

ISO 11137-1:2025-04 (E)

Sterilization of health care products - Radiation - Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices

Contents

Page

Foreword	iv
Introduction	viii
1 Scope	1
2 Normative references	2
3 Terms and definitions	2
4 General	9
5 Sterilizing agent characterization	9
5.1 Sterilizing agent	9
5.2 Microbicidal effectiveness	9
5.3 Material effects	10
5.4 Environmental considerations	10
6 Process and equipment characterization	10
6.1 Process	10
6.2 Equipment	10
7 Product definition	11
8 Process definition	12
8.1 Establishing the maximum acceptable dose, $D_{\max,acc}$	12
8.2 Establishing the sterilization dose, D_{ster}	12
8.3 Specifying the maximum acceptable dose and the sterilization dose	12
8.4 Transference of maximum acceptable, verification or sterilization dose between radiation sources	13
8.4.1 Transference of maximum acceptable dose	13
8.4.2 Transference of verification dose or sterilization dose	13
9 Validation	13
9.1 Installation qualification (IQ)	13
9.2 Operational qualification (OQ)	13
9.3 Performance qualification (PQ)	14
9.4 Review and approval of validation	15
10 Routine monitoring and control	16
11 Product release from sterilization	17
12 Maintaining process effectiveness	17
12.1 Demonstration of continued effectiveness	17
12.1.1 General	17
12.1.2 Frequency of determinations of bioburden	17
12.1.3 Frequency of sterilization dose audits	18
12.2 Recalibration	19
12.3 Maintenance of equipment	19
12.4 Requalification of equipment	19
12.5 Assessment of change	20
Annex A (informative) Guidance on this document	21
Bibliography	37