

ISO/TS 11137-4:2020 (E)

Sterilization of health care products — Radiation — Part 4: Guidance on process control

Contents

	Foreword
	Introduction
1	Scope
2	Normative references
3	Terms, definitions and symbols
3.1	General
3.2	Symbols
4	Principles applied in validating and controlling an irradiation process
4.1	General
4.2	Use of the dose measurement at the monitoring location
4.2.1	General
4.2.2	D _{mon} as an indirect measurement of dose to product
4.2.3	D _{mon} as a process monitor
4.2.4	D _{min} or D _{max} as a direct measurement of dose to product
4.3	Monitoring of critical process parameters
5	Establishing process target doses
5.1	Inputs and steps in establishing a process target dose
5.1.1	General
5.1.2	Process validation inputs (installation, operational and performance qualification)
5.1.3	Additional inputs
5.1.4	Determine σ_{process}
5.1.5	Product dose specifications
5.1.6	Select coverage factor k
5.1.7	Setting process target doses
5.1.8	Analyse process output
5.1.9	Review
5.2	Performance qualification outputs
5.2.1	General
5.2.2	Experimental design for PQ
5.2.3	Processing categories
5.3	Components of σ_{process}
5.3.1	General
5.3.2	Components related to measurement uncertainty
5.3.3	Components related to process variability
5.3.4	Combining components of uncertainty
5.3.5	Reducing σ_{process}
5.4	Establishing process target doses
5.4.1	Coverage factors
5.4.2	Process factors
5.4.3	Choice of target processing parameters
5.4.4	Assessing process capability
6	Routine monitoring and control
6.1	General
6.2	Product handling
6.2.1	Receipt of product
6.2.2	Loading

- 6.2.3 Unloading
- 6.2.4 Storage
- 6.2.5 Shipment
- 6.3 Processing of product
 - 6.3.1 General
 - 6.3.2 Processing parameters
 - 6.3.3 Location of dosimeters
 - 6.3.4 Partially filled containers
 - 6.3.5 Process interruptions
 - 6.3.5.1 Interpreting dosimeters following a process interruption
 - 6.3.5.2 Process interruptions which require the movement of irradiation containers
 - 6.3.5.3 Process interruptions for products capable of supporting microbial growth
 - 6.3.6 Transitions between densities
- 6.4 Special processing conditions
 - 6.4.1 Off-carrier processing
 - 6.4.2 Irradiation of product under modified environmental conditions
 - 6.4.2.1 General
 - 6.4.2.2 Dosimetric considerations for validating and processing in a modified environment
 - 6.4.2.3 Process considerations when using refrigerants
 - 6.4.2.4 Process interruptions when using modified environmental conditions
- 6.5 Process output interpretation
 - 6.5.1 General
 - 6.5.2 Using an acceptance range based on $D_{monster}$ and $D_{monmax,acc}$
 - 6.5.3 Using an acceptance range with alert and action levels
 - 6.5.4 Using an acceptance range based on process monitoring
 - 6.5.5 Investigation of a dose measurement outside of expectation
- 6.6 Collection and analysis of data
 - 6.6.1 General
 - 6.6.2 Dosimeter data trending
 - 6.6.3 Parametric data trending
 - 6.6.4 Statistical process control
- 7 Release of product from the irradiation process
- 8 Maintaining process effectiveness
 - 8.1 General
 - 8.2 Assessment of changes made to the product
 - 8.3 Assessment of changes made to the equipment
- Annex A (informative) Examples of setting process target dose ranges and interpretation of process output
 - A.1 General
 - A.2 Example 1
 - A.2.1 Example description
 - A.2.2 Process specification
 - A.2.3 PQ dose measurements
 - A.2.4 Components of $\sigma_{process}$
 - A.2.5 Process factors
 - A.2.6 Process target dose range calculation
 - A.2.7 Example of application of an acceptance range
 - A.2.8 Additional considerations
 - A.3 Example 2
 - A.3.1 Example description
 - A.3.2 Process specification
 - A.3.3 PQ dose measurements
 - A.3.4 Components of $\sigma_{process}$
 - A.3.5 Process factors
 - A.3.6 Process target dose range calculation
 - A.3.7 Example of application of an acceptance range
 - A.3.8 Additional considerations
 - A.4 Example 3
 - A.4.1 Example description
 - A.4.2 Process specification
 - A.4.3 PQ dose measurements

A.4.4	Components of σ_{process}
A.4.5	Process factors
A.4.6	Process target dose range calculation
A.4.7	Example of application of an acceptance range
A.4.8	Additional considerations
A.5	Example 4
A.5.1	Example description
A.5.2	Process specification
A.5.3	PQ dose measurements
A.5.4	Components of σ_{process}
A.5.5	Process factors
A.5.6	Process target dose range calculation
A.5.7	Example of application of an acceptance range
A.5.8	Additional considerations
A.6	Example 5
A.6.1	Example description
A.6.2	Process specification
A.6.3	PQ dose measurements
A.6.4	Components of σ_{process}
A.6.5	Process factors
A.6.6	Process target dose range calculation
A.6.7	Example of application of an acceptance range
A.6.8	Additional considerations

Page count: 55