

ANNEX I

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

B. PERSONNEL

1. The personnel in tissue establishments must be available in sufficient number and be qualified for the tasks they perform. The competency of the personnel must be evaluated at appropriate intervals specified in the quality system.
2. All personnel should have clear, documented and up-to-date job descriptions. Their tasks, responsibilities and accountability must be clearly documented and understood.
3. Personnel must be provided with initial/basic training, updated training as required when procedures change or scientific knowledge develops and adequate opportunities for relevant professional development. The training programme must ensure and document that each individual:
 - (a) has demonstrated competence in the performance of their designated tasks;
 - (b) has an adequate knowledge and understanding of the scientific/technical processes and principles relevant to their designated tasks;
 - (c) understands the organisational framework, quality system and health and safety rules of the establishment in which they work, and
 - (d) is adequately informed of the broader ethical, legal and regulatory context of their work.