

### Contents

	Foreword
	Introduction
1	Scope
2	Normative references
3	Terms and definitions
4	General requirements
4.1	General
4.2	Impartiality
4.3	Confidentiality
5	Structural requirements
6	Resource requirements
6.1	General
6.2	Personnel
6.2.1	General
6.2.2	Competence and competence assessment
6.2.3	Training
6.3	Facilities/dedicated areas and environmental conditions
6.4	Externally provided processes, products and services
6.5	Equipment
7	Process requirements
7.1	General
7.2	Collection of biological material and associated data
7.2.1	Documented information requirements
7.2.2	Pre-acquisition information
7.2.3	Collection procedure
7.3	Reception and distribution of biological material and associated data
7.3.1	Access principles
7.3.2	Reception
7.3.3	Distribution
7.4	Transport of biological material and associated data
7.5	Traceability of biological material and associated data
7.6	Preparation and preservation of biological material
7.7	Storage of biological material
7.8	Quality control of biological material and associated data
7.8.1	General
7.8.2	Quality control of processes
7.8.3	Quality control of data
7.9	Validation and verification of methods
7.9.1	General
7.9.2	Validation
7.9.3	Verification
7.10	Management of information and data
7.11	Nonconforming output
7.11.1	General
7.11.2	Control of nonconforming output
7.12	Report requirements

- 7.12.1 General
- 7.12.2 Content of the report
- 7.13 Complaints

**8 Quality management system requirements**

- 8.1 Options
  - 8.1.1 General
  - 8.1.2 Option A
  - 8.1.3 Option B
- 8.2 Documented information for the quality management system (Option A)
- 8.3 Control of quality management system documents (Option A)
- 8.4 Control of records (Option A)
- 8.5 Actions to address risks and opportunities (Option A)
- 8.6 Improvement (Option A)
- 8.7 Corrective action for nonconforming output (Option A)
- 8.8 Internal audits (Option A)
- 8.9 Quality management reviews (Option A)

**Annex A (normative) Documentation requirements**

- A.1 General
- A.2 Acquisition
- A.3 Transport
- A.4 Preparation/preservation
- A.5 Testing
- A.6 Storage
- A.7 Distribution and disposal

**Annex B (informative) Implementation guidance for Annex A**

- B.1 General
- B.2 Acquisition
- B.3 Transport
- B.4 Preparation/preservation
- B.5 Testing
- B.6 Storage
- B.7 Distribution and disposal

**Annex C (informative) Quality management system options**

Page count: 36