ISO 17511:2020-04 (E)

In vitro diagnostic medical devi ces - Requirements for establishing metrological traceability of values assigned to calibrators, trueness control materials and human samples

Contents

Page

Foreword ... **vi**

Introduction ... **viii**

1 Scope ... **1**

2 Normative references ... **2**

3 Terms and definitions, symbols and abbreviated terms ... **2**

4 General requirements to be fulfilled by a manufacturer for establishing, validating and documenting metrological traceability of human sample values determined with a specified IVD MD ... **19**

4.1 Requirements for documenting metrological traceability of measured quantity values ... 19
4.2 Definition of the measurand ... 19
4.3 Specifications for maximum allowable expanded measurement uncertainty, ***Umax(y)*** ... 20
4.3.1 General requirements ... 20
4.3.2 Scope of the specification ... 20
4.4 Defining the calibration hierarchy ... 20
4.4.1 General requirements ... 20
4.4.2 Measured quantity ... 21
4.4.3 Highest level of metrological traceability ... 21
4.4.4 Traceability to SI ... 21
4.4.5 Non-SI traceable IVD MDs ... 21
4.4.6 Number of levels in the specified hierarchy ... 21
4.5 Selection and requirements for RMs and calibrators ... 21
4.5.1 General requirements ... 21
4.5.2 Characteristics to be documented ... 21
4.5.3 Higher order RMs that conform with ISO 15194 ... 22
4.5.4 RMs not conforming to ISO 15194 ... 22
4.5.5 Commutability of RMs ... 22
4.5.6 Exception to commutability assessment requirements ... 23
4.5.7 Application of a non-commutable CRM ... 23
4.5.8 Alternative RMs ... 23
4.5.9 Augmentation of alternative RMs ... 23
4.5.10 Non-commutable end-user IVD MD calibrators ... 24
4.6 Selection and requirements for MPs ... 24
4.6.1 Rationale for selection of MPs and documentation responsibility ... 24
4.6.2 Metrological status of MPs ... 24
4.6.3 Reference measurement laboratories ... 24
4.6.4 Impact of influence quantities ... 25
4.6.5 Changes in the measured quantity within a calibration hierarchy ... 25
4.7 Estimating uncertainty of assigned values for end-user IVD MD calibrators ... 25
4.7.1 General requirements ... 25
4.7.2 Documentation for method of estimating u_{cal} ... 26
4.7.3 Statistical considerations and scope of u_{cal} estimates ... 26
4.7.4 Expression of u_{cal} ... 26
4.7.5 Product modifications ... 27
4.7.6 Information to be provided to the end-user ... 28
4.8 Validation of metrological traceability of values assigned to an IVD MD calibrator ... 28
4.8.1 General validation requirements ... 28
4.8.2 Validation strategies ... 28

4.8.3 Test design considerations and acceptance criteria 29
4.8.4 Calibration hierarchies with an available RMP 29
4.8.5 Calibration hierarchies with no available RMP 29
4.8.6 Calibration hierarchies with no RMPs and no CRMs 29
4.8.7 Validation of design changes to an end-user IVD MD calibrator 30
4.9 Additional calibration hierarchy documentation responsibilities 30
4.9.1 Obligation to end-users 30
4.9.2 Maintaining documentation 30
4.9.3 Third party manufacturers of IVD MD calibrators 30
4.9.4 Modifications introduced by independent entities 30
4.9.5 Calibration hierarchies supporting IVD MDs developed by a single entity for its own use 31
4.9.6 RMs other than end-user IVD MD calibrators 31
4.9.7 EQA and PT materials with claims of metrologically traceable target values 31

5 Model calibration hierarchies for metrological traceability 31
5.1 Elements of the description of a calibration hierarchy 31
5.2 Cases with RMPs and primary RMs 32
5.2.1 General considerations 32
5.2.2 Definition of the measurand 33
5.2.3 Selecting RMPs 34
5.2.4 Primary RMPs 34
5.2.5 Primary calibrators 35
5.2.6 Assigning a value to a secondary RM or calibrator 35
5.2.7 Commutability of secondary RMs 35
5.2.8 Manufacturer's Selected MP 35
5.2.9 Working calibrators 35
5.2.10 Manufacturer's standing MP 36
5.2.11 Manufacturer's end-user calibrator 36
5.2.12 u_{cal} of the assigned value of the end-user calibrator 36
5.2.13 End-user IVD MD 36
5.3 Cases with a primary RMP that defines the measurand 36
5.3.1 General Considerations 36
5.3.2 Definition of the measurand 38
5.3.3 Higher order RMP that defines the measurand 38
5.3.4 The primary RMP and definition of the measurand 38
5.3.5 Documentation of the primary RMP 38
5.3.6 Assignment of values to secondary RMs 39
5.3.7 Manufacturer's selected MP 39
5.3.8 Manufacturer's working calibrator 39
5.3.9 Manufacturer's standing MP 40
5.3.10 Manufacturer's end-user calibrator 40
5.3.11 End-user IVD MD 40
5.4 Cases for measurands defined by a RMP calibrated with a particular primary calibrator 40
5.4.1 General considerations 40
5.4.2 Definition of the measurand 41
5.4.3 Value assignment of the primary RM 42
5.4.4 Value assignment of the primary calibrator 42
5.4.5 Selection and intended use of the RMP in the calibration hierarchy 42
5.4.6 Manufacturer's selected MP 42
5.4.7 Manufacturer's working calibrator 42
5.4.8 Manufacturer's standing MP 43
5.4.9 End-user IVD MD calibrator 43
5.4.10 End-user IVD MD 43
5.5 Cases with an international conventional calibrator that defines the measurand 43
5.5.1 General considerations 43
5.5.2 The international conventional calibrator — Material description 45
5.5.3 Value assignment of an international conventional calibrator 45
5.5.4 Commutability of an international conventional calibrator 45
5.5.5 Calibration and selection of the manufacturer's selected MP 46
5.5.6 Characteristics and value assignment of the manufacturer's working calibrator 46
5.5.7 Manufacturer's standing MP 46
5.5.8 End-user IVD MD calibrator 46
5.5.9 End-user IVD MD 46

5.6 Cases with metrological traceability supported by an international harmonisation protocol 46
5.6.1 General Considerations 46
5.6.2 International harmonisation protocol 47
5.6.3 Assignment of values to harmonisation RMs 48
5.6.4 Application of harmonisation RMs 48
5.6.5 End-user IVD MD 48
5.7 Cases for measurands with metrological traceability only to manufacturer's internal arbitrarily defined RM(s) 48
5.7.1 General considerations 48
5.7.2 Selection of RMs 49
5.7.3 Manufacturer's Selected MP 50
5.7.4 Manufacturer's Standing MP 50
5.7.5 End-user IVD MD calibrators 50
5.7.6 End-user IVD MD 50
5.7.7 Documentation of the calibration hierarchy 50
6 Labelling information to be provided to end-users by the manufacturer 51
Bibliography 52