

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 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.