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