Site visit audit report on compliance with HTA requirements

NHS Blood and Transplant

HTA licensing number 40056

Licensed for

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

Under the Quality and Safety of Organs Intended for Transplantation Regulations 2012, as amended by the Quality and Safety of Organs Intended for Transplantation (Amendment) Regulations 2014.

28 – 31 March 2017

Summary of Audit findings

NHS Blood and Transplant (the establishment) was found to have met all assessment criteria.

Although the HTA found that the establishment had met the all of the assessment criteria, advice has been given to the establishment in relation to donor characterisation procedures, procedural documentation, organ traceability forms and the use of new transport boxes.

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	Heart	Lung	Liver	Kidney	Small Bowel	Pancreas
Adult deceased	**DC, OC, T**	**DC, OC, T**	**DC, OC, T, P**	**DC, OC, T, P**	**DC, OC, T**	**DC, OC, T, P**
Paediatric deceased	**DC, OC, T**	**DC, OC, T**	**DC, OC, T, P**	**DC, OC, T, P**	**DC, OC, T**	**DC, OC, T, P**

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)

Background to the establishment and description of audit activities undertaken

NHS Blood & Transplant (NHSBT) is a Special Health Authority with responsibilities for organ donation and transplantation across the United Kingdom. NHSBT (the establishment) has been licensed by the HTA since September 2012 under the Quality and Safety of Organs Intended for Transplantation Regulations 2012, as amended by the Quality and Safety of Organs Intended for Transplantation (Amendment) Regulations 2014.

The establishment's Organ Donation and Transplant (ODT) Directorate manages the National Transplant Database, the NHS Organ Donor Register and provides a dedicated 24 hour service that assists with the identification, referral and progression of organ donation from deceased donors, and ensures that donated organs are matched and allocated to recipient patients. Matching and allocation processes take into account multiple parameters to help assure appropriate allocation of organs including potential cold ischaemic times, the characterisation of the donors, clinical condition of the recipients and logistical considerations relating to travel between donor and recipient premises. The establishment also performs the matching and allocation in non-directed altruistic and paired / pooled living donations and maintain records of organ traceability. In addition, the establishment commissions the National Organ Retrieval Service (NORS) teams which undertake deceased donor organ retrievals. However, although the NORS teams are commissioned by the establishment, when undertaking licensable activity during deceased organ retrieval, the teams act under the HTA ODT licences of their base hospitals and not the establishment's ODT licence.

An audit of the establishment's HTA ODT licence (licence number 40056) was undertaken between the 28 and 31 March 2017. During the audit, the NHSBT duty office in Bristol and Donor Records Department (DRD) in Liverpool were visited. During the visits, discussions were held with various staff regarding donor identification, donor and organ characterisation, mobilisation of retrieval teams and organ allocation. In addition, discussions around staff training, current projects being undertaken by NHSBT and organ transport containers were also held.

Discussions regarding donation and theatre procedures were held with four specialist nurses for organ donation (SNODs) from four different regions including the South West team, South Wales team, North West team and the Northern team. The SNODs were joined during these discussions by the relevant team manager, the regional team manager and a member of the establishment's quality team. Discussions with the SNODs and managers focussed on:-

- how they are made aware of potential donors,
- how they confirm that consent is in place for organ donation or who they would speak with in order to seek consent,
- processes relating to donor and organ characterisation,
- sending samples for mandatory serological testing, tissue typing and standard biochemical blood analysis,
- receiving results of characterisation assessments,
- gathering donor behavioural history, and,
- gathering information regarding previous medical conditions and treatments from the donor's current/previous clinical notes and GP.

Notification of a potential donor can be received directly by a SNOD who is embedded and working within a hospital via clinical staff working at the hospital, or it may be received by the establishment's duty office. The duty office receives referrals in cases of European donors; all UK donors are referred through a SNOD. Whether consent for organ donation is in place or consent will be sought by the SNOD, the SNOD identifies the most appropriate members of a potential donor's family or someone with whom the donor is in a qualifying relationship with, to discuss organ donation with them. If consent is confirmed, the SNOD notifies the duty office and starts undertaking the donor and organ characterisation assessments. These assessments, including laboratory test results and details of previous clinical and behavioural histories, are entered electronically into a dedicated donor record using the SNOD's handheld tablet computer. Once uploaded, the data is added to NHSBT's national transplant database (NTxD) against the donor's individual record and is used by the duty office to undertake the

organ matching and allocation process which identifies possible suitable organ recipients. Donor and organ characterisation information from NTxD is available for potential implanting centres to review once an offer of an organ has been made to a recipient on their waiting list via NHSBT's electronic offering system (EOS).

The organ and donor characterisation processes are described in multiple procedural and guidance documents, some of which were reviewed by the audit team during the audit. Procedures reviewed include:-

- GP Assessment, Donor Characterisation, Physical Assessment
- Diagnostics Infections, Diagnostics Blood Tests, Blood Tests Required for Organ Donation, Management of Blood Test Results pre-donation, Management of Blood Test Results post-donation, and,
- SNOD handover procedure.

There have been significant changes to procedures for entering donor and organ characterisation information onto the NTxD since the introduction of the tablet computers. These enable SNODs to enter testing and other characterisation information directly onto the establishment's database. Previously, information was recorded on paper forms and transcribed onto the database; the new direct entry procedure removes a step involving the transcription of data and therefore helps to mitigate some of the risk of errors being made when entering data. The audit team found that the procedural documentation met the requirements of the Regulations. During the audit however, it was found that some of the procedural documents have not been updated to reflect the changes in practice brought about by the introduction of the new tablet computers used for data entry. For example, the document describing how SNODs handover between each other during a donation reflected the previous, paper based system. The establishment indicated that procedural documents are being updated as they reach their assigned review dates and the example given above had been identified as a document that would benefit from an earlier update rather than waiting for its scheduled review. Advice has been given to the establishment regarding prioritising the review of some key documents that have been affected by changes, which may help to strengthen the establishment's processes (see advice item 2).

Organ retrieval teams are mobilised by the establishment's duty office who work in collaboration with the SNOD to liaise with the team regarding expected retrieval and travel times. During the travel undertaken by the retrieval teams and the organ retrieval itself, the SNOD can be involved, jointly with the duty office, with maintaining contact with the recipient centres and advising them of any issues related to the donor or organ, or changes to organ retrieval and transit times. When the retrieval team arrives at the donor hospital the SNOD facilitates a review by the lead retrieval surgeons of the organ and donor characterisation information, past medical history, donor blood test results including blood group and consent information. Once retrieved, inspected and prepared for transport, the donor organ can be packed into the transport container by a perfusionist who is part of the retrieval team or the SNOD (SNODs may pack only kidneys, pancreases and hearts for valve isolation). The SNOD also ensures that the appropriate paperwork accompanies the organ to the recipient centre and the transport box is appropriately labelled. Again, appropriate procedural documents supporting these processes were in place and reviewed during the audit.

The establishment is preparing to deploy a new type of transport box which will be used to transport kidneys, pancreases and hearts that are being transported to tissue establishments for heart valve isolation. These new boxes have been assessed by the establishment with regards to their suitability and were shown to the audit team during the audit. It is planned by the establishment that although the boxes' entire lid can be removed, the clasps on one side of the lid will remain permanently sealed and act as a hinge. Only the clasps on the opposite side of the lid should be unsealed upon receipt allowing the lid to be opened by retrieval and

transplant teams. A procedural document describing the use of the boxes has been developed and establishment staff trained in the use of the boxes. Advice has been given to the establishment regarding reminding all staff that may use the new boxes, as to the appropriate method for use (including sealing and unsealing) (see advice item 7).

The establishment has a service level agreement (SLA) with the organisation providing organ transport services. The transport SLA was reviewed during the audit and included details of expected response times to mobilisation calls, details of when to update the duty office of any issues during transport that may effect journey time such as breakdown or traffic delays, and also details of timeframes within which any adverse incident must be reported to the establishment. The audit team also reviewed the establishment's systems for reporting and investigating serious adverse events and serious adverse reactions in addition to less serious incident reporting and investigation which follows the same procedures. Examples of incidents that had been reported were reviewed during the audit in addition to the associated investigation and corrective actions identified.

During the audit a review of donor records was undertaken by the audit team with records being selected for review as detailed below:

- One donor's details were taken from the establishment's national transplant database at the duty office.
- A completed and closed donor file from 18 months before the date of the audit was requested from archival storage.
- Ten hard copy donor files were selected at random from the file store at the DRD representing donations from the previous six months.

The audit of all of these donor records was undertaken in different ways to reflect the various sources of the files. These are detailed below:-

Donor details taken from the national transplant database
Donor identification details, consent details and some characterisation information including serological blood test results, donor blood group and biochemical test results were chosen at random from the electronic national transplant database at the duty office in Bristol. At the DRD in Liverpool, the corresponding paper donor file was found and the details taken from the electronic system cross checked with the hard copy data within the donor file. All data correlated between the paper and electronic records and no anomalies were found.

Donor file from 18 months prior to the date of the audit
Details of donor identification, the consent form, serological blood test results, donor blood group, creatinine levels, glomerular filtration rate (GFR), alanine aminotransferase test (ALT), summary of organs retrieved and transplanted, HTA-A forms including details of perfusion fluids used, GP medical history faxes and organ handover form were taken and compared against the electronic record in the establishment's EOS database. All data correlated between the paper and electronic records and no anomalies were found.

Ten donor files taken at random from donor records department
Details of donor identification, the consent form, serological blood test results, donor blood group, creatinine levels, glomerular filtration rate (GFR), alanine aminotransferase test (ALT), summary of organs retrieved and transplanted, HTA-A forms including details of perfusion fluids used, GP medical history faxes and organ handover form were taken and compared against the electronic record in the establishment's donor path database which is used by SNODs to enter donor and organ characterisation data. In most cases data correlated between the paper and electronic records however, two anomalies within the donor files were identified during the audit.

In the first donor file where an anomaly was found, an organ handover from had not been filed. This form is used to record details of the driver picking up an organ from the retrieval centre and the time at which the organ leaves the recipient centre. In conjunction with other traceability information recorded by the recipient centres, the departure time of an organ on the handover form is used to calculate the travel time for the organ between retrieval and transplant sites. The establishment notified the audit team that some other donor files have been identified where the donor handover form had not been filed as expected. The finding has been reported via the internal incident reporting system and is being investigated. The donor file identified during the audit had been closed, however, there was no annotation within the file to record that the organ handover form was missing from the file. The document checklist which captures the presence of the organ handover form within the donor file had been marked 'not applicable' rather than noting that the form was absent. In addition, there was no file note to highlight that an incident relating to the missing form had been reported. Including details of the incident report within the file may be helpful in any future reviews of the donor file. Advice has been given to the establishment regarding capturing the concessionary closure of the donor files (see advice item 6).

Within the second donor file where an anomaly was found, records showed that the relevant Coroner had been contacted regarding a potential donor to enquire if the Coroner could permit organ donation. The contact with the Coroner had been recorded within an appropriate record within donor path, however, the area within donor path where the communication had been recorded was not viewable via EOS by NORS teams or transplant teams. Advice has been given to the establishment regarding assessing whether making Coronial communications visible to NORS and transplant teams via EOS may facilitate the donation and transplant process (see advice item 3).

Advice

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

No.	Assessment Criterion	Advice
1.	CT1	The establishment is currently undertaking a review of donor characterisation procedures. The audit team understand that the report has identified some variation in donor characterisation assessment procedures between the various teams and microbiology laboratories around the country. The establishment is advised to consider the results of the review when they are available later during 2017 and to assure themselves that the variation identified does not pose an increased risk to the organs and recipients, or that any risks identified has measures developed to mitigate against them.
2.	CT1	During the audit it was found that some of the procedural documents have not been updated to reflect the changes in practice brought about by changes in procedures, for example, the introduction of tablet computers used by the SNODs or the introduction of the donor records department. The establishment has already identified that some documents will need updating and they are being updated as they reach their assigned review dates, however, the establishment is advised to prioritise the review of key documents for example, those describing the handover processes between SNODs during a donation process, or handling of GP assessments by the donor records department.

No.	Assessment Criterion	Advice
3.	CT1	The establishment is advised to consider whether making the outcomes of communications with a Coroner viewable to NORS teams, regardless of the donor path tab it is recorded within, as this may help facilitate the NORS and transplant teams' review of the relevant donor information.
4.	CT3	During the audit of donor files a case where organs had been biopsied prior to being sent to the recipient centres, with the biopsies having been taken for research purposes, was reviewed. The HTA-A form for the kidney had been annotated to indicate that a research biopsy had been taken, however the HTA-A form for the liver had no record of the biopsy. The establishment is advised to remind all surgeons taking biopsies for use in research that records should be made on the corresponding HTA-A organ forms so that the implanting surgeon is aware of the additional characterisation information relating to the organs.
5.	P3 & TC1	Fluids used when perfusing pancreases at retrieval are potentially recorded using multiple documents including either an associated liver HTA-A form, associated kidney HTA-A form and the organ specific pancreas form. The audit of donor records showed that perfusion fluids were being recorded appropriately in the donor cases selected for review. The establishment may wish to consider however making the current organ specific form for pancreases into a pancreas HTA-A form as it contains much of the information recorded on other HTA-A forms and would remove the need to record details of pancreas retrieval and perfusion on other HTA-A forms.
6.	TP1	During the audit of donor files a case where the organ handover form, used to record details of the driver picking up an organ from the retrieval centre, and the time at which the organ leaves the recipient centre, had not been included in the file as expected. The establishment informed the audit team that this and some other cases where the organ handover form had not been filed as expected had been identified during closure of the files and these instances have been reported as an incident internally. The establishment is advised to annotate the donor files where it has been found that the organ handover forms are not present and reference the incident report that has been submitted. This annotation should also record that the donor files have undergone concessionary closure by highlighting that the files had been closed in the knowledge that not all of the required documentation was present.
7.	TP2	The establishment is planning to introduce a new type of transport box which will be used to transport kidneys, pancreases and hearts that are being transported to tissue establishments for heart valve isolation. A procedural document describes the sealing of the new box lids by using a plastic tie around the clasps on one side and then, after packing the organ and closing the clasps on the other side, the use of a second sealing tie. The procedure however is not explicit that in order to appropriately seal both sides of the lid, the second sealing tie should be placed around the claps on the opposite side of the lid to the first. As these boxes are significantly different to

No.	Assessment Criterion	Advice
		the ones which are currently in use, there could be a risk that establishment staff and staff at recipient centres do not seal and unseal the boxes as the establishment envisages, which may pose a risk of boxes being used incorrectly. The establishment is advised to remind both establishment staff and staff at recipient centres regarding the correct use of the new transport boxes and specifically, the addition and removal of the sealing ties.

Concluding comments

Areas of good practice were observed during the audit, some of which are included in the report below.

- The establishment demonstrated a culture of continuous improvement. Since the previous audit in 2013 new procedures and ways of working have been introduced to facilitate establishment staff in undertaking their work. The two major changes include the systems within the duty office which have improved robustness, the organ offering processes, and the tablet computers which all SNODs have been issued with. The tablet computers not only facilitate data entry by the SNODs but also have in-built tools to facilitate accurate donor characterisation. An example of this relates to haemodilution calculations. By entering donor data and information about transfusions of blood and infusions of crystalloids or colloids, information about the haemodiltuion status of the donor is automatically generated which may help to prompt establishment staff to seek a pre-haemodiluted blood sample to be used for testing if one is available. In addition to facilitating data entry, the tablet computers also allow SNODs to access guidance and procedural documentation for reference if needed.

- In addition to the establishment's new IT systems, reviews around other processes have been on going or have started during the period since the last audit. Two examples include the assessment of new transport boxes for kidneys and pancreases and a review into donor and organ characterisation processes. Again, these two initiatives demonstrate that the establishment is seeking to review its processes to assure itself of their continued suitability.

- Finally, during the audit, discussions were held with establishment staff with responsibility for training during which the training of newly appointed SNODs was discussed in detail. Training of SNODs is another area that has evolved since the last audit. New modular training and work based shadowing has been introduced which culminates in SNODs undertaking simulated exercises to utilise their training and experience to date in a non-clinical training environment. In addition to training for new SNODs, courses for SNODs who are established in the role and are competent have been introduced so that they can develop further and learn leadership skills with respect to transplant activities. Also, throughout the audit, training records for SNODS and other establishment staff, for example duty office staff, were reviewed and these included various competency based assessments and records of mandatory training.

The HTA has given advice to the establishment with respect to donor characterisation procedures, procedural documentation, organ traceability forms and the use of new transport boxes.

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

Report sent for factual accuracy: 3 May 2017

Report returned with comments: 18 May 2017

Final report issued: 31 May 2017

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.

HTA assessment criteria

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.
CT2) Donors and organs are characterised before implantation by the collection of information specified in Part A of the Annex to the Directive.
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.
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.
CT5) Tests required for donor and organ characterisation are carried out by laboratories with CPA or UKAS accreditation.
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.

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.
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.
R3) Reusable instruments used in retrieval are subject to a validated cleaning and sterilisation procedure for removal of infectious agents, which is documented.
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.
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.
P2) Reusable instruments used in organ preservation are subject to a validated cleaning and sterilisation procedure for removal of infectious agents, which is documented.
P3) Records of perfusion fluid coming into contact with organs are made on the appropriate HTA A and B forms.
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.
TP2) The organ shipping container is suitable for transport of the specified organ.
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.
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.
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.
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.
I2) Compliance with the conditions of preservation and transport outlined in the framework document are verified prior to proceeding to implant an organ.

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.
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.
TC2) There is an identification system for donor and recipient to identify each donation and each of the organs and recipients associated with it.
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.
Serious adverse events and adverse 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.
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.
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.
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.
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.
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.