

ISO 35001:2019-11 (E)

Biorisk management for laboratories and other related organisations

Contents	Page
Foreword	v
Introduction	vi
1 Scope	1
2 Normative references	1
3 Terms and definitions	1
4 Context of the organization	7
4.1 Understanding the organization and its context	7
4.2 Understanding the needs and expectations of interested parties	8
4.3 Determining the scope of the biorisk management system	8
4.4 Biorisk management system	8
5 Leadership	8
5.1 Leadership and commitment	8
5.2 Policy	9
5.3 Roles, responsibilities, and authorities	9
5.3.1 Top management	10
5.3.2 Senior management	10
5.3.3 Biorisk management committee	10
5.3.4 Biorisk management advisor	11
5.3.5 Scientific management	11
6 Planning	12
6.1 Actions to address risks and opportunities	12
6.1.1 Hazard and/or threat identification and analysis	12
6.1.2 Risk assessment	12
6.1.3 Risk mitigation	13
6.1.4 Performance evaluation	13
6.2 Biorisk management objectives and planning to achieve them	13
7 Support	14
7.1 Resources	14
7.1.1 Worker health programme	14
7.2 Competence	15
7.2.1 Behavioural factors and worker management	15
7.2.2 Personnel reliability measures	15
7.3 Awareness	16
7.3.1 Training	16
7.4 Communication	16
7.5 Documented information	17
7.5.1 General	17
7.5.2 Creating and updating	17
7.5.3 Control of documented information	17
7.5.4 Information security	18
7.6 Non-employees	18
7.7 Personal security	18
7.8 Control of suppliers	18

8	Operation	19
8.1	Operational planning and control	19
8.2	Commissioning and decommissioning	19
8.3	Maintenance, control, calibration, certification, and validation	20
8.4	Physical security	20
8.5	Biological materials inventory	20
8.6	Good microbiological technique	20
8.7	Clothing and personal protective equipment (PPE)	20
8.8	Decontamination and waste management	20
8.9	Emergency response and contingency planning	21
8.9.1	Emergency scenarios	21
8.9.2	Emergency plan training	21
8.9.3	Emergency exercises and simulations	21
8.9.4	Contingency plans	21
8.10	Transport of biological materials	21
8.10.1	Transport security	22
9	Performance evaluation	22
9.1	Monitoring, measurement, analysis, and evaluation	22
9.2	Internal audit	22
9.3	Management review	23
10	Improvement	23
10.1	General	23
10.2	Incident, nonconformity, and corrective action	24
10.3	Continual improvement	24
	Bibliography	26