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INTERNATIONAL ORGANIZATION OF LEGAL METROLOGY

Third Committee Draft of a Recommendation on

Protein Measuring Instruments for Cereal Grain and Oil Seeds

Part 1: Metrological and technical requirements
Part 2: Metrological controls and performance tests
Part 3: Report format for type evaluation

OIML TC17/SC8 Secretariat: Australia

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TITLE OF THE CD (English):
OIML R XXX
Third Committee Draft of a Recommendation on Protein Measuring Instruments for Cereal Grain and Oilseeds
Part 1: Metrological and technical requirements
Part 2: Metrological controls and performance tests
Part 3: Report format for type evaluation

EXPLANATORY NOTE

Legend to versions of 3CD with track changes shown:
Black text – original text from 2CD (Feb 2010);
Green text – original text that has been relocated elsewhere in the document by the secretariat;
Brown text, strikeouts – changes and deletions to software and security requirements proposed by Germany;
Blue text and strikeouts – changes and deletions to the document applied by the secretariat.

Revisions to 2CD N6 (2010) were proposed during combined meetings of TC17/SC1 and SC8 in Orlando, Florida in September 2011.
The major changes in 3D N7 address the critical issues:

- Scope of the document (not all provisions are applicable to nitrogen determination instruments)
- Extent of harmonisation with R 59 tests (National discretion for the type evaluation calibration assessments)
- Effect of moisture basis MPE (MPEs and limits are specified for P_{DRY}, convert for P_{MB})
- Reference and rated operating ranges for temperature
- Requirement for CRMs directly produced from the reference method (for type evaluation accuracy test)
- Maximum error shift permitted for the sample temperature sensitivity (STS) test revised
- Revised proposal for software requirements (e.g. software identification, sealing) and type evaluation examinations. Certain requests accommodated, e.g. allowance for authorised bias adjustments.

For details on the agreed changes, refer to the following documents:
1) Minutes of the TC17/SC8 meeting in the document titled: *20100927-28 Significant decisions on 2CD R document 20110117.doc*
2) All comments and discussion on the 2CD in the Excel file titled: *201010- Meeting resolutions and discussion re collated TC 17 SC 8 comments 2CD N6.xls* (Tab: Collated comments on 2CD).
NOTE: The measurement uncertainty associated with whole-grain P_{MB} CRMs was not limited to 0.1 % P_{MB} as agreed at the TC17/SC8 meeting. Given some of the larger MPEs in Table 1, a limit of 0.1 % P_{MB} for the expanded uncertainty may not be necessary in calculation of pooled $\bar{y}$ and SDD at type evaluation and the error during verification.

Several modifications applied by the secretariat that were not discussed at the TC17/SC8 meeting have been outlined below. The reasons behind these changes are also in the above mentioned Excel file (Tab: Other changes).

- 2CD clause 2: General and D 31 terms added, definitions for general terms moved to Annex F, reproducibility conditions clarified as recommended by the VIM definition.
- 2CD clause 4.2: Moved to 3CD Annex C that contains the performance test procedures.
- 2CD clauses 4.1, 4.3 and 5.1, 5.8: Restructured and sub-divided into 3CD clauses 4.1, 4.2, 4.3 and 5.1.2
- 2CD clause 4.4. Measurement standards: Moved to Annex B in 3CD.
- 2CD clauses 4.7.1 and 4.8: Combined to 3CD 4.4
- 2CD clause 4.7.2: “Basic instrument tests” replaced with “Error due to changes in the instrument over time”
- Accuracy and precision tests at reference conditions and sample temperature sensitivity (STS) test, are combined into a set of tests titled “Calibration assessment” (3CD 4.7).
- 3CD clause 4.5.1 added to summarise how a calibrated instrument can be deemed as accurate under the rated operating conditions provided it passes type evaluation tests, examinations and verification.
- 2CD Table 1: Column 2 heading changed from “Type evaluation MPE” to “Max $\bar{y}$ pooled”, requirements for canola were deleted.
- 2CD clause 5.10.3: Restructured and moved to 3CD 9.5 under Metrological supervision.
- 2CD clause 8: Moved to all the performance tests to Annex C.
- 2CD clauses 6.2 and 6.3 were simplified and OIML guidance documents D 9 and D 20 referenced.
- Part 3 test report: Calibration information form modified, examination checklists inserted.

Contact the TC17/SC8 secretariat for further information.

CONTENTS

FOREWORD

The International Organization of Legal Metrology (OIML) is a worldwide, intergovernmental organization whose primary aim is to harmonize the regulations and metrological controls applied by the national metrological services, or related organizations, of its Member States. The four main categories of OIML publications are:

International Recommendations (OIML R), which are model regulations that establish the metrological characteristics required of certain measuring instruments and which specify methods and equipment for checking their conformity; the OIML Member States shall implement these Recommendations to the greatest possible extent;

International Documents (OIML D), which are informative in nature and intended to improve the work of the metrological services;

International Basic Publications (OIML B), which define the operating rules of the various OIML structures and systems;

International Guides (OIML G), which are informative in nature and which are intended to give guidelines for the application of certain requirements to legal metrology.

OIML Draft Recommendations, Documents and Guides are developed by Technical Committees or Subcommittees which are formed by the Member States. Certain international and regional institutions also participate on a consultation basis. Cooperative agreements are established between OIML and certain institutions, such as ISO and IEC, with the objective of avoiding contradictory requirements; consequently, manufacturers and users of measuring instruments, test laboratories, etc. may apply simultaneously OIML publications and those of other institutions.

International Recommendations, International Documents and International Guides are published in French (F) and English (E) and are subject to periodic revision.

This publication - reference OIML R XX, edition 201X (E) - was developed by the OIML Technical TC 17/SC 8 *Instruments for quality analysis of agricultural products*. It was approved for final publication by the International Committee of Legal Metrology in 201X

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Bureau International de Métrologie Légale
11, rue Turgot - 75009 Paris - France
Telephone: 33 (0)1 48 78 12 82
Fax: 33 (0)1 42 82 17 27
E-mail: biml@oiml.org
Internet: www.oiml.org

PART 1: METROLOGICAL AND TECHNICAL REQUIREMENTS

1 SCOPE

This Recommendation includes metrological and technical requirements and the test methods for metrological control of digital, self-indicating measuring instruments used to determine the protein content of grain and oilseeds for commercial transactions. It specifies accuracy requirements including maximum permissible errors (MPEs) for verification and other error limits for type evaluation tests.

The provisions in this document are based on the performance of instruments that estimate the mass fraction of protein constituents in grain and oilseeds via inferential means. Instruments involved in the reference method of grain protein measurement (e.g. full or partial automation of the methods listed in Annex A) are not specifically covered, but may still qualify for type approval is the requirements in the document are met. This Recommendation is not meant to preclude the application of new technologies to grain protein measurement.

2 TERMINOLOGY

2.1 General metrology and legal metrology terms

The following terms used in this document, are consistent with the definitions in OIML V2 *International Vocabulary Metrology – Basic and General Concepts and Associated Terms* (VIM:2010) [1] and OIML V1 *International Vocabulary of Terms in Legal Metrology* (VILM-3CD:2012) [2]. This section is limited to additional information such as context that the general term is used in this Recommendation.
NOTE: Definitions from the VIM and VILM have been reproduced in alphabetical order in Annex F.

Reference	General term	Additional notes
VILM 2.06	type (pattern) approval	
VILM 2.05	type (pattern) evaluation	
VILM 2.10	verification of a measuring instrument	
VIM 2.13	accuracy; measurement accuracy	In this Recommendation, the accuracy of a calibrated type of instrument is assessed by the mean and standard deviation of the measurement error across various samples encompassing the measurement range. A type of instrument is presumed to be capable of fulfilling accuracy requirements over the rated operating range and during potential disturbances if, during exposure to influence factor variations, the maximum limits for the error shift and fault are not exceeded. An instrument may be verified as sufficiently accurate at the presented conditions of use provided it meets the requirements of type examination and performance tests, i.e. it is an approved type, and the errors in-service are within the maximum permissible error (MPE).
VIM 3.11	adjustment	For protein measuring instruments, alignment with the reference method is typically accomplished through a bias adjustment to the calibration equation. Adjustment of unfixed hardware and/or software parameters may also be conducted, e.g. to ensure that the response is reproducible across a number of instruments prior to calibration transfer.
VIM 5.14	certified reference material (CRM)	For testing purposes, the transfer standards linking P_{MB} values from the reference method to calibrated instruments that are under test shall be whole-grain reference materials (RMs) certified for P_{MB}. Refer to Annex B for guidelines on producing whole-grain CRMs. Further information on CRMs in general is in OIML D 18 [3].
VIM 4.26	maximum permissible error (MPE); limit of error	The MPE and other limits for type evaluation tests on various kinds of grain are listed in clause 4.5.
VIM 2.16	measurement error; error	
VIM 2.10	measured quantity value, measured value; indication	Unless specified otherwise, the measured quantity value is a single P_{MB} indication on a sample.
VIM 4.9	rated operating condition	

VIM 4.11	reference condition	
VIM 5.13	reference material (RM)	
VIM 5.18	reference quantity value	In this Recommendation, the P_{MB} of the whole-grain CRM is the reference quantity value at verification and for assessing the integrity of calibrations at type evaluation. To calculate the error shift or fault when a CRM is not used, the reference quantity value is the mean P_{MB} at reference conditions prior to test.
VIM 2.21	repeatability; measurement repeatability	
VIM 2.20	repeatability condition of measurement	
VIM 2.25	reproducibility; measurement reproducibility	In this Recommendation, the reproducibility of measurements between units of the same type of instrument under reference conditions is assessed by the standard deviation of differences over a set of samples (SDD_I). The reproducibility of measurements from one instrument when select influence factors are varied is assessed by the magnitude of the error shift or fault.
VIM 2.24	reproducibility condition of measurement	For the tests in this Recommendation, the conditions changed and unchanged are specified below:

Test for measurement reproducibility	Specification of the reproducibility conditions of measurement	
	Varied	Constant
Tests for time related effects The magnitude of an error shift indicates the level of reproducibility in measurements taken at different times on the same instrument	Measurement day/time	Instrument (same unit) Measurement procedure Operating conditions Location Operator Sample
Tests for influence variations within the rated operating conditions The magnitude of an error shift indicates the level of measurement reproducibility while select influence factors are varied within the rated operating conditions	Influence(s) in the title of the test, e.g. ambient temperature and humidity; supply voltage Sample temperature (change inevitable during climatic tests).	All other influence factors Instrument (same unit) Measurement procedure Measurement day/time Location Operator Sample (except sample temperature during climatic tests)
Tests for disturbances The magnitude of a fault indicates the level of measurement reproducibility while disturbances are applied (or after exposure)	Disturbance in the title of the test, e.g. voltage interruptions, electromagnetic fields, mechanical shock.	All other influence factors Instrument (same unit) Measurement procedure Measurement day/time Location Operator Sample
Assessment of calibrations in the submitted type SDD_I indicates the level of reproducibility in measurements from two units of the same type	Instrument	Type of instrument Measurement procedure Operating conditions Measurement day/time Location Operator Sample

2.2 Other definitions

This clause defines terms applicable to protein measuring instruments, and also includes definitions from OIML D 11 *General requirements for electronic measuring instruments* [4] and OIML D 31 *General requirements for software controlled measuring instruments* [5].

2.2.1 audit trail [OIML D 31, 3.1.2]

Continuous data file containing a time stamped information record of events, e.g. changes in the values of parameters of a device or software updates, or other activities that are legally relevant and which may influence the metrological characteristics.

2.2.2 calibration equation; calibration

The set of calibration coefficients for one kind of grain to convert raw instrument data into a protein content measurement.

2.2.3 cryptographic means [further information in OIML D 31, 3.1.11]

Encryption of data by the sender (storing or transmitting program) and description by the receiver (reading program) with the purpose of hiding information from unauthorised persons. Electronic signing of data with the purpose of enabling the receiver or user of the data to verify the origin of the data, i.e. to prove their authenticity.

2.2.4 error shift

With reference to a certified measurement standard: Difference between the mean error of indication [while one or more influence quantities are varied within the rated operating conditions] and the mean intrinsic error of a measuring instrument.

If a certified measurement standard is not used, the error shift is the difference between the indication under rated operating conditions, and the mean indication at reference conditions prior to test. The measured values in the calculation of an error shift exhibited by a protein measuring instrument on a grain sample are shown below:

Mean error of indication		Mean intrinsic error	
Measured quantity value	Reference quantity	Measured quantity value	Reference quantity
Mean of P_{MB} indications under rated operating conditions	If CRM is used- P_{MB} of CRM	Mean of P_{MB} indications at reference conditions prior to test	If CRM is used- P_{MB} of CRM

NOTE: To calculate the 'pooled' error shift (i.e. pooled across the measurement range), the mean measured values are first averaged over several different samples representing the measurement range.

2.2.5 fault [OIML D11, 3.9]

[With reference to a certified measurement standard]: Difference between the error of indication [during or after exposure to a disturbance] and the mean intrinsic error of a measuring instrument.

D 11 NOTES

1 Principally, a fault is the result of an undesired change of data contained in of flowing through an electronic measuring instrument.

2 From the definition it follows that a "fault is a numerical value which is expressed either in a unit of measurement or as a relative value.

If a certified measurement standard is not used, a fault is the difference between a single indication during or after a disturbance, and the mean indication at reference conditions prior to test. The measured values in the calculation of a fault exhibited by a protein measuring instrument on a grain sample are shown below:

Measurement error (error of indication)		Mean intrinsic error	
Measured quantity value	Reference quantity	Measured quantity value	Reference quantity
Single P_{MB} indication during or after the disturbance	If CRM is used- P_{MB} of CRM	Mean of P_{MB} indications at reference conditions prior to test	If CRM is used- P_{MB} of CRM

2.2.6 grain

For the purpose of this document, the term grain is taken to mean those cereal grains and oilseeds listed in column 1 of Table 1.

2.2.7 integrity of programs, data or parameters

Assurance that the programs, data or parameters have not been subjected to any unauthorized or unintended changes while the use, transfer, storage, repair or maintenance.

2.2.8 intrinsic error [OIML D 11, 3.7]

Error of a measuring instrument, determined under reference conditions.

2.2.9 legally relevant [OIML D 31, 3.1.29]

Software/hardware/data or part of the software/hardware/data of a measuring instrument which interferes with properties regulated by legal metrology, e.g. the accuracy of the measurement or the correct functioning of the measuring instrument.

2.2.10 moisture basis (M_B)

The basis moisture concentration, expressed as a percentage by mass, specified by the national responsible body for reporting protein content of the particular grain type.

2.2.11 networked instrument

An instrument that is linked, either electronically or manually under a quality system, to an instrument aligned with a whole-grain certified reference material so that its performance may be monitored on a daily basis or according to a schedule set by the quality system administrator.

2.2.12 open network [OIML D 31, 3.1.35]

Network of arbitrary participants (electronic devices with arbitrary functions). The number, identity and location of a participant can be dynamic and unknown to the other participants. This is in contrast to a closed network [D 31, 3.1.6] which is a network of a fixed number of participants with a known identity functionality and location.

2.2.13 protein content (P_{MB})

The concentration of protein in a grain sample, expressed as a percentage by mass, calculated at the moisture basis (M_B).

2.2.14 protein measuring instrument; instrument; unit

An instrument that infers the content of protein in grain samples that are within the scope of its calibration.
NOTE: An instrument may be approved with multiple calibrations in order to analyse more than one kind of grain.

2.2.15 significant fault

Fault exhibited by the equipment under test that is greater than the values listed in clause 4.5 Table 1 column 8 (adjusted to the relevant M_B).
The following faults are not considered to be a significant fault, even when they exceed the maximum value:

a) faults arising from simultaneous and mutually independent cause (e.g. EM fields and discharges) originating in a measuring instrument or in its checking facilities;
b) faults implying the impossibility to perform any measurement;
c) transitory faults being momentary transitions in the indication, which cannot be interpreted, memorised or transmitted as a measurement result.

2.2.16 universal computer [OIML D 31, 3.1.54]

Computer that is not constructed for a specific purpose but that can be adapted to the metrological task by software. In general this software is founded on an operating system that permits loading and excution of software for specific purposes.

2.2.17 validation [OIML D 31, 3.1.56]

Confirmation by examination and provision of objective evidence (i.e. information that can be proved true, based on facts obtained from observations, measurement, test, etc.) that the particular requirements for the specific intended use are fulfilled. In the present case the related requirements are those of this Recommendation.

2.3 Abbreviations and acronyms

AC: alternating current
CRM: certified reference material
EM: electromagnetic
EMC: electromagnetic compatibility
e.m.f.: electromotive force
ESD: electrostatic discharge
EUT: equipment under test
F_{nom}: nominal frequency
IEC: International Electrotechnical Committee
ISO: International Organization for Standardization
M_B : moisture basis (see 2.2.10)
MPE: maximum permissible error
$MPE_{0\%}$: maximum permissible error calculated at dry basis
n_m number of measurements on a sample taken under repeatability conditions
OIML: International Organization of Legal Metrology
P_M: protein concentration at the actual "as is" moisture concentration of the sample
P_{MB}: mass percentage protein content calculated at the moisture basis (see clause 2.2.13)
RH: relative humidity
RH_{ref}: reference relative humidity during a test
RM: reference material
SD: standard deviation
SDD: standard deviation of differences
STS: sample temperature sensitivity
T_{ref}: reference temperature during a test
ΔT: magnitude of the temperature difference between a sample and an instrument at T_{ref}
ΔT_{max}: maximum ΔT specified by the national responsible body for type testing
$\Delta T_{C,\,max}$: maximum permitted ΔT_{max} below T_{ref} (if unequal to $\Delta T_{H,\,max}$)
$\Delta T_{H,\,max}$: maximum permitted ΔT_{max} above T_{ref}
T_C: minimum environmental temperature specified by the national responsible body for type testing
T_H: maximum environmental temperature specified by the national responsible body for type testing
$T_{C,sample}$: minimum grain sample temperature specified by the national responsible body type testing
$T_{H,sample}$: maximum grain sample temperature specified by the national responsible body type testing
U_{nom}: nominal test voltage
V_{nom}: nominal mains voltage
$\bar{y}$: the bias of the pooled mean P_{MB}

3 UNITS OF MEASUREMENT

3.1 The unit of measurement used for protein content of a grain sample is percentage protein by mass (see clause 2.2.13). The abbreviation for percentage by mass is % w/w. Conventionally, the percentage symbol alone (%) is used.

3.2 P_M is the protein concentration at the actual moisture concentration of the sample. To allow comparison across samples with varying moisture levels, the protein concentration P_M, must be converted to P_{MB}, which is the protein content at a basis moisture concentration.

$$P_{MB} = P_M \times \frac{100 - M_B}{100 - M} \qquad \textbf{Equation 1}$$

where: M = the actual (as is) moisture concentration of the sample
M_B = the moisture basis for the kind of grain

3.3 The national responsible body shall clearly specify the moisture basis (M_B) for all applicable kinds of grain.

4 METROLOGICAL REQUIREMENTS

4.1 Applicable grains and protein content (P_{MB}) measuring ranges – specification

4.1.1 Due to climatic and crop variability, the national responsible body shall specify commercially important protein content (P_{MB}) ranges for the grains listed in Table 1. These are examples of the kinds of grain (calibrations) for which a protein measuring instrument manufacturer may seek national approval.

4.1.2 The manufacturer shall specify the kinds of grain that the instrument can analyse with respective measuring ranges that shall encompass commercially important P_{MB} ranges specified by the national responsible body.

4.2 Instrument environmental operating temperature – specification

4.2.1 The measured values displayed by a protein measuring instrument shall meet the accuracy specification regardless of the environmental temperature, unless the national responsible body permits limitations on the conditions in which the instrument can be used.

4.2.2 In the latter case, the national responsible body shall specify the range of ambient temperatures (T_C to T_H) in which the instrument can be used to take P_{MB} measurements for commercial purposes. The T_C to T_H specification shall include the temperature range 10 ºC to 30 ºC.

4.2.3 The manufacturer may specify a wider temperature range than the T_C to T_H required by the national responsible body in order to meet international requirements. The manufacturer may request type testing and approval over the wider environmental operating temperature range (i.e. for that particular type approval application, the manufacturer specified ranges are adopted as T_C to T_H).

4.3 Grain sample operating temperature – specification

4.3.1 Specification of the sample temperature range

4.3.1.1 The measured values displayed by a protein measuring instrument shall meet the accuracy specification when the sample temperature is between 2 ºC and 45 ºC unless the national responsible body permits a narrower range.

4.3.1.2 In the latter case, the national responsible body shall specify the temperature range ($T_{C,sample}$ to $T_{H,sample}$) of samples analysed for commercial purposes. For each kind of grain, the $T_{C,sample}$ to $T_{H,sample}$ specification shall include the temperature range 10 ºC to 30 ºC.

4.3.1.3 In order to meet international requirements, the manufacturer may specify a wider sample temperature range for each kind of grain than $T_{C,sample}$ to $T_{H,sample}$ specified by the national responsible body. The manufacturer may request type testing and approval over the wider sample temperature range (i.e. for that particular type approval application, the manufacturer specified ranges are adopted as $T_{C,sample}$ to $T_{H,sample}$).

4.3.2 Specification of the sample and instrument maximum temperature differential (ΔT_{max})

4.3.2.1 An instrument at reference temperature (T_{ref}) shall be able to analyse cooler or warmer samples within the range $T_{C,sample}$ to $T_{H,sample}$ regardless of the magnitude of the sample and instrument temperature differential (ΔT). This requirement may be limited in effect if the national responsible body permits a limit on the temperature differential (i.e. ΔT_{max} or $\Delta T_{C,\,max}$ and $\Delta T_{H,\,max}$ for cold and hot samples if unequal) in which the instrument is used.

4.3.2.2 In the latter case, the national responsible body shall specify the value of ΔT_{max} (or $\Delta T_{C,max}$ and $\Delta T_{H,max}$) for taking P_{MB} measurements for commercial purposes. The instrument shall be able to take into account a ΔT of at least 10 °C, i.e. $10 < \Delta T_{C,max} < T_{ref} - T_{C,sample}$ < and/or $10 < \Delta T_{H,max} < T_{H,sample} - T_{ref}$.

4.3.2.3 In order to meet international requirements, the manufacturer may specify a maximum allowable ΔT that is larger than the ΔT_{max} specified by the national responsible body. The manufacturer may request type testing and approval at the larger maximum allowable ΔT (i.e. for that particular type approval application, the manufacturer specification is adopted as ΔT_{max}).

4.3.3 Provisions in absence of a manufacturer-specified sample temperature range

A manufacturer declaration regarding the sample temperature range or a maximum allowable ΔT may be unfeasible if the submitted type is not able to measure sample temperature and/or the calibration does not account for sample temperature variations. The operating procedure and/or metrological tests defined by the national responsible body shall ensure that the requirements in clauses 4.7.2 and 4.8.1 are met.

4.4 Influence quantities – specification

4.4.1 Rated operating ranges for influence factors

a)	Ambient temperature:	Operating range specified by the national responsible body (T_C to T_H). See clause 4.3 for requirements
b)	Relative humidity:	Up to 90%, no condensation
c)	Atmospheric pressure:	86 kPa to 106 kPa
d)	Power voltage:	-15% to +10% of mains or test voltage
e)	Power frequency:	nominal frequency, F_{nom}
f)	Instrument tilt position:	5% or maximum allowable on level indicator where indicator is present

4.4.2 Disturbance tests for electronic instruments

a) AC mains voltage dips, short interruptions and voltage variations: reduction to 0% (0.5 cycle), reduction to 0% (1 cycle), reduction to 70% (25 / 30(1) cycles), reduction to 0% (250 / 300(1) cycles).
b) Bursts (transients) on AC mains: Amplitude 1kV, repetition rate 5 kHz
c) Radiated radio-frequency fields, electromagnetic fields: 26 MHz - 2 GHz, 10 V/m
d) Conducted radio-frequency fields: 0.15 MHz – 80(2) MHz, 10 V (e.m.f.)
e) Electrostatic discharge – direct application: Up to 6 kV contact discharge
f) Electrostatic discharge – indirect application: Up to 8 kV air discharge
g) Mechanical shock: 1 fall up to 50 mm on a bottom edge
h) Storage temperature (extreme shipping conditions): -20 ºC to 50 ºC

NOTES:
(1)The cycle counts apply for 50 Hz / 60 Hz respectively
(2) Testing up to 26 MHz is permitted. Refer to clause C.6.4 for conditions.

4.5 Maximum permissible error (MPE) and other accuracy requirements

4.5.1 Overview

Provided that the overall error on each P_{MB} measurement is less than the maximum permissible error (MPE), an instrument with a P_{MB} calibration that has been approved for a particular kind of grain may be verified as sufficiently accurate under the presented conditions of use.

The error shift or fault on the measured protein content (P_{MB}) of a sample shall not exceed the limit specified for the type evaluation test, in order to presume that a calibrated instrument can comply with the MPE over the rated operating ranges and in the event of a disturbance. In this Recommendation, error shifts and faults are primarily attributed to variations in the instrument hardware and considered calibration-independent.

Other tests shall be performed on every P_{MB} calibration submitted at type evaluation to ensure that calibrations are sufficiently accurate and robust. The P_{MB} errors shall be 'pooled' (i.e. averaged) over different samples of the same kind of grain to obtain a single value representing the bias or imprecision of the calibration over the legally relevant measurement range, for example:

- $\bar{y}$, the bias of the mean P_{MB} 'pooled' over a set of samples spanning the P_{MB} measurement range;
- pooled *SD*, the standard deviation of repeat measurements pooled over a set of samples that span the P_{MB} measurement range;
- *SDD*, the standard deviation of differences (i.e. standard deviation of the error of a single P_{MB} indication) over a set of samples that span the P_{MB} measurement range;
- pooled error shift, the error shifts calculated from the Sample Temperature Sensitivity test (STS), pooled over a set of high or low moisture content samples spanning the P_{MB} measurement range.

4.5.2 Accuracy requirements for various kinds of grain – specification

The MPE and other requirements (e.g. imprecision limits) for measurements of protein content in various kinds of grain are presented in Table 1 on the adjoining page. These are recommended values that apply to measurements of the protein content at dry basis ($P_{0\%}$) from all instruments used in commercial transactions irrespective of their principles of operation.

For protein measuring instruments used in commercial transactions, the same MPE is applied across all test samples of the same kind of grain regardless of the P_{MB} level.

4.5.3 Conversion of dry basis MPE and limits for measurements at other M_B

The dry basis MPEs in Table 1 (MPE_{DRY} or $MPE_{0\%}$) shall be appropriately scaled down when the indicated protein content is not at dry matter basis. The MPE at other basis moisture concentrations (MPE_{MB}) can be calculated from the relevant values in Table 1 using Equation 2:

$$MPE_{MB} = \frac{100 - M_B}{100} \times MPE_{0\%} \qquad \textbf{Equation 2}$$

where: M_B = moisture basis for reporting the protein concentration on the kind of grain

The limiting values for *SDD*, pooled *SD*, SDD_I, error shift and fault in columns 3 – 8 of Table 1 will be scaled down accordingly for the relevant M_B.

For type evaluation, the adjusted values shall be rounded to two decimal places half away from zero, e.g. 0.275 becomes 0.28 and -0.275 becomes -0.28. Adjusted values for the MPE at verification shall be rounded to one decimal place, half away from zero, e.g. 0.356 becomes 0.4 and -0.356 becomes -0.4.

4.5.4 Reference method - specification

The errors during verification and the values of $\bar{y}$ and *SDD* that are both used to assess the accuracy of calibrations at type evaluation, are calculated with reference to whole-grain measurement standards with certified P_{MB} values, i.e. certified reference materials (CRMs).

The national responsible body shall define the reference method for calculating the protein content of grain applicable to the certification of whole-grain reference materials (RM). Where possible, methods based international standards such as ISO publications shall be used (see Annex A). Additional guidance on the production and handling whole-grain RMs and CRMs are included in Annex B.

Table 1: Maximum permissible error (MPE) and other accuracy requirements expressed in percentage protein by mass (%) at dry basis[1].

Kind of grain	TYPE EVALUATION TESTS							IN-FIELD TESTS
	Calibration assessment (instrument at reference conditions)					Reproducibility assessment		Verification & inspection
	Accuracy		Repeatability	Reproducibility (two units)	Sample temp sensitivity (STS)	Influence factor rated operating range	Disturbance	Rated operating ranges
	[2] Max $\bar{y}$ (pooled)	Max *SDD*	Max *SD* (pooled)	Max SDD_I	Max error shift (pooled)	Max error shift	Max fault	MPE
column 1	column 2	column 3	column 4	column 5	column 6	column 7	column 8	column 9
Wheat	± 0.30	Absolute value of col 2	Absolute value of col 2 × 0.5	Absolute value of col 2	col 2	col 2 × 0.7	col 2	± 0.4
Barley	± 0.40							± 0.5
Rice	± 0.50							± 0.6
Corn	± 0.50							± 0.8
Soybean	± 0.55							± 0.8
Lupins	± 1.0							± 1.2
Triticale	Note [3]							Note [3]
Rye	Note [3]							Note [3]

NOTES:

1 Refer to clause 4.5.3 for conversion of the above listed values of the dry basis MPE/ limits to another basis moisture concentration (M_B)

2 This was labelled as “Type evaluation MPE” in 2CD N6

3 Recommended MPEs for triticale and rye can be added in future revisions of the publication.

4.6 Maximum permissible error (MPE) at verification

Instruments shall be designed, manufactured and used with appropriate calibrations so that during verification, errors do not exceed the value for the MPE shown in Table 1 column 9 (adjusted to the relevant M_B).

In-field surveillance is under the control of the national responsible body. In-field conditions are represented by the rated operating conditions specified in clause 4.4. The instrument in service shall not be operated while exposed to influence quantities outside the ranges applied during type evaluation.

4.7 Requirements for calibrations

4.7.1 Accuracy and precision requirements at reference conditions

Under the reference test conditions specified in Annex C, each calibration submitted for approval with the type of protein measuring instrument shall be statistically tested for accuracy with set of whole-grain CRMs. Each set shall encompass the legally relevant P_{MB} range and represent all the varieties of grain in the scope of the calibration under test.

Instruments shall be designed, manufactured and used with appropriate calibrations so that the calculated measures of bias and imprecision, i.e. $\bar{y}$, *SDD*, pooled *SD* and SDD_I, do not exceed the limits in Table 1 column 2 (adjusted to the relevant M_B) or the corresponding limits for imprecision in Table 1 columns 3, 4 and 5.

4.7.2 Sample temperature sensitivity (STS)

Each calibration submitted for approval with the type of instrument shall be tested for sample temperature sensitivity (STS) with high and low moisture samples at the $\Delta T_{C,max}$ and $\Delta T_{H,max}$ specified by the national responsible body or the manufacturer (see clause 4.3.2).

Instruments shall be designed, manufactured and used with appropriate calibrations so that the pooled error shift on a set of samples – treated in accordance with $\Delta T_{C,max}$ and $\Delta T_{H,max}$ – does not exceed the maximum limit shown Table 1 column 6 (adjusted to the relevant M_B).

4.8 Error due to variations in influence quantities

4.8.1 Variation of select influence factor(s) within the rated operating ranges

Instruments shall be designed and manufactured so that all functions continue to operate as designed and the error shift does not exceed the limit in Table 1 column 7 when selected influence factors are varied within the rated operating ranges shown in clause 4.4.1.

4.8.2 Effect of disturbances on electronic instruments

In the event of disturbances as severe as those specified in clause 4.4.2, significant faults as defined in clause 2.2.15 shall either not occur or shall be detected and acted upon by means of checking facilities as described in clause 5.1.

4.9 Error due to changes in the instrument over time

Changes within the instrument over time shall not compromise the measurement accuracy.

4.9.1 The error shift on measurements taken immediately after the instrument is switched on shall be within the limit in Table 1 column 7 where no warm-up time is specified. If a warm-up time is specified, the error shift on measurements taken after this warm-up time shall be within the limit.

4.9.2 Any error shift due to instrumental drift over a period of at least four weeks shall remain stable (i.e. not exceed the limit shown in Table 1 column 7).

5 TECHNICAL REQUIREMENTS

5.1 Checking facilities

5.1.1 Suppression of P_{MB} measured values in the event of a significant fault

A protein measuring instrument shall automatically prevent further measurements and clearly indicate if a significant fault has occurred by an appropriate error message, unambiguous warning or blanking the display.

5.1.2 Suppression of P_{MB} measured values outside of operating ranges

A protein measuring instrument shall automatically prevent further measurements and clearly indicate when a type-approved operating range is exceeded by an appropriate error message, unambiguous warning or blanking the display.
The operator shall not be required to judge the precise temperature of sample required to make an accurate measurement.

Examples of type-approved operating ranges:
a) Instrument P_{MB} measuring range for each kind of grain (see clause 4.1)
b) Instrument environmental temperature range, T_C to T_H (see clause 4.2)
c) Sample temperature range, $T_{C,sample}$ to $T_{H,sample}$, for each kind of grain (see clause 4.3.1)
d) Maximum sample and instrument temperature differential (ΔT_{max}) for each kind of grain (see clause 4.3.2)

5.1.3 Instrument warm up period

When a protein measuring instrument is turned on, it shall not display or record any measured values until the operating temperature necessary for accurate measurement has been attained. This requirement may not be necessary for instruments which do not require any warm up time.

5.2 Manufacturer's manual

The manufacturer shall provide with each protein measuring instrument, a manual that describes the installation, operation, and routine maintenance of the instrument and its accessories. In addition, the manual must include the following information:
a) name and address of the manufacturer;
b) the type or pattern of the instrument with which it is intended to be used;
c) date of issue;
d) the kind or varieties of grain for which the instrument is designed to be used within the scope of national requirements;
e) the limitations of use, including, but not confined to the P_{MB} measurement range(s), grain sample temperature, maximum allowable temperature difference between grain sample and instrument, instrument operating temperature range, voltage and frequency ranges, electromagnetic interferences and electromagnetic compatibility.

This manual shall be supplied to the owner/user of the instrument in the official language(s) of the countries where it is used or in a language accepted by the national responsible body.

5.3 Markings

5.3.1 General markings

Instruments shall be clearly and permanently marked for the purpose of identification with the following:
a) manufacturer's name or mark;
b) model designation;
c) serial number given by the manufacturer; and
d) approval marking of the national responsible body, if the instrument is approved.

5.3.2 Location of markings

Markings shall be grouped together in a clearly visible location, either on a permanently attached nameplate or on part of the instrument. The required information shall be readily observable without disassembly.

5.4 Sample input and calibration selection

5.4.1 Selection of calibration on the instrument

5.4.1.1 On protein measuring instruments that have a different calibration for each kind of grain, provision shall be made for the selection of the calibration applicable to the sample, for example, via a user menu listing the kinds of grain that the instrument is approved to measure.

5.4.1.2 To prevent misuse, the selection of calibration via the user interface shall be unambiguous and visible to all parties present, i.e. the displayed calibration name shall correspond with the kind of grain being analysed.

5.4.2 Sampling and minimum sample size

5.4.2.1 The grain protein measuring instrument shall not require the operator to judge the precise volume or weight needed to make an accurate protein content measurement.

5.4.2.2 The minimum allowable sample size for analysis of P_{MB} shall be 100 g or 400 kernels or seeds whichever is smaller, except where the national responsible body determines otherwise.

5.4.2.3 The national responsible body shall specify minimum guidelines for the sampling of bulk or packed cereals for testing. These may be based on voluntary international standards (e.g. ISO 13690 (1999) *Cereals, pulses and milled products – Sampling of static batches* [6]).

5.5 Instrument construction

5.5.1 Grain protein measuring instruments and all accessory equipment shall be of such materials, design, and construction as to make it probable that, under normal service conditions:

a) accuracy will be maintained,
b) operating parts will continue to function as intended, and
c) adjustments will remain secure and stable.

5.5.2 Undue stresses, deflections, or distortions of parts shall not occur to the extent that accuracy is detrimentally affected.

5.5.3 The housing shall be constructed so that the main components of the instrument are protected from dust and moisture.

5.5.4 When the principle of measurement of a protein measuring instrument requires the use of a grinding mill, the mill shall be considered an integral part of the measurement process. The appropriate mill type shall be designated by instrument manufacturer. A milling unit shall accompany the submitted instrument so its suitability for the measurement process may be assessed during type evaluation tests.

5.6 Level indicating means

5.6.1 The instrument shall be equipped with a level indicator and levelling adjustments if its performance is changed by an amount greater than the maximum error shift when the instrument is moved from a level position into a position that is out of level in any upright direction by up to 5% (approximately 3º).

5.6.2 The level-indicating means shall be readable without any disassembly of the instrument.

5.7 Presentation of the measured value

5.7.1 Grain protein measuring instruments shall be equipped with a digital indicating element which shall not display any protein concentration values before the end of the measurement cycle.

5.7.2 Measurement results shall be displayed as percent protein by mass (%) at the moisture basis. Subdivisions of this unit shall be in terms of decimal subdivisions (not fractions).

5.7.3 The display shall permit protein concentration value determination to a resolution of at least 0.1% P_{MB}. The 0.1% P_{MB} resolution is for commercial transactions; the display on sample instruments submitted for type evaluation shall permit 0.01% P_{MB} resolution.

5.7.4 On multi-constituent instruments (e.g. instruments which also measure grain moisture content), provision shall be made for displaying and recording the constituent label to make it clear which constituent is associated with each of the displayed values.

5.7.5 The minimum height for the digits used to display protein content shall be 10 mm. Numbers and symbols of units shall be presented in accordance with OIML D 2 [7].

5.8 Durable recording of measured values

5.8.1 The national responsible body may require instruments to be equipped with an internal recording element and/or a communication interface that permits interfacing with an external recording element.

5.8.2 Correspondence between displayed information and remote recording element shall be verified.

5.8.3 The measurement records shall include as a minimum: the measurement date and time, unique identification of the instrument, grain type, P_{MB} results and units as displayed, calibration version identification, error messages and constituent labels (on multi-constituent meters).

5.8.4 A recording element shall not record any protein concentration values before the end of the measurement cycle.

5.8.5 If data storage is required, the measurement data must be stored automatically when the measurement is concluded.

5.8.6 The storage device must have sufficient permanency to ensure that the data are not corrupted under normal storage conditions and there shall be sufficient memory storage for any particular application.

6 REQUIREMENTS FOR SOFTWARE-CONTROLLED DEVICES AND SECURITY

The requirements of OIML D 31 [5], have to be fulfilled. In general, the risk associated with the software of protein measuring instruments is severity level I, which requires validation in accordance with procedure A in clauses 6.3 and 6.4 of D 31. For types that are likely to be used in an open network, the risk in increased to severity level II which necessitates cryptographic means of protection and validation by procedure B.

6.1 Specification of software requirements

6.1.1 For instruments and modules operated by software, the manufacturer shall describe or declare how the software is implemented within the instrument or module, i.e. if it is installed in a fixed hardware and software environment (embedded) or on an universal computer system (implemented into the housing or external).

The legally relevant software shall fulfil the following requirements:

6.1.2 The software shall be clearly identifiable via a unique software version and a checksum. In the normal operation mode of the instrument, the software version and the checksum shall be displayed or printed out on command or shall be displayed during the start up procedure of the instrument.

6.1.3 The measuring algorithms and functions shall be appropriate and functionally correct as evidenced by the instrument correctly displaying and recording the measurement result and the required accompanying information. It shall be possible to examine algorithms and functions where required.

6.1.4 The conformity of the legally relevant software on each instrument to that in the approved type shall be at level (b) described in D 31 clause 5.2.5.

6.1.5 It shall be possible to display or print on demand the current settings for parameters that affect legally relevant characteristics.

6.1.6 Further measurements shall not be possible when a significant fault is detected.

6.1.7 If the software of the instrument is separated in legally relevant part and non-relevant parts, the requirements of D 31 clause 5.2.1.2 have to be fulfilled.

6.1.8 Cryptographic protection of data as indicated in D 31 clause 5.2.3 is required for instruments used in an when using an open network.

6.1.9 For instruments/ measuring systems using an internal or external universal computer, the legally relevant software shall be operated only in the environment specified for its correct functioning. If necessary to secure the correct functioning of the legally relevant software, the operating system shall be fixed to a defined invariant configuration.

NOTE: A fixed environment for software is also required for instruments in open networks or when software changes on a verified instrument is permitted without an appointed verifier onsite (i.e. the 'Traced Updates' described in D 31 clause 5.2.6.3).

6.2 Electronic data storage

Legally relevant data that is stored or transmitted in an insecure environment (e.g. an open network), shall fulfil the following additional requirements:

6.2.1 The data shall be protected by software means to guarantee the authenticity and integrity. The software that displays or further processes the measurement values and accompanying data shall check the time of measurement, authenticity and integrity of the data after having read them from the insecure storage or after having received them from an insecure transmission channel. If an irregularity is detected, the data shall be discarded or marked unusable. For instruments that are part of an open network, data encryption is required unless the national responsible body determines otherwise.

NOTE: Software modules that prepare data for storing or sending, or that check data after reading or receiving, belong to the legally relevant software part.

6.2.2 The measurement shall not be inadmissibly influenced by a transmission delay.

6.2.3 If a transmission interruption occurs because the network services become unavailable, no measurement data shall be lost. The measurement process should be stopped to avoid the loss of measurement data.

6.3 Software documentation

In addition to the documentation required in clause 7.1.2 the manufacturer shall submit the following:

Documentation	Application notes and/or examples
Description of the legally relevant software, incorporating how the requirements are met	
Description of the operating system security	For e.g. password protection
Description of the software sealing method(s)	
Overview of the system hardware, highlighting any hardware components that are deemed legally relevant or performing legally relevant functions	For e.g. topology block diagram, type of computer(s), type of network
Description of the accuracy of the algorithms	Example algorithms – filtering of A/D conversion results, rounding algorithms
Declaration of the hardware and software environment, including minimum resources and configuration necessary for correct functioning of the instrument	Applicable for types of instrument requiring a universal computer.
Description of the user interface, menus and dialogues	
Description of the software identification which has to be clearly assigned to the legally relevant functions	If applicable, include a description of all encryption means
Clear instructions on how to check the actual software identification against the reference number as listed in the type approval certificate.	This reference may be additionally marked on or displayed by the instrument.

Documentation	Application notes and/or examples
List of commands of each hardware interface of the measuring instrument/ electronic device/ sub-assembly	Include a statement of completeness
List of durability errors that are detected by the software	If necessary, include a description of the detecting algorithms
Description of data sets stored or transmitted	
List of significant faults that are detected and a description of the detecting algorithm	Applicable where fault detection is achieved by software means
Operating manual which clearly identifies al operational controls, indications, and features	Example features – switches, lights, displays and push buttons

6.4 Provision for software and calibration security

6.4.1 Sealing

Provision shall be made for appropriate sealing by mechanical, electronic and/or cryptographic means, making any change that affects the metrological integrity of the instrument impossible or evident. Calibrations, zero-setting and test point adjustments are considered to affect metrological characteristics and must be sealed.
NOTE: Examples for appropriate sealing means are: mechanical sealings, audit logs, access only via interfaces protected by cryptographic means.

After securing and/or verification, the software of an instrument shall not be modifiable or uploadable via any interface or by other means without breaking the seal.

6.4.2 Safeguards against fraudulent use

For protection against fraudulent use, the following requirements have to be fulfilled.

6.4.2.1 The legally relevant software shall be secured against unauthorised modification, loading or changes by swapping of the memory device. In addition to mechanical sealing, technical means may be necessary to secure measuring instruments having an operating system or an option to load software.

6.4.2.2 Only clearly documented functions are allowed to be activated by the user interface, which shall be realised in such a way that it does not facilitate fraudulent use.

6.4.2.3 Parameters that fix the legally relevant characteristics of the measuring instrument shall be secured against unauthorised modification. If necessary for the purpose of verification, it shall be possible to display or print the current parameter settings.

6.4.2.4 National responsible bodies may restrict the access to any of the device-specific parameters.

NOTE: Device-specific parameters may be adjustable or selectable only in a special operational mode of the instrument. They may be classified as those that should be secured (unalterable) and those that may be accessed (adjustable parameters) by an authorised person, e.g. the instrument owner ormanufacturer representative. Type-specific parameters have identical values for all specimens of a type and are fixed at type approval

6.4.2.5 The national responsible body may require protein measuring instruments in service to be positioned so that all interested parties present have the possibility of seeing all the measurement operations, not limited to the indicating or recording device(s).

PART 2: METROLOGICAL CONTROLS AND PERFORMANCE TESTS

7 TYPE EVALUATION AND APPROVAL

Each type (pattern) of a protein measuring instrument used for trade shall be submitted to the type approval procedure. Without authorisation from the national responsible body, no modification may be made to an approved type.

7.1 Application

General application requirements are available from the national responsible body. The application for type approval shall be accompanied by:

a) at least two sample instruments representative of the submitted type for testing according to the full program in Annex C; and
b) descriptive documents and drawings.

7.1.1 Sample instruments

7.1.1.1 Manufacturers shall provide the national responsible body with at least two instruments and an operating manual. The sample instruments shall be in full working order and shall include all functions and calibrations to be examined for type approval.

7.1.1.2 It is recommended that a third (additional) unit is provided in order to expedite the climatic performance tests. This additional unit will be maintained at reference conditions and used to monitor P_{MB} stability of grain samples as they are cycled through various temperature and humidity settings during the climatic tests.

7.1.1.3 If the protein measuring instrument is a module (i.e. part of a system that includes other than metrological functions), only parts associated with P_{MB} measurements may be submitted for evaluation. This is particularly relevant where testing the instrument as a whole is difficult or impossible, or where modules are manufactured and/or placed on the market as separate units to be incorporated in a complete instrument.

7.1.2 Documentation

In addition to the listed documents, the applicant may submit other evidence to support the assumption that the design and characteristics of the type comply with the requirements of this Recommendation.

Required documentation	Application notes and/or examples
General description of the instrument	Functional description; measurement principle.
General characteristics of the instrument	Manufacturer; manufacturer specifications for the rated operating ranges e.g. ambient temperature, voltage; manufacturer specifications for the sample temperature and maximum differential between instrument and sample; single or multi-calibration
Drawings of general arrangement and details of metrological interest	Safeguards, restrictions, securing components, adjustment devices, controls, protected access to adjustment operations; calibration selection and display; place for application of control marks, descriptive markings and conformity and/or approval marks.
Description of calibrations submitted for approval	Calibration principle; calibration names and version number; limitations of use e.g. applicable kinds of grain, P_{MB} measuring ranges, min/max moisture content of samples; regression data (e.g. number of points, data sources, reference method, validation results); calibration equation, values for fixed and adjustable parameters.
Descriptions and characteristic data for all devices and sub-assemblies of the instrument.	Examples of devices: printing device; memory storage device, levelling device and indicator; sample receptacle (input and output); other functions (if not limited to P_{MB} measurements).
Technical description, drawings and plans of devices, sub-assemblies	Devices involved in the measurement principle (e.g. for NIR – spectroscope, transducers, receptors and data integrators); electrical connection elements including length of signal lines; indicator (e.g. block and schematic diagrams, internal processing and data exchange via interface).
Declarations of the manufacturer	e.g. for interfaces, for protected access to instrument and calibration adjustment parameters, for other software based operations.

Required documentation	Application notes and/or examples
Samples of all intended print-outs	
Information concerning special cases	Subdivision of instrument into legally relevant modules (if the processes are not limited to P_{MB} measurements); operating conditions (if different to requirements in clause); suppression of results outside rated ranges; reaction of the instrument to significant faults; functioning of the display after switch-on.
Results of tests performed by the manufacturer using protocols from Parts 2 and 3	Or tests from other laboratories using protocols from Parts 2 and 3. Include scope of third-party accreditation/ proof of competence.
Certificates of other type approvals or separate tests	Relating to other modules of the submitted instrument, together with testing protocols.
Additional documents according to clause 6.3	For software-controlled instruments.
Drawing or photo of the instrument	The principle of application and the location of verification and securing marks shall be shown.
Manufacturer's manual according to clause 5.2	A draft is permitted.

7.2 Examinations

7.2.1 Administrative examination

The national responsible body shall review the documentation submitted against the requirements in clause 7.1.2 to determine if it is adequate and correct. The operating manual, which may be a draft, shall be assessed for its completeness and clarity of operating instructions.

7.2.2 Examination against metrological and technical requirements

The national responsible body shall visually inspect the instrument to ensure compliance with the documentation (e.g. specifications by the manufacturer).

The documentation, in conjunction with at least one sample instrument, shall be examined to confirm compliance with metrological or technical requirements in this Recommendation that cannot be evaluated during the performance tests (e.g. markings and sealing mechanisms). Suitable checks shall be performed on the instrument to establish confidence that all the functions are in accordance with the documentation. Reactions to significant faults need not be triggered.

7.2.3 Software examination

The national responsible body may opt to complete validation (software examination) after the performance tests. Compliance with the requirements of clause 6 and those related to software protection is confirmed by the validation methods described in Annex D. If a particular requirement does not apply to the type, it shall be marked as "not applicable" in Part 3 *Examination checklist – software*.

7.3 Performance tests

Whole-grain measurement standards used in the performance tests shall fulfil the requirements in Annex B.
At least two sample units shall be tested according to the conditions and procedures in Annex C. The type of instrument is presumed to comply with the metrological requirements in clauses 4.7, 4.8, 4.9 as indicated below if it passes the following performance tests:

Metrological requirements	Test(s) for compliance
Requirements for calibrations [4.7]	Assessment of calibrations in the submitted type [C.7] Accuracy and precision at reference conditions [C.7.1] Sample temperature sensitivity (STS) [C.7.2]
Variation of select influence factor(s) within the rated operating ranges [4.8.1]	Tests for influence variations within the rated operating conditions [C.5] Instrument levelling [C.5.1] Cold [C.5.2] Dry heat [C.5.3] Damp heat [C.5.4] AC mains voltage variation [C.5.5]

Effect of disturbances on electronic instruments [4.8.2] NOTE: Instruments that do not contain any active electronic circuits (e.g. transistors, IC's, radio tubes), are presumed to comply without being subject to the disturbance tests.	Tests for disturbances [C.6] AC mains voltage dips, short interruptions and voltage variations [C.6.1] Bursts (transients) on AC mains [C.6.2] Radiated radiofrequency, electromagnetic susceptibility [C.6.3] Conducted radio-frequency fields [C.6.4] Electrostatic discharges [C.6.5] Mechanical shock [C.6.6] Storage temperature (extreme shipping conditions) [C.6.7]
Error due to changes in the instrument over time [4.9]	Tests for time related effects [C.4] Instrument warm-up time [C.4.1] Instrument drift and instability [C.4.2]

7.4 Test report

The report on the tests carried out for type approval shall contain, as a minimum, the items of information prompted by the test report format provided in Part 3. The manufacturer shall be provided specific comments about any test failures.

8 INITIAL VERIFICATION

A new instrument shall undergo initial verification only after type approval. Further to the provisions below, general guidance for the development of verification protocols is included in OIML D 20 *Initial and subsequent verification of instruments and processes* [8].

8.1 Legal status of the instrument submitted for verification

Initial verification includes a procedure to ensure that the individual measuring instruments conform to the approved type and the metrological requirements in clause 4.6 under typical in-service conditions. But, notwithstanding this initial verification carried out by the appropriate Legal Authority or under its responsibility, the manufacturer has the full responsibility to ensure that the instrument complies with the requirements in this Recommendation (i.e. Production of measuring instruments shall be in conformance with the approved type).

8.2 Examination

Before starting the tests, the examinations to be performed include:

a) assessment of the instrument and surroundings;
b) visual inspection to determine conformance with the approved type and to obtain a general appraisal of its design and construction;
c) completeness and the correctness of the inscriptions; and
d) the presence, completeness, and the language of the documentation meant for the user.

8.3 Test procedure

The national responsible body shall specify the test procedure to determine if the performance of a protein measuring instrument meets the accuracy requirements, or whether the instrument requires servicing and/or adjustment. Whole-grain reference material with certified P_{MB} values, i.e. CRMs as described in Annex B, shall be used.

8.4 Verification marks, seals and document

After successful initial verification, the verification marks and/or the sealing shall be attached and/or an accompanying document shall be made up according to national requirements.

9 METROLOGICAL SUPERVISION

Further to the provisions below, relevant to protein measuring instruments, general guidance can be found in OIML D 9 *Principles of metrological supervision* [9].

9.1 Reverification (subsequent verification)

9.1.1 Frequency

Reverification is mandatory after any repair, adjustment or change that affects metrological performance of an instrument that has been initially verified.

The obligation of reverification in absence of any metrologically significant changes and the mandatory time interval is subject to national requirements. Due to the seasonal variability of crops mentioned in clause 9.5.1, this Recommendation proposes annual reverification of instruments, with the interval not to exceed 18 months.

9.1.2 Examination and tests

Reverification shall only be performed provided that:

a) Earlier verification has been successfully performed and the appropriate verification marks are undamaged;
b) The period elapsed since the previous verification does not exceed the mandatory reverification period (if one is prescribed); and
c) Seals are not broken.

Deviation from any of the listed conditions suggests of a breach of metrological controls, and may necessitate implementation of corrective actions (e.g. removal of the instrument service, investigation, initial verification) in accordance with national requirements.

As with initial verification, reverification shall be carried out according to the procedure specified by the national responsible body.

While consideration of instrument conformity, installation and suitability are afforded at initial verification, reverification shall focus on the following:

a) instrument and calibration accuracy;
b) software integrity;
c) appropriateness of use; and
d) adequacy of maintenance.

9.2 In-service surveillance

For countries without a system of mandatory reverification, metrological supervision may consist of random or scheduled checks (in-service surveillance) of the following:

- the presence of the correct, valid and undamaged verification marks and seals
- accuracy of P_{MB} measurements performed using whole-grain CRMs
- evidence of regular maintenance according to the manufacturers' instructions

9.3 Routine performance monitoring

The national responsible body may require the user of a protein measuring instrument to carry out a routine performance check before and/or after a series of protein content measurements. The purpose is to ensure adequate measurement reproducibility across networked instruments and to monitor instrument drift so that corrective adjustments are carried out before the measurement error exceeds the MPE.

For regular performance checks, a sub-set of the verification procedure may be adopted using secondary standards. Routine monitoring is not intended to be as thorough as the tests for accuracy during verification, however the frequency of performance checks is expected to surpass that of verification.

9.4 Maintenance and reconfiguration of the approved software

Only versions of the legally relevant software that conform to the approved type are approved for use.

The assessment and approval of software versions other than those submitted at type evaluation of the instrument is at the discretion of the national responsible body. Full examination as described with Annex D, or a sub-set of the validation procedure (in accordance with the changes declared by the manufacturer and the risk determined by the examiner), is recommended.

Updating the legally relevant software of a verified protein measuring instrument should be considered as:

- a modification of the instrument, when exchanging the software with another approved version
- a repair of the instrument when, re-installing the same version.

In general, this necessitates verification in accordance with the guidelines for *Verified Update* in D 31 [5] clause 5.2.6.2. In the place of a Verified Update, the national responsible body may allow for a *Traced Update* as described in D 31 clause 5.2.6.2. A prerequisite for this provision is approval by the national responsible body that implementation of the software in the instrument fulfils the requirements for Traced Updates.

9.5 In-field updates to grain calibrations

9.5.1 Seasonal variability of crops and inevitability calibration updates

Grain protein measuring instruments measure P_{MB} indirectly via multivariate calibrations, e.g. in NIR instruments the spectral data from which P_{MB} is inferred is affected to some extent by other constituents and physical properties of the grain.

A calibration based on the discrete properties of a particular grain crop, may not be valid for subsequent grain crops due to seasonal variability in chemical and physical properties.

The national responsible body may therefore authorise updates on the grain P_{MB} calibrations based on grain data collected during the current and/or recent years to accommodate for the seasonal and crop year variations. The national responsible body may also require retention of the data is used to adjust the grain calibrations.

9.5.2 Calibration Version

A protein measuring instrument must be capable of displaying the calibration constants that are adjustable and a unique calibration name or a unique calibration version number for use in verifying the version of the calibration in use to make P_{MB} measurements.

9.5.3 Security of calibrations and reverification

There shall be provision to allow only authorised persons to change calibrations. The security level for updating grain calibrations shall fulfil the same security level as for the software installation.

In addition, changes to the grain calibrations of the instrument shall be impossible or recorded in an audit trail. Changes to grain calibration data are downloaded to a verified instrument using available communication interfaces. These may not be considered as software changes that require a change to the software identification on the type approval certificate, however reverification of each modified instrument is required.

If calibration constants are digitally stored in an electronically alterable form, the instrument shall be designed to make automatic checks to detect corruption. An error message must be displayed if calibration constants have been electronically corrupted and no further measurement shall be possible.

The national responsible body may authorise a calibration update process which is not a Verified Update, provided that the instrument fulfils the requirements for Traced Updates at type evaluation as first mentioned in clause 9.4. The procedure for reverification on an instrument following a calibration update is determined by the national responsible body and may vary from the reverification processes described in clauses 8 and 9.1.2.

ANNEX A. REFERENCE METHODS

A.1 Protein content calculation from nitrogen determination

A.1.1 Dumas Combustion — Total Nitrogen Determination

For example: "ISO/DTS 16634.2" [10]

Note: Dumas (combustion) nitrogen values may be greater than corresponding Kjeldahl values, particularly at higher nitrogen levels.

A.1.2 Improved Kjeldahl Method — Total Nitrogen Determination

For example: ISO standards using the Kjeldahl method, i.e. “EN ISO 5983-2 Animal feeding stuffs – Determination of nitrogen content and calculation of crude protein content – Part 2: Block digestion/steam distillation method [11]

A.2 Moisture content measurements

Examples:
AACC International Method 44-15-02 – Moisture – Air-Oven Methods
ISO 6540:1980 – Maize – Determination of moisture content (of milled grains and on whole grains)
ISO 665:2000 – Oilseeds – Determination of moisture and volatile matter content
ISO 771:1977 – Oilseed residues – Determination of moisture and volatile matter content
ISO 6496:1999 – Animal feeding stuffs – Determination of moisture and other volatile matter content
ISO 711:1985 – Cereals and cereal products – Determination of moisture content – Basic reference method
ISO 712:1998 – Cereals and cereal products – Determination of moisture content – Routine reference method

ANNEX B. WHOLE-GRAIN MEASUREMENT STANDARDS

B.1 Whole-grain reference material (RM) certified for protein content (CRM for P_{MB})

Whole-grain reference materials (RMs) with certified P_{MB} values (i.e. CRMs for P_{MB}) shall be used to provide reference quantity values during verification of protein measuring instruments and in type evaluation tests concerned with the accuracy of P_{MB} calibrations at reference conditions. These shall be homogenous, moisture-stable samples representative of the grain traded in the region with P_{MB} values certified using a reference test method.

B.1.1 Reference method traceability

The national responsible body shall specify the reference method, according to the options listed in Annex A, for assigning a P_{MB} value to each whole-grain reference material (RM).

Essentially, a reference method allows the P_{MB} of a sample to be inferred from direct measurement of the mass fraction nitrogen in the sample and a direct measurement of the moisture content. The procedure applied shall contain provisions for verifying the calibration of the reference method using a nationally recognised measurement standard for nitrogen (i.e. a CRM for nitrogen concentration).
NOTE: Systematic errors in the execution of the reference method may be reduced by having traceability to the results of a collaborative survey of several reference method laboratories (i.e. an interlaboratory test). Refer to ISO/TS 16634-2 Annex E [10] for example results.

B.1.2 Suitability of the whole-grain CRM for use in verification

Third party laboratory accreditation of the reference method and sampling systems may be pursued to ensure that the whole-grain CRMs generated are adequate for determining the error during verification of protein measuring instruments.

The size of grain sample analysed by the reference method and a protein measuring instrument may differ and the resulting whole-grain CRMs are not always used on a protein measuring instrument immediately. It is therefore important to consider the inhomogeneity of the sample and any compositional variations over time when assigning a P_{MB} value and evaluating the uncertainty.
Refer to ISO Guide 34 *General and statistical principles for certification* [12] for further guidance on development of valid methods to traceably assign values to the properties of reference materials (RMs) and evaluation of the associated uncertainty.

The grain protein reference method shall be applied with sufficient repetitions of the complete measurement cycle, on a representative portions of the whole-grain RM. The expanded uncertainty of the mean P_{MB} assigned to the whole-grain CRM, calculated with a coverage factor of two, should be appropriate for verification (i.e. within a third of the MPE for for that kind of grain).

B.1.3 Suitability of the whole-grain CRM for assessment of calibrations at reference conditions

SDD is the standard deviation of at least 30 bias-corrected measurement errors from different CRMs. A limit for the uncertainty associated with certified P_{MB} values in the calculation of *SDD* is difficult to specify compared to the certified P_{MB} values at verification, which is concerned with the measurement errors on individual CRMs.

However, poor reproducibility in the reference method and/or a lack of consideration for sample inhomogeneity, can result in enlarged *SDD* values that can be wrongly attributed to the calibrations under test. The expanded uncertainty associated with the P_{MB} value of any CRM used in the assessment of calibrations at type evaluation shall be therefore limited to one third of the value in clause 4.5 Table 1 column 9.
NOTE: The values calculated for pooled S*D,* and SDD_I are not dependent on certified P_{MB} values.

B.2 Practical instructions for test samples

B.2.1 Source

Particularly for the assessment of calibrations in clause C.7, the characteristics of the standards (reference materials) used as test samples shall be representative of the grain being traded. Foreign produce i.e. samples

based on the grain harvested in another country or region, may not be suitable for the assessment of calibrations due to climatic and crop variability.

B.2.2 Moisture content

Unless dried or moistened grain is commonly traded, all test samples shall be naturally occurring grain, i.e. the moisture should not be adjusted by soaking the sample in water or by spraying with water or by extended exposure to high humidity air. The moisture level must not make the sample susceptible to mould which can occur at relatively low levels for certain grain types e.g. over 13% moisture for wheat.

B.2.3 Sample records

The sample records should include: the identification number assigned, the date received, source, grain type, protein content, moisture, and other pertinent information.

B.2.4 Sample handling and storage

Upon receipt the integrity of the moisture-tight sample enclosure should be checked and a new enclosure used if necessary. Most grain samples are to be stored at 2 °C to 8 °C prior to use.

Prior to testing, samples are removed from cold storage and equilibrated overnight to room temperature.
NOTE: Except during analysis, a test sample is returned to its enclosure during the performance tests.

B.2.5 Sample cleaning

The sample must be free from insects, foreign seeds and any other foreign material. The condition of the sample (odour, appearance, damage, remaining foreign material, etc.) is recorded on the sample record. Spatial inhomogeneity in a bulk sample is minimised as much as possible by mixing.

B.2.6 Sample size

Unless the certificate of analysis permits otherwise, the entire CRM shall be analysed. Where RMs are permitted in a test, the cleaned bulk sample that has been mixed must be divided into representative portions slightly in excess of the amounts needed for analysis using the protein measuring instrument or where necessary, the reference method.

ANNEX C. TYPE EVALUATION TEST PROCEDURES

C.1 General

C.1.1 This mandatory annex defines the program of performance tests intended to ensure that the submitted type of protein measuring instrument, perform and function as intended under a specified range of conditions as required in clause 4.4. The procedures from clauses C.5.2 to C.6.6 are in accordance with OIML D 11 *General requirements for electronic measuring instruments* [4].

C.1.2 With exception of the tests for mechanical shock and storage temperature, the disturbance tests are described for a single instrument, i.e. one sample unit is the equipment under test (EUT). The remaining procedures illustrate two units undergoing a test simultaneously, i.e. the EUT is two sample units. The national responsible body may modify these procedures to accommodate for the number of units received.

C.2 Instrument preconditioning, conditioning and recovery

C.2.1 To test the rated operating temperature range and sample temperature sensitivity, the facility for suppressing measurements or results outside specified temperature ranges shall be disabled prior to these tests.

C.2.2 The guidelines for preconditioning, conditioning and recovery listed in the relevant test standard shall be observed. Where there are no preconditioning guidelines, the instrument shall be stabilised according to the manufacturer's specifications.

C.2.3 Prior to assessing the calibrations under reference conditions in accordance with clause C.7.1, the EUT may be adjusted so that the intrinsic error is as close to zero as possible.

C.2.4 Particularly during disturbance tests, the EUT shall not be adjusted at any time during the test except to reset if a significant fault has been indicated.

C.3 Type evaluation test conditions

C.3.1 Reference conditions

Unless otherwise specified by the test procedure, the influence ranges below define the reference conditions under which the mean P_{MB} reference value or the intrinsic error is determined for each influence factor test.

*Ambient temperature (T_{ref}):	20 °C – 27 °C
*Relative humidity (RH_{ref}):	30 – 70 %
Atmospheric pressure:	86 kPa to 106 kPa (see note below)
Power voltage:	nominal mains or test voltage, V_{nom} or U_{nom}
Power frequency:	nominal frequency, F_{nom}
Instrument tilt:	level at 0º ± 0.1º
Dust ingress:	negligible (see note below)

Note: As these can expect to be fulfilled without specific measures in normal laboratory conditions, it is not deemed necessary to measure/monitor these values.

Reference conditions applicable to grain samples have been marked by asterisks (*).

During each test, the temperature (T_{ref}) and relative humidity (RH_{ref}) shall not vary by more than ±2 °C and ±10 % respectively within the allowable ranges.

C.3.2 Influence quantities

Influence quantity values representing the rated operating conditions and potential disturbances on electronic instruments are indicated in clause 4.4. When the effect of one influence quantity or disturbance is being evaluated, all other influence quantities and disturbances are to be held relatively constant, at values close to reference conditions.

C.3.3 Sample temperature

The grain sample temperature shall be T_{ref} during each test, except for the sample temperature sensitivity (STS) tests and the climatic tests. The sample temperature range and ΔT_{max} according to clause 4.3 shall be observed during all tests.

During the climatic tests, the effect of thermal cycling on the P_{MB} measurements of grain samples shall be monitored using a spare instrument of the same type maintained under reference conditions.

C.4 Tests for time related effects

C.4.1 Instrument warm-up time

EUT	Two or more sample instruments of the submitted type
Grain sample	One sample with mid-range P_{MB}, 12 - 14% moisture. Wheat is the preferred kind of grain.
Test procedure (in brief)	Six P_{MB} measurements on the sample are taken using each unit, at every test condition: i) EUT at reference conditions, immediately after power is switched on or after the warm-up time ii) EUT at reference conditions, well after the instrument has warmed-up and stabilised
Suggested steps	1) The EUT is powered off and equilibrated at reference conditions with the grain sample. 2) The EUT is powered on and after waiting for the manufacturer specified* warm-up time, a series of P_{MB} measurements is taken – alternating between the units after each single measurement – until six P_{MB} measurements are recorded for each instrument. 3) After waiting for one hour or twice the manufacturer recommended warm-up time (whichever is greater), another series of P_{MB} measurements is taken using the EUT as described in step 2. *Where the manufacturer has not specified a warm-up time, it is assumed that turning the power on will immediately provide accurate results. The sample would be tested immediately upon the EUT being powered on and then again after 1 hour.
Test result	The error shift on the grain sample is calculated for each unit. Error shift = Mean P_{MB} (step 3, condition ii) – Mean P_{MB} (step 2, condition i)
Acceptance requirements	All error shift values shall be within the limit in clause 4.5 Table 1 column 7 (adjusted to the relevant M_B). All operational functions shall operate as designed.

C.4.2 Instrument drift and instability

EUT	Two or more sample instruments of the submitted type
Grain samples	One set from a single grain type comprised of three samples that represent the legally relevant P_{MB} range (i.e. one sample for each low, mid and high P_{MB}). Wheat is the preferred kind of grain.
Test procedure (in brief)	This test is commenced prior to other type evaluation tests (except of the warm-up time test). Six P_{MB} measurements on the sample are taken using each unit, at every test condition: i) EUT at reference conditions, prior to any influence factor and disturbance tests. ii) EUT at reference conditions, after at least 4 weeks but less than 6 weeks has elapsed, prior to any disturbance tests or changes to the EUT.
Suggested steps	1) The EUT and grain samples are stabilised under reference conditions. 2) A series of P_{MB} measurements is taken on the first grain sample – alternating between the units after each single measurement – until six P_{MB} measurements are recorded for each instrument. The second and third samples in the set are analysed in the sample manner. 3) After at least four weeks* and prior to any disturbance tests, further P_{MB} measurements are taken using the EUT on the same three samples, as described in step 2. *The minimum time period for assessing instrument stability shall be four weeks without any modifications, repairs, or adjustments performed on the EUT. However, the EUT may be cycled through various influence factor variations (within the rated operating ranges) followed by recovery at reference conditions. In the event of a modification to the EUT within the four week period, the instrument drift and instability test shall be recommenced.
Test result	The error shift on every grain sample is calculated for each unit. Error shift = Mean P_{MB} (step 3, condition ii) – Mean P_{MB} (step 2, condition i)
Acceptance requirements	All error shift values shall be within the limit in clause 4.5 Table 1 column 7 (adjusted to the relevant M_B). All operational functions shall operate as designed.

C.5 Tests for influence variations within the rated operating conditions

C.5.1 Instrument levelling

EUT	Two or more sample instruments of the submitted type
Grain sample	One sample with mid-range P_{MB}, 12 - 14% moisture. Wheat is the preferred kind of grain.
Test procedure (in brief)	Six P_{MB} measurements on the sample are taken using each unit, at every test condition: i) EUT at reference alignment ii) EUT tilted in at least two orientations* iii) EUT after recovery at reference alignment
Test severity	Instruments without level indicators: 5% (approximately 3°) Instruments with level indicators: maximum allowable tilt limit on the indicator
Suggested steps	1) The EUT mounted on level surface, is powered on and equilibrated at reference conditions with the grain samples. 2) A series of P_{MB} measurements is taken – alternating between the units after a single measurement – until six measurements are recorded for each instrument. 3) The EUT is tilted and another series of P_{MB} measurements is taken using the EUT as described in step 2 4) Further P_{MB} measurements are taken using the EUT as described in step 2 at the other orientations* of tilt 5) The EUT is returned ot the reference alignment and step 2 is repeated. *A minimum of 2 orientations of tilt shall be applied e.g. front to back and left to right (select the direction with the greatest effect is chosen).
Test result	The error shift on the grain sample is calculated at every tilt orientation for each unit. Error shift (tilt 1) = Mean P_{MB} (step 3, tilt orientation 1) – Mean P_{MB} (step 2, condition i) Error shift (tilt 2) = Mean P_{MB} (step 4, tilt orientation 2) – Mean P_{MB} (step 2, condition i) Error shift (recovery) = Mean P_{MB} (step 5, condition iii) – Mean P_{MB} (step 2, condition i)
Acceptance requirements	All values for the error shift shall be within the limit in clause 4.5 Table 1 column 7 (adjusted to the relevant M_B). All operational functions shall operate as designed.

C.5.2 Cold

EUT	Two sample instruments of the submitted type, set-up according to clause C.2.1.
Spare unit	A sample instrument of the submitted type, set-up according to clause C.2.1 and maintained at reference conditions for the duration of the test.
Grain samples	One set from a single grain type comprised of three samples that represent the legally relevant P_{MB} range (i.e. one sample for each low, mid and high P_{MB}). Wheat is the preferred kind of grain. Except during an analysis, each sample is kept in its enclosure during the test. Samples used in a climatic test shall not be reused in other tests.
Standards	IEC 60068-2-1 [13], IEC 60068-3-1 [14]
Test method and procedure (in brief)	Test A: Cold The test consists of exposure to the specified minimum temperature under “free air” conditions for the specified time. The change of temperature shall not exceed 1 °C/min during heating up and cooling down. IEC specifies that the power to the EUT shall be switched off before the temperature is raised. Six P_{MB} measurements on every sample are taken using each unit, at every test condition: i) EUT and grain samples at reference temperature ii) EUT after exposure to cold, grain samples at minimum temperature iii) EUT and grain samples after recovery at reference temperature
Sample monitoring	To ensure that cooling and recovery do not change the P_{MB} of grain samples significantly, the grain samples are monitored throughout the test by a spare unit. NOTE: Where the manufacturer-specified maximum ΔT between instrument and sample is less than T_{ref} - T_C, it will not be possible to take a P_{MB} on the cold sample. In Step 6 below, take six P_{MB} measurements on each unit instead of only two, and then proceed to Step 12.
Test severity	Exposure duration (after EUT stabilisation): 2 h; Minimum temperature: T_C or 10 ºC T_C is the minimum temperature in the operating range specified by the national responsible body. If an operating range is not declared then the minimum range of 10 ºC to 30 ºC will

	apply.
Suggested steps	1) The EUT is powered on and stabilised at reference temperature. 2) In a separate chamber, the spare unit is powered on and equilibrated at reference temperature with the grain samples. 3) Sample 1 is analysed once on instrument 1, then once on instrument 2, then once on the spare unit. Further P_{MB} measurements are taken across the three units in the same manner, until six P_{MB} measurements are recorded for each instrument. 4) Step 3 is repeated for the other two grain samples. 5) The EUT and grain samples are subjected to the minimum temperature and stabilised. 6) All the cold grain samples are analysed in turn on both units of the EUT, alternating between the two instruments, until two P_{MB} measurements per grain samples are recorded for each instrument. 7) Sample 1 is analysed three times on the spare unit as quickly as possible. 8) Immediately after step 15, sample 1 is analysed once on both units of the EUT. 9) Steps 7 – 8 are repeated on the other two samples. 10) The samples are retained at the location of the EUT for as long as necessary to equilibrate at the minimum temperature. Each sample is analysed once on both units of the EUT again. 11) Steps 7 – 10 are repeated. 12) After ensuring that six P_{MB} measurements on each cold sample are recorded for each instrument, the EUT and grain samples are recovered to reference temperature. 13) Steps 3 – 4 are repeated.
Test result	Values for the error shift on every grain sample are calculated at each test condition for each unit (of the EUT). Error shift (cold) = (Mean P_{MB} condition ii – Mean P_{MB} condition i) – Correction* Error shift (recovery) = (Mean P_{MB} condition iii – Mean P_{MB} condition i) – Correction* *Application of a correction is required if a significant change in the sample P_{MB} during cooling and/or recovery is indicated by the sample stability test.
Grain sample stability test and correction	The P_{MB} variation on a grain sample *calculated from measurements on the spare unit*, shall be within the limit in Table 1 column 7 (adjusted to the relevant M_B) for no correction to apply. Sample P_{MB} variation (cold) = Mean P_{MB} (condition ii) – Mean P_{MB} (condition i) Sample P_{MB} variation (recovery) = Mean P_{MB} (condition iii) – Mean P_{MB} (condition i) Any sample P_{MB} variation that exceeds the limit, shall be applied as a correction, e.g.: Sample P_{MB} variation (cold) = Correction for error shift (cold) Sample P_{MB} variation (recovery) = Correction for error shift (recovery) NOTE: If it is not possible to obtain a value for the Sample P_{MB} variation (cold) select not applicable (NA) on the test report.
Acceptance requirements	All values for the error shift (i.e. with any necessary correction) shall be within the limit in clause 4.5 Table 1 column 7 (adjusted to the relevant M_B). All operational functions shall operate as designed.

C.5.3 Dry heat

EUT	Two sample instruments of the submitted type, set-up according to clause C.2.1.
Spare unit	A sample instrument of the submitted type, set-up according to clause C.2.1 and maintained at reference conditions for the duration of the test.
Grain samples	One set from a single grain type comprised of three samples that represent the legally relevant P_{MB} range (i.e. one sample for each low, mid and high P_{MB}). Wheat is the preferred kind of grain. Except during analysis, each sample is kept in its enclosure during the test. Samples used in a climatic test shall not be reused in other tests.
Standards	IEC 60068-2-2 [13], IEC 60068-3-1 [15]
Test method and procedure (in brief)	Test B: Dry heat The test consists of exposure to the specified maximum temperature under "free air" conditions for the specified time. The change of temperature shall not exceed 1 °C/min during heating up and cooling down. The absolute humidity of the test atmosphere shall not exceed 20 g/m^3. When testing is performed at temperatures lower than 35 °C, the relative humidity

	shall not exceed 50%. Six P_{MB} measurements on every sample are taken using each unit, at every test condition: i) EUT and grain samples at reference temperature ii) EUT and grain samples after dry heat exposure iii) EUT and grain samples after recovery at reference temperature
Sample monitoring	To ensure that heating and recovery do not change the P_{MB} of grain samples significantly, the grain samples are monitored throughout the test by a spare unit. NOTE: Where the manufacturer-specified maximum ΔT between instrument and sample is less than $T_H - T_{ref}$ it will not be possible to take a P_{MB} on the hot sample. In Step 6 below, take six P_{MB} measurements on each unit instead of only two, and then proceed to Step 12.
Test severity	Exposure duration (after EUT stabilisation): 2 h; Maximum temperature: T_H or 30 ºC T_H is the maximum temperature in the operating range specified by the national responsible body. If an operating range is not declared then the minimum range of 10 ºC to 30 ºC will apply.
Suggested steps	1) The EUT is powered on and stabilised at reference temperature. 2) In a separate chamber, the spare unit is powered on and equilibrated at reference temperature with the grain samples. 3) Sample 1 is analysed once on instrument 1, then once on instrument 2, then once on the spare unit. Further P_{MB} measurements are taken across the three units in the same manner, until six P_{MB} measurements are recorded for each instrument. 4) Step 3 is repeated for the other two grain samples. 5) The EUT and grain samples are subjected to the maximum temperature and stabilised. 6) All the hot grain samples are analysed in turn on both units of the EUT, alternating between the two instruments, until two P_{MB} measurements per grain samples are recorded for each instrument. 7) Sample 1 is analysed three times on the spare unit as quickly as possible. 8) Immediately after step 15, sample 1 is analysed once on both units of the EUT. 9) Steps 7 – 8 are repeated on the other two samples. 10) The samples are retained at the location of the EUT for as long as necessary to equilibrate at the maximum temperature. Each sample is analysed once on both units of the EUT again. 11) Steps 7 – 10 are repeated. 12) After ensuring that six P_{MB} measurements on each hot sample are recorded for each instrument, the EUT and grain samples are recovered to reference temperature. 13) Steps 3 – 4 are repeated.
Test result	Values for the error shift on every grain sample are calculated at each test condition for each unit (of the EUT). Error shift (dry heat) = (Mean P_{MB} condition ii – Mean P_{MB} condition i) – Correction* Error shift (recovery) = (Mean P_{MB} condition iii – Mean P_{MB} condition i) – Correction* *Application of a correction is required if a significant change in the sample P_{MB} during heating and/or recovery is indicated by the sample stability test.
Grain sample stability test and correction	The P_{MB} variation on a grain sample *calculated from measurements on the spare unit*, shall be within the limit in Table 1 column 7 (adjusted to the relevant M_B) for no correction to apply. Sample P_{MB} variation (dry heat) = Mean P_{MB} (condition ii) – Mean P_{MB} (condition i) Sample P_{MB} variation (recovery) = Mean P_{MB} (condition iii) – Mean P_{MB} (condition i) Any sample P_{MB} variation that exceeds the limit, shall be applied as a correction, e.g.: Sample P_{MB} variation (dry heat) = Correction for error shift (dry heat) Sample P_{MB} variation (recovery) = Correction for error shift (recovery) NOTE: If it is not possible to obtain a value for the Sample P_{MB} variation (dry heat) select not applicable (NA) on the test report.
Acceptance requirements	All values for the error shift (i.e. with any necessary correction) shall be within the limit in clause 4.5 Table 1 column 7 (adjusted to the relevant M_B). All operational functions shall operate as designed.

C.5.4 Damp heat

EUT	Two sample instruments of the submitted type, set-up according to clause C.2.1.

Spare unit	A sample instrument of the submitted type, set-up according to clause C.2.1 and maintained at reference conditions for the duration of the test.
Grain samples	One set from a single grain type comprised of three samples that represent the legally relevant P_{MB} range (i.e. one sample for each low, mid and high P_{MB}). Wheat is the preferred kind of grain. Except during analysis, each sample is kept in its enclosure during the test. Samples used in a climatic test shall not be reused in other tests.
Standards	IEC 60068-2-78 [16], IEC 60068-3-4 [17]
Test method and procedure (in brief)	Test Cab: Damp heat, steady state The test consists of exposure to the specified maximum temperature and the specified constant relative humidity for the specified time. The change of temperature shall not exceed 1 °C/min during heating up and cooling down. The absolute humidity of the test atmosphere shall not exceed 20 g/m^3. When testing is performed at temperatures lower than 35 °C, the relative humidity shall not exceed 50%. Six P_{MB} measurements on every sample are taken using each unit, at every test condition: i) EUT and grain samples at reference temperature ii) EUT after damp heat exposure, grain samples at maximum temperature and RH iii) EUT and grain samples after recovery at reference conditions NOTE: To ensure that heating, increased humidity and recovery do not change the P_{MB} of grain samples significantly, the grain samples are monitored throughout the test by a spare unit.
Sample monitoring	To ensure that heating, exposure to moisture and recovery do not change the P_{MB} of grain samples significantly, the grain samples are monitored throughout the test by a spare unit. NOTE: Where the manufacturer-specified maximum ΔT between instrument and sample is less than $T_H - T_{ref}$ it will not be possible to take a P_{MB} on the hot sample. In Step 6 below, take six P_{MB} measurements on each unit instead of only two, and then proceed to Step 12.
Test severity	Exposure duration (after EUT stabilisation): 2 days; Maximum RH: 90% Maximum temperature: T_H or 30 ºC T_H is the maximum temperature in the operating range specified by the national responsible body. If an operating range is not declared then the minimum range of 10 ºC to 30 ºC will apply.
Suggested steps	1) The EUT is powered on and stabilised at reference temperature. 2) In a separate chamber, the spare unit is powered on and equilibrated at reference temperature with the grain samples. 3) Sample 1 is analysed once on instrument 1, then once on instrument 2, then once on the spare unit. Further P_{MB} measurements are taken across the three units in the same manner, until six P_{MB} measurements are recorded for each instrument. 4) Step 3 is repeated for the other two grain samples. 5) The EUT and grain samples are subjected to the maximum temperature and humidity and stabilised. The exposure duration is observed. 6) All the hot grain samples are analysed in turn on both units of the EUT, alternating between the two instruments, until two P_{MB} measurements per grain samples are recorded for each instrument. 7) Sample 1 is analysed three times on the spare unit as quickly as possible. 8) Immediately after step 15, sample 1 is analysed once on both units of the EUT. 9) Steps 7 – 8 are repeated on the other two samples. 10) The samples are retained at the location of the EUT for as long as necessary to equilibrate at the maximum temperature. Each sample is analysed once on both units of the EUT again. 11) Steps 7 – 10 are repeated. 12) After ensuring that six P_{MB} measurements on each hot sample are recorded for each instrument, the EUT and grain samples are recovered to reference temperature. 13) Steps 3 – 4 are repeated.
Test result	Values for the error shift on every grain sample are calculated at each test condition for each unit (of the EUT). Error shift (damp heat) = (Mean P_{MB} condition ii – Mean P_{MB} condition i) – Correction* Error shift (recovery) = (Mean P_{MB} condition iii – Mean P_{MB} condition i) – Correction*

	*Application of a correction is required if a significant change in the sample P_{MB} during heating and/or recovery is indicated by the sample stability test.
Grain sample stability test and correction	The P_{MB} variation on a grain sample *calculated from measurements on the spare unit*, shall be within the limit in Table 1 column 7 (adjusted to the relevant M_B) for no correction to apply. Sample P_{MB} variation (damp heat) = Mean P_{MB} (condition ii) – Mean P_{MB} (condition i) Sample P_{MB} variation (recovery) = Mean P_{MB} (condition iii) – Mean P_{MB} (condition i) Any sample P_{MB} variation that exceeds the limit, shall be applied as a correction, e.g.: Sample P_{MB} variation (damp heat) = Correction for error shift (damp heat) Sample P_{MB} variation (recovery) = Correction for error shift (recovery) NOTE: If it is not possible to obtain a value for the Sample P_{MB} variation (damp heat) select not applicable (NA) on the test report.
Acceptance requirements	All values for the error shift (i.e. with any necessary correction) shall be within the limit in clause 4.5 Table 1 column 7 (adjusted to the relevant M_B). All operational functions shall operate as designed.

C.5.5 AC mains voltage variation

EUT	Two or more sample instruments of the submitted type
Grain sample	One sample with mid-range P_{MB}, 12 - 14% moisture. Wheat is the preferred kind of grain.
Standards	IEC/TR 61000-2-1 [18], IEC 61000-4-1 [19]
Test method and procedure (in brief)	Variation in AC mains power voltage The test consists of exposure to the specified power condition for a period sufficient for achieving temperature stability and for performing the required measurements. Ten P_{MB} measurements on the sample are taken using each unit, at every test condition: i) EUT at nominal test voltage (U_{nom}) ii) EUT at the upper voltage limit ii) EUT at the lower voltage limit iii) EUT after recovery at nominal test voltage (U_{nom}) NOTE: In case of three phase mains power, the voltage variation shall apply for each phase successively.
Test severity	Stabilising period after voltage change: 30 min Test voltage upper limit: U_{nom} +10%; Test voltage lower limit: U_{nom} -15% The values of U_{nom} are those marked on the measuring instrument. In case a range is specified, the "-" relates to the lowest value and the "+" to the highest value of the testing range.
Suggested steps	The units are tested in sequence at each test condition, i.e. all ten P_{MB} measurements are taken in succession on one unit before the next unit. The order that the instruments are tested at each condition shall be randomised.
Test result	The error shift on the grain sample is calculated at every voltage setting for each unit. Error shift (high voltage) = Mean P_{MB} (test condition ii) – Mean P_{MB} (test condition i) Error shift (low voltage) = Mean P_{MB} (test condition iii) – Mean P_{MB} (test condition i) Error shift (recovery) = Mean P_{MB} (test condition iv) – Mean P_{MB} (test condition i)
Acceptance requirements	All values for the error shift shall be within the limit in clause 4.5 Table 1 column 7 (adjusted to the relevant M_B). All operational functions shall operate as designed. The standard deviation of repeat P_{MB} measurements at any voltage level shall not exceed 0.10%.

C.6 Tests for disturbances

C.6.1 AC mains voltage dips, short interruptions and voltage variations

EUT	One sample instrument of the submitted type (repeat the test for another unit)
Grain sample	One sample with mid-range P_{MB}, 12 - 14% moisture. Wheat is the preferred kind of grain.
Standards	IEC 61000-4-11 [20], IEC 61000-6-1 [21], IEC 61000-6-2 [22]
Test method	Short-time reductions in mains voltage
Test procedure	Over four tests, the EUT is subjected to voltage reductions and interruptions of varying intensity and duration.A test generator suitable to reduce for a defined period of time the

(in brief)	amplitude of the AC mains voltage is used. The performance of the test generator shall be verified before connecting to the EUT. The mains voltage interruptions and reductions shall be repeated with a time interval less than the time required for a single measurement so that at least one voltage interruption occurs per measurement. At least 10 cycles are necessary for each test to enable the required number of measurements. The functional performance of the EUT is observed (e.g. displayed indications and/or error messages) while ten P_{MB} measurements are taken at every test condition.
Test severity	Test condition a) U_{nom} to zero for a duration equal to half a cycle of frequency Test condition b) U_{nom} to zero for a duration equal to one cycle of frequency Test condition c) U_{nom} to 70% reduction for a duration equal to 25/30* cycles of frequency Test condition d) U_{nom} to zero for a duration equal to 250/300* cycles of frequency *Values are for 50 Hz and 60 Hz respectively
Test result	The fault on each P_{MB} measurement is calculated with the mean of six P_{MB} measurements at reference conditions as the reference P_{MB} value. For example: Fault = P_{MB} measured value (during disturbance) – Mean P_{MB} prior test Exemption from the definition of a significant fault in clause 2.2.15 is considered for any values of fault exceeding the limit in clause 4.5 Table 1 column 8 (adjusted to the relevant M_B).
Acceptance requirements	One of the following shall be fulfilled: 1) The effect of the disturbance shall not exceed a significant fault and all operational functions shall operate as designed. 2) The instrument shall detect and react to a significant fault by either an error message or blanking the display (see clause 5.1.1).

C.6.2 Bursts (transients) on AC mains

EUT	One sample instruments of the submitted type (a repeat cycle is required for another unit)
Grain sample	One sample with mid-range P_{MB}, 12 -14% moisture. Wheat is the preferred kind of grain.
Standards	IEC 61000-4-1 [19], IEC 61000-4-4 [23]
Test method	Electrical bursts
Test procedure (in brief)	The test consists of subjecting the EUT to bursts of double exponential waveform transient voltages. All bursts shall be applied during the same measurement in symmetrical mode and asymmetrical mode. The characteristics of the burst generator shall be verified before connecting the EUT. The duration of the test shall not be less than 1 min for each amplitude and polarity. The injection network on the mains shall contain blocking filters to prevent the burst energy being dissipated in the mains. The functional performance of the EUT is observed (e.g. displayed indications and/or error messages) while at least ten P_{MB} measurements on the sample are taken with the bursts applied.
Test severity	Amplitude (peak value): 1 kV; Repetition rate: 5 kHz Number of test cycles: At least 10 positive and 10 negative randomly phased bursts shall be applied at 1000 V. The bursts are applied during all the time necessary to perform a measurement.
Test result	The fault on each P_{MB} measurement is calculated with the mean of six P_{MB} measurements at reference conditions as the reference P_{MB} value. Fault = P_{MB} measured value (during disturbance) – Mean P_{MB} prior test Exemption from the definition of a significant fault in clause 2.2.15 is considered for any values of fault exceeding the limit in clause 4.5 Table 1 column 8 (adjusted to the relevant M_B).
Acceptance requirements	One of the following shall be fulfilled: 1) The effect of the disturbance shall not exceed a significant fault and all operational functions shall operate as designed. 2) The instrument shall detect and react to a significant fault by either an error message or blanking the display (see clause 5.1.1).

C.6.3 Radiated radiofrequency, electromagnetic susceptibility

EUT	One sample instruments of the submitted type (a repeat cycle is required for another unit)
Grain sample	One sample with mid-range P_{MB}, 12 -14% moisture. Wheat is the preferred kind of grain.
Standards	IEC 61000-4-3 [24]
Test method	Radiated, radio-frequency, electromagnetic field immunity test
Test procedure (in brief)	The test procedure involves the exposure of the EUT to electromagnetic field strength as specified by the severity level and field uniformity as defined by the referred standard. The specified field strength shall be established prior to the actual testing (i.e. without EUT in the field). The EM field can be generated in different facilities, however the use of which is limited by the dimensions of the EUT and the frequency range of the facility: a) the strip line is used at low frequencies (below 30MHz or in some cases 150MHz) for small EUT; b) the long wire is used at low frequencies (below 30 MHz) for larger EUT; c) dipole antennas or antennas with circular polarisation placed at least 1 m from the EUT are used at high frequencies. The field shall be generated in two orthogonal polarisations and the frequency range shall be scanned slowly. If antennas with circular polarisation (i.e. log-spiral or helical antennas) are used to generate the electromagnetic field, a change in the position of the antennas is not required. When the test is carried out in a shielded enclosure to comply with international laws prohibiting interference on radio communications, care needs to be taken to handle reflections from the walls. The frequency ranges to be considered are swept with the modulated signal, pausing to adjust the RF signal level or to switch oscillators and antennas as necessary. Where the frequency range is swept incrementally, the step size shall not exceed 1% of the preceding frequency value. The dwell time of the amplitude modulated carrier at each frequency shall not be less than the time necessary for the EUT to be exercised and to respond, but shall in no case be less than 0.5 s. The sensitive frequencies (e.g. clock frequencies) shall be analysed separately. The functional performance of the EUT is observed (e.g. displayed indications and/or error messages). As many P_{MB} measurements as possible are taken over the sweep across the frequency range.
Test severity	EM frequency range: 26 MHz– 2 GHz; Field strength: Radiated 10 V/m Modulation: 80 % AM, 1 kHz sine wave
Test result	The fault on each P_{MB} measurement is calculated with the mean of six P_{MB} measurements at reference conditions as the reference P_{MB} value. Fault = P_{MB} measured value (during disturbance) – Mean P_{MB} prior test Exemption from the definition of a significant fault in clause 2.2.15 is considered for any values of fault exceeding the limit in clause 4.5 Table 1 column 8 (adjusted to the relevant M_B).
Acceptance requirements	One of the following shall be fulfilled: 1) The effect of the disturbance shall not exceed a significant fault and all operational functions shall operate as designed. 2) The instrument shall detect and react to a significant fault by either an error message or blanking the display (see clause 5.1.1).

C.6.4 Conducted radio-frequency fields

EUT	One sample instruments of the submitted type (a repeat cycle is required for another unit)
Grain sample	One sample with mid-range P_{MB}, 12 -14% moisture. Wheat is the preferred kind of grain.
Standards	IEC 61000-4-6 [25]
Test method	Immunity to conducted disturbances, induced by radio-frequency fields
Test procedure (in brief)	The test procedure involves the use of radio frequency EM current, simulating the influence of EM fields coupled or injected into the power ports and I/O ports of the EUT using coupling/decoupling devices as defined in the referred standard. The performance of the test equipment consisting of an RF generator, (de-coupling devices, attenuators, etc. shall be verified. The functional performance of the EUT is observed (e.g. displayed indications and/or error

	messages) while at least ten P_{MB} measurements on the sample are taken with the conducted radio-frequency fields applied.
Test severity	EM frequency range: 0.15 – 80* MHz; RF amplitude (50 Ω): 10 V (e.m.f) Modulation: 80 % AM, 1 kHz sine wave *For the frequency range 26-80 MHz, the testing laboratory may carry out the test according to clause C.6.3. However, in case of dispute, the result from the test according to clause C.6.5 shall prevail.
Test result	The fault on each P_{MB} measurement is calculated with the mean of six P_{MB} measurements at reference conditions as the reference P_{MB} value. Fault = P_{MB} measured value (during disturbance) – Mean P_{MB} prior test Exemption from the definition of a significant fault in clause 2.2.15 is considered for any values of fault exceeding the limit in clause 4.5 Table 1 column 8 (adjusted to the relevant M_B).
Acceptance requirements	One of the following shall be fulfilled: 1) The effect of the disturbance shall not exceed a significant fault and all operational functions shall operate as designed. 2) The instrument shall detect and react to a significant fault by either an error message or blanking the display (see clause 5.1.1).

C.6.5 Electrostatic discharges

EUT	One sample instruments of the submitted type (a repeat cycle is required for another unit)
Grain sample	One sample with mid-range P_{MB}, 12 -14% moisture. Wheat is the preferred kind of grain.
Standards	IEC 61000-4-2 [26]
Test method	Section 2: Electrostatic discharge (ESD) immunity test
Test procedure (in brief)	A capacitor of 150PF is charged by a suitable d.c. voltage source. The capacitor is then discharged through the EUT by connecting one terminal to ground (chassis) and the other via 330 Ω to surfaces which are normally accessible to the operator. The test includes the paint penetration method, if appropriate. For direct discharges, the air discharge shall be used where the contact discharge method cannot be applied. Before starting the tests, the performance of the ESD generator shall be verified. For EUT not equipped with a ground terminal, the EUT shall be fully discharged between discharges. Direct application: In the contact discharge mode to be carried out on conductive surfaces, the electrode shall be in contact with the EUT. In the air discharge mode on insulated surfaces, the electrode is approached to the EUT and the discharge occurs by spark. Indirect application: The discharges are applied in the contact mode to coupling planes mounted in the vicinity of the EUT. The functional performance of the EUT is observed (e.g. displayed indications and/or error messages) while at least ten P_{MB} measurements on the sample are taken with the discharges applied.
Test severity	Air discharge voltage: 2,4,6, 8 kV; Contact discharge voltage: 2, 4, and 6 kV Number of test cycles: At least one direct discharge and one indirect discharge shall be applied during the one measurement. The time interval between successive discharges shall be at least 10 seconds.
Test result	The fault on each P_{MB} measurement is calculated with the mean of six P_{MB} measurements at reference conditions as the reference P_{MB} value. Fault = P_{MB} measured value (during disturbance) – Mean P_{MB} prior test Exemption from the definition of a significant fault in clause 2.2.15 is considered for any values of fault exceeding the limit in clause 4.5 Table 1 column 8 (adjusted to the relevant M_B).
Acceptance requirements	One of the following shall be fulfilled: 1) The effect of the disturbance shall not exceed a significant fault and all operational functions shall operate as designed. 2) The instrument shall detect and react to a significant fault by either an error message or blanking the display (see clause 5.1.1).

C.6.6 Mechanical shock

EUT	Two or more sample instruments of the submitted type
Grain sample	One sample with mid-range P_{MB}, 12 -14% moisture. Wheat is the preferred kind of grain.
Standards	IEC 60068-2-31 [27]
Test method	Dropping on to a face
Test procedure (in brief)	Each unit of the EUT, placed in its normal position of use on a rigid surface, is tilted towards one bottom edge and then is allowed to fall freely onto the test surface. The height of fall is the distance between the opposite edge and the test surface. However, the angle made by the bottom and the test surface shall not exceed 30º. After the fall, a series of P_{MB} measurements is taken – alternating between the units after each single measurement – until ten P_{MB} measurements are recorded for each instrument. The functional performance of the EUT is observed (e.g. displayed indications and/or error messages).
Test severity	Height of fall: 50 mm; Number of falls (on bottom edge): 1
Test result	The fault on each P_{MB} measurement is calculated with the mean of six P_{MB} measurements at reference conditions as the reference P_{MB} value. Fault = P_{MB} measured value (after disturbance) – Mean P_{MB} prior test Exemption from the definition of a significant fault in clause 2.2.15 is considered for any values of fault exceeding the limit in clause 4.5 Table 1 column 8 (adjusted to the relevant M_B).
Acceptance requirements	One of the following shall be fulfilled: 1) The effect of the disturbance shall not exceed a significant fault and all operational functions shall operate as designed. 2) The instrument shall detect and react to a significant fault by either an error message or blanking the display (see clause 5.1.1).

C.6.7 Storage temperature (extreme shipping conditions)

EUT	Two or more sample instruments of the submitted type
Grain sample	One sample with mid-range P_{MB}, 12 -14% moisture. Wheat is the preferred kind of grain.
Test procedure (in brief)	1) The EUT is placed in the environmental chamber. 2) The chamber temperature is then increased to maximum temperature over a 1 hour period and maintained at that temperature for 3 hours. 3) The chamber temperature is then decreased to minimum temperature over a 1 hour period and maintained at that temperature for 3 hours. 4) The temperature cycle is repeated. 5) The EUT is equilibrated under reference conditions for at least 12 hours unpowered. 6) After the specified warm-up period, a series of P_{MB} measurements is taken – alternating between the units after each single measurement – until ten P_{MB} measurements are recorded for each instrument. The functional performance of the EUT is observed (e.g. displayed indications and/or error messages).
Test severity	Minimum temperature: -20 ºC; Maximum temperature: 50 ºC
	The fault on each P_{MB} measurement is calculated with the mean of six P_{MB} measurements at reference conditions as the reference P_{MB} value. Fault = P_{MB} measured value (after disturbance) – Mean P_{MB} prior test Exemption from the definition of a significant fault in clause 2.2.15 is considered for any values of fault exceeding the limit in clause 4.5 Table 1 column 8 (adjusted to the relevant M_B).
Acceptance requirements	One of the following shall be fulfilled: 1) The effect of the disturbance shall not exceed a significant fault and all operational functions shall operate as designed. 2) The instrument shall detect and react to a significant fault by either an error message or blanking the display (see clause 5.1.1).

C.7 Assessment of calibrations in the submitted type

C.7.1 Accuracy and precision at reference conditions

Grain sample sets	To evaluate each submitted P_{MB} calibration, a set of test samples comprised of at least 30 different whole-grain CRMs is required. The samples in each set shall represent the kind(s) of grain in the scope of the calibration under test. The P_{MB} values shall evenly cover the full measurement range specified for the kind(s) of grain (see clause 4.1), i.e. there shall be near equal number of samples in each of the following intervals: low P_{MB}, medium P_{MB}, and high P_{MB}. Whole-grain reference materials (RMs) with indicative P_{MB} values that are later assigned a P_{MB} value using the reference method (i.e. certified) are also permitted. Each RM sample shall be large enough to divide into two portions – one portion sufficient for the instrument and another portion sufficient for reference method analysis. Assessment and control of spatial inhomogeneity in the larger sample is paramount for this approach. One grain sample set is adequate for testing a calibration on at least two sample units of the submitted type.
Test procedure – suggested steps	As two sample units of the submitted type are tested simultaneously, references to the EUT mean both instruments. Each set of test samples representing one grain type (GT) submitted for approval will be tested entirely in succession. 1) The EUT is powered on and allowed to equilibrate under reference conditions with the grain samples. 2) The first sample in the set for grain type 1 (GT1) is opened and if it is not a CRM, a portion of the RM is put aside for reference method analysis. 3) The remainder of first test sample of GT1 is analysed with the EUT, alternating between the units after each single measurement, until three measurements are recorded for each instrument. 4) Steps 2 – 3 are repeated on the remaining test samples in the set (i.e. other GT1 samples). 5) If applicable, steps 2 – 4 are repeated on the remaining sets, (i.e. GT2, GT3, etc.). 6) If RMs are used in place of CRMs, reference P_{MB} values are obtained for RM portions segregated in step 2.
Result: Accuracy test – pooled bias of mean and SDD	The extent of inaccuracy is indicated by the error of P_{MB} values pooled over all the samples in the set, $\bar{y}$, together with the Standard Deviation of the Differences, *SDD*, which is the standard deviation of the measurement error corrected for the bias (y) on each sample. An improved estimation of $\bar{y}$ (also known as the 'instrument bias') is possible by using the mean P_{MB} in the calculation of y for each sample. For the *SDD*, only a single P_{MB} value (the first, j=1) from each sample is considered in the error calculation to emulate conventional measurements. $\bar{y} = \frac{1}{n}\sum_{i=1}^{n} y_i$ **Equation 3** $SDD = \sqrt{\frac{\sum_{i=1}^{n}\left(y_{i,j=1} - \bar{y}_{i,j=1}\right)^2}{n-1}}$ **Equation 4** where, $y_i = \bar{x}_i - r_i$ $\bar{x}_i = \frac{1}{3}\sum_{j=1}^{3} x_{i,j}$ (i.e. the mean of 3 measurements on sample i, under repeatability conditions) $y_{i,j=1} = x_{i,j=1} - r_i$ (i.e. the error on first P_{MB} measurement on sample i) $\bar{y}_{i,j=1} = \frac{1}{n}\sum_{i=1}^{n} y_{i,j=1}$ r_i = certified P_{MB} value for sample i $x_{i,j=1}$ = first P_{MB} measurement on the sample i n = number of samples in the set (30 CRMs minimum)
Result: Instrument	The repeatability of a measurement is indicated by the Standard Deviation, *SD*, of the 'three replicates' (three measurements performed under repeatability conditions). The repeatability of

repeatability test – Pooled SD of replicates	an instrument with a particular calibration is assessed by pooling *SD* across all the samples in the set (refer to Equation 5). The acceptance requirement (adjusted to the relevant M_B). $Pooled\ SD = \sqrt{\frac{\sum_{i=1}^{n}\sum_{j=1}^{3}\left(x_{i,j} - \bar{x}_i\right)^2}{2n}}$ **Equation 5** where, $x_{i,j}$ = measured P_{MB} value for sample i and replicate j, $\bar{x}_i = \frac{1}{3}\sum_{j=1}^{3} x_{i,j}$ (i.e. the mean of 3 measurements on sample i, performed under repeatability conditions) n = number of samples in the set (30 CRMs minimum)
Result: Instrument reproducibility test – SD of differences between two instruments	Reproducibility between two instruments with the same calibration is assessed by calculating the standard deviation of differences, SDD_I (refer to Equation 6). Variations in the performance of both units are minimised under reference conditions, therefore the calculated value of SDD_I is expected to be the lowest possible for the type of instrument. $SDD_I = \sqrt{\frac{\sum_{i=1}^{n}\left(d_i - \bar{d}\right)^2}{n-1}}$ **Equation 6** where, $\bar{d} = \frac{1}{n}\sum_{i=1}^{n} d_i$ $d_i = \bar{x}_i^{(1)} - \bar{x}_i^{(2)}$ $\bar{x}_i^{(1)} = \frac{1}{3}\sum_{j=1}^{3} x_{i,j}^{(1)}$ (i.e. the mean of 3 measurements on sample i, on instrument 1) $\bar{x}_i^{(2)} = \frac{1}{3}\sum_{j=1}^{3} x_{i,j}^{(2)}$ (i.e. the mean of 3 measurements on sample i, on instrument 2) n = number of samples in the set (30 CRMs minimum)
Acceptance requirements	Values for the following shall not exceed the following limits in clause 4.5 Table 1 (adjusted to the relevant M_B). $\bar{y}$ (Equation 3) and *SDD* (Equation 4) – the limits in columns 2 and 3 respectively Pooled *SD* (Equation 5) – the limit in column 4 SDD_I (Equation 6) – the limit in column 5

C.7.2 Sample temperature sensitivity (STS)

EUT	Two sample instruments of the submitted type
Grain samples	One set for each P_{MB} calibration (grain type) submitted for approval. A set is comprised of six samples that represent the legally relevant P_{MB} range at two moisture levels (i.e. a low and high moisture sample in each low, mid and high P_{MB} ranges). Except during analysis, each sample is kept in its enclosure during the test. Samples used used to test STS shall not be reused in other tests. NOTE: A duplicate sample set is recommended in case of retesting at a later date (following recalibration or modification due to a failed STS).
Test procedure (in brief)	Three P_{MB} measurements on every sample are taken using each unit, at every test condition: i) Grain samples at the reference temperature, $T_{ref}^{(1)}$ ii) Grain samples cooled to $T_{ref} - \Delta T_{C,max}$ iii) Grain samples recovered to the reference temperature, $T_{ref}^{(2)}$ iv) Grain samples heated to $T_{ref} + \Delta T_{H,max}$ v) Grain samples recovered to the reference temperature, $T_{ref}^{(3)}$ NOTE: The EUT is maintained at T_{ref} for the duration of the test
Test severity	Sample temperature: $T_{ref} \pm \Delta T_{max}$ where:

(sample and instrument temperatures)	ΔT: magnitude of the temperature difference between a sample and an instrument at T_{ref} ΔT_{max}: maximum ΔT specified by the national responsible body for type testing $\Delta T_{C,\,max}$: maximum permitted ΔT_{max} below T_{ref} (if unequal to $\Delta T_{H,\,max}$) $\Delta T_{H,\,max}$: maximum permitted ΔT_{max} above T_{ref} $T_{ref} + \Delta T_H < 45$ °C, however, the ΔT_H and ΔT_C need not be equal.
Suggested steps	1) The EUT is powered on and equilibrated at reference conditions with the grain samples. 2) Sample 1 of grain type 1 (GT1) is analysed, alternating between the units after each single measurement, until three P_{MB} measurements are recorded for each instrument. 3) Step 2 is repeated for the remainder of the sample set (i.e. other GT1 samples, followed by all GT2 samples, ending with GT4). 4) All the grain samples are placed in the environmental cabinet set at $T_{ref} - \Delta T_{C,max}$ and allowed equilibrate for at least four hours. 5) A cold GT1 sample 1 is removed from the cabinet and temperature is checked using a thermometer. The grain sample must be within ± 2 °C of the target temperature before analysing once on instrument 1. 6) GT1 sample 1 is returned to the cabinet. GT1 sample 2 is analysed once on instrument 2. NOTE: Each instrument is given 10 min to equilibrate to ambient conditions before the next sample is analysed. 7) In order to efficiently analyse all the samples, all the odd numbered samples are analysed on instrument 1 and all the even numbered samples on instrument 2 starting with GT1, followed by GT2, ending with GT4 (cycle 1). GT1 samples should be reconditioned to the target temperature by the time GT4 samples analyses are completed. NOTE: If there are less than four grain types, samples may require additional time to equilibrate in the cabinet to before further testing. Sample temperatures are checked before analysis. All the odd numbered samples are then analysed on instrument 2 and the even numbered samples on instrument 1 (cycle 2) to complete one measurement of the all the cold samples on both instruments. Cycle 1 and cycle 2 are repeated (twice) until three P_{MB} measurements on every cold sample are recorded for each instrument. 8) After all the cold analyses are performed, the grain samples are equilibrated (recovered) at reference conditions for at least four hours. 9) Steps 2 – 3 are repeated. 10) All the grain samples are placed in the environmental cabinet set at $T_{ref} + \Delta T_{H,max}$ and allowed to equilibrate for at least four hours. 11) All the hot grain samples are analysed using the same test sequence applied for the cold samples in step 7. 12) After three P_{MB} measurements on every hot sample are recorded for each instrument, the grain samples are equilibrated (recovered) at reference conditions for at least 4 hours. 13) Steps 2 – 3 are repeated.
Test result	For each instrument, values for the pooled error shift are calculated at the high and low moisture levels for every grain type by pooling the measured values from 3 samples. Two values of the pooled error shift are calculated at each level of moisture based on the following differences: $\Delta T_{C,max}$ pooled shift = Mean P_{MB} 3 cold samples – Mean P_{MB} 3 samples at $T_{ref}^{(1)}$ & $T_{ref}^{(2)}$ $\Delta T_{H,max}$ pooled shift = Mean P_{MB} 3 hot samples – Mean P_{MB} 3 samples at $T_{ref}^{(2)}$ & $T_{ref}^{(3)}$ Four values of pooled error shift are calculated for each grain type.
Acceptance requirements	All values for the pooled error shift shall be within the limit in clause 4.5 Table 1 column 6 (adjusted to the relevant M_B). All operational functions shall operate as designed.
Grain sample stability check	To ensure that thermal processing and recovery are not changing the P_{MB} of grain samples significantly, the P_{MB} variation in the grain samples, shall be within the limit in Table 1 column 7 (adjusted to the relevant M_B). Sample variation (1st recovery) = Mean P_{MB} sample at $T_{ref}^{(2)}$ – Mean P_{MB} sample at $T_{ref}^{(1)}$ Sample variation (2nd recovery) = Mean P_{MB} sample at $T_{ref}^{(3)}$ – Mean P_{MB} sample at $T_{ref}^{(2)}$

ANNEX D. SOFTWARE EXAMINATION

Further guidance is included in Part 3 *Examination checklist – software*

Refer to D 31 clause 6.3.2 for the specific items of interest associated with the following validations methods:
AD – Analysis of documentation and specification and validation of the design
VFTM – Validation by functional testing of the metrological functions
VFTSw – Validation by functional testing of the software functions

More intensive examinations such as code inspection and walkthrough (CIWT) and software module testing (SMT) are only required if the software-controlled instrument is used in an open network.

D 11	Requirement	Validation procedure A (normal examination level)	Validation procedure B (extended examination level)	Comment
5.1.1	Software identification	AD + VFTSw	AD + VFTSw + CIWT	Select "B" if high conformity is required
5.1.2	Correctness of algorithms and functions	AD + VFTM	AD + VFTM + CIWT/SMT	
Software protection				
5.1.3.1	Prevention misuse	AD + VFTSw	AD + VFTSw	
5.1.3.2	Fraud protection	AD + VFTSw	AD + VFTSw + DFA/CIWT/SMT	Select "B" in case of high risk of fraud
Support of hardware features				
5.1.4.1	Support of fault detection	AD + VFTSw	AD + VFTSw + CIWT + SMT	Select "B" if high reliability is required
5.1.4.2	Support of durability protection	AD + VFTSw	AD + VFTSw + CIWT + SMT	Select "B" if high reliability is required
Specifying and separating relevant parts and specifying interfaces of parts				
5.2.1.1	Separation of electronic devices and sub-assemblies	AD	AD	
5.2.1.2	Separation of software parts	AD	AD + DFA/CIWT	
5.2.2	Shared indications	AD + VFTM/ VFTSw	AD + VFTM/ VFTSw + DFA/CIWT	
5.2.3	Storage of data, transmission via communication systems	AD + VFTSw	AD + VFTSw + CIWT/SMT	Select "B" if transmission of measurement data in open system is foreseen
5.2.3.1	The measurement value stored or transmitted shall be accompanied by all relevant information necessary for future legally relevant use	AD + VFTSw	AD + VFTSw + CIWT/SMT	Select "B" in case of high risk of fraud
5.2.3.2	The data shall be protected by software means to guarantee authenticity, integrity and, if necessary correctness of the information of the time of measurement	AD + VFTSw	/	
5.2.3.3	For a high protection level it is necessary to apply cryptographic methods	/	AD + VFTSw + SMT	
5.2.3.4	Automatic storing	AD + VFTSw	AD + VFTSw + SMT	
5.2.3.5	Transmission delay	AD + VFTSw	AD + VFTSw + SMT	Select "B" in case of high risk of fraud, e.g. transmission in open systems
5.2.3.6	Transmission interruption	AD + VFTSw	AD + VFTSw + SMT	Select "B" in case of high risk of fraud, e.g. transmission in open systems
5.2.3.7	Time stamp	AD + VFTSw	AD + VFTSw + SMT	
5.2.4	Compatibility of operating systems and hardware, portability	AD + VFTSw	AD + VFTSw + SMT	
Maintenance and re-configuration				
5.2.6.2	Verified Update	AD	AD	
5.2.6.3	Traced Update	AD + VFTSw	AD + VFTSw + CIWT/SMT	Select "B" in case of high risk of fraud

ANNEX E. BIBLIOGRAPHY

1	ISO/IEC Guide 99; OIML V 2-200 (2007) International Vocabulary of Metrology – Basic and General Concepts and Associated Terms (VIM: 2007)	An international agreement on terminology, prepared as a collaborative work of experts appointed by BIPM, IEC, IFCC, ISO, IUPAC, IUPAP and OIML. This vocabulary covers subjects relating to measurement and includes information on the determination of physical constants and other fundamental properties of materials and substances. In practice, these publications are usually referred to as the "VIM".
2	OIML V1 (2000) International Vocabulary of Terms in Legal Metrology (VIML)	No abstract available
3	OIML D 18 (2008) The use of certified reference materials in fields covered by metrological control exercised by national services of legal metrology. Basic principles	No abstract available
4	OIML D 11 (2004) General requirements for electronic measuring instruments	The primary aim of this International Document is to provide OIML Technical Committees and Subcommittees with guidance for establishing appropriate metrological performance testing requirements for influence quantities that may affect the measuring instruments covered by International Recommendations.
5	OIML D 31 (2008) General requirements for software controlled measuring instruments	Specifies the general requirements applicable to software related functionality in measuring instruments and gives guidance for verifying the compliance of an instrument with these requirements.
6	ISO 13690 (1999) Cereals, pulses and milled products - Sampling of static batches	
7	OIML D 2 (2007) Legal units of measurement	No abstract available
8	OIML D 20 Initial and subsequent verification of instruments and processes	No abstract available
9	OIML D 9 Principles of metrological supervision	No abstract available
10	ISO/TS 16634-2 Food products – Determination of the total nitrogen content by combustion according to the Dumas principle and calculation of the crude protein content	
11	EN ISO 5983-2. Animal feeding stuffs — Determination of nitrogen content and calculation of crude protein content — Part 2: Block digestion/steam distillation method	
12	ISO Guide 34 (2006). General and statistical principles for certification	ISO Guide 35:2006 gives statistical principles to assist in the understanding and development of valid methods to assign values to properties of a reference material, including the evaluation of their associated uncertainty, and establish their metrological traceability. Reference materials (RMs) that undergo all steps described in ISO Guide 35:2006 are usually accompanied by a certificate and called a certified reference material (CRM). This Guide will be useful in establishing the full potential of CRMs as aids to ensure the comparability, accuracy and compatibility of measurement results on a national or international scale. In order to be comparable across borders and over time, measurements need be traceable to appropriate and stated references. CRMs play a key role in implementing the concept of traceability of measurement results in chemistry, biology and physics among other sciences dealing with materials and/or samples. Laboratories use these CRMs as readily accessible measurement standards to establish traceability of their measurement results to international standards. The property values carried by a CRM can be made traceable to SI units or other internationally agreed units during production. ISO Guide 35:2006

		explains how methods can be developed that will lead to well established property values, which are made traceable to appropriate stated references. It covers a very wide range of materials (matrices), ranging from gas mixtures to biological materials, and a very wide range of properties, ranging from chemical composition to physical and immunoassay properties.
13	IEC 60068-2-1 (1990-05) with amendments 1 (1993-02) and 2 (1994-06) Environmental testing, Part2: Tests, Test A: Cold	Concerns cold tests on both non-heat-dissipating and heat dissipating specimens
14	IEC 60068-3-1 (1974-01) + Supplement A (1978-01) Environmental testing Part 3 Background information, Section 1: Cold and dry heat tests	Gives background information for Tests A: Cold (IEC 68-2- 1), and Tests B: Dry heat (IEC 68-2-2). Includes appendices on the effect of: chamber size on the surface temperature of a specimen when no forced air circulation is used; airflow on chamber conditions and on surface temperatures of test specimens; wire termination dimensions and material on surface temperature of a component; measurements of temperature, air velocity and emission coefficient. Supplement A gives additional information for cases where temperature stability is not achieved during the test.
15	IEC 60068-2-2 (1974-01), with amendments 1 (1993-02) and 2 (1994-05) Environmental testing Part2: Tests. Test B: Dry heat	Contains Test Ba: Dry heat for non-heat-dissipating specimen with sudden change of temperature; Test Bb: Dry heat for non-heat-dissipating specimen with gradual change of temperature; Test Bc: Dry heat for heat-dissipating specimen with sudden change of temperature; Test Bd: Dry heat for heat-dissipating specimen with gradual change of temperature. The 1987 reprint includes IEC No. 62-2-2A
16	IEC 60068-2-78 (2001-08) Environmental testing - Part 2-78: Tests -Test Cab: Damp heat, steady state (IEC 60068-2-78 replaces the following withdrawn standards: IEC 60068-2-3, test Ca and IEC 60068-2-56, test Cb)	Provides a test method for determining the suitability of electrotechnical products, components or equipment for transportation, storage and use under conditions of high humidity. The test is primarily intended to permit the observation of the effect of high humidity at constant temperature without condensation on the specimen over a prescribed period. This test provides a number of preferred severities of high temperature, high humidity and test duration. The test can be applied to both heat-dissipating and non-heat dissipating specimens. The test is applicable to small equipment or components as well as large equipment having complex interconnections with test equipment external to the chamber, requiring a set-up time which prevents the use of preheating and the maintenance of specified conditions during the installation period.
17	IEC 60068-3-4 (2001-08) Environmental testing - Part 3-4: Supporting documentation and guidance - Damp heat tests	Provides the necessary information to assist in preparing relevant specifications, such as standards for components or equipment, in order to select appropriate tests and test severities for specific products and, in some cases, specific types of application. The object of damp heat tests is to determine the ability of products to withstand the stresses occurring in a high relative humidity environment, with or without condensation, and with special regard to variations of electrical and mechanical characteristics. Damp heat tests may also be utilized to check the resistance of a specimen to some forms of corrosion attack.
18	IEC/TR 61000-2-1 (1990-05) Electromagnetic compatibility (EMC) Part 2: Environment Section 1: Description of the environment - Electromagnetic environment for low frequency conducted disturbances and signalling in public power supply systems	Has the status of a technical report, and gives information on the various types of disturbances that can be expected on public power supply systems. The following disturbance phenomena are considered: - harmonics - inter-harmonics - voltage fluctuations - voltage dips and short supply interruptions - voltage unbalance - mains signalling – power frequency variation - DC components
19	IEC 61000-4-1 (2000-04) Basic EMC Publication Electromagnetic compatibility (EMC) Part 4: Testing and measurement techniques Section 1: Overview of IEC 61000-4 series	Gives applicability assistance to the users and manufacturers of electrical and electronic equipment on EMC standards within the IEC 61000-4 series on testing and measurement techniques. Provides general recommendations concerning the choice of relevant tests
20	IEC 61000-4-11 (2004-03) Electromagnetic compatibility (EMC) - Part	Defines the immunity test methods and range of preferred test levels for electrical and electronic equipment connected to low-voltage power

	4-11: Testing and measuring techniques - Voltage dips, short interruptions and voltage variations immunity tests	supply networks for voltage dips, short interruptions, and voltage variations. This standard applies to electrical and electronic equipment having a rated input current not exceeding 16 A per phase, for connection to 50 Hz or 60 Hz AC networks. It does not apply to electrical and electronic equipment for connection to 400 Hz AC networks. Tests for these networks will be covered by future IEC standards. The object of this standard is to establish a common reference for evaluating the immunity of electrical and electronic equipment when subjected to voltage dips, short interruptions and voltage variations. It has the status of a Basic EMC Publication in accordance with IEC Guide 107.
21	IEC 61000-6-1 (1997-07) Electromagnetic compatibility (EMC) - Part 6: Generic standards - Section 1: Immunity for residential, commercial and light-industrial environments	Defines the immunity test requirements in relation to continuous and transient, conducted and radiated disturbances, including electrostatic discharges, for electrical and electronic apparatus intended for use in residential, commercial and light-industrial environment, and for which no dedicated product or product-family standard exists. Immunity requirements in the frequency range 0 kHz to 400 GHz are covered and are specified for each port considered. This standard applies to apparatus intended to be directly connected to a low-voltage public mains network or connected to a dedicated DC source which is intended to interface between the apparatus and the low-voltage public mains network.
22	IEC 61000-6-2 (1999-01) Electromagnetic compatibility (EMC) - Part 6-2: Generic standards – Immunity for industrial environments	Applies to electrical and electronic apparatus intended for use in industrial environments, for which no dedicated product or product-family immunity standard exists. Immunity requirements in the frequency range 0 Hz to 400 GHz are covered, in relation to continuous and transient, conducted and radiated disturbances, including electrostatic discharges. Test requirements are specified for each port considered. Apparatus intended to be used in industrial locations are characterized by the existence of one or more of the following: – a power network exists powered by a high or medium voltage power transformer dedicated for the supply of an installation feeding a manufacturing or similar plant; industrial, scientific and medical (ISM) apparatus; heavy inductive or capacitive loads are frequently switched; and currents and associated magnetic fields are high.
23	IEC 61000-4-4 (2004-07) Electromagnetic compatibility (EMC) Part 4-4: Testing and measurement techniques - Electrical fast transient/burst immunity test	Establishes a common and reproducible reference for evaluating the immunity of electrical and electronic equipment when subjected to electrical fast transient/burst on supply, signal, control and earth ports. The test method documented in this part of IEC 61000-4 describes a consistent method to assess the immunity of an equipment or system against a defined phenomenon. The standard defines:test voltage waveform; range of test levels; test equipment; verification procedures of test equipment; test set-up; and test procedure.The standard gives specifications for laboratory and post-installation tests.
24	IEC 61000-4-3 consolidated Edition 2.1 (2002-09) with amendment 1 (2002-08) Electromagnetic compatibility (EMC) Part 4: Testing and measurement Techniques Section 3: Radiated, radio-frequency, electromagnetic field immunity test	Applies to the immunity of electrical and electronic equipment to radiated electromagnetic energy. Establishes test levels and the required test procedures. Establishes a common reference for evaluating the performance of electrical and electronic equipment when subjected to radio-frequency electromagnetic fields.
25	IEC 61000-4-6 (2003-05) with amendment 1 (2004-10) Electromagnetic compatibility (EMC) Part 4: Testing and measurement techniques Section 6: Immunity to conducted disturbances, induced by radio-frequency fields	Relates to the conducted immunity requirements of electrical and electronic equipment to electromagnetic disturbances coming from intended radio-frequency (RF) transmitters in the frequency range 9 kHz up to 80 MHz. Equipment not having at least one conducting cable (such as mains supply, signal line or earth connection), which can couple the equipment to the disturbing RF fields is excluded. This standard does not intend to specify the tests to be applied to particular apparatus or systems. Its main aim is to give a general basic reference to all concerned product committees of the IEC. The product committees (or users and manufacturers of equipment) remain responsible for the appropriate choice of the test and the severity level to be applied to their equipment.

26 IEC 61000-4-2 (1995-01) with amendment 1 (1998-01) and amendment 2 (2000-11) Basic EMC Publication Electromagnetic compatibility (EMC) Part 4: Testing and measurement techniques Section 2: Electrostatic discharge immunity test. Consolidated Edition: IEC 61000-4-2 (2001-04) Ed. 1.2	This publication is based on IEC 60801-2 (second edition: 1991). It relates to the immunity requirements and test methods for electrical and electronic equipment subjected to static electricity discharges, from operators directly, and to adjacent objects. It additionally defines ranges of test levels which relate to different environmental and installation conditions and establishes test procedures. The object of this standard is to establish a common and reproducible basis for evaluating the performance of electrical and electronic equipment when subjected to electrostatic discharges. In addition, it includes electrostatic discharges which may occur from personnel to objects near vital equipment
27 IEC 60068-2-31 (1969-01) with amendment 1 (1982-01) Environmental testing Part 2: Tests Test Ec: Drop and topple, primarily for equipment-type specimens	Determines the effect on a specimen of simple standard treatments which are representative of the knocks and jolts likely to occur during repair work or rough handling on a table or bench. Has the status of a basic safety publication in accordance with IEC Guide 104.
28 WELMEC Guide 7.2, March 2012 Issue 5 Software Guide (Measuring Instruments Directive 2004/22/EC)	This document provides guidance to all those concerned with the application of the Measuring Instruments Directive (European Directive 2004/22/EC; MID), especially for software-equipped measuring instruments. It addresses both manufacturers of measuring instruments and notified bodies which are responsible for conformity assessment of MID instruments. By following the Guide, compliance with the software related requirements contained in the MID can be assumed.

ANNEX F. GENERAL METROLOGY & LEGAL METROLOGY TERMS (INFORMATIVE)

F.1 VIM definitions

F.1.1 accuracy; measurement accuracy [2.13]

Closeness of agreement between a measured quantity value and a true quantity value of the measurand.
VIM NOTES
1 The concept of 'measurement accuracy' is not a quantity and is not given a numerical quantity value. A measurement is said to be more accurate when it offers a smaller measurement error.
2 The term "measurement accuracy" should not be used to measurement trueness and the term measurement precision should not be used for "measurement accuracy", which, however, is related to both concepts.
3 'Measurement accuracy' is sometimes understood as closeness of agreement between measured quantity values that are being attributed to the measurand.

F.1.2 adjustment [further information in VIM 3.11]

Set of operations carried out on a measuring system so that it provides prescribed indications corresponding to given values of a quantity to be measured.

F.1.3 certified reference material; CRM [further information in VIM 5.14 and OIML D 18]

Reference material, accompanied by documentation issued by an authoritative body and providing one or more specified property values with associated uncertainties and traceabilities, using valid procedures.

F.1.4 maximum permissible error (MPE); limit of error [further information in VIM 4.26]

Extreme value of measurement error, with respect to a known reference quantity value, permitted by specifications or regulations for a given measurement, measuring instrument, or measuring system.

F.1.5 measurement error; error [further information in VIM 2.16]

Measured quantity value minus a reference quantity value.

9.5.4 measured quantity value; measured value [further information in VIM 2.10]

Quantity value representing a measurement result.

F.1.6 rated operating condition [4.9]

Operating condition that must be fulfilled during measurement in order that a measuring instrument or measuring system performs as designed.
VIM NOTE: Rated operating conditions generally specify intervals of values for a quantity being measured and for any influence quantity.

F.1.7 reference condition [4.11]

Operating condition prescribed for evaluating the performance of a measuring instrument or measuring system or for comparison of measurement results
NOTES
1 Reference conditions specify intervals of values of the measurance and influence quantities.
2 In IEC 60050-300, item 311-06-02, the term "reference condition" refers to an operating condition under which the specified instrumental measurement uncertainty is the smallest possible.

F.1.8 reference material; RM [further information in VIM 5.13]

Material, sufficiently homogeneous and stable with reference to specified properties, which has been established to be fit for its intended use in measurement or in examination of nominal properties.

F.1.9 reference quantity value; reference value [further information in VIM 5.18]

Quantity value used as a basis for comparison with values of quantities of the same kind.

F.1.10 repeatability; measurement repeatability [2.21]

Property of a measuring system to provide closely similar indications for replicated measurements of the same quantity under repeatability conditions. Repeatability may be expressed quantitively in terms of the dispersion parameters of the indications of the measuring sytem.

F.1.11 repeatability condition of measurement [2.20]

Condition of measurement in a set of conditions including the same measurement procedure, same operator, same measuring system, same operating conditions, same location and replicate measurements over a short period of time.

F.1.12 reproducibility; measurement reproducibility [2.25]

Measurement precision under reproducibility conditions of measurement. Relevant statistical terms are given in ISO 5725-1:1994 and ISO 5725-2:1994.

F.1.13 reproducibility conditions of measurement [2.24]

Condition of measurement, out of a set of conditions that includes different locations, operators, measuring systems, and replicate measurements on the same or similar objects.
VIM NOTES
1 The different measuring systems may use different measurement procedures.
2 A specification should give the conditions changed and unchanged to the extent practical.

F.2 VILM2 3CD definitions

F.2.1 type (pattern) evaluation [2.05]

Conformity assessment procedure on one or more specimens of an identified type (pattern) of measuring instruments which results in an evaluation report and/or an evaluation certificate.

F.2.2 type approval [2.06]

Decision of legal relevance, based on the review of the type evaluation report, that the type of a measuring instrument complies with the relevant statutory requirements and results in the issuance of the type approval certificate.
NOTE: In ISO/IEC 17000:2004 which defines terms relating to conformity assessment, *approval* is defined as: permission for a product or process to be marketed or used for stated purposes or under stated conditions.

F.2.3 verification of a measuring instrument [2.10]

Conformity assessment procedure (other than type evaluation) which results in the affixing of a verification mark and/or issuing of a verification certificate.
NOTE: Further information can be found in VIM 2.44 which defines *verification* generally as: provision of objective evidence that a given item fulfils specified requirements.

PART 3: TEST REPORT FORMAT FOR TYPE EVALUATION

INTRODUCTION

This Report Format applies for any kind of protein measuring instrument for grain (independent of its technology). It presents a standardized format for the results of the various tests and examinations, described in Part 2 clause 7 of OIML R xxx (201x), to which a type of protein measuring instrument for grain shall be submitted with a view to its approval based this OIML Recommendation.

It is recommended that all metrology services or laboratories evaluating and/or testing types of protein measuring instrument for grain according to OIML R xxx (201x), or to national or regional regulations based on that Recommendation, use this Report Format, directly or after translation into a language other than English or French. In case of a translation, it is highly recommended to leave the structure and the numbers of the clauses unchanged: in this case most of the contents are also understandable for those who can not read the language of the translation.

It is also recommended that this Report Format in English or in French (or in both languages) be transmitted by the country performing the tests to the relevant authorities of another country, when requested for issuing a national or regional type-approval.

In the practical application of the Report Format, a cover page shall be included by the Issuing Authority, and clauses XXX- XXX (as necessary) shall be included as a minimum.

APPLICABILITY OF THIS TEST REPORT FORMAT

In the framework of the *OIML Certificate System for Measuring Instruments*, and the OIML *Mutual Acceptance Arrangement* (MAA) applicable to protein measuring instrument for grain in conformity with OIML R xxx (201x), use of this report format is mandatory, in French and/or in English with translation into the national languages of the countries issuing such certificates, if appropriate.

Implementation of this Report Format is informative with regard to the implementation of OIML Recommendation OIML R xxx (201x) in national regulations.

GUIDANCE FOR THE APPLICATION OF THIS TEST REPORT FORMAT

Refer to Part 1 clause 2 of of OIML R xxx (201x) for definitions of terms, acronyms and symbols used.

The name(s) or symbol(s) of the unit(s) used to express test results shall be specified in each form.

For each test, the "SUMMARY OF TYPE EVALUATION" and the "TYPE EVALUATION CHECKLIST" shall be completed according to this example:

	PASSED	FAILED	Remarks
when the instrument has passed the test or inspection:	X		
when the instrument has failed the test or inspection:		X	
when the test or inspection is not applicable:			NA

NOTE: In the example (Excel) test reports for the climatic tests and calibration assessment, the examiner shall indicate Y (yes) / N (no) / NA (not applicable) under the field for RESULT by selecting the applicable option in the drop down list.

The white spaces in the headings of the report should always be filled in according to the following example:

	At start	At end	
Temp:	20.1	20.3	ºC
RH:			%
Date:			yy:mm:dd
Time:			hh:mm:ss

Where:
Temp: temperature
RH: relative humidity
Date / time the date and time that the test is performed

In case a prescribed test is not relevant for the type of instrument to be tested, the reason why the test is omitted shall be clearly stated in the field "Remarks" or "Comments"

The number of the report and the page numbers shall be completed in the heading.

THE EVALUATION REPORT

The format for the report is given on the following pages

Cover page by the issuing authority

CONTENTS OF THE REPORT

1 AUTHORITY, RESPONSIBLE FOR THIS REPORT

Name	
Address	
Report number	
Application number	
Period of tests	
Date of issuing this Report	
Name and signature of the responsible person	
Stamp(s) (if applicable)	

2 SYNOPSIS OF THE RESULTS OF THE EXAMINATION AND TESTS

The tested specimen fulfils ALL the applicable requirements in OIML R XXX (201x)
☐ Yes ☐ No
Remarks:

3 SUMMARY OF THE RESULTS OF THE EXAMINATION AND TESTS

3.1 Examinations

R xxx Part 1	Metrological and technical and software requirements	PASSED	FAILED	Location of details in Report
3	Units of measurement	☐	☐	
4	Metrological requirements			
4.1	Applicable grains and protein content (PMB) measuring ranges – specification	☐	☐	
4.2	Instrument environmental operating temperature – specification	☐	☐	
4.3	Grain sample operating temperature – specification	☐	☐	
4.4	Influence quantities – specification	☐	☐	
4.5	Maximum permissible error (MPE) and other accuracy requirements	☐	☐	
4.7	Requirements for calibrations	☐	☐	Refer to clause 3.2
4.8	Error due to variations in influence quantities	☐	☐	
4.9	Error due to changes in the instrument over time	☐	☐	
5	Technical requirements			
5.1	Checking facilities	☐	☐	
5.2	Manufacturer's manual	☐	☐	
5.3	Markings	☐	☐	
5.4	Sample input and calibration selection	☐	☐	
5.5	Instrument construction	☐	☐	
5.6	Level indicating means	☐	☐	
5.7	Presentation of the measured value	☐	☐	
5.8	Durable recording of measured values	☐	☐	
6	Requirements for software-controlled devices and security			
6.1	Specification of software requirements	☐	☐	
6.2	Electronic data storage	☐	☐	
6.3	Software documentation	☐	☐	
6.4	Provision for software and calibration security	☐	☐	

3.2 Type evaluation tests

R xxx Part 2	Type approval tests	PASSED	FAILED	Location of details in Report
C.4	Tests for time related effects			
C.4.1	Instrument warm-up time	☐	☐	
C.4.2	Instrument drift and instability	☐	☐	
C.5	Tests for influence variations within the rated operating conditions			
C.5.1	Instrument levelling	☐	☐	
C.5.2	Cold	☐	☐	
C.5.3]	Dry heat	☐	☐	
C.5.4	Damp heat	☐	☐	
C.5.5	AC mains voltage variation	☐	☐	
C.6	Tests for disturbances			
C.6.1	AC mains voltage dips, short interruptions and voltage variations	☐	☐	
C.6.2	Bursts (transients) on AC mains	☐	☐	
C.6.3	Radiated radiofrequency, electromagnetic susceptibility	☐	☐	
C.6.4	Conducted radio-frequency fields	☐	☐	
C.6.5	Electrostatic discharges	☐	☐	
C.6.6	Mechanical shock	☐	☐	
C.6.7	Storage temperature (extreme shipping conditions)	☐	☐	
C.7	Assessment of calibrations in the submitted type			
C.7.1	Accuracy and precision at reference conditions	☐	☐	
C.7.2	Sample temperature sensitivity (STS)	☐	☐	

4 GENERAL INFORMATION ABOUT THE APPLICATION

4.1 Manufacturer

Company	
Address	

4.2 Applicant

Company		
Representative		
Address		
Reference		
Date of application		
Applicant authorized by the manufacturer (documented)	☐ Yes	☐ No
Statement that no concurrent application for OIML type evaluation has been made to any other OIML Issuing Authority (see OIML B 003, 3.1.2)	☐ Yes	☐ No

Remarks:

4.3 Information concerning the type

Information, indicated on the instrument	
Manufacturer's trade mark	
Year of manufacture	
Type designation	
Model number *(if applicable)*	
Serial number(s) of the sample(s)	
Type description of the main transducer	
Serial number of the measuring transducer	
etc	
Electrical power	
Identification of software	

Relevant external/internal photographs taken during the examination and tests:

Remarks:

4.4 Information on the submitted calibrations

Calibration principle:

Calibration #:	1	2	3	Etc.
Calibration name:				
Version number:				
Limitations of use e.g. -				
Applicable kind of grain:				
P_{MB} measuring range:				
P_{MB} indication range:				
Minimum and maximum moisture content of samples:				
$T_{C,sample}$ and $T_{H,sample}$: (see Rxxx clause 4.3.1)				
ΔT_{max} or $\Delta T_{C,max}$ and $\Delta T_{H,max}$: (see Rxxx clause 4.3.2)				
Regression information e.g. -				
Number of data points:				
Data sources and dates:				
Reference method(s):				
Validation results:				
Calibration equation info e.g. -				
Fixed parameters and values:				
Adjustable parameters and values (current and default):				
Other information:				

4.5 Accessories, supplied by the applicant

Battery (if applicable)	type	
	nominal voltage	
	number required	
Operating instructions		
Data printer (if applicable)		
Data storage		
Cables		
etc		
Other accessories:		

4.6 Additional information concerning the type

Additional remarks and/or information (connection equipment, interfaces, etc.):

4.7 Results of previous tests that were taken into account

Details:

4.8 Selection of sample instruments

Justification for samples used:

In case the tests and evaluation are valid for more versions, give full details of the types, versions, measuring ranges ,etc.:

4.9 Adjustments, modifications and repairs made to the samples during the testing:

4.10 Testing laboratories involved in the tests

(This table to be completed for each test laboratory)

Name			
Address			
Application number			
Tests by this laboratory			
Date/period of tests			
Name(s) of test engineer(s)			
Accredited by		Number:	Expires (date):
Accreditation includes R XXX	☐ Yes	Edition:	☐ No
Details of relevant peer assessment or assessment by other means			
In case tests have been performed on an other location than the premises of this laboratory, give details here			
Name of the responsible person			
Date of signature			
Stamp (if applicable) and signature of the responsible person			

Remarks:

5 INFORMATION CONCERNING THE TEST EQUIPMENT AND GRAIN TEST SAMPLES USED FOR THE TYPE EVALUATION

(including details of simulations and the way uncertainties are taken into account, including the level of "risk" like for instance 95% or k=2)

Information about the grain test samples (RMs) used in type evaluation

Reference method used to generate whole-grain CRMs

6 EXAMINATION DETAILS

6.1 Examination checklist – metrological and technical requirements

R xxx Part 1	Checks on the metrological and technical requirements (*) Clause contains requirements be addressed by the national responsible body.	PASSED	FAILED	Comments
3	**Units of measurement**			
3.1	The measurement of the protein content is expressed in percentage by mass (% w/w). The percentage symbol alone (%) is also permitted.	☐	☐	
3.2	For each kind of grain, the measured protein content is expressed at one basis moisture concentration or moisture basis (M_B). The protein content at the actual "as is" moisture content of the sample is scaled to the protein content at the moisture basis (P_{MB}) according to Equation 1.	☐	☐	
3.3*	The moisture basis (M_B) for expressing the protein content of each kind of grain on the type has been specified by the national responsible body. Examiner to append and/or reference the national specification.	☐	☐	
4	**Metrological requirements**			
4.1*	Applicable grains and protein content (PMB) measuring ranges – specification			
4.1.1*	The national responsible body has specified commercially important P_{MB} measurement ranges for the kinds of grain on which P_{MB} measurements are subject to national approval. Table 1 contains examples of grains that are commercially important in certain countries/regions. Examiner to append and/or reference the national specification for the P_{MB} measurement ranges on commercially important grains.	☐	☐	
4.1.2	The kinds of grain that can be analysed by the submitted type of instrument and the corresponding P_{MB} measuring range for each kind, has been declared by the manufacturer. The P_{MB} measuring range of the instrument encompasses the commercially important range specified by the national responsible body. Examiner to append and/or reference the manufacturer's specification.	☐	☐	
4.2*	Instrument environmental operating temperature – specification			
4.2.1*	The submitted type provides accurate P_{MB} measurements in all the environmental temperatures possible in the country/region, unless a limited operating range has been permitted by the national responsible body. Examiner to indicate whether a limited range for the environmental operating temperature is permitted. ☐ Yes ☐ No If the answer is 'No' the temperatures applied during type testing should include all the possible environmental temperatures in that particular country.	☐	☐	
4.2.2*	The following only applies if the answer to 4.2.1 is 'Yes'- The national responsible body has specified the range of ambient temperatures (T_C to T_H) in which the instrument can be used to take P_{MB} measurements for commercial purposes. The temperature range T_C to T_H includes 10 °C to 30 °C. Examiner to append the national specification or indicate the values for T_C and T_H.	☐	☐	T_C T_H
4.2.3*	The following only applies if the answer to 4.2.1 is 'Yes' and 4.2.2 is a 'Pass'- In cases where the manufacturer-specified environmental operating range is wider the T_C to T_H specified by the national responsible body, the manufacturer may request for the wider range to be adopted for their type evaluation. Examiner to indicate whether the manufacturer has specified a wider range than specified by the national responsible body. ☐ Yes ☐ No If the answer is 'Yes', indicate whether the manufacturer specification has been adopted as T_C to T_H for this particular type evaluation. ☐ Yes ☐ No If the previous answer is 'Yes', append the manufacturer specification and indicate the revised values for T_C to T_H.	☐	☐	Values for approval of this type: T_C T_H

R xxx Part 1	Checks on the metrological and technical requirements (*) Clause contains requirements be addressed by the national responsible body.	PASSED	FAILED	Comments
4.3*	Grain sample operating temperature – specification			
4.3.1	Specification of the sample temperature range			
4.3.1.1 *	The submitted type provides accurate P_{MB} measurements on samples that are between 2 ºC to 45 ºC in temperature, unless a limited operating range has been permitted by the national responsible body. Examiner to indicate whether a limited range for the grain sample temperature is permitted. ☐ Yes ☐ No If the answer is 'No' the temperature of grain samples during type testing should encompass the range 2 ºC to 40 ºC.	☐	☐	
4.3.1.2 *	The following only applies if the answer to 4.3.1.1 is 'Yes'- The national responsible body has specified the range of ambient temperatures ($T_{C,sample}$ to $T_{H,sample}$) in which the instrument can be used to take P_{MB} measurements for commercial purposes. The temperature range $T_{C,sample}$ to $T_{H,sample}$ includes 10 ºC to 30 ºC. Examiner to append national specification to report or indicate the values for $T_{C,sample}$ and $T_{H,sample}$ for each kind of grain.	☐	☐	$T_{C,sample}$ = $T_{H,sample}$ =
4.3.1.3 *	The following applies if the answer to 4.3.1.1 is 'Yes' and 4.3.1.2 is a 'Pass'- In cases where the manufacturer-specified sample operating range is wider the $T_{C,sample}$ to $T_{H,sample}$ specified by the national responsible body, the manufacturer may request for the wider range to be adopted for their type evaluation. Examiner to indicate whether the manufacturer has specified a wider range than specified by the national responsible body. ☐ Yes ☐ No If the answer is 'Yes', indicate whether the manufacturer specification has been adopted as $T_{C,sample}$ to $T_{H,sample}$ for this particular type evaluation. ☐ Yes ☐ No If the previous answer is 'Yes', append the manufacturer specification and indicate the revised values for $T_{C,sample}$ to $T_{H,sample}$ for each kind of grain.	☐	☐	Values for approval of this type: $T_{C,sample}$ = $T_{H,sample}$ =
4.3.2	Specification of the sample and instrument maximum temperature differential (ΔTmax)			
4.3.2.1 *	The instrument at reference temperature (T_{ref}), provides accurate P_{MB} measurements on samples within the range $T_{C,sample}$ to $T_{H,sample}$ regardless of the magnitude of the sample and instrument temperature differential (ΔT). This is not applicable if the national responsible body allows limitations on ΔT during operation. Examiner to indicate whether a maximum limit for ΔT (i.e. ΔT_{max}) is permitted. ☐ Yes ☐ No If the answer is 'No' the following values shall be applied during type testing: $\Delta T_{C,max} = T_{ref} - T_{C,sample}$ and $\Delta T_{H,max} = T_{H,sample} - T_{ref}$.	☐	☐	
4.3.2.3 *	The following only applies if the answer to 4.3.2.1 is 'Yes'- The national responsible body has specified a ΔT_{max} in which the instrument can be used to take P_{MB} measurements for commercial purposes. The value of ΔT_{max} (or $\Delta T_{C,max}$ and $\Delta T_{H,max}$, if unequal about T_{ref}) is at least 10 ºC. Examiner to append national specification to report or indicate the values for ΔT_{max} (or $\Delta T_{C,max}$ and $\Delta T_{H,max}$) for each kind of grain.	☐	☐	ΔT_{max} =
4.3.2.3 *	The following applies if the answer to 4.3.1.1 is 'Yes' and 4.3.1.2 is a 'Pass'- In cases where the manufacturer-specified maximum ΔT is larger than ΔT_{max} specified by the national responsible body, the manufacturer may request for the larger differential to be adopted for their type evaluation. Examiner to indicate whether the manufacturer has specified a larger maximum differential than ΔT_{max} specified by the national responsible body. ☐ Yes ☐ No If the answer is 'Yes', indicate whether the manufacturer specification has been adopted as ΔT_{max} for this particular type evaluation. ☐ Yes ☐ No If the previous answer is 'Yes', append the manufacturer specification and indicate the revised values for ΔT_{max} (or $\Delta T_{C,max}$ and $\Delta T_{H,max}$) for each kind of grain.	☐	☐	Value for approval of this type: ΔT_{max} =

R xxx Part 1	Checks on the metrological and technical requirements (*) Clause contains requirements be addressed by the national responsible body.	PASSED	FAILED	Comments
4.3.3*	Provisions in absence of a manufacturer-specified sample temperature range: Where a manufacturer is not able to declare a sample temperature range or a maximum allowable ΔT, the national responsible body has testing and/or operating procedures in place to ensure that accurate P_{MB} measurements are possible within the testing ranges specified for type evaluation (i.e. $T_{C,sample}$ to $T_{H,sample}$ and ΔT_{max}). Examiner to indicate whether the manufacturer has declared a sample operating range. ☐ Yes ☐ No If the answer is 'No' append and/or provide reference the relevant national testing and/or operating procedures.	☐	☐	
4.4*	Influence quantities – specification			
4.4.1*	Rated operating ranges for influence factors specified by the national responsible body conform to the international standard. Examiner to indicate reasons for deviations.	☐	☐	
4.4.2*	Disturbance tests for electronic instruments specified by the national responsible body conform to the international standard. Examiner to indicate reasons for deviations.	☐	☐	
4.5*	Maximum permissible error (MPE) and other accuracy requirements			
4.5.2*	Accuracy requirements for various kinds of grain – specification by the national responsible body for each kind of grain conform to the international standard. Examiner to indicate reasons for deviations.	☐	☐	
4.5.4*	Reference method - specification for P_{MB} measurements by the national responsible body is based on an international standard. Examiner to indicate reasons for deviations and to append and/or reference the test procedure.	☐	☐	
5	**Technical requirements**			
5.1	Checking facilities			
5.1.1	Suppression of *PMB* measured values in the event of a significant fault There is provision for the instrument to automatically prevent further measurement and clearly indicate if a significant fault has occurred by an appropriate error message, unambiguous warning or blanking the display.	☐	☐	
5.1.2	Suppression of *PMB* measured values outside of operating ranges The instrument automatically prevents further measurements and clearly indicates when a type-approved operating range is exceeded by an appropriate error message, unambiguous warning or blanking the display. Taking an accurate P_{MB} measurement does not rely on the operator to gauge of adjust the temperature of the sample.	☐	☐	
5.1.3	Instrument warm up period: No values are displayed until the required warm-up period has elapsed, otherwise the instrument produces accurate measurements immediately.	☐	☐	
5.2	Manufacturer's manual	☐	☐	
5.3	Markings			
5.3.1	General markings	☐	☐	
5.3.2	Location of markings	☐	☐	
5.4	Sample input and calibration selection			
5.4.1	Selection of calibration on the instrument			
5.4.1.1	On instruments with different calibrations, the user is able to select the calibration applicable for the sample to be analysed.	☐	☐	

R xxx Part 1	Checks on the metrological and technical requirements (*) Clause contains requirements be addressed by the national responsible body.	PASSED	FAILED	Comments
5.4.1.2	The selection of the calibration (grain type) on the user interface is unambiguous and visible to all parties present, i.e. during the measurement it can be verified that the selected (displayed) calibration corresponds with the sample analysed.	☐	☐	
5.4.2	Sampling and minimum sample size			
5.4.2.1	The instrument does not require the operator to judge the precise volume or weight required to make an accurate P_{MB} measurement.	☐	☐	
5.4.2.2	The size of the sample analysed is at least 100 g or 400 kernels or seeds which ever is smaller, except where the national responsible body indicates otherwise. Examiner to indicate whether sample smaller than the international recommendation are permitted. ☐ Yes ☐ No	☐	☐	
5.4.2.3	The national responsible has specified minimum guidelines for the sampling of bulk or packed cereals for testing and are based on international standards. Examiner to indicate reasons for deviations.	☐	☐	
5.5	Instrument construction			
5.5.1	Nothing observed in the design and construction of the grain protein measuring instruments and accessory equipment that will make it prone to inaccuracy, malfunction and fraud under normal service conditions.	☐	☐	
5.5.2	Day to day forces on the parts shall not affect the accuracy of the instrument.	☐	☐	
5.5.3	The housing protects the main components from dust and moisture.	☐	☐	
5.5.4	Where a grinding mill is required for operation of the instrument, the manufacturer has designated the type and submitted a mill withthe units to undergo type testing.	☐	☐	
5.6	Level indicating means			
5.6.1	The instrument is equipped with a level indicator and levelling adjustment facility if the accuracy of the instrument is affected by tilting up to 5%.	☐	☐	
5.6.2	The level indicating device is legible without disassembly of the instrument.	☐	☐	
5.7	Presentation of the measured value			
5.7.1	The instrument is equipped with a digital indicating element which shall not display any P_{MB} values until the end of a measurement cycle.	☐	☐	
5.7.2	P_{MB} values shall be displayed according to the unit of measurement (%). Sub-divisions is expressed in decimal form (not fractions).	☐	☐	
5.7.3	The display resolution for commercial transaction is 0.1% P_{MB}. The display on the units submitted for type testing allow for 0.01% P_{MB} resolution.	☐	☐	
5.7.4	The display on multi-constituent instruments have constituent labels so it is clear which constituent is associated with each measured value.	☐	☐	
5.7.5	The height of the displayed digits is at least 10 mm.	☐	☐	
5.8*	Durable recording of measured values			
5.8.1	Examiner to indicate whether instruments are required to be equipped with an internal element and/or communication that permits interfacing with an external recording element. ☐ Yes ☐ No If the answer is 'No", indicate 'NA' for the requirements below that do not apply.	☐	☐	
5.8.2	The recorded information corresponds with the displayed information.	☐	☐	

R xxx Part 1	Checks on the metrological and technical requirements (*) Clause contains requirements be addressed by the national responsible body.	PASSED	FAILED	Comments
5.8.3	The measurement records include all of the following: the measurement date and time, unique ID of the instrument, grain type (calibration used), calibration version identification, error messages, and constituent labels (on multi-constituent devices).	☐	☐	
5.8.4	No P_{MB} values are recorded before the end of a measurement cycle.	☐	☐	
5.8.5	Where data storage is required, the measurement data is stored automatically at the end of the measurement cycle.	☐	☐	
5.8.6	The storage device has sufficient permanency to ensure that data is not corrupted under normal storage conditions and there is sufficient memory for the application.	☐	☐	

6.2 Examination checklist – software

In addition, refer to Annex D for the appropriate validation method(s) for specific requirements.

R xxx Part 1	Checks on the requirements for software and security	PASSED	FAILED	Comment
6.2	Submitted software documentation is complete NOTE: To check validity of documentation systematically, refer to Welmec guide 7.2 [28]	☐	☐	
6.1.1	Manufacturer description/declaration of software implementation within the instrument of module.	☐	☐	
6.1.2	Software clearly identifiable via an unique software version and a checksum which can be displayed or printed out on command or is displayed during the start up procedure of the instrument.	☐	☐	
6.1.3	Measuring algorithms and functions are appropriate and functionally correct. NOTE: Conduct further examinations and tests if necessary	☐	☐	
6.1.4	Conformity of the legally relevant software to that in the approved type verified as level (b) as confirmed by the following: - the identity of parts of the legally relevant source code; and - for the rest of the legally relevant software, the identity of the legally relevant functions described in the documentation.	☐	☐	
6.1.5	The current settings for parameters that affect legally relevant characteristics can be displayed or printed on demand.	☐	☐	
6.1.6	Further measurements are not possible when a significant fault is detected.	☐	☐	
6.1.7	The requirements in D 31 clause 5.2.1.2 are fulfilled (if the software of the instrument is separated into legally relevant part and non-relevant parts)	☐	☐	
6.1.8	Cryptographic protection of data has been implemented, if there is high likelihood for the type to be used in an open network.	☐	☐	
6.1.9	The legally relevant software can only be operated in the environment specified for its correct functioning (for instruments/ measuring systems using an internal or external universal computer). NOTE: The operating system may be fixed to a defined invariant configuration.	☐	☐	
6.4.1	Appropriate sealing of the instrument making any change that affects the metrological characteristics impossible or evident. NOTE: Calibrations, zero-setting and test point adjustments must be sealed.	☐	☐	
6.4.1, 6.4.2	The software of an instrument is not modifiable or uploadable via any interface or by other means without breaking the seal.	☐	☐	
6.4.2	Only clearly documented functions are allowed to be activated by the user interface, that is realized in a way that it does not facilitate fraudulent use.	☐	☐	
6.4.2	Restrictions on device-specific parameters (if any) placed by the national responsible body have been observed.	☐	☐	
6.2.1	Software that displays or further processes the measurement values and accompanying data after having read them from the insecure (external) storage or after having received them from an insecure transmission channel shall check the time of measurement, authenticity and integrity of the data. If an irregularity is detected, the data shall not be used.	☐	☐	
6.2.2	The measurement shall not be influenced by a transmission delay. I	☐	☐	
6.2.3	If a transmission interruption occurs because the network services become unavailable, no measurement data shall be lost.	☐	☐	
9.5.2	The calibration constants that are adjustable and unique calibration names, or calibration version numbers can be displayed and printed on demand.	☐	☐	
9.5.3	The software has been implemented in the instrument in a manner that fulfils the requirements for Traced Updates in D 31 clause 5.2.6.2. (Applicable in countries where Traced Updates are permitted in place of Verified Updates.)	☐	☐	

7 REPORT FOR PERFORMANCE TESTS

7.1 Tests for time-related effects

7.1.1 Instrument warm-up time

Observer:	
Instrument 1 ID	
Instrument 2 ID	
Sample ID	

	At start	At end	
Temp:			ºC
RH:			%
Date & Time:			yy:mm:dd hh:mm:ss

Instrument	EUT P_{MB}				Results summary				
	After warm up		1 hour after being switched on or 2x the warm up time (whichever is greater)		Error shift	Min and max error shift Table 1 col 7	PASSED	FAILED	Remarks
	n_m per sample=5	mean	n_m per sample=5	mean					
1									
2									

Check if: Calculated error shift(s) are within the min and max limits All instrument functions operated as designed	☐ Passed ☐ Failed

7.1.2 Instrument drift and instability

Observer:	
Instrument 1 ID	
Instrument 2 ID	

Stage 1	At start	At end	
Temp:			ºC
RH:			%
Date & Time:			yy:mm:dd hh:mm:ss

Observer:	

Stage 2	At start	At end	
Temp:			ºC
RH:			%
Date & Time:			yy:mm:dd hh:mm:ss

Instrument	P_{MB} range	EUT P_{MB}				Results summary				
		Prior to influence and disturbance tests (Stage 1)		After test program (Stage 2)		Error shift	Min and max error shift Table 1 col 7	PASSED	FAILED	Remarks
		n_m per sample=5	mean	n_m per sample=5	mean					
1	Low									
	Med									
	High									
2	Low									
	Med									
	High									

Check if: Calculated error shift(s) are within the min and max limits All instrument functions operated as designed	☐ Passed ☐ Failed

7.2 Tests for influence factor variations within the rated operating ranges

7.2.1 Instrument levelling

			At start	At tilt	At end	
Observer:						
Instrument 1 ID		Temp:				ºC
Instrument 2 ID		RH:				%
Sample ID		Date & Time:				yy:mm:dd hh:mm:ss
Level indicator	Y / N	Degree of tilt*				º

*Without a level indicator, tilt to 5%. With a level indicator, tilt instrument to the limits of the indicator

Instrument	Orientation	EUT P_{MB}				Results summary				
		During tilt position		Returned to reference level		Error shift	Min and max error shift{ Table 1 col 7	PASSED	FAILED	Remarks
		n_m per sample=6	mean	n_m per sample=6	mean					
1	Reference level									
	Left or right tilt*									
	Front or back tilt*									
2	Reference level									
	Left or right tilt*									
	Front or back tilt*									

*Choose direction with the most influence

Check if: Calculated error shift(s) are within the min and max limits All instrument functions operated as designed	☐ Passed ☐ Failed

7.2.2 Cold

*For instruments where $\Delta T_{Cmax} < T_{ref} - T_C$, values in G41:G58 shall be left blank. Select NA in J19:J21.

			Starf ref	Cold	Recovery	
Observer:		EUT ambient temp:				°C
Type:		EUT ambient RH:				%
Instrument 1 ID:		Sample temp:				°C
Instrument 2 ID:		Spare ambient temp:				°C
Spare instrument ID:		Spare ambient RH:				%
		Date commenced:				ddmmyyyy
		Time commenced:				hh:mm

General comments on test settings:

Displayed name	Error shift limits		Sample info		Nominal values		P_{MB} variation (sample stability)		Correction required? (Y or N or NA)	
GT	Min	Max	number	ID	P_{MB}	moisture	Cold	Recovery	Cold	Recovery
			1							
			2							
			3							

Sample number	Instrument	Error shift		Corrected error shift		RESULTS SUMMARY (Pass/fail)		
		Cold	Recovery	Cold	Recovery	Comments	Instrument	Type
1	1							
2								
3								
1	2							
2								
3								

Cold [OIML Rxxx-2, clause C.5.2.1] - continued - calculations and raw data entry

Sample number	Mean P_{MB} (Start - ref)			Mean P_{MB} (Cold EUT + grain)			Mean P_{MB} (Recovery)		
	Instr. 1	Instr. 2	Spare-ref	Instr. 1	Instr. 2	*Spare-ref	Instr. 1	Instr. 2	Spare-ref
1									
2									
3									

Sample number	P_{MB} (Start - ref)			P_{MB} (Cold EUT + grain)			P_{MB} (Recovery)		
	Instr. 1	Instr. 2	Spare-ref	Instr. 1	Instr. 2	*Spare-ref	Instr. 1	Instr. 2	Spare-ref
1									
2									
3									
Comments									

7.2.3 Dry Heat

*For instruments where $\Delta T_{Hmax} < T_{ref} - T_H$ values in G41:G58 shall be left blank. Select NA in J19:J21.

			Starf ref	Dry heat	Recovery	
Observer:		EUT ambient temp:				°C
Type:		EUT ambient RH:				%
Instrument 1 ID:		Sample temp:				°C
Instrument 2 ID:		Spare ambient temp:				°C
Spare instrument ID:		Spare ambient RH:				%
		Date commenced:				ddmmyyyy
		Time commenced:				hh:mm

General comments on test settings:

Displayed name	Error shift limits		Sample info		Nominal values		P_{MB} variation (sample stability)		Correction required? (Y or N or NA)	
GT	Min	Max	number	ID	P_{MB}	moisture	Dry heat	Recovery	Dry heat	Recovery
			1							
			2							
			3							

Sample number	Instrument	Error shift		Corrected error shift		RESULTS SUMMARY (Pass/fail)		
		Dry heat	Recovery	Dry heat	Recovery	Comments	Instrument	Type
1	1							
2								
3								
1	2							
2								
3								

Dry heat [OIML Rxxx-2, clause C.5.3.1] - continued - calculations and raw data entry

Sample number	Mean P_{MB} (Start - ref)			Mean P_{MB} (DryH EUT + grain)			Mean P_{MB} (Recovery)		
	Instr. 1	Instr. 2	Spare-ref	Instr. 1	Instr. 2	*Spare-ref	Instr. 1	Instr. 2	Spare-ref
1									
2									
3									

Sample number	P_{MB} (Start - ref)			P_{MB} (DryH EUT + grain)			P_{MB} (Recovery)		
	Instr. 1	Instr. 2	Spare-ref	Instr. 1	Instr. 2	*Spare-ref	Instr. 1	Instr. 2	Spare-ref
1									
2									
3									
Comments									

7.2.4 Damp heat steady state

*For instruments where $\Delta T_{Hmax} < T_{ref} - T_H$, values in G41:G58 shall be left blank. Select NA in J19:J21.

		Starf ref	Damp H	Recovery	
Observer:					
Type:	EUT ambient temp:				°C
Instrument 1 ID:	EUT ambient RH:				%
Instrument 2 ID:	Sample temp:				°C
Spare instrument ID:	Spare ambient temp:				°C
	Spare ambient RH:				%
	Date commenced:				ddmmyyyy
	Time commenced:				hh:mm

General comments on test settings:

Displayed name	Error shift limits		Sample info		Nominal values		P_{MB} variation (sample stability)		Correction required? (Y or N or NA)	
GT	Min	Max	number	ID	P_{MB}	moisture	Damp H	Recovery	Damp H	Recovery
			1							
			2							
			3							

Sample number	Instrument	Error shift		Corrected error shift		RESULTS SUMMARY (Pass/fail)		
		Damp H	Recovery	Damp H	Recovery	Comments	Instrument	Type
1	1							
2								
3								
1	2							
2								
3								

Damp heat [OIML Rxxx-2, clause C.5.4.1] - continued - calculations and raw data entry

Sample number	Mean P_{MB} (Start - ref)			Mean P_{MB} (DampH EUT + grain)			Mean P_{MB} (Recovery)		
	Instr. 1	Instr. 2	Spare-ref	Instr. 1	Instr. 2	*Spare-ref	Instr. 1	Instr. 2	Spare-ref
1									
2									
3									

Sample number	P_{MB} (Start - ref)			P_{MB} (DampH EUT + grain)			P_{MB} (Recovery)		
	Instr. 1	Instr. 2	Spare-ref	Instr. 1	Instr. 2	*Spare-ref	Instr. 1	Instr. 2	Spare-ref
1									
2									
3									
Comments									

7.2.5 Mains voltage variations

Observer:	
Instrument 1 ID	
Instrument 2 ID	
Sample ID	

	Influence				
	At start U_{nom}	U_{nom} +10%	U_{nom} -15%	At end U_{nom}	
Temp:					ºC
RH:					%
Date & Time:					yy:mm:dd hh:mm:ss
Test voltage					V
Test frequency					Hz

Note other details about the influence settings here:

Instrument 1 P_{MB}								Results summary						
Prior test		Over V U_{nom}+10%		Under V U_{nom}-15%		Recovery		Error shift			Min and max error shift Table 1 col 7	PASSED	FAILED	Remarks
n_m=10	mean	n_m=10	mean	n_m=10	mean	n_m=10	mean	over V	under V	recovery				

Instrument 2 P_{MB}								Results summary						
Prior test		Over V U_{nom}+10%		Under V U_{nom}-15%		Recovery		Error shift			Min and max error shift Table 1 col 7	PASSED	FAILED	Remarks
n_m=10	mean	n_m=10	mean	n_m=10	mean	n_m=10	mean	over V	under V	recovery				

Check if: SD ≤ 0.10% Calculated error shift(s) are within the min and max limits All instrument functions operated as designed	☐ Passed ☐ Failed

7.3 Tests for disturbances

7.3.1 AC mains voltage dips and short interruptions

Observer:	
Instrument 1 ID	
Instrument 2 ID	
Sample ID	

	At start	At end	
Temp:			ºC
RH:			%
Date & Time:			yy:mm:dd hh:mm:ss

	n_m =10		mean
Reference P_{MB} No disturbance			
Maximum limit on fault (refer to Table 1 column 8):			

Note other details about the disturbance settings (voltage cycling) here:

Settings				Results				
Test	Voltage reduction		Duration (cycles)	Instr. 1 P_{MB} n_m=10	Fault	Fault < Max fault	Sig fault detected & acted upon	Remarks
	new V	% reduction						
a	0	100	0.5					
b	0	100	1					
c		70	25 / 30					
d	0	100	250 / 300					

Repeat the tests using instrument 2

Check acceptance requirements	☐ Passed	☐ Failed

7.3.2 Electrical Bursts

Observer:	
Instrument ID	
Sample ID	

	At start	At end	
Temp:			ºC
RH:			%
Date & Time:			yy:mm:dd hh:mm:ss

L = phase, N = neutral,
PE = protective earth, G = ground

Maximum limit on fault (refer to Table 1 column 8):	

Note other details about the disturbance settings here:

Settings		Instrument 1 P_{MB}			Results summary			
Connection	Test V (kV) & Polarity	Prior to disturbance (reference)		Test	Fault	Fault < Max fault	Sig fault detected & acted upon	Remarks
		n_m=10	mean	n_m=10				
L ↓ G	+1							
	-1							
N ↓ G	+1							
	-1							
PE ↓ G	+1							
	-1							

Repeat the test using instrument 2

Check acceptance requirements	☐ Passed	☐ Failed

7.3.3 Radiated, radio-frequency, electromagnetic fields

Observer:	
Instrument 1 ID	
Instrument 2 ID	
Sample ID	

	At start	At end	
Temp:			°C
RH:			%
Date & Time:			yy:mm:dd hh:mm:ss

Note: V = vertical, H = horizontal

Note other details about the disturbance settings here:

Maximum limit on fault (refer to Table 1 column 8):	

Settings		P_{MB} prior disturbance (reference)	Test		Results summary				
EUT side	Antenna polarisation	n_m=10	Frequency (MHz)	EUT P_{MB}	Fault	Fault < Max fault	Sig fault detected & acted upon	Remarks
Front	V	mean	26					
			2000					
	H	n_m=10	26 2000					
Left	V	n_m=10	26 2000					
	H	n_m=10	26 2000					
Right	V	n_m=10	26 2000					
	H	n_m=10	26 2000					
Rear	V		26 2000					
	H		26 2000					

Repeat the test using instrument 2

Check acceptance requirements	☐ Passed	☐ Failed

7.3.4 Conducted, radio-frequency fields

Observer:	
Instrument ID	
Sample ID	

	At start	At end	
Temp:			ºC
RH:			%
Date & Time:			yy:mm:dd hh:mm:ss

Note other details about the disturbance settings here:

Maximum limit on fault (refer to Table 1 column 8):	

Settings	P_{MB} prior disturbance (reference)	Test		Results summary			
Name of cable or interface	n_m=10	Frequency (MHz)	Instr. 1 P_{MB}	Fault	Fault < Max fault	Sig fault detected & acted upon	Remarks
		0.15					
	mean						
		80*					
		0.15					
	mean						
		80*					
	n_m=10	0.15 80*					
	n_m=10	0.15 80*					

*Testing from 26 MHz is permitted. Refer to clause C.6.4 for conditions.

Repeat the test using instrument 2

Check acceptance requirements	☐ Passed	☐ Failed

7.3.5 Electrostatic discharge

7.3.5.1 Direct application

Observer:	
Instrument 1 ID	
Instrument 2 ID	
Sample ID	

	At start	At end	
Temp:			ºC
RH:			%
Date & Time:			yy:mm:dd hh:mm:ss

Contact discharge (Y / N)	
Paint penetration (Y / N)	
*Air discharge (Y / N)	
Maximum limit on fault (refer to Table 1 column 8):	

Note other details about the disturbance settings (e.g. repeat interval) here:

Settings		Instrument 1 P_{MB}			Results summary			
Test V (kV)	Polarity	Prior to disturbance (reference)		Test	Fault	Fault < Max fault	Sig fault detected & acted upon	Remarks
		n_m=10	mean	n_m=10				
2	+							
	-							
4	+							
	-							
6	+	n_m=10		n_m=10				
	-	n_m=10		n_m=10				
8*	+	n_m=10		n_m=10				
	-	n_m=10		n_m=10				

Repeat the test using instrument 2

Check acceptance requirements	☐ Passed	☐ Failed

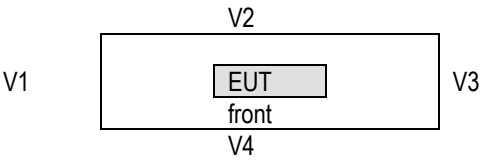
7.3.5.2 Indirect application

Observer:	
Instrument 1 ID	
Instrument 2 ID	
Sample ID	

	At start	At end	
Temp:			ºC
RH:			%
Date & Time:			yy:mm:dd hh:mm:ss

Notes: H = horizontal, V = vertical
Refer to diagram for vertical coupling plane positions

Polarity (+ / -)	
Maximum limit on fault (refer to Table 1 column 8):	



Settings		Instrument 1 P_{MB}			Results summary			
Coupling plane position	Test V (kV)	Prior to disturbance (reference)		Test	Fault	Fault < Max fault	Sig fault detected & acted upon	Remarks
		n_m=10	mean	n_m=10				
H	2							
	4	n_m=10		n_m=10				
	6	n_m=10		n_m=10				
V1	2	n_m=10		n_m=10				
	4	n_m=10		n_m=10				
	6	n_m=10		n_m=10				
V2	2	n_m=10		n_m=10				
	4	n_m=10		n_m=10				
	6	n_m=10		n_m=10				
V3	2	n_m=10		n_m=10				
	4	n_m=10		n_m=10				
	6	n_m=10		n_m=10				
V4	2	n_m=10		n_m=10				
	4	n_m=10		n_m=10				
	6	n_m=10		n_m=10				

Repeat the test using instrument 2

Check acceptance requirements	☐ Passed	☐ Failed

7.3.6 Mechanical shock

Observer:	
Instrument ID	
Sample ID	

	At start	At end	
Temp:			ºC
RH:			%
Date & Time:			yy:mm:dd hh:mm:ss

Note details about the influence settings (e.g. heating/cooling cycles here:

Maximum limit on fault (refer to Table 1 column 8):

Instrument 1 P_{MB}			Results summary			
Prior to disturbance (reference)		After disturbance	Fault	Fault < Max fault	Sig fault detected & acted upon	Remarks
n_m=10	mean	n_m=10				

Instrument 2 P_{MB}			Results summary			
Prior to disturbance (reference)		After disturbance	Fault	Fault < Max fault	Sig fault detected & acted upon	Remarks
n_m=10	mean	n_m=10				

Check acceptance requirements	☐ Passed	☐ Failed

7.3.7 Storage temperature

Observer:	
Instrument 1 ID	
Instrument 2 ID	
Sample ID	

	At start	At end	
Temp:			ºC
RH:			%
Date & Time:			yy:mm:dd hh:mm:ss

Note details about the influence settings (e.g. heating/cooling cycles here:

Maximum limit on fault (refer to Table 1 column 8):

Instrument 1 P_{MB}			Results summary			
Prior to disturbance (reference)		After disturbance	Fault	Fault < Max fault	Sig fault detected & acted upon	Remarks
n_m=10	mean	n_m=10				

Instrument 2 P_{MB}			Results summary			
Prior to disturbance (reference)		After disturbance	Fault	Fault < Max fault	Sig fault detected & acted upon	Remarks
n_m=10	mean	n_m=10				

Check acceptance requirements	☐ Passed	☐ Failed

7.4 Tests to assess the submitted calibrations

7.4.1 Accuracy and precision at reference conditions

			Start ref	End ref	
Observer:		Ambient temp:			°C
Type:		Ambient RH:			%
Instrument 1 ID:		Date commenced:			ddmmyyyy
Instrument 2 ID:		Time commenced:			hh:mm

			Limits								
Calibrations submitted			Pooled y		SDD	Pooled SD	SDD_I	RESULTS SUMMARY (Pass/fail)			
Number	Name	M_B (%)	Min	Max	Max	Max	Max	Accuracy	Repeat.	Reprod.	Comments
GT1											
GT2											
*											

* Add cells for additional calibrations if necessary

Calibration	Sample info		Reference values		Sample info		Reference values		Sample info		Reference values	
number	number	ID	P_{MB}	moisture	number	ID	P_{MB}	moisture	number	ID	P_{MB}	moisture
GT1	1				11				21			
	2				12				22			
	3				13				23			
	4				14				24			
	5				15				25			
	6				16				26			
	7				17				27			
	8				18				28			
	9				19				29			
	10				20				30			
GT2	1				11				21			
	2				12				22			
	3				13				23			
	4				14				24			
	5				15				25			
	6				16				26			
	7				17				27			
	8				18				28			
	9				19				29			
	10				20				30			

* Add cells for additional calibrations and/or samples if necessary

Accuracy and precision [OIML Rxxx-2, clause C.7.1] - continued - calculations - accuracy 1

		Instr.1	Instr. 2
Requirements for pooled y fulfilled and all functions operated as designed	Pass/fail		

Calibration	Sample	Mean P_{MB}			Error (y)		Pooled y			
number	number	reference	Instr. 1	Instr. 2	Instr. 1	Instr. 2	Instr. 1	Instr. 2	MinLimit	MaxLimit
GT1	1									
	2									
	3									
	4									
	5									
	6									
	7									
	8									
	9									
	10									
	11									
	12									
	13									
	14									
	15									
	16									
	17									
	18									
	19									
	20									
	21									
	22									
	23									
	24									
	25									
	26									
	27									
	28									
	29									
	30									
*										

* Add cells for additional calibrations and/or samples if necessary

Accuracy and precision [OIML Rxxx-2, clause C.7.1] - continued - calculations - accuracy 2

Requirements for SDD fulfilled and all functions operated as designed

	Instr.1	Instr. 2
Pass/fail		

Calibration number	Sample number	Reference P_{MB}	P_{MB} (j=1)		Error (y,j=1)		SDD		
			Instr. 1	Instr. 2	Instr. 1	Instr. 2	Instr. 1	Instr. 2	MaxLimit
GT1	1								
	2								
	3								
	4								
	5								
	6								
	7								
	8								
	9								
	10								
	11								
	12								
	13								
	14								
	15								
	16								
	17								
	18								
	19								
	20								
	21								
	22								
	23								
	24								
	25								
	26								
	27								
	28								
	29								
	30								
*									

* Add cells for additional calibrations and/or samples if necessary

Accuracy and precision [OIML Rxxx-2, clause C.7.1] - continued - calculations - repeatability

Requirements for repeatability fulfilled and all functions operated as designed

	Instr.1	Instr. 2
Pass/fail		

Calibration number	Sample number	SD		SD^2 (variance)		Pooled SD		
		Instr. 1	Instr. 2	Instr. 1	Instr. 2	Instr. 1	Instr. 2	MaxLimit
GT1	1							
	2							
	3							
	4							
	5							
	6							
	7							
	8							
	9							
	10							
	11							
	12							
	13							
	14							
	15							
	16							
	17							
	18							
	19							
	20							
	21							
	22							
	23							
	24							
	25							
	26							
	27							
	28							
	29							
	30							
*								

* Add cells for additional calibrations and/or samples if necessary

Accuracy and precision [OIML Rxxx-2, clause C.7.1] - continued - calculations - reproducibility

Requirements for reproducibility fulfilled and all functions operated as designed

	Instr.1	Instr. 2
Pass/fail		

Calibration number	Sample number	Mean P_{MB}		d	SDD_l	SSD_l
		Instr. 1	Instr. 2			MaxLimit
GT1	1					
	2					
	3					
	4					
	5					
	6					
	7					
	8					
	9					
	10					
	11					
	12					
	13					
	14					
	15					
	16					
	17					
	18					
	19					
	20					
	21					
	22					
	23					
	24					
	25					
	26					
	27					
	28					
	29					
	30					
*						

* Add cells for additional calibrations and/or samples if necessary

Accuracy and precision [OIML Rxxx-2, clause C.7.1] - continued - raw data entry

Calibration number	Sample number	P_{MB} @ ref		Comments	Sample number	P_{MB} @ ref		Comments	Sample number	P_{MB} @ ref		Comments
		Instr. 1	Instr.2			Instr. 1	Instr.2			Instr. 1	Instr.2	
GT1	1				11				21			
	2				12				22			
	3				13				23			
	4				14				24			
	5				15				25			
	6				16				26			
	7				17				27			
	8				18				28			
	9				19				29			
	10				20				30			
*												

* Add cells for additional calibrations and/or samples if necessary

7.4.2 Sample temperature sensitivity

Observer:
Type:
Instrument 1 ID:
Instrument 2 ID:

	Start ref	Tref - ΔTC	Recov 1	Tref + ΔTH	Recov 2	
Ambient temp:						°C
Ambient RH:						%
Sample temp:						°C
Date commenced:						ddmmyyyy
Time commenced:						hh:mm

General comments on test settings:

Calibrations submitted and tested			Limits Pooled error shift		RESULTS SUMMARY	
number	Displayed name	M_B (%)	Min	Max	Pass/fail	Comments
GT1						
GT2						
*						

* Add cells for additional calibrations if necessary

Calibration	Sample info			Nomimal values	
number	moisture	number	ID	P_{MB}	moisture
GT1	low m	1			
		2			
		3			
	high m	4			
		5			
		6			
GT2	high m	1			
		2			
		3			
	low m	4			
		5			
		6			
*					

* Add cells for additional calibrations if necessary

Sample temperature sensitivity (STS) [OIML Rxxx-2, clause C.7.2] - continued - calculations

Instrument 1 only

Calibration	Sample info		Mean P_{MB}					Error shift		Pooled error shift		RESULT	Limits pooled e/shift	
number	moisture	number	Start ref	Tref - ΔTC	Recov 1	Tref + ΔTH	Recov 2	Tref - ΔTC	Tref + ΔTH	Tref - ΔTC	Tref + ΔTH	Pass/fail	Min	Max
GT1	low m	1												
		2												
		3												
	high m	4												
		5												
		6												
GT2	high m	1												
		2												
		3												
	low m	4												
		5												
		6												
*														

* Add cells for additional calibrations if necessary

All functions operated as intended: [ ] Pass/fail

Instrument 2 only

Calibration	Sample info		Mean P_{MB}					Error shift		Pooled error shift		RESULT	Limits pooled e/shift	
number	moisture	number	Start ref	Tref - ΔTC	Recov 1	Tref + ΔTH	Recov 2	Tref - ΔTC	Tref + ΔTH	Tref - ΔTC	Tref + ΔTH	Pass/fail	Min	Max
GT1	high m	1												
		2												
		3												
	low m	4												
		5												
		6												
GT2	high m	1												
		2												
		3												
	low m	4												
		5												
		6												
*														

* Add cells for additional calibrations if necessary

All functions operated as intended: [ ] Pass/fail

Sample temperature sensitivity (STS) [OIML Rxxx-2, clause C.7.2] - continued - raw data entry

Calibration	Sample info		P_{MB} (start ref)		P_{MB} (Tref - ΔTC)		P_{MB} (recov 1)		P_{MB} (Tref + ΔTH)		P_{MB} (recov 2)		Comments
number	moisture	number	Instr. 1	Instr.2	Instr. 1	Instr.2	Instr. 1	Instr.2	Instr. 1	Instr.2	Instr. 1	Instr.2	e.g. functionality
GT1	low m	1											
		2											
		3											
	high m	4											
		5											
		6											
GT2	high m	1											
		2											
		3											
	low m	4											
		5											
		6											
*													

* Add cells for additional calibrations if necessary