

DIN EN 14065:2016-08 (E)

Textiles - Laundry processed textiles - Biocontamination control system

Contents		Page
European foreword		4
Introduction		5
1	Scope	6
2	Normative references	6
3	Terms and definitions	6
4	General principles and requirements	9
4.1	Principles and framework	9
4.2	General requirements	10
5	Alignment with a quality management system	10
6	Application of the Risk Analysis and Biocontamination Control system to laundries	10
6.1	General	10
6.2	Prerequisites and preliminary actions for establishing a RABC system	10
6.2.1	Management commitment	10
6.2.2	Constitution of the RABC team	10
6.2.3	Prerequisites programme (PRP)	11
6.2.4	Determination of the intended end use of the textile	12
6.2.5	Preparation of laundry flow diagram(s)	12
6.2.6	Process specification	12
6.2.7	Training awareness and competency	12
6.2.8	Purchasing information	12
6.3	Application of the seven principles for implementing the RABC system	12
6.3.1	General	12
6.3.2	Principle 1: List of microbiological hazards and list of control measures	12
6.3.3	Principle 2: Determine the Critical Control Points (CCPs) and Control Points (CPs)	13
6.3.4	Principle 3: Establish the target levels and tolerance limits for each CCP	13
6.3.5	Principle 4: Establish a monitoring programme for each CCP	13
6.3.6	Principle 5: Establish corrective actions	14
6.3.7	Principle 6: Establish the RABC system checking procedures	14
6.3.8	Principle 7: Establish a documentation system	15
Annex A (informative)	Rationale for application of RABC in laundries	16
A.1	Introduction	16
A.2	The process	16
A.3	Variations in intended use	16
A.4	Variations in market sector	17
A.4.1	General	17
A.4.2	Food sector	17
A.4.3	Healthcare	17
A.4.4	Cleanrooms	17
Annex B (informative)	Examples of prerequisites	18
B.1	General	18
B.2	Premises and structures	18

DINEN14065:2016-08 EN 14065:2016 (E) B.3 Cleaning	18
B.4 Personnel	18
B.5 Equipment	19
B.6 Foreign bodies and inappropriate materials	19
B.7 Supplies	19
B.8 Monitoring of PRP effectiveness	19
Annex C (informative) Examples and guidance for risk assessment	20
Annex D (informative) Control concepts illustration	23
Annex E (informative) Examples of wash process aspects	24
Annex F (informative) Examples of approaches to process validation for laundries	25
F.1 General	25
F.2 Introduction to Process Validation	25
F.2.1 Overview	25
F.2.2 Key to terms	25
F.2.3 Process Validation Model for Laundries	25
F.3 Considerations for developing validation plans	26
F.3.1 Prior to validation	26
F.3.2 Examples	26
F.4 Guidance on basic validation elements	27
F.4.1 General	27
F.4.2 Use of historical data	27
F.4.3 Performance Qualification (PQ)	27
F.4.4 Operational Qualification (OQ)	28
F.4.5 Installation Qualification (IQ)	28
F.4.6 Design Qualification (DQ)	28
F.5 Guidance on more developed validation elements	28
F.5.1 Worst case challenge	28
F.5.2 Experimental Design	28
F.6 Parametric release	29
Annex G (informative) Synopsis of EN ISO 9001:2008 and EN 14065:2016	30
Bibliography	34