POLICY POL246/3

Accreditation of Laboratories under the Organ Quality and Safety Regulations

This Policy replaces *POL246/2*	**Copy Number**
	Effective **09/04/19**

Summary of Significant Changes

Removal of reference to Clinical Pathology Accreditation (CPA), which became obsolete in September 2018.

Addition of reference to a new process for H & I laboratories to notify NHSBT of accreditation status changes or disruption of service.

Policy

NHS Blood and Transplant (NHSBT) holds a Procurement licence (40056) under the Quality and Safety of Organs Intended for Transplantation Regulations (2012); licensed for the activity of 'donor and organ characterisation'.

This legislation requires that laboratories which carry out testing of organ donors are accredited by the United Kingdom Accreditation Service (UKAS) to ISO 15189:2012.

UKAS accreditation also provides NHSBT with assurance that laboratories carrying out donor testing are doing so to accepted standards in relation to staff, facilities and equipment. Such standards reduce the risk of inaccurate results and thereby ensure patient safety.

This policy describes how NHSBT ODT works within the requirements of the Regulations to endeavour to use UKAS accredited laboratories.

1. Introduction

The Quality and Safety of Organs Intended for Transplantation Regulations (2012) sets out a requirement that laboratories undertaking screening as part of donor characterisation meet certain standards.

The HTA DIRECTS that tests required for donor and organ characterisation are carried out by laboratories with suitably qualified or trained and competent personnel and adequate facilities and equipment.

The HTA considers that laboratories which hold current accreditation by the United Kingdom Accreditation Service (UKAS) to the internationally recognised standard ISO 15189:2012 will meet the requirement and NHSBT should endeavour to use only UKAS accredited laboratories.

Laboratory accreditation status can be checked here

The HTA Framework document states that there is an expectation that '*licence holders to establish the accreditation status of laboratories that are frequently used for donor or organ characterisation, and to review and update this information on a regular basis'*.

Furthermore '*Licence holders should not use a laboratory with an unknown or unaccredited status unless justified on the basis of risk to the quality and safety of the organ or to the recipient. This should be documented for reference in event of a serious adverse event or serious adverse reaction'*.

2. Operational Implementation

Following dialogue with the HTA about the practical difficulties in complying with this requirement, NHSBT have agreed the following operational implementation of the requirements:

NHSBT ODT facilitate and enable transplantation. NHSBT ODT does not directly commission laboratories and therefore do not have any direct governance over their practices. NHSBT ODT are responsible for requesting the tests, collating the results and passing the information on to the appropriate Transplant Unit for the assessment of risk associated with that donor.

NHSBT ODT use NHS laboratories which undertake the testing of significant numbers of samples for the general population of the hospital concerned. Therefore, if there was a significant risk associated with the use of the NHS laboratory this would be managed by the hospital Governance processes and is highly likely to be known by the clinicians caring for the patient. This is of particular relevance for the haematology/blood transfusion, biochemistry and histopathology laboratories.

A Specialist Nurse – Organ Donation (SNOD) working within the Trust/Health Boards on an honorary contract alongside a Clinical Lead Organ Donation (CLOD) would be made aware of any significant laboratory issues which may affect the quality and safety of a potential recipient. The SNOD/CLOD can ensure that this information is shared with their local team and ODT Quality Assurance for advice on how to proceed if an issue exists. On discussions with the Trust/Health Board involved and a clinical/scientific and regulatory risk review from NHSBT, an alternative laboratory may be used if necessary.

It is envisaged that this would be a very rare occurrence and would be managed on a case by case basis depending on associated risk.

3. H&I Laboratories

SOP5546 (H&I laboratory – Operational Disruption – Hub Operations) details the steps to be taken for NHS laboratories, Hub Operations and SNODs when a H&I laboratory identifies that there is a potential disruption to the testing service provided, which may impact on the organ donation process. Disruption may include, but is not limited to, issues affecting the accreditation status of the laboratory. INF1466 (Back-up Laboratories for Deceased Donor Tissue Typing Testing) provides a list of back up laboratories for deceased donor tissue typing following the identification of potential disruption to the testing service of individual H&I laboratories.