

ISO/TR 22442-4:2010-12 (E)

Medical devices utilizing animal tissues and their derivatives - Part 4: Principles for elimination and/or inactivation of transmissible spongiform encephalopathy (TSE) agents and validation assays for those processes

Contents		Page
Foreword		iv
Introduction		v
1	Scope	1
2	Normative references	1
3	Terms and definitions	2
4	Elimination of TSE agents: basic considerations	2
4.1	General	2
4.1.1	TSEs of concern	2
4.1.2	Animal tissues of concern	2
4.1.3	Tissues infected with TSE agents	2
5	Potential methods to eliminate TSE agents	3
5.1	Methods for inactivating infectivity	3
5.1.1	General	3
5.1.2	Physical methods for inactivating TSE infectivity	3
5.1.3	Chemical methods for inactivating TSE infectivity	4
5.2	Methods for removing TSE infectivity without inactivating infectivity	5
6	Experimental validation of methods for eliminating TSE agents from medical devices utilizing non-viable animal tissues	6
6.1	General	6
6.2	Defining of product families for purposes of designing TSE process validation studies	6
6.3	Selection and testing of product for establishing and verifying the infecting dose of TSE agent	6
6.4	TSE agent spiking materials	6
6.5	Availability of bioassay animals (conventional and transgenic mice, other rodents, farm animals)	7
6.6	Potential development of cell culture assays for infectivity	7
6.7	Correlations between PrPTSE and infectivity assays	7
6.8	Reductions in infectivity compared with failure to detect at limits of detection	8
6.9	Determining numbers of replicate validations needed to support inferences of reduction in infectivity rather than variations in assay performance	8
6.10	Requirements for step-wise reductions in PrPTSE and infectivity verses whole-process validation	8
Bibliography		9