ANNEX I

Requirements for accreditation, designation, authorisation or licensing of tissue establishments as referred to in Article 3

E.DOCUMENTATION AND RECORDS

1. There must be a system in place that results in clearly defined and effective documentation, correct records and registers and authorised Standard Operating Procedures (SOPs), for the activities for which accreditation/designation/authorisation/licensing is sought. Documents must be regularly reviewed and must conform to the standards laid down in this Directive. The system must ensure that work performed is standardised, and that all steps are traceable; i.e. coding, donor eligibility, procurement, processing, preservation, storage, transport, distribution or disposal, including aspects relating to quality control and quality assurance.

2. For every critical activity, the materials, equipment and personnel involved must be identified and documented.

3. In the tissue establishments all changes to documents must be reviewed, dated, approved, documented and implemented promptly by authorised personnel.

4. A document control procedure must be established to provide for the history of document reviews and changes and to ensure that only current versions of documents are in use.

5. Records must be shown to be reliable and a true representation of the results.

6. Records must be legible and indelible and may be handwritten or transferred to another validated system, such as a computer or microfilm.

7. Without prejudice to Article 9(2), all records, including raw data, which are critical to the safety and quality of the tissues and cells shall be kept so as to ensure access to these data for at least 10 years after expiry date, clinical use or disposal.

8. Records must meet the confidentiality requirements laid down in Article 14 of Directive 2004/23/EC. Access to registers and data must be restricted to persons authorised by the responsible person, and to the competent authority for the purpose of inspection and control measures.