

ISO 24088-1:2022-07 (E)

Biotechnology - Biobanking of microorganisms - Part 1: Bacteria and archaea

Contents		Page
Foreword		v
Introduction		vi
1	Scope	1
2	Normative references	1
3	Terms and definitions	1
4	General requirements	4
4.1	General	4
4.2	Legal requirements	4
4.3	Health and safety	5
4.3.1	General	5
4.3.2	Chemical safety	5
4.3.3	Biosafety and biorisk	5
4.3.4	Personal protective equipment	6
4.4	Biosecurity and access	6
4.4.1	General	6
4.4.2	Access to biosecure area(s)	7
4.5	Relocation of microbial materials	7
5	Personnel	7
6	Facilities	8
6.1	General	8
6.2	Biosafety cabinets	8
6.3	Back-up storage facilities	8
7	Critical equipment for microbial biobanking	8
7.1	General	8
7.2	Calibration	8
7.3	Incubators	8
7.4	Refrigerators	9
7.5	Ultra-low temperature electrically powered storage	9
7.6	Liquid nitrogen storage system/liquid nitrogen supply	9
7.7	Freeze dryer	9
7.8	Automated storage systems	9
7.9	Autoclave	9
8	Process requirements	10
8.1	Acquisition or deposit	10
8.1.1	General	10
8.1.2	Review of requests to deposit material(s)	10
8.1.3	Decision regarding requests to deposit materials	11
8.1.4	Confirmation of materials and associated data	11
8.2	Authentication	11
8.3	Purity and passage control	11
8.3.1	General	11
8.3.2	Contamination with other microorganisms	12
8.3.3	Passage control	12

8.4	Preparation, preservation and storage	12
8.4.1	General	12
8.4.2	Preparation of distribution stock and master stock	12
8.4.3	Preparation, preservation and storage of derivatives from microorganism(s)	14
8.5	Distribution	14
8.5.1	General	14
8.5.2	Review and acceptance of distribution requests	14
8.5.3	Distribution agreement	14
8.6	Packaging	15
8.7	Transport	15
9	Complaint management	15
10	Management of information and data	15
10.1	Information system requirements	15
10.1.1	General	15
10.1.2	Microbial material identification system	15
10.1.3	Minimum data set	15
10.1.4	Recommended data set for microbial materials	16
10.1.5	Microbial biobank accession number	16
10.1.6	Production lot number	16
10.1.7	Location	16
10.2	Inventory management	16
11	Quality control, validation and verification	16
11.1	General	16
11.2	Quality control of processes, microbial materials and associated data	16
11.3	Validation and verification of methods	17
12	Reporting	17
	Bibliography	18