Commission Directive 2006/17/EC of 8 February 2006 implementing Directive 2004/23/EC of the European Parliament and of the Council as regards certain technical requirements for the donation, procurement and testing of human tissues and cells (Text with EEA relevance)

Article 1

Definitions

For the purposes of this Directive, the following definitions apply:

(a) ‘reproductive cells’ means all tissues and cells intended to be used for the purpose of assisted reproduction;

(b) ‘partner donation’ means the donation of reproductive cells between a man and a woman who declare that they have an intimate physical relationship;

(c) ‘direct use’ means any procedure where cells are donated and used without any banking;

(d) ‘quality system’ means the organisational structure, defined responsibilities, procedures, processes, and resources for implementing quality management and includes all activities which contribute to quality, directly or indirectly;

(e) ‘standard operating procedures’ (SOPs) means written instructions describing the steps in a specific process, including the materials and methods to be used and the expected end product;

(f) ‘validation’ (or ‘qualification’ in the case of equipment or environments) means establishing documented evidence that provides a high degree of assurance that a specific process, SOP, piece of equipment or environment will consistently produce a product meeting its predetermined specifications and quality attributes; a process is validated to evaluate the performance of a system with regard to its effectiveness based on intended use;

(g) ‘traceability’ means the ability to locate and identify the tissue/cell during any step from procurement, through processing, testing and storage, to distribution to the recipient or disposal, which also implies the ability to identify the donor and the tissue establishment or the manufacturing facility receiving, processing or storing the tissue/cells, and the ability to identify the recipient(s) at the medical facility/facilities applying the tissue/cells to the recipient(s); traceability also covers the ability to locate and identify all relevant data relating to products and materials coming into contact with those tissues/cells;

(h) ‘procurement organisation’ means a health care establishment or a unit of a hospital or another body that undertakes the procurement of human tissues and cells and that may not be accredited, designated, authorised or licensed as a tissue establishment.