Directive 2004/23/EC of the European Parliament and of the Council of 31 March 2004 on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells

CHAPTER IV

PROVISIONS ON THE QUALITY AND SAFETY OF TISSUES AND CELLS

Article 16

Quality management

1 Member States shall take all necessary measures to ensure that each tissue establishment puts in place and updates a quality system based on the principles of good practice.

2 The Commission shall establish the Community standards and specifications referred to in Article 28(c) for activities relating to a quality system.

3 Tissue establishments shall take all necessary measures to ensure that the quality system includes at least the following documentation:

— standard operating procedures,
— guidelines,
— training and reference manuals,
— reporting forms,
— donor records,
— information on the final destination of tissues or cells.

4 Tissue establishments shall take all necessary measures to ensure that this documentation is available for inspection by the competent authority or authorities.

5 Tissue establishments shall keep the data necessary to ensure traceability in accordance with Article 8.

Article 17

Responsible person

1 Every tissue establishment shall designate a responsible person who shall at least fulfil the following conditions and have the following qualifications:

a possession of a diploma, certificate or other evidence of formal qualifications in the field of medical or biological sciences awarded on completion of a university course of study or a course recognised as equivalent by the Member State concerned;

b at least two years' practical experience in the relevant fields.

2 The person designated in paragraph 1 shall be responsible for:

a ensuring that human tissues and cells intended for human applications in the establishment for which that person is responsible are procured, tested, processed, stored and distributed in accordance with this Directive and with the laws in force in the Member State;

b providing information to the competent authority or authorities as required in Article 6;

c implementing the requirements of Articles 7, 10, 11, 15, 16 and 18 to 24 within the tissue establishment.

3 Tissue establishments shall inform the competent authority or authorities of the name of the responsible person referred to in paragraph 1. Where the responsible person is permanently or temporarily replaced, the tissue establishment shall immediately inform the competent authority of the name of the new responsible person and the date on which the duties of that person commence.

Article 18

Personnel

Personnel directly involved in activities relating to the procurement, processing, preservation, storage and distribution of tissues and cells in a tissue establishment shall be qualified to perform such tasks and shall be provided with the training referred to in Article 28(c).

Article 19

Tissue and cell reception

1 Tissue establishments shall ensure that all donations of human tissues and cells are subjected to tests in accordance with the requirements referred to Article 28(e) and that the selection and acceptance of tissues and cells comply with the requirements referred to in Article 28(f).

2 Tissue establishments shall ensure that human tissue and cells and associated documentation comply with the requirements referred to in Article 28(f).

3 Tissue establishments shall verify and record the fact that the packaging of human tissue and cells received complies with the requirements referred to in Article 28(f). All tissues and cells that do not comply with those provisions shall be discarded.

4 The acceptance or rejection of received tissues/cells shall be documented.

5 Tissue establishments shall ensure that human tissues and cells are correctly identified at all times. Each delivery or batch of tissues or cells shall be assigned an identifying code, in accordance with Article 8.

6 Tissue and cells shall be held in quarantine until such time as the requirements relating to donor testing and information have been met in accordance with Article 15.

Article 20

Tissue and cell processing

1 Tissue establishments shall include in their standard operating procedures all processes that affect quality and safety and shall ensure that they are carried out under controlled conditions. Tissue establishments shall ensure that the equipment used, the working environment and process design, validation and control conditions are in compliance with the requirements referred to in Article 28(h).

2 Any modifications to the processes used in the preparation of tissues and cells shall also meet the criteria laid down in paragraph 1.

3 Tissue establishments shall include in their standard operating procedures special provisions for the handling of tissues and cells to be discarded, in order to prevent the contamination of other tissues or cells, the processing environment or personnel.

Article 21

Tissue and cell storage conditions

1 Tissue establishments shall ensure that all procedures associated with the storage of tissues and cells are documented in the standard operating procedures and that the storage conditions comply with the requirements referred to in Article 28(h).

2 Tissue establishments shall ensure that all storage processes are carried out under controlled conditions.

3 Tissue establishments shall establish and apply procedures for the control of packaging and storage areas, in order to prevent any situation arising that might adversely affect the functioning or integrity of tissues and cells.

4 Processed tissues or cells shall not be distributed until all the requirements laid down in this Directive have been met.

5 Member States shall ensure that tissue establishments have agreements and procedures in place to ensure that, in the event of termination of activities for whatever reason, stored tissues and cells shall be transferred to other tissue establishment or establishments accredited, designated, authorised or licensed in accordance with Article 6, without prejudice to Member States' legislation concerning the disposal of donated tissues or cells, according to the consent pertaining to them.

Article 22

Labelling, documentation and packaging

Tissue establishments shall ensure that labelling, documentation and packaging conform to the requirements referred to in Article 28(f).

Article 23

Distribution

Tissue establishments shall ensure the quality of tissues and cells during distribution. Distribution conditions shall comply with the requirements referred to in Article 28(h).

Article 24

Relations between tissue establishments and third parties

1 Tissue establishments shall establish written agreements with a third party each time an external activity takes place which influences the quality and safety of tissues and cells processed in cooperation with a third party, and in particular in the following circumstances:

a where a tissue establishment entrusts one of the stages of tissue or cell processing to a third party;

b where a third party provides goods and services that affect tissue or cell quality and safety assurance, including their distribution;

c where a tissue establishment provides services to a tissue establishment which is not accredited;

d where a tissue establishment distributes tissue or cells processed by third parties.

2 Tissue establishments shall evaluate and select third parties on the basis of their ability to meet the standards laid down in this Directive.

3 Tissue establishments shall keep a complete list of the agreements referred to in paragraph 1 that they have established with third parties.

4 Agreements between tissue establishments and third parties shall specify the responsibilities of the third parties and detailed procedures.

5 Tissue establishments shall provide copies of agreements with third parties at the request of the competent authority or authorities.