

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.