

ISO 31513:2026-08 (E)

Temperature validation methods of temperature-controlled storage and land transport

Contents	Page
Foreword	iv
Introduction	v
1 Scope	1
2 Normative references	1
3 Terms and definitions	1
4 Temperature validation procedure	3
5 Temperature validation method	4
5.1 Defining user requirement specifications (URS)	4
5.1.1 General	4
5.1.2 Temperature control	5
5.1.3 Data management and integrity	5
5.1.4 Equipment and system requirements	5
5.1.5 Operational and process requirements	5
5.2 Setting of validation plan	6
5.3 Checking of equipment and systems	6
5.4 Performing of temperature mapping	7
5.4.1 Data logger setup	7
5.4.2 Data logger placement	7
5.4.3 Loading quantity and pattern	7
5.4.4 Temperature data collection	8
5.5 Additional tests	8
5.5.1 General	8
5.5.2 Temperature recovery test (door opening test)	9
5.5.3 Thermal conductivity test (power failure test)	9
5.5.4 Humidity mapping	9
5.6 Data analysis	10
6 Re-qualification	10
7 Change control	10
8 Reporting	10
Annex A (Informative) Examples of temperature validation report	11
Bibliography	13