donors. The establishment does not carry out any living donor work.	**N/A**
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.	The establishment does not carry out any further characterisation work prior to implantation, any tests or additional information being requested from the donor hospital SN-OD. No living donor work is carried out.	**N/A**
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.	The establishment stores all patient files and related records either within the transplant unit record store or off-site at a dedicated document storage facility. NOP 006 "Transfer and storage of donor and organ characterisation information and storage of traceability data" has been adopted by the establishment. Advice has been provided under this assessment criterion.	**None**

CT5) Tests required for donor and organ characterisation are carried out by laboratories with CPA accreditation.	The establishment carries out confirmatory microbiology, virology and immunological testing, the results of which are only available post-implantation and which inform the patient's post transplantation drug therapy. The laboratories used are CPA accredited and evidence of this was reviewed during the audit.	**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.	Information on organ offers received by the transplant coordinator is discussed with the implanting surgeon and updates passed on as they become available. Handwritten notes detailing information received and passed on to the implanting surgeon are made on various forms used by the establishment staff. The responsibility to carry out this role is contained within the job descriptions of relevant staff, forms part of the establishment's "Cardiothoracic Transplant Retrieval Protocol" (Retrieval Protocol) and the establishment has adopted NOP 006. Advice has been provided under this assessment criterion.	**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.	No living retrieval is carried out. The NORS team follow the Retrieval Protocol which details the responsibility to check consent is in place prior to retrieval. The NHSBT surgical safety checklist is used in advance of commencement of the retrieval operation to record the checking of consent.	**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.	The Trust's "Policy for Management of Medical Devices" references the need for material and equipment used throughout the Trust to meet the requirements of 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.	Reusable instruments are cleaned and sterilised by an external company. Certificated evidence of that company's compliance with relevant requirements was exhibited during the audit.	**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.	No living donor work is carried out at the establishment.	**N/A**

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.	The Trust's "Policy for Management of Medical Devices" references the need for material and equipment used throughout the Trust to meet the requirements of the Medical Devices Regulations.	**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.	Reusable instruments are cleaned and sterilised by an external company. Certificated evidence of that company's compliance with relevant requirements was exhibited during the audit.	**None**
P3) Records of perfusion fluid coming into contact with organs are made on the appropriate HTA A and B forms.	Batch numbers of perfusion fluids are recorded on HTA A and B forms and on various other record forms used by the establishment.	**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.	The Retrieval Protocol provides guidance on how organs are to be prepared for transport, and the contracted transport supplier's "Transport Policy" and "Driver's Handbook" details procedures to be followed to ensure integrity is maintained during transport and transport time is minimised.	**None**
TP2) The organ shipping container is suitable for transport of the specified organ.	The establishment has used proprietary cool boxes for the transport of organs over a period exceeding 20 years with no issues relating to suitability. The establishment plans to use NHSBT supplied boxes when they become available.	**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.	The establishment use labels which meet the needs of the framework document and now include contact details for the NHSBT duty office rather than details of the donor hospital. Where a retrieved organ is to be accompanied to the establishment by the retrieval team, relevant documentation accompanies the organ, but the box itself is not always labelled. Advice has been provided under this assessment criterion.	**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.	The relevant documentation is enclosed within liquid proof envelopes placed in the organ transport box used for transporting the organ to the recipient hospital. The requirement for this is included within the Retrieval Protocol. At the establishment, donor and organ characterisation information is passed to the surgical team by the transplant co-ordinator and Electronic Offering System (EOS) records are printed off and made available to the implanting surgeon. The establishment has also adopted NOP 006. Advice has been provided under this criterion.	**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.	The contracted transport provider's "Driver's Handbook" details the requirement for any incident during transport to be reported to the transplant co-ordinator.	**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.	The requirement to identify the donor and verify relevant information is contained within the Retrieval Protocol, the responsibility of staff to do so is contained within job descriptions and in checklist/flowcharts used by staff in advance of the implantation. The establishment has also adopted NOP 002 "Verification of Donor Identity, Consent/Authorisation and Organ and Donor Characterisation in Deceased and Living Donation and Transplantation" and NOP 006. Advice has been provided under this assessment criterion.	**None**
I2) Compliance with the conditions of preservation and transport outlined in the framework document are verified prior to proceeding to implant an organ.	The transplant co-ordinator or surgical team scrub nurse verify that packaging is intact and ice levels have been maintained during transport. Checklists and record sheets completed by receiving staff and the perfusionist involved in the implantation of the organ are used to confirm that maximum ischaemic times have not been exceeded.	**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.	Evidence of risk-benefit analyses recorded in recipient patient files was exhibited to the HTA during the audit.	**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.	The responsibilities of members of the retrieval team to complete HTA A and B forms are detailed in the Retrieval Protocol and the transplant co-ordinator is responsible for the return of HTA A and B forms to NHSBT. The establishment has adopted NOP 006. Advice has been provided under this assessment criterion.	**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.	Donors are identified using NHSBT donor numbers, and left or right lungs are identified by appropriate labelling. Recipients are identified by name, date of birth, hospital number and NHS 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.	All records relating to transportation of organs are retained within files stored at the establishment. The establishment retains all records relating to transplant on site in specific storage, or at a dedicated off site document storage facility. Records are kept permanently at present. Reference is made to assessment criterion CT4.	**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.	The establishment has adopted NHSBT SOP 3888/1 "Reporting an Organ Donation or Transplantation Incident to NHSBT" for use by staff, and staff appeared to be familiar with the type of incidents which would be classed as serious adverse events or reactions. Incidents are also reported internally, using the Trust system. Advice has been provided under this assessment criterion.	**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.	Reference is made to assessment criterion S1 above.	**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.	The contracted transport provider requires drivers to report all incidents occurring during transport of organs to the transplant co-ordinator and this is detailed within the "Driver's Handbook". As part of their CPA accreditation the laboratories used by the establishment must have reporting systems in place and evidence that laboratory staff are aware of the need to report incidents or events to the establishment was exhibited to the HTA shortly after the audit.	**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.	All staff employed by the Trust are required to maintain appropriate professional registration. Surgical trainees undertake supervised training and, prior to being allowed to carry out retrieval operations unsupervised, undertake a competency based assessment and certification procedure. Nursing staff undertake competency based assessment. All staff are subject to annual appraisal within the Trust and for surgical staff this includes review of morbidity and mortality data.	**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.	All staff undergo induction training and are required to undertake job specific Continuous Professional Development as part of Personal Development Plans agreed during the appraisal process.	**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.	All transplant activities at the establishment and retrievals undertaken by the establishment's NORS team are carried out under the guidance of registered medical practitioners. Evidence of registration was exhibited to the HTA during the audit. The responsibilities of medical staff during retrievals and for some elements of transplant are detailed in the Retrieval Protocol and the establishment has adopted NOP 005 "Activities To Be Performed Under The Guidance Of A Registered Medical Practitioner in Deceased and Living Donation and Transplantation". Advice has been provided under this assessment criterion.	**None**

Advice

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

No.	Assessment Criterion	Advice
1.	CT4, TC3	The establishment is advised to review NOP 006 to accurately reflect local procedures where files and records relating to living transplant recipients are retained on site within the transplant unit and those relating to deceased transplant patients are stored in archives off site. Alternatively the establishment may wish to incorporate local policy and practice relating to records within the establishment's protocol documentation.
2.	CT6, TP4	The establishment is advised to review NOP 006 in tandem with the "Cardiothoracic Transplant Retrieval Protocol" in order to consider whether local practice relating to the transmission of donor and organ characterisation information to the implanting surgeon is accurately reflected. The establishment is also advised to consider whether local practice relating to the receipt and transfer of donor and organ characterisation information to the implanting surgeon could be reflected in the establishment's protocol document rather than being referred to within various different documents, job descriptions etc. The establishment is further advised to consider the use of a communications log sheet, with continuation sheets, designed to allow the date and time of telephone calls, persons involved and information received or given to be recorded accurately in an easily accessible format.
3.	TP3	The establishment is advised to label organ transport boxes being used to transport retrieved organs, even when accompanied at all times by the retrieval team. As labelling of organ boxes is a mandatory requirement detailed in "The Quality and Safety of Organs Intended for Transplantation – a documentary framework", the HTA considered whether this should be reflected as a minor shortfall. However, taking into account the relative risks involved where organs are transported by or with the retrieval team and the on-going delay to the issuing of approved organ boxes by NHSBT, the HTA has decided that this is a matter for advice only.
4.	I1	The establishment is advised to review NOP 002 and NOP 006 in tandem with its protocol documentation to ensure that local practice relating to verification of donor identity and information relating to the donor and organ is accurately reflected.
5.	TC1	The establishment is advised to review NOP 006 in tandem with its protocol documentation and transplant co-ordinator information to ensure that local practice relating to return of HTA A and B forms to NHSBT is accurately reflected.
6.	S1	The establishment is advised to consider amending SOP 3888/1 to include reference to the need to report incidents on the Trust incident reporting system, as well as to NHSBT.

7.	GN3	The establishment is advised to review NOP 005 in tandem with it's protocol documentation to ensure that local practice relating to the responsibilities of medical practitioners involved in transplantation activities is accurately reflected in a document which is easily accessible to staff.
8.	N/A	The HTA notes that local procedures to be followed by staff are detailed within various sources, including the Cardiothoracic Transplant Retrieval Protocol, transplant co-ordinator guidance documentation, Cardiothoracic Retrieval Scout Information and related protocol for donor optimisation, as well as checklists and flowcharts. The establishment has also adopted the National Operating Procedures with little or no amendment. The establishment is advised to consider consolidating relevant procedural guidance to staff into a limited number of documents in order that changes in procedure or updates to documents can easily be disseminated to staff and document control better managed. In doing so, the establishment is advised to consider whether the NOPs should be further adapted to more accurately reflect local practice, or to incorporate the mandatory elements of the NOPs into revised versions of existing protocol and guidance documentation.

Concluding comments

The HTA saw various examples of good practice at the establishment. There appears to be a very close working relationship between all staff within the unit.

The establishment has devised a Cardiothoracic Transplant Retrieval Protocol, which defines the responsibilities of staff involved in organ retrieval and provides them with guidance on procedures to be followed. This also provides some detail relating to elements of the communication with implanting surgical teams.

The establishment uses trained nurses specialising in organ retrieval to form "Scout" teams with surgeons sent in advance of the full retrieval team to facilitate early donor management in an effort to improve the quality of organs subsequently retrieved.

The service provided at the establishment is consultant led, junior or trainee surgeons being trained by consultants and undergoing a defined competency based training and assessment procedure, which has been devised by the establishment working together with another cardiothoracic transplant unit. Following training and assessment the retrieval surgeons are certified by the establishment as being qualified to retrieve organs unsupervised.

Implantation is carried out by consultant led surgical teams and retrieval team surgeons assist in implantation operations to further inform their training. As many organs retrieved by the NORS team within the local area are destined for implantation at the establishment, this integrated training means that retrieval surgeons understand the requirements of implant surgeons when carrying out the retrieval surgery.

The establishment takes part in the Early Donor Management project and is also one of the centres carrying out Ex Vivo Lung Perfusion, both projects intended to improve the quality of organs for transplantation.

As well as identifying recipients by usual methods, information sheets accessible to implanting surgical staff have passport sized photographs of the recipient, to further aid accurate patient identification,

The HTA has given advice to the establishment with respect to elements of its procedural documentation as guidance to staff on procedures is found in various sources.

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

Report sent for factual accuracy: 19 August 2013

Report returned with comments: 6 September 2013

Final report issued: 6 September 2013

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.