Commission Directive 2006/86/EC of 24 October 2006 implementing Directive 2004/23/EC of the European Parliament and of the Council as regards traceability requirements, notification of serious adverse reactions and events and certain technical requirements for the coding, processing, preservation, storage and distribution of human tissues and cells (Text with EEA relevance)

ANNEX I

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

A. ORGANISATION AND MANAGEMENT

1. A responsible person must be appointed having qualifications and responsibilities...
2. A tissue establishment must have an organisational structure and operational...
3. Every tissue establishment must have access to a nominated medical...
4. There must be a documented quality management system applied to...
5. It must be ensured that the risks inherent in the...
6. Agreements between tissue establishments and third parties must comply with...
7. There must be a documented system in place, supervised by...
8. In the event of termination of activities the agreements concluded...
9. There must be a documented system in place that ensures...

B. PERSONNEL

1. The personnel in tissue establishments must be available in sufficient...
2. All personnel should have clear, documented and up-to-date job descriptions....
3. Personnel must be provided with initial/basic training, updated training as...

C. EQUIPMENT AND MATERIALS

1. All equipment and material must be designed and maintained to...
2. All critical equipment and technical devices must be identified and...
3. New and repaired equipment must be tested when installed and...
4. Maintenance, servicing, cleaning, disinfection and sanitation of all critical equipment...
5. Procedures for the operation of each piece of critical equipment,...
6. The procedures for the activities for which accreditation/designation/ authorisation/licensing is sought,...

D. FACILITIES/PREMISES

1. A tissue establishment must have suitable facilities to carry out...
2. When these activities include processing of tissues and cells while...
3. Unless otherwise specified in point 4, where tissues or cells...
4. A less stringent environment than specified in point 3 may...
5. In point 4(a), (b), (c) and (d), an environment must...
6. When the activities for which accreditation/designation/authorisation or licensing is sought...
7. Critical parameters (e.g. temperature, humidity, air quality) must be controlled,...
8. Storage facilities must be provided that clearly separate and distinguish...
9. The tissue establishment must have written policies and procedures for...

E. DOCUMENTATION AND RECORDS

1. There must be a system in place that results in...
2. For every critical activity, the materials, equipment and personnel involved...
3. In the tissue establishments all changes to documents must be...
4. A document control procedure must be established to provide for...
5. Records must be shown to be reliable and a true...
6. Records must be legible and indelible and may be handwritten...
7. Without prejudice to Article 9(2), all records, including raw data,...
8. Records must meet the confidentiality requirements laid down in Article...

F. QUALITY REVIEW

1. An audit system must be in place for the activities...
2. Deviations from the required standards of quality and safety must...
3. Corrective actions must be documented, initiated and completed in a...
4. The tissue establishment should have processes in place for review...

ANNEX II

Requirements for the authorisation of tissue and cell preparation processes at the tissue establishments as referred to in Article 4

The competent authority shall authorise each tissue and cell preparation...

A. RECEPTION AT THE TISSUE ESTABLISHMENT

(2) Identification of the clinician or end-user/facility
(3) Type of tissues and cells
(4) Product identification
(5) Identification of the recipient
(6) Date of application
(7) Single European Code (if applicable)

ANNEX VII

THE STRUCTURE OF THE SINGLE EUROPEAN CODE

DONATION IDENTIFICATION SEQUENCE
PRODUCT IDENTIFICATION SEQUENCE EU TISSUE ESTABLISHMENT CODE...

ANNEX VIII

Data to be recorded in the EU Tissue Establishment Compendium

A. Tissue establishment information
1. Name of the tissue establishment
2. National or international code of tissue establishment
3. Name of the organisation in which the tissue establishment is...
4. Address of the tissue establishment
5. Publishable contact details: functional e-mail address, phone and fax

B. Details on the authorisation, accreditation, designation, or license of the...
1. Name of the authorising, accrediting, designating or licensing competent authority...
2. Name of the national competent authority or authorities responsible for...
3. Name of the authorisation, accreditation, designation or licence holder (if...
4. Tissues and cells for which the authorisation, accreditation, designation or...
5. Activities actually carried out for which the authorisation, accreditation, designation...
6. Status of the authorisation, accreditation, designation or license (authorised, suspended,...
7. Details of any conditions and exemptions added to the authorisation...

(**1**) OJ L 102, 7.4.2004, p. 48.

(**2**) http://pharmacos.eudra.org/F2/eudralex/vol-4/home.htm and OJ L 262, 14.10.2003, p. 22.

(**3**) OJ L 38, 9.2.2006, p. 40.