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INTERNATIONAL ORGANIZATION OF LEGAL METROLOGY

~~Fourth~~ Fifth 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 ~~(copy of Excel file)~~

OIML TC17/SC8 Secretariat: Australia

Participating Nations:

Australia, Brazil, Canada,
Germany, Japan, New Zealand, Republic of Korea,
Russian Federation, Slovakia, United States of America

Observing Nations:

Czech Republic, France, Poland, Serbia

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Title: ~~Improved CD4~~ CD5 of a Recommendation on Protein Measuring Instruments for Cereal Grain and Oilseeds

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[x] discussion at (date and place of meeting): ~~A meeting of TC17/SC8 in conjunction with TC 17/SC1 is proposed for July 23 -25 2013 in the USA.~~

[x] vote (P-members only) and comments by **14 November 2014**

TITLE OF THE CD (English):

OIML R xxx

~~Fourth~~ Fifth Committee Draft of a Recommendation on Protein Measuring Instruments for Cereal Grain and Oilseeds

Part 1: Metrological and technical requirements

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EXPLANATORY NOTE

Legend to versions of 5CD with track changes shown:

Black text – original text from 4CD (April 2013) and changes resulting in the 'Improved 4CD' (July 2013);

Coloured text – changes resulting in the 5CD (August 2014).

3CD July 2012

Revisions to 2CD N6 (2010) were proposed during combined meetings of TC17/SC1 and SC8 in Orlando, Florida in September 2011.

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 to the 2CD that were not discussed at the TC17/SC8 meeting are also detailed in the above mentioned Excel file (Tab: Other changes).

4CD April 2013

Refer to the file titled: *ALL - 201210 3CD TC17-SC8 comments4.xls* for a list of comments received on the 3CD and the secretariat response.

Refer to the following Excel and PDF files for Part 3: Report format for type evaluation.

20130408 - 4CD Grain Protein Measurements - Part 3 Test Report.xls

20130408 - 4CD Grain Protein Measurements - Part 3 Test Report.pdf

'Improved 4CD' July 2013

Revisions to the 4CD are based on the comments received from CA, DE, FR, JP, PL, and US in June – July 2013. Refer to the file: *201307-Collated comments-4CD-TC17_SC8_p1.docx* for details.

Meeting participants are encouraged to consider the proposed changes when discussing the collated 4CD comments and issues.

5CD August 2014

The 'Improved 4CD' was considered during combined meetings of TC17/SC1 and SC8 in Washington DC in July 2013 The rationale for the amendments resulting in the 5CD are indicated in the TC17/SC8 meeting minutes: *20140221 - TC17-SC8-p1 2013 Meeting Minutes.pdf*.

Refer to the following Excel file to view the calculations and form selection options for Part 3: Report format for type evaluation.

201407 - 5CD Protein in grain - Part 3 Test Report.xlsx

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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;

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This publication - reference OIML R xxx, 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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PART 1: METROLOGICAL AND TECHNICAL REQUIREMENTS

1 SCOPE

This Recommendation includes metrological and technical requirements and test methods for the 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 that modify the test sample in order to infer the protein content are not specifically covered, but may still qualify for type approval if 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 basic terminology used in this document is consistent with the definitions in OIML V2 *International Vocabulary Metrology – Basic and General Concepts and Associated Terms* (VIM) [1] and OIML V1 (2DV revision) *International Vocabulary of Terms in Legal Metrology* (VILM) [2].

Table 1 is limited to additional information such as context that the general term is used in this Recommendation. Some definitions from the VIM and VILM have been reproduced in alphabetical order in Annex F.

Table 1: Additional notes on the general terms in this Recommendation.

Reference	General term	R xxx additional notes
VILM 2.05	type approval	--
VILM 2.04	type (pattern) evaluation	--
VILM 2.09	verification of a measuring instrument	--
VIM 2.13	accuracy; measurement accuracy	--
VIM 3.11	adjustment	For protein measuring instruments, alignment with the reference method is typically accomplished through a bias adjustment to the calibration equation. Other mechanisms that require a higher level of expertise (e.g. adjustment of the calibration equation slope, modification of hardware/ software components or settings) may be less accessible due to increased security requirements.
VIM 5.14	certified reference material (CRM)	Refer to Annex B for guidelines on producing whole-grain CRMs. Further general information is in OIML D 18 [3].
VIM 4.26	maximum permissible error (MPE); limit of error	The MPE and other limits for tests on the type of instrument and various grain calibrations are listed in clause 4.5 Table 4.
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 used to assess the measurement accuracy at verification and to assess the accuracy of calibrations at type evaluation. Where a CRM is not used, the reference quantity value is the mean P_{MB} at reference conditions prior to a 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 (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 summarised in Annex C clause C.3.4.

2.2 Other definitions

This clause defines terms applicable to grain protein measuring instruments, the assessment of multivariate calibrations 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 accuracy of a grain protein calibration; calibration accuracy

Performance characteristic of a calibration assessed at reference conditions.

The assessment requires calculation of $\bar{y}$, the bias over a set of test samples or the 'calibration bias', and the standard error of prediction *(SEP)* which is the standard deviation of measurement errors from the same sample set.

Refer to Annex C clause C.7.1 for the calculation of $\bar{y}$ and *SEP* from measured values. The limiting values for $\bar{y}$ and *SEP* in clause 4.5 Table 4 shall be observed in order to deem a calibration as sufficiently accurate.

2.2.2 average error shift

Algebraic mean of error shift values calculated from samples of the same grain type with different P_{MB} levels. The resulting 'average' value is indicative of the average variation over the encompassed measurement range, as opposed to the variation in measured values at one point of the range.

NOTE: In this Recommendation, reference to a resulting 'mean' value is reserved for the mean of replicated measurements, i.e. the mean of measured values on the same test sample (usually taken under repeatability conditions).

2.2.22.2.3 calibration equation; calibration

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

NOTE: Both these terms are used in the same context as 'calibration function' in Note 1 of VIM 2.39.

2.2.32.2.4 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.

2.2.42.2.5 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. Refer to Table 2 for the relevant measured values in the calculation of errors.

NOTE: If a certified measurement standard is not used, the error shift is the difference between two measured values: the indication under rated operating conditions and the mean indication at reference conditions prior to test.

Table 2: Measured values for calculating the error shift exhibited by the instrument.

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

2.2.52.2.6 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 or 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.

Refer to Table 3 for the relevant measured values in the calculation of errors.

NOTE: 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.

Table 3: Measured values for calculating the fault exhibited by the instrument during or after a disturbance.

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~~2.2.7 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 4 with samples that comply with any limits specified by the national responsible body for the sample temperature (see clause 4.3).

~~2.2.7~~2.2.8 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~~2.2.9 intrinsic error [OIML D 11, 3.7]

Error of a measuring instrument, determined under reference conditions.

NOTE: The grain sample ~~tested is~~ would also be at the reference conditions.

~~2.2.9~~2.2.10 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~~2.2.11 basis moisture content; 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.

NOTE: When the specified M_B is 0%, the reported protein content is at 'dry basis'.

~~2.2.11~~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, clause 3.1.6] which is a network of a fixed number of participants with a known identity functionality and location.

~~Pooling [change to 'average error shift']~~

~~2.2.12~~2.2.13 protein content (P_{MB})

The concentration of protein in a grain sample, expressed as a percentage by mass, calculated at the basis moisture content (M_B). When the specified M_B is 0%, the reported protein content is at 'dry basis' (i.e. $P_{0\%}$).

~~2.2.13~~2.2.14 protein measuring instrument; instrument; unit

An instrument that infers the protein content 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 type of grain.

~~2.2.14~~2.2.15 sample temperature sensitivity (STS)

Measurement variation (relative to the P_{MB} values obtained at reference conditions) resulting from the range of grain sample temperatures permitted in commercial measurements.

NOTE: STS is controlled in approved P_{MB} calibrations. During assessment, a limit is placed on the value of the ~~pooled~~ average error shift caused by allowable temperature variations.

~~2.2.15~~2.2.16 significant fault

Fault exhibited by the equipment under test that is greater than the values listed in clause 4.5 Table 4 column 10.

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; and

(c) transitory faults being momentary transitions in the indication, which cannot be interpreted, memorised or transmitted as a measurement result.

~~2.2.16~~2.2.17 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 execution of software for specific purposes.

~~2.2.17~~2.2.18 (software) 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
AM	amplitude modulation
ASD	acceleration spectral density
CRM	certified reference material
EM	electromagnetic
EMC	electromagnetic compatibility
ESD	electrostatic discharge
EUT	equipment under test
IEC	International Electrotechnical Committee
ISO	International Organization for Standardization
M	actual 'as is' moisture content of a sample
M_B	basis moisture content specified by the national responsible body (see 2.2.11)
MPE	(also $MPE_{MB>0\%}$ for the purpose of Equation 2) maximum permissible error scaled to the relevant M_B
$MPE_{0\%}$	maximum permissible error at dry basis (i.e. M_B = 0%)
OIML	International Organization of Legal Metrology
P_M	mass percentage protein content at the actual ~~'as is'~~ moisture content
P_{MB}	mass percentage protein content calculated at the basis moisture content (see clauses 2.2.13 and 3.2)
RF	radio frequency
RH	relative humidity
RM	reference material
RMS	root mean square
SEP	standard error of prediction (see C.7.1)
SD	standard deviation (see C.7.1)
SDD_I	SD of differences (see C.7.1)
STS	sample temperature sensitivity
t	actual temperature during a test
~~T~~t_{ref}~~:~~	reference temperature during a test
Δ~~T~~*t*~~-~~	magnitude of the temperature difference between a sample and an instrument at Tt_{ref}
Δ~~T~~t_{max}	maximum Δ~~T~~t specified by the national responsible body for type testing
Δ~~T~~$t_{C,\ max}$	maximum permitted Δ~~T~~t_{max} below ~~T~~t_{ref} (applicable only if unequal to Δ~~T~~$t_{H,\ max}$)
Δ~~T~~$t_{H,\ max}$	maximum permitted Δ~~T~~t_{max} above ~~T~~t_{ref} (applicable only if unequal to Δ~~T~~$t_{C,\ max}$)
~~T~~t_C	minimum environmental temperature specified by the national responsible body for type testing
~~T~~t_H	maximum environmental temperature specified by the national responsible body for type testing
~~T~~$t_{C,sample}$	minimum grain sample temperature specified by the national responsible body type testing
~~T~~$t_{H,sample}$	maximum grain sample temperature specified by the national responsible body type testing
ȳ	bias of a calibration (see C.7.1)

2.4 Additional symbols and subscripts used in equations

d_i	difference in $\bar{x}_i$ from two units (same type)
$\bar{d}$	d_i ~~pooled~~ averaged over n test samples
i	identifier for a test sample in a set of n samples
j	identifier for a measured value in a series obtained by repeated measurements
n	number of test samples with different P_{MB} levels of the same grain type used in a test
r_i	certified P_{MB} value for test sample i
x	a measured P_{MB} value for test sample i
$\bar{x}_i$	mean x for test sample i
y	error of measured P_{MB} value for test sample i
$\bar{y}_i$	mean y for test sample i
$\bar{y}$	$\bar{y}_i$ ~~pooled~~ averaged over n test samples (i.e. the bias of a calibration)

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

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

where: M = the moisture content of the sample
M_B = the basis moisture content for the type of grain

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

4 METROLOGICAL REQUIREMENTS

4.1 Applicable grains and P_{MB} measuring ranges – specification

4.1.1 Due to climatic and crop variability, the national responsible body shall specify commercially important P_{MB} ranges for the types of grain listed in Table 4. These are examples of the grain calibrations for which a protein measuring instrument manufacturer may seek national approval.

4.1.2 The manufacturer shall specify the types of grain and respective P_{MB} measuring ranges that the instrument can analyse. Manufacturer specified measuring ranges shall include any commercially important P_{MB} ranges specified by the national responsible body.

4.2 Instrument environmental operating temperature – specification

4.2.1 The errors on the measured values displayed by a protein measuring instrument shall meet the MPE in Table 4 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 (Tt_C to Tt_H) in which the instrument can be used to take P_{MB} measurements for commercial purposes. The Tt_C to Tt_H specified shall include the temperature range 10 ºC to 30 ºC.

4.2.3 The manufacturer may specify a wider temperature range than the Tt_C to Tt_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 Tt_C to Tt_H).

4.3 Grain sample operating temperature – specification

4.3.1 Specification of the sample temperature range

4.3.1.1 The errors on the measured values displayed by a protein measuring instrument shall meet the MPE in Table 4 regardless of the sample temperature unless the national responsible body permits limitations on the temperature of grain that can be tested.

4.3.1.2 In the latter case, the national responsible body shall specify the temperature range (T$t_{C,sample}$ to T$t_{H,sample}$) allowed for grain samples tested for commercial purposes. For each type of grain, the T$t_{C,sample}$ to T$t_{H,sample}$ specified shall include the temperature range 2 ºC to 40 ºC as a minimum.

4.3.1.3 In order to meet international requirements, the manufacturer may specify a wider sample temperature range for each type of grain than T$t_{C,sample}$ to T$t_{H,sample}$ 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$t_{C,sample}$ to T$t_{H,sample}$).

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

4.3.2.1 An instrument at reference temperature (~~T~~t_{ref}) shall be able to analyse cooler or warmer samples within the range ~~T~~$t_{C,sample}$ to ~~T~~$t_{H,sample}$ regardless of the magnitude of the sample and instrument temperature differential (Δ~~T~~t). This requirement may be limited in effect if the national responsible body permits a limit on the temperature differential (i.e. Δ~~T~~t_{max} or Δ~~T~~$t_{C,\,max}$ and Δ~~T~~$t_{H,\,max}$ 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 Δ~~T~~t_{max} (or Δ~~T~~$t_{C,max}$ and Δ~~T~~$t_{H,max}$) for taking P_{MB} measurements for commercial purposes. The instrument shall be able to take into account a Δ~~T~~t of at least 10 °C.

4.3.2.3 In order to meet international requirements, the manufacturer may specify a maximum allowable Δ~~T~~t that is larger than the Δ~~T~~t_{max} specified by the national responsible body. The manufacturer may request type testing and approval at the larger maximum allowable Δ~~T~~t (i.e. for that particular type approval application, the manufacturer specification is adopted as Δ~~T~~t_{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 Δ~~T~~t may not be feasible 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

The following influence quantities have the potential to reduce the accuracy or cause a grain protein measuring instrument to malfunction. An influence quantity that is not within any of the ranges in clause 4.4.1 also qualifies as being a disturbance, although its effect on measurements is not specifically assessed at type evaluation.

4.4.1 Rated operating conditions

(a) Ambient temperature:	Operating range specified by the national responsible body (~~T~~t_C to ~~T~~t_H). See clause 4.2 for requirements
(b) Relative humidity:	Up to 85%, no condensation
(c) Atmospheric pressure:	86 kPa to 106 kPa
(d) Power voltage:	-15% to +10% of nominal mains or test voltage
(e) Power frequency:	nominal frequency, f_{nom}
(f) Instrument tilt position:	Up to 5% or ~~up to~~ the maximum limit on the level indicator where ~~an indicator~~ one is present
(g) Battery voltage*:	9 V – 16 V (nominally 12 V), or 16 – 32 V (nominally 24 V)

(*) These ranges apply to instruments used for commercial purposes while powered by a vehicle battery.

4.4.2 Disturbances

(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[(2)] MHz - 2 GHz, 10 V/m

(d) Conducted radio-frequency fields: 0.15 MHz – 80[(3)] 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) Storage temperature (extreme shipping conditions): -20 ºC to 5~~0~~5[(4)] ºC

(h) Random vibration[(4)]: total frequency range 10 – 150 Hz, total RMS level 7 ms^{-2}, ASD level 10 – 20 Hz: 1 m^2s^{-3}, ASD level 20 -150 Hz: 13 dB/octave

NOTES:

(1) The cycle counts apply for 50 Hz / 60 Hz respectively

(2) Testing from 80 MHz is permitted. Refer to clause C.6.3.

(3) Testing up to 26 MHz is permitted. Refer to clause C.6.4.

(4) The national responsible body may apply a lower maximum limit

(5) Only applicable to portable instruments that are designed not to require reverification after transportation between different sites.

4.5 Maximum permissible error (MPE) and other accuracy requirements

4.5.1 Overview

Provided that the error on each P_{MB} measurement is less than the MPE in Table 4 column 3, an instrument with a P_{MB} calibration that has been approved for a particular grain type may be verified as sufficiently accurate under the presented conditions of use.

The error shift or fault shall not exceed the limit specified in either column 9 or column 10 of Table 4 during type evaluation tests. This result supports the presumption that a calibrated instrument can comply with the MPE over the rated operating ranges or in the event of a disturbance. In this Recommendation, error shifts and faults are primarily attributed to variations in the performance of the instrument hardware, not the calibration.

The calibration assessment and sample temperature sensitivity (STS) test shall be performed on every P_{MB} calibration submitted to ensure the calibrations are sufficiently accurate and robust. The P_{MB} errors shall be ~~'pooled' (i.e.~~ averaged~~)~~ over different samples of the grain type. This results in a single value for the following parameters that represents the bias or imprecision of the calibration over the legally relevant measurement range:

- $\bar{y}$, the bias of the mean P_{MB} over a set of samples spanning the P_{MB} measurement range;
- *SEP*, the standard deviation of the errors for the set of samples;
- pooled *SD*, the standard deviation of repeated measurements ~~pooled~~ averaged over the set of samples;
- SDD_I, the standard deviation of differences in the mean P_{MB} from two units over the set of samples;
- ~~pooled~~ average error shift, the error shifts calculated from the STS test, ~~pooled~~ averaged over a set of high or low moisture content samples in the P_{MB} measurement range.

Refer to Table 4 for the limits on the values calculated for $\bar{y}$, *SEP*, pooled *SD*, SDD_I, and the STS ~~pooled~~ average error shift.

4.5.2 Accuracy requirements for various types of grain – specification

The MPE and other requirements (e.g. limits on the imprecision) for measurements of protein content in various grain types are presented in Table 4. These are recommended values that apply to measurements of P_{MB} including the protein content at dry basis (i.e. $P_{0\%}$). They apply to all instruments used in commercial transactions irrespective of their principles of operation.

NOTE: The same MPE is applied across all test samples of the same grain type 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 4 shall be appropriately scaled down when the indicated protein content is not at dry matter basis, i.e. the specified M_B is greater than zero. The MPE at any M_B > 0% can be calculated from the relevant values of $MPE_{0\%}$ using Equation 2:

$$MPE_{MB>0\%} = MPE_{0\%} \times (1 - \frac{M_B}{100}) \qquad \textbf{Equation 2}$$

where: M_B = basis moisture content for the type of grain

The limiting values for *SEP*, pooled *SD*, SDD_I, error shift and fault in Table 4 are scaled 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 *SEP* used to assess the calibration accuracy at type evaluation are calculated with reference to certified reference materials (CRMs), i.e. whole-grain measurement standards with certified P_{MB} values.

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 4: MPE and other accuracy requirements expressed in percentage protein by mass (%) at dry basis or M_B [(1)]

TEST SAMPLE		FIELD TESTS	TYPE EVALUATION TESTS						
Grain type[(2)]	M_B	Verification	Calibration assessment (instrument at reference conditions)					Reproducibility assessment	
		Rated operating condition	Accuracy		Repeatability	Reproducibility (two units)	Sample temp sensitivity (STS)	Influence factor rated operating condition	Disturbance
		MPE (%)	Max ȳ (%)	Max *SEP* (%)	Max pooled *SD* ~~(pooled)~~ (%)	Max SDD_I (%)	Max average error shift (%)	Max error shift (%)	Fault limit (%)
column 1	column 2	column 3	column 4	column 5	column 6	column 7	column 8	column 9	column 10
Wheat	0%	±0.4	±0.34	Absolute value of col 4	Absolute value of col 4 × 0.5	Absolute value of col 4 × 0.6	col 4	col 4 × 0.7	col 4
	$M_B > 0\%$	$\pm 0.4 \times (1 - \frac{M_B}{100})$	$\pm 0.34 \times (1 - \frac{M_B}{100})$						
Barley	0%	±0.5	±0.40						
	$M_B > 0\%$	$\pm 0.5 \times (1 - \frac{M_B}{100})$	$\pm 0.40 \times (1 - \frac{M_B}{100})$						
Rice	0%	±0.6	±0.50						
	$M_B > 0\%$	$\pm 0.6 \times (1 - \frac{M_B}{100})$	$\pm 0.50 \times (1 - \frac{M_B}{100})$						
Corn	0%	±0.8	±0.50						
	$M_B > 0\%$	$\pm 0.8 \times (1 - \frac{M_B}{100})$	$\pm 0.50 \times (1 - \frac{M_B}{100})$						
Soybean	0%	±0.8	±0.63						
	$M_B > 0\%$	$\pm 0.8 \times (1 - \frac{M_B}{100})$	$\pm 0.63 \times (1 - \frac{M_B}{100})$						
Lupins	0%	±1.2	±1.0						
	$M_B > 0\%$	$\pm 1.2 \times (1 - \frac{M_B}{100})$	$\pm 1.0 \times (1 - \frac{M_B}{100})$						

NOTES:

(1) Refer to clause 4.5.3 for instructions on rounding calculated values and the equation converting the MPE/ limits at dry basis to another M_B.

(2) Recommended MPEs for other grain types (e.g. triticale and rye) can be added in future revisions of the publication.

(3) The limits in Table 4 apply to values (e.g. ȳ, *SEP*, pooled *SD*, SDD_I, error shift, fault) that are calculated according to *Test result* in Annex C.

4.6 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 4 column 3.

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 Calibration 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. $\bar{y}$, *SEP*, pooled *SD* and SDD_I, do not exceed the limits in Table 4.

4.7.2 Limited sample temperature sensitivity (STS)

Each calibration submitted for approval with the type of instrument shall be tested for STS with high and low moisture samples at the Δ~~T~~t_{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~~ average error shift for a set of samples does not exceed the limit shown Table 4 column 8.

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 4 column 9 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 2.2.16 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 4 column 9 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 4 column 9).

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 when 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

5.1.2.1 A protein measuring instrument shall automatically and clearly indicate when one of the following type-approved operating ranges is exceeded, by an appropriate error message, unambiguous warning or blanking the display.

(a) Instrument environmental temperature range, ~~T~~t_C to ~~T~~t_H (see clause 4.2)

(b) Sample temperature range, ~~T~~$t_{C,sample}$ to ~~T~~$t_{H,sample}$, for each grain type (see clause 4.3.1)

(c) Maximum sample and instrument temperature differential (Δ~~T~~t_{max}) for each grain type (see clause 4.3.2)

5.1.2.2 The instrument shall automatically prevent further measurements as long as the respective influence factor or sample characteristic remains outside the type-approved ranges.

5.1.2.3 The operator shall not be required to judge the precise ambient temperature and the temperature of the sample in order to make an accurate measurement.

5.1.3 Suppression of P_{MB} values or warnings outside of the approved measuring range

P_{MB} measured values that are outside of the type approved range for the calibration (see clause 4.1) shall be suppressed unless it is accompanied by an appropriate error message or unambiguous warning.

5.1.4 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 type 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.

5.3.3 Marking operational controls, indications and features

All operational controls, indications, indicating switches, features, light displays and push button shall be clearly identifiable. Keys visible only to the operator need only be marked to the extent that a trained operator can understand the function of each key.

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 grain type, it shall be possible to select the calibration applicable to the test sample, for example, via a user menu listing the grain types that the instrument is approved to measure.

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

5.4.2 Sampling and minimum sample size

5.4.2.1 The operator shall not be required to judge the precise volume or weight required by the instrument to make an accurate P_{MB} measurement.

5.4.2.2 The minimum allowable sample size for measurement 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 24333 (2009) *Cereals and cereal products – Sampling* [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 process of measurement 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 If tilting the instrument in any upright direction by up to 5% (approximately 3º) reduces the accuracy of the instrument, it shall be equipped by a level indicator and level adjustment means to reduce the likelihood that it will be tilted when placed in service.

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 content values before the end of the measurement cycle.

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

5.7.3 The display shall permit protein content 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].

6 REQUIREMENTS FOR SOFTWARE-CONTROLLED DEVICES AND SECURITY

The software requirements are based on OIML D 31 [5].

~~Commercial application of P_{MB} measured values typically occurs at the same time and place as the measurement. Provided that any data transmission is limited to a secure environment (i.e. a closed network), t~~The risk associated with the software of protein measuring instruments is level I. Validation in accordance with Procedure A in clauses 6.3 and 6.4 of D 31 are adequate for solutions implemented to fulfil requirements at the normal severity level.

Commercial application of P_{MB} measured values typically occurs at the same time and place as the measurement.

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).

6.1.2 Legally relevant software shall be clearly identifiable via a unique software version or a checksum. In the normal operation mode of the instrument, the software version or 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 Legally relevant 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~~ validate algorithms and functions where required by metrological tests.

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. In types where selected functions or parts of the source code can be modified, it shall be possible to detect software variations, e.g. via checksum values.

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

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

6.1.7 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~~ where cryptographic data protection is implemented 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).

6.1.8 ~~If measured values are likely to be used at another place or later time, other than the place or time of measurement, t~~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, for example, a printer.~~,~~ In this case, ~~6.2.6 C~~correspondence between displayed information and remote recording element shall be verified.

~~**6.1.9**~~

~~**6.1.10**~~**6.1.9** The national responsible body may apply the requirements in clause 6.3, if measurement data has to leave the measuring instrument and be stored or transmitted in an insecure environment before it is used for commercial purposes.

6.2 ~~Electronic d~~Data storage ~~and transmission~~

~~Data storage~~

6.2.1 ~~6.2.3~~ If ~~data~~ storage of legally relevant data is required by the national responsible body, the measurement data must be stored automatically when the measurement is ~~concluded~~finished.

NOTE: A recording element shall not record any protein content values before the end of the measurement cycle.

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.

6.2.2 ~~6.2.1~~ The measurement value stored ~~or transmitted~~ shall be accompanied by all relevant information necessary for future legally relevant use. The measurement records shall include as a minimum: unambiguous identifier of the measurement ~~(e.g. consecutive numbers enabling assignment to values printed on an invoice, or the test sample identifierID)~~, 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). Acceptable examples of a measurement identifier include consecutive numbers enabling assignment to values printed on an invoice, or a test sample ID.

6.3 Data transmission

Where the transmission of legally relevant measurement data ~~have to leave the measuring instrument (electronic device, sub-assembly) and be stored or transmitted~~ in ~~an insecure environment~~ open networks ~~before they are used for commercial purposes, (the national authorities may consider this as legally relevant and)~~ presents opportunities for fraud or misuse with serious consequences for an important market of the country, the following additional requirements may be appl~~y~~ied:

~~6.2.2~~ The data shall be protected by software means described in D 31 clause 5.2.3.2 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.~~

6.3.1 ~~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.~~

6.3.2 If ~~C~~cryptographic protection of data as indicated in D 31 clause 5.2.3.3 ~~may be required by the national responsible body if protein measuring instruments are used in an open network.~~ is employed to achieve protection at the severity II level, Procedure B methods are recommended for validating this aspect of the software ~~at the severity II level~~.

6.3.3 ~~6.2.4~~ The measurement shall not be inadmissibly influenced by a transmission delay.

6.3.4 ~~6.2.5~~ 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.

~~6.2.6 Correspondence between displayed information and remote recording element shall be verified.~~

~~Where legally relevant measurement data have to leave the measuring instrument (electronic device, sub-assembly) and be stored or transmitted in an insecure environment before they are used for commercial purposes, the following requirements apply:~~

~~**6.2.1** The measurement value stored or transmitted shall be accompanied by all relevant information necessary for future legally relevant use. The measurement records shall include as a minimum: unambiguous identifier of the measurement (e.g. consecutive numbers enabling assignment to values printed on an invoice, or the test sample ID), 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).~~

~~**6.2.2** 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.~~

~~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.~~

~~Cryptographic protection of data as indicated in D 31 clause 5.2.3.3 may be required by the national responsible body if protein measuring instruments are used in an open network. Procedure B methods are recommended validating this aspect of the software at the severity II level.~~

~~**6.2.3** If data storage is required, the measurement data must be stored automatically when the measurement is concluded.~~

~~NOTE: A recording element shall not record any protein content values before the end of the measurement cycle.~~

~~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.~~

~~**6.2.4** The measurement shall not be inadmissibly influenced by a transmission delay.~~

~~**6.2.5** 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~~6.4 Provision for software and calibration security

~~6.3.1~~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.

~~Examples for appropriate sealing means are: mechanical sealing, event counter, audit trail, and access only via interfaces protected by cryptographic means.~~

~~NOTE: An audit trail is a continuous data file containing a time stamped information record of events that are legally relevant and which may influence the metrological characteristics e.g. changes in the values of parameters of a device or software updates.~~

Refer to Annex G which contains practical guidance for sealing protein measuring instruments, including consideration of sealable parameters and details of sealing mechanisms, e.g. metrological audit trails.

~~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.~~

~~6.3.2~~6.4.2 Safeguards against fraudulent use

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

~~6.3.2.1~~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 that have an operating system or an option to load software.

~~6.3.2.2~~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.

~~6.3.2.3~~6.4.2.3 Parameters that fix the legally relevant characteristics of the measuring instrument shall be secured against unauthorised modification. I~~f necessary for the purpose of verification, i~~t shall be possible to display or print the current parameter settings.

~~6.3.2.4~~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 or manufacturer representative.~~ Type-specific parameters have identical values for all specimens of a type and are fixed at type approval.

~~6.3.2.5~~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).

~~6.4~~6.5 Software documentation

In addition to the requirements in clause 7.1.2 the manufacturer shall submit the software documentation described in Table 5.

Table 5: Examples of software documentation and application notes

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.
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, e.g. for a spectrometer – an alert for the user to clean lenses/windows or to replace LED when radiation intensities fall below threshold values.	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 all operational controls, indications, and features	Example features – switches, lights, displays and push buttons

PART 2: METROLOGICAL CONTROLS AND PERFORMANCE TESTS

OIML recognises that the ideal legal metrological control strategy for one country or region is not necessarily the ideal for all others. OIML D 16 *Principles of assurance of metrological control* [8], discusses the factors to consider in order to design and implement more effective control systems. Part 2 of this Recommendation is based on a system with several elements comprising type evaluation and approval, initial verification and metrological supervision.

7 TYPE EVALUATION AND APPROVAL

Each type of a protein measuring instrument used for trade shall be submitted for type approval. 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 the P_{MB} stability of grain samples after they are cycled through various temperature and humidity settings during the climatic tests.

NOTE: In absence of a third unit, another approved type of protein measuring instrument can be used to monitor the sample stability.

7.1.1.3 If the protein measuring instrument is a module (i.e. part of a system that includes non-metrological functions), manufacturers are permitted to submit only parts associated with P_{MB} measurements 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 file

In addition to the documents listed in Table 6, 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.

Table 6: Contents of a documentation file submitted for type evaluation.

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 types 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).

Required documentation	Application notes and/or examples
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.
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.
Additional documents according to clause 6.5	For software-controlled instruments.
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.
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 is confirmed by the validation methods described in Annex D. If a particular requirement does not apply to the submitted type, it shall be marked as "not applicable" in Part 3 *Examination checklist – requirements for software controlled devices and security*.

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 it passes the performance tests in Table 7:

Table 7: Tests to demonstrate compliance with selected metrological requirements.

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]

Metrological requirements	Test(s) for compliance
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] Variation in voltage supplied by external 12V and 24 V road vehicle batteries [C.5.6]
Effect of disturbances on instruments [4.8.2] NOTES: (1) 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 electrical disturbance tests. (2) Only applicable to portable instruments that are designed not to require reverification after transportation between different sites.	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 [C.6.3] Conducted radio-frequency electromagnetic fields [C.6.4] Electrostatic discharges [C.6.5] Storage temperature (extreme shipping conditions) [C.6.6] Random vibration(2) [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* [9].

8.1 Legal status of the instrument submitted for verification

Initial verification includes a procedure to ensure that 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* [10].

9.1 Reverification (subsequent verification)

9.1.1 Frequency

Reverification is mandatory after any repair, adjustment or change that affects the 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 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 'linked instruments' and to monitor instrument drift so that corrective adjustments are carried out before the measurement error exceeds the MPE.

NOTE: A 'linked instrument' is defined as being linked, either electronically or manually under a quality system, to an instrument aligned with a whole-grain CRM. This allows the performance to be monitored on a daily basis or according to a schedule set by the quality system administrator.

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 that is used to adjust the grain calibrations.

9.5.2 Calibration ~~V~~version

Only approved P_{MB} calibrations shall be used for the applicable grain types and P_{MB} ranges specified by the national responsible body (see clause 4.1). To facilitate audits on the calibrations, a protein measuring instrument must be capable of displaying the calibration constants that are adjustable, and a unique name or a unique version number for every calibration available for use~~,~~.

9.5.3 Security of calibrations and reverification

There shall be provision to allow only authorised persons to change calibrations, for example, bias adjustments. ~~The security level for updating grain calibrations shall fulfil the same security level as for software installation.~~ In addition, changes to the grain calibrations of the instrument shall be impossible or recorded in an audit trail. Refer to Annex G for guidance on methods of sealing.

Changes to grain calibration data may be downloaded to a verified instrument using available communication interfaces. The national responsible body may not consider these 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. PROTEIN CONTENT CALCULATION FROM NITROGEN DETERMINATION (MANDATORY)

The national responsible body shall specify the relationship between the measured nitrogen content and protein content assigned to whole-grain reference materials used to test protein measuring instruments.

The moisture content measurements that are used to adjust the calculated protein content to the relevant M_B shall meet the requirements of OIML R 59 or international reference methods therein.

A.1 Dumas combustion – total nitrogen determination

For example: "ISO/DTS 16634.2 (2009)" [11]

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

A.2 Improved Kjeldahl method — total nitrogen determination

For example: ISO 20483 (2006) Determination of the nitrogen content and calculation of the crude protein content – Kjeldahl method [12]

A.3 Other method of total nitrogen determination

ANNEX B. WHOLE-GRAIN MEASUREMENT STANDARDS (MANDATORY)

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

Whole-grain 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 sufficiently 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 RM.

Essentially, a reference method allows the P_{MB} of a sample to be inferred from direct measurement of the nitrogen mass fraction 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 [11] 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 level of spatial inhomogeneity and any compositional variations over time when assigning a P_{MB} value to an RM and evaluating the uncertainty.

Refer to ISO Guide 35 *General and statistical principles for certification* [13] 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.

To produce a CRM, the grain protein reference method shall be applied with sufficient repetitions of the complete measurement cycle, on 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 ideally be within a third of the MPE for the grain type.

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

SEP is the standard deviation of at least 30 measurement errors from different CRMs. A limit for the uncertainty associated with certified P_{MB} values in the calculation of *SEP* 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 the level of inhomogeneity can result in enlarged *SEP* values that can be wrongly attributed to the calibrations under test. It is recommended that the expanded uncertainty associated with the P_{MB} value of any CRM used in the assessment of calibrations is limited to one third of the value in clause 4.5 Table 4 column 3.

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

The characteristics of the standards (reference materials) used as test samples shall be representative of the grain being traded in the region. This is particularly important for the assessment of calibrations in clause C.7. 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 or spraying the sample with water or by extended exposure to high humidity air. Before storing a sample for any length of time, ensure that the moisture level does not make it susceptible to mould, which can occur at relatively low levels for certain types of grain 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 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 visibly 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 (MANDATORY)

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.6.5 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 test, 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 Prior to commencing the climatic tests and the STS test, the facility for suppressing measurements or results outside specified temperature ranges shall be disabled to ensure that error shift values can be calculated during the 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~~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

N~~ote~~OTE: ~~As these can expect to be fulfilled without specific measures in normal laboratory conditions, i~~It is not deemed necessary to ~~measure/~~monitor these values beyond measures specified in the test standard/ procedure.

Any reference condition applicable to grain samples has been marked by an asterisk (*).

During each test, the ~~T~~t_{ref} and 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~~t_{ref} during each test, except for the sample temperature sensitivity (STS) tests and the climatic tests. The sample temperature range and Δ~~T~~t_{max} according to clause 4.3 shall be observed during all tests.

After 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.3.4 Summary of the tests concerned with measurement reproducibility

To define the reproducibility conditions, Table 8 specifies the conditions changed and unchanged.

Table 8: Conditions changed and unchanged in the measurement reproducibility tests

Measurement reproducibility test	Conditions of measurement	
	Varied	Constant
Tests for time related effects [C.4] The magnitude of an error shift indicates the level of reproducibility in measurements taken at different times on the same instrument	Measurement time or session	Instrument (same unit) Measurement procedure Operating conditions Location Operator Sample
Tests for influence variations within the rated operating conditions [C.5] 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 session (still the same session if within 48 hours) Location Operator Sample (except sample temperature during climatic tests)
Tests for disturbances [C.6] 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 session Location Operator Sample
Assessment of calibrations in the submitted type [C.7] SDD_I indicates the level of reproducibility in measurements from two units of the same type	Instrument unit	Type of instrument Measurement procedure Operating conditions Measurement session Location Operator Sample

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} and stable moisture content. Allowable grains are specified by the national responsible body. Wheat is the preferred grain type.
Test procedure (in brief)	~~Six~~ Five 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 warm-up 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~~ five 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 shall 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 4 column 9. 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}). Allowable grains are specified by the national responsible body. Wheat is the preferred grain type.
Test procedure	This test is commenced prior to other type evaluation tests (except of the warm-up time test). ~~Six~~ Five P_{MB} measurements on the sample are taken using each unit, at every test condition:

(in brief)	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~~ five 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 4 column 9. 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} and stable moisture content. Allowable grains are specified by the national responsible body. Wheat is the preferred grain type.
Test procedure (in brief)	~~Six~~ Five 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~~ five 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 to 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 4 column 9. 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}). Allowable grains are specified by the national responsible body. Wheat is the preferred grain type. 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 [14], IEC 60068-3-1 [15]
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~~ Five 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.
Test severity	Exposure duration (after EUT stabilisation): 2 h; Minimum temperature: ~~T~~t_C or 10 ºC ~~T~~t_C is the minimum temperature in the operating range specified by the national responsible body.
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~~ five 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 three P_{MB} measurements per grain samples are recorded for each instrument. 7) 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 ~~three times~~ twice on both units of the EUT again. 8) After ensuring that ~~six~~ five P_{MB} measurements on each cold sample are recorded for each instrument, the EUT and grain samples are recovered to reference temperature. 9) 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) 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 4 column 9 for no correction to apply. 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 (recovery) = Correction for error shift (recovery)
Acceptance requirements	All values for the error shift (i.e. with any necessary correction) shall be within the limit in clause 4.5 Table 4 column 9. 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}). Allowable grains are specified by the national responsible body. Wheat is the preferred grain type. 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 [16], 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~~ Five 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.
Test severity	Exposure duration (after EUT stabilisation): 2 h; Maximum temperature: ~~T~~t_H or 30 ºC ~~T~~t_H is the maximum temperature in the operating range specified by the national responsible body.
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~~ five 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 ~~three~~ five P_{MB} measurements per grain samples are recorded for each instrument. ~~7) 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 three times on both units of the EUT again.~~ ~~8~~7) After ensuring that ~~six~~ five P_{MB} measurements on each hot sample are recorded for each instrument, the EUT and grain samples are recovered to reference temperature. ~~9~~8) 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) 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 4 column 9 for no correction to apply. 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 (recovery) = Correction for error shift (recovery)
Acceptance requirements	All values for the error shift (i.e. with any necessary correction) shall be within the limit in clause 4.5 Table 4 column 9. 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}). Allowable grains are specified by the national responsible body. Wheat is the preferred grain type. Except during analysis, each sample is kept in its enclosure during the test. The enclosed samples are only introduced to the damp heat 2 hours prior to testing. Samples used in a climatic test shall not be reused in other tests.
Standards	IEC 60068-2-78 [17], IEC 60068-3-4 [18]
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~~ Ten 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
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 by a spare unit.
Test severity	Exposure duration (after EUT stabilisation): 2 days; Maximum RH: 85% Maximum temperature: ~~T~~t_H or 30 ºC ~~T~~t_H is the maximum temperature in the operating range specified by the national responsible body.
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~~ twice on instrument 1, then ~~once~~ twice on instrument 2, then ~~once~~ twice on the spare unit. Further P_{MB} measurements are taken across the three units in the same manner, until ~~six~~ ten P_{MB} measurements are recorded for each instrument. 4) Step 3 is repeated for the other two grain samples. 5) The EUT is subjected to the maximum temperature and humidity and stabilised. The exposure duration is observed. Two hours prior to the end of the exposure duration, the enclosed grain samples are introduced to damp heat conditions.

	6) All the hot grain samples are analysed in turn on both units of the EUT, alternating between the two instruments, until ~~three~~ five P_{MB} measurements per grain samples are recorded for each instrument. 7) 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 ~~three~~ five times on both units of the EUT again. 8) After ensuring that ~~six~~ ten P_{MB} measurements on each hot sample are recorded for each instrument, the EUT and grain samples are recovered to reference temperature. 9) 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) 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 4 column 9 for no correction to apply. 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 (recovery) = Correction for error shift (recovery)
Acceptance requirements	All values for the error shift (i.e. with any necessary correction) shall be within the limit in clause 4.5 Table 4 column 9. 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} and stable moisture content. Allowable grains are specified by the national responsible body. Wheat is the preferred grain type.
Standards	IEC/TR 61000-2-1 [19], IEC 61000-4-1 [20]
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 4 column 9. 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.5.6 Variation in voltage supplied by external 12V and 24 V road vehicle batteries

EUT	Two or more sample instruments of the submitted type
Grain sample	One sample with mid-range P_{MB} and stable moisture content. Allowable grains are specified by the national responsible body. Wheat is the preferred grain type.
Standards	ISO 16750-2 [21]
Test method and procedure (in brief)	Variation in supply voltage. The test comprises exposure to the specified maximum and minimum power supply voltage conditions for a period sufficient for achieving temperature stability and performing the required measurements at these conditions. ~~Six~~ 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 lower voltage limit ii) EUT at the upper voltage limit iii) EUT after recovery at nominal test voltage (U_{nom}) The power is switched off after each test condition and switched on at the next test voltage.
Test severity	Stabilising period after voltage change: 30 min 12 V battery – test voltage lower limit: 9 V, test voltage upper limit: 16 V. 24 V battery – test voltage lower limit: 16 V, test voltage upper limit: 32 V. The values of U_{nom} are those marked on the measuring instrument.
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 (low voltage) = Mean P_{MB} (test condition ii) – Mean P_{MB} (test condition i) Error shift (high 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 4 column 9. All operational functions shall operate as designed.

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} and stable moisture content. Allowable grains are specified by the national responsible body. Wheat is the preferred grain type.
Standards	IEC 61000-4-11 [22], IEC 61000-6-1 [23], IEC 61000-6-2 [24]
Test method	Short-time reductions in mains voltage
Test procedure (in brief)	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 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~~ five 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 2.2.16 is considered for any values of fault exceeding the limit in clause 4.5 Table 4 column 10.
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 instrument~~s~~ of the submitted type ~~(a repeat cycle is required for another unit)~~
Grain sample	One sample with mid-range P_{MB} stable moisture content. Allowable grains are specified by the national responsible body. Wheat is the preferred grain type.
Standards	IEC 61000-4-1 [20], IEC 61000-4-4 [25]
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~~ five 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 2.2.16 is considered for any values of fault exceeding the limit in clause 4.5 Table 4 column 10.
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 fields

EUT	One sample instrument~~s~~ of the submitted type ~~(a repeat cycle is required for another unit)~~
Grain sample	One sample with mid-range P_{MB} and stable moisture content. Allowable grains are specified by the national responsible body. Wheat is the preferred grain type.
Standards	IEC 61000-4-3 [26]
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 30 MHz 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 *For the frequency range 26 - 80 MHz, the testing laboratory may carry out the test according to clause C.6.4.
Test result	The fault on each P_{MB} measurement is calculated with the mean of ~~six~~ five 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 2.2.16 is considered for any values of fault exceeding the limit in clause 4.5 Table 4 column 10.
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 electromagnetic fields

EUT	One sample instrument~~s~~ of the submitted type ~~(a repeat cycle is required for another unit)~~
Grain sample	One sample with mid-range P_{MB} and stable moisture content. Allowable grains are specified by the national responsible body. Wheat is the preferred grain type.

Standards	IEC 61000-4-6 [27]
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.6.4 shall prevail.
Test result	The fault on each P_{MB} measurement is calculated with the mean of ~~six~~ five 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 2.2.16 is considered for any values of fault exceeding the limit in clause 4.5 Table 4 column 10.
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 instrument~~s~~ of the submitted type ~~(a repeat cycle is required for another unit)~~
Grain sample	One sample with mid-range P_{MB} and stable moisture content. Allowable grains are specified by the national responsible body. Wheat is the preferred grain type.
Standards	IEC 61000-4-2 [28]
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~~ five 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 2.2.16 is considered for any values of fault exceeding the limit in clause 4.5 Table 4 column 10.
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 Storage temperature (extreme shipping conditions)

EUT	Two or more sample instruments of the submitted type

Grain sample	One sample with mid-range P_{MB} and stable moisture content. Allowable grains are specified by the national responsible body. Wheat is the preferred grain type.
Test procedure (in brief)	1) The EUT is placed in the environmental chamber. 2) 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. 3)The chamber temperature is then increased to maximum temperature over a 1 hour period and maintained at that temperature for 3 hours. ~~3~~4) The chamber temperature is then decreased to minimum temperature over a 1 hour period and maintained at that temperature for 3 hours. ~~4~~5) The temperature cycle is repeated. ~~5~~6) The EUT is equilibrated under reference conditions for at least 12 hours unpowered. ~~6~~7) After the specified warm-up period, a series of P_{MB} measurements is taken again – 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: 5~~0~~5 ºC or a lower temperature specified by the national responsible body.
Test result	The fault on each P_{MB} measurement is calculated with the mean of ten 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 2.2.16 is considered for any values of fault exceeding the limit in clause 4.5 Table 4 column 10.
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 Random vibration

EUT	~~Two or more~~ One sample instrument~~s~~ of the submitted type
Grain sample	One sample with mid-range P_{MB} and stable moisture content. Allowable grains are specified by the national responsible body. Wheat is the preferred grain type.
Standards	IEC 60068-2-47 [29], IEC 60068-2-64 [30], IEC 60068-3-8 [31]
Test method	Exposure to random vibration
Test procedure (in brief)	The EUT shall be mounted on a rigid fixture by its normal mounting means so that the gravitational force acts in the same direction as it would be in normal use. After having been switched off, vibrations shall be applied in three mutually perpendicular axes for at least two minutes per axis. After the vibrations, the EUT is switched on and the warm-up period is observed, 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	Vibration duration per axis: 1 h; Total frequency range: 10 Hz – 150 Hz; Total RMS level: 7 ms^{-2}; ASD level 10 Hz – 20 Hz: 1 m^2s^{-3}; ASD level 20 Hz – 150 Hz: – 3 dB/octave.
Test result	The fault on each P_{MB} measurement is calculated with the mean of ~~six~~ five 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 2.2.16 is considered for any values of fault exceeding the limit in clause 4.5 Table 4 column 10.
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 grain in the scope of the calibration under test. The P_{MB} values shall evenly cover the full measurement range specified for the type 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 in 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. Prior to assessing the calibrations the EUT may be adjusted so that the intrinsic error is as close to zero as possible. 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 – average bias of mean and *SEP*	The extent of inaccuracy is indicated by the error of P_{MB} values averaged over all the samples in the set, $\bar{y}$, together with the Standard Error of Prediction, *SEP*, which is the standard deviation of the measurement error on each sample. An improved estimation of $\bar{y}$ (also known as the 'calibration bias') is possible by using the mean P_{MB} in the calculation of y for each sample. For the *SEP*, 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** $SEP = \sqrt{\frac{\sum_{i=1}^{n}\left(y_{i,j=1} - \bar{y}_{i,j=1}\right)^2}{n-1}}$ **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 repeatability test – Pooled SD of replicates	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 an instrument with a particular calibration is assessed by averaging the *SD* across all the samples in the set (refer to Equation 5). . $Pooled\ SD = \sqrt{\frac{\sum_{i=1}^{n}\sum_{j=1}^{3}\left(x_{i,j} - \bar{x}_i\right)^2}{2n}}$ **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. $$SDD_I = \sqrt{\frac{\sum_{i=1}^{n}(d_i - \bar{d})^2}{n-1}}$$ **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 4. ȳ (Equation 3) and *SEP* (Equation 4) – the limits in columns 4 and 5 respectively Pooled *SD* (Equation 5) – the limit in column 6 SDD_I (Equation 6) – the limit in column 7

C.7.2 Sample temperature sensitivity (STS)

EUT	Two sample instruments of the submitted type set-up according to clause C.2.1.
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 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 and instrument temperatures)	Sample temperature: $t_{ref} \pm \Delta t_{max}$ where: 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} (if unequal to $\Delta t_{C,\ max}$) $t_{ref} + \Delta t_H < 45$ °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~~t_{ref} + Δ~~T~~$t_{H,max}$ 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 average error shift are calculated at the high and low moisture levels for every grain type by averaging the measured values from 3 samples. Two values of the average error shift are calculated at each level of moisture based on the following differences: Δ~~T~~$t_{C,max}$ average error shift = Mean P_{MB} 3 cold samples – Mean P_{MB} 3 samples at ~~T~~$t_{ref}^{(1)}$ & ~~T~~$t_{ref}^{(2)}$ Δ~~T~~$t_{H,max}$ average error shift = Mean P_{MB} 3 hot samples – Mean P_{MB} 3 samples at ~~T~~$t_{ref}^{(2)}$ & ~~T~~$t_{ref}^{(3)}$ Four values of pooled error shift are calculated for each grain type.
Acceptance requirements	All values for the average error shift shall be within the limit in clause 4.5 Table 4 column 8. 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 4 column 9. Sample variation (1st recovery) = Mean P_{MB} sample at ~~T~~$t_{ref}^{(2)}$ – Mean P_{MB} sample at ~~T~~$t_{ref}^{(1)}$ Sample variation (2nd recovery) = Mean P_{MB} sample at ~~T~~$t_{ref}^{(3)}$ – Mean P_{MB} sample at ~~T~~$t_{ref}^{(2)}$

ANNEX D. SOFTWARE EXAMINATION (MANDATORY)

Further details are included in OIML R xxx Part 3 *Examination checklist – requirements for software controlled devices and security*.

Refer to D 31 clause 6.3.2 for the specific items of interest associated with the following validations methods recommended for a grain protein measuring instrument:

AD – Analysis of documentation and specification and validation of the design [D 31, 6.3.2.1]

VFTM – Validation by functional testing of the metrological functions [D 31, 6.3.2.2]

VFTSw – Validation by functional testing of the software functions [D 31, 6.3.2.3]

Refer to Welmec Guide 7.2 [32] for a systematic method of checking the submitted software documentation.

Software and security checks in R xxx	D 31 reference	Validation method(s)
6.1 Specification of the software requirements		
6.1.1 – Description of how software is implemented	--	AD
6.1.2 – Software identification	5.1.1	AD + VFTSw
6.1.3 – Correctness of algorithms and functions	5.1.2	AD + VFTM
6.1.4 – Conformity of manufactured devices to the approved type (validation during type evaluation is optional)	5.2.5	AD + VFTSw
6.1.~~6~~5 – Support of fault detection	5.1.4.1	AD + VFTSw
6.1.6 – Separation of software parts	5.1.2.1	AD
6.1.7 – Compatibility of operating systems and hardware	5.2.4	AD + VFTSw
6.1.8 – Specification of national requirements for recording of the measurement data.	--	--
6.~~2~~1.~~1~~9 – Specification of national requirements for measurement data used at another place or time via an insecure environment.	--	--
6.2 ~~Electronic d~~Data storage ~~and transmission~~		
6.2.1 – Automatic storing	5.2.3.4.a	AD + VFTSw
6.2.2 – Storage of necessary measurement information	5.2.3.1	AD + VFTSw
6.3 Data transmission		
6.~~2.~~3.1 – Protection to ensure authenticity, integrity and correctness 6.3.2 – Cryptographic means of data protection may be required*.	5.2.3.2	AD + VFTSw (+ SMT)
~~6.2.4 – Automatic storing~~	~~5.2.3.4.a~~	~~AD + VFTSw~~
6.~~2~~3.~~5~~3 – Transmission delay	5.2.3.5	AD + VFTSw
6.~~2~~3.~~6~~4 – Transmission interruption	5.2.3.6	AD + VFTSw
6.4 Provision for software and calibration security		
6.4.1 – Sealing	5.1.3.2.d	AD + VFTSw
6.4.2 – Fraud protection	5.1.3.2.a - c	AD + VFTSw
6.~~3~~5 Software documentation	6.1.1	--
9.4 Maintenance and reconfiguration of the approved software		
Requirements for Traced Updates (if permitted)	5.2.6.2	AD + VFTSw
9.5 In-field updates to grain calibrations		
9.5.3 – Security of calibrations and reverification	5.2.6.1 and/or 5.2.6.2	AD + VFTSw

*More intensive examination such as software module testing (SMT) may be required by the national responsible body if it mandates cryptographic means of data protection in instruments that are allowed to be used in open networks.

ANNEX E. BIBLIOGRAPHY (INFORMATIVE)

1 ISO/IEC Guide 99; OIML V 2-200 (2012) International Vocabulary of Metrology – Basic and General Concepts and Associated Terms (VIM)
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.

2 OIML V1 (2DV revision 2012) International Vocabulary of Terms in Legal Metrology (VIML)

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

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 24333 (2009) Cereals and milled cereals -– Sampling
Specifies requirements for the dynamic or static sampling, by manual or mechanical means, of cereals and cereal products, for assessment of their quality and condition.

7 OIML D 2 (2007) Legal units of measurement

8 OIML D 16 (2011) Principles of assurance of metrological control

9 OIML D 20 (1998) Initial and subsequent verification of instruments and processes

10 OIML D 9 (2004) Principles of metrological supervision

11 ISO/TS 16634-2 (2009) Food products – Determination of the total nitrogen content by combustion according to the Dumas principle and calculation of the crude protein content

12 ISO 24083 (2006) Determination of the nitrogen content and calculation of the crude protein content – Kjeldahl method
Specifies a method for the determination of the nitrogen content of cereals, pulses and derived products, according to the Kjeldahl method, and a method for calculating the crude protein content. The method does not distinguish between protein nitrogen and non-protein nitrogen.

13 ISO Guide 35 (2006). General and statistical principles for certification
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).

14 IEC 60068-2-1 (1990-05) with amendments 1 (1993-02) and 2 (1994-06) Environmental testing, Part 2: Tests, Test A: Cold
Concerns cold tests on both non-heat-dissipating and heat dissipating specimens.

15 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).

16 IEC 60068-2-2 (1974-01), with amendments 1 (1993-02) and 2 (1994-05) Environmental testing Part 2: 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.

17 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.

18 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.

19 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.

20 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

21 ISO 16750-2:2006 Road vehicles – Environmental conditions and testing for electrical and electronic equipment Part 2: Electrical loads

Specifies electrical loads and corresponding tests and requirements for the mounting of electric and electronic systems and components on road vehicles. It is applicable to environmental conditions and tests affecting electrical and electronic equipment mounted directly on or in the vehicle. It does not cover electromagnetic compatibility (EMC).

22 IEC 61000-4-11 (2004-03) Electromagnetic compatibility (EMC) – Part 4-11: Testing and measuring techniques - Voltage dips, short interruptions and voltage variations immunity tests

Defines the immunity test methods and range of preferred test levels for electrical and electronic equipment connected to low-voltage power supply networks for voltage dips, short interruptions, and voltage variations.

23 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.

24 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.

25 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.

26 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.

27 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.

28 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.

29 IEC 60068-2-47 Ed 3.0 (2005-4) Environmental testing Part 2-47: Tests Mounting of specimens for vibration, impact and similar dynamic tests

Provides methods of mounting components, and mounting requirements for equipment and other articles, for the families of dynamic tests in IEC 60068-2, that is impact (Test E), vibration (Test F) and acceleration, steady-state (Test G).

30 IEC 60068-2-64 Ed 2.0 (2008-04) Environmental testing – Part 2-64: Test methods, Test Fh: Vibration, broad-band random and guidance

Determines the adequacy of specimens to resist dynamic loads without unacceptable degradation of its functional and/or structural integrity when subjected to the specified random vibration test requirements.

31 IEC 60068-3-8 Ed. 1.0 (2003-08) Environmental testing – Part 3-8: Supporting documentation and guidance - Selecting amongst vibration tests

Provides guidance for selecting amongst the IEC 60068-2 stationary vibration test methods Fc sinusoidal, Fh random and F(x) Mixed mode vibration. The different steady-state test methods and their aims are briefly described in Clause 4. Transient test methods are not included.

32 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 [VIM 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 calibration [VIM 2.39]

operation that, under specified conditions, in a first step, establishes a relation between the quantity values with measurement uncertainties provided by measurement standards and corresponding indications with associated measurement uncertainties and, in a second step, uses this information to establish a relation for obtaining a measurement result from an indication

VIM NOTES

1 A calibration may be expressed by a statement, calibration function, calibration diagram, calibration curve, or calibration table. In some cases, it may consist of an additive or multiplicative correction of the indication with associated measurement uncertainty.

2 Calibration should not be confused with adjustment of a measuring system, often mistakenly called "self-calibration", nor with verification of calibration.
3 Often, the first step alone in the above definition is perceived as being calibration.

F.1.4 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.1.5 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.1.6 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.1.7 rated operating condition [VIM 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.1.8 reference condition [VIM 4.11]

Operating condition prescribed for evaluating the performance of a measuring instrument or measuring system or for comparison of measurement results

VIM NOTES

1 Reference conditions specify intervals of values of the measurand 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.1.9 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.1.10 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.1.11 repeatability; measurement repeatability [VIM 2.21]

Measurement precision under a set of repeatability conditions of measurement .

F.1.12 repeatability condition of measurement [VIM 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.1.13 reproducibility; measurement reproducibility [VIM 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.1.14 reproducibility conditions of measurement [VIM 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 VILM (2DV revision 2012) definitions

F.2.1 type (pattern) evaluation [VILM 2.04]

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.

VILM NOTE: ‘Pattern’ is used in legal metrology with the same meaning as ‘type’; in the entries below, only ’type’ is used.

F.2.2 type approval [VILM 2.05]

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.

VILM NOTE: See also A1.26.

F.2.3 verification of a measuring instrument [VILM 2.09]

Conformity assessment procedure (other than type evaluation) which results in the affixing of a verification mark and/or issuing of a verification certificate.

VILM NOTE: See also OIML V2-200:2010, 2.44.

ANNEX G. PHILOSOPHY FOR SEALING (INFORMATIVE)

This Annex highlights considerations for determining which parameters on a grain protein measuring instrument require sealing. It also provides examples of sealing methods, such as metrological audit trails, and the minimum requirements for an effective seal.

G.1 ~~Definitions~~Terminology specific to this Annex

G.1.1 Adjustment mode

An operational mode of a ~~device~~ measuring instrument which enables the user to make adjustments to sealable parameters, including changes to configuration parameters.

G.1.2 Adjustment

A change in the value of ~~a device's~~ the sealable calibration parameters or the sealable configuration parameters of an instrument.

G.1.3 Audit trail

An electronic count and/or information record of the changes to the values of the calibration or configuration parameters of a ~~device~~measuring instrument. ~~(The term addresses all forms of audit described in this paper).~~

~~Calibration parameter~~

~~Any adjustable parameter that can affect measurement or performance accuracy; and due to its nature, needs to be updated on an ongoing basis to maintain device accuracy (e.g. span adjustments, linearization factors, and coarse zero adjustments).~~

~~Configuration parameter~~

~~Any adjustable or selectable parameter for device that can affect the accuracy of a transaction or can significantly increase the potential for fraudulent use of the device and, due to its nature, needs to be updated only during device installation or upon replacement of a component (e.g. division value (increment), sensor range, and units of measurement).~~

G.1.4 Enabling/inhibiting sealable hardware

Physically sealable hardware, such as a two-position switch located on a remotely configurable ~~device~~ instrument that enables and inhibits the ~~capability to receive adjustment values or changes to~~ sealable ~~configuration~~ parameters of the instrument from being changed from a remote device.

G.1.5 Event

While in adjustment mode, a~~A~~n action in which:

- one or more changes are made to configuration parameters, or
- adjustments are made to one value (or values for a set of values) for a calibration parameter (e.g. adjustments for a set of calibration factors to linearize device output)~~, while in adjustment mode~~.

If no adjustment is made, then there is no event. In the case of a centralized audit trail, the same values for the same parameter sent to multiple devices shall be considered to be the same event. In the case of a centralized event logger, the event logger must identify both the device and the parameter that was changed.

G.1.6 Event counter

A non-resettable counter that increments once each time the mode that permit changes to sealable parameters is entered and one or more changes are made to sealable ~~calibration or configuration~~ parameters of ~~a device~~the instrument.

~~NOTE: An event counter shall have a capacity of at least 1000 values (e.g. 000 to 999).~~

G.1.7 Event logger

A form of audit trail containing a series of records where each record contains the number from the event counter corresponding to the change to a sealable parameter, the identification of the parameter that was changed, the time and date when the parameter as changed, and the new value of the parameter.

G.1.8 Physical seal

A physical means, such as lead and wire, used to seal a device to detect access to those adjustable features that are required to be sealed.

G.1.9 Remote configuration capability

The ability to adjust a weighing or measuring device instrument or change its sealable parameters from or through some other device that is not itself necessary to the measurement operation of the weighing or measuring device or is not permanent part of that devicethe instrument.

G.1.10 Remote device

A device that (1) is not required for the measurement operation of the primary device instrument or computing the transaction information in one or more of the available operating modes for commercial measurements, or (2) is not a permanent part of the primary devicemeasuring instrument. In the context of this paperAnnex, a remote device has the ability to adjust another device a measuring instrument or change its sealable configurable parameters.

G.1.11 Remotely configurable device

Any weighing or measuring instrument with remote configuration capability that permits sealable configuration or calibration parameter values to be deleted, appended to, modified, or substituted in whole or in part by downloading over any type of communications link from another device, such as a geographically local or remote console or computer, whether or not the secondary apparatus is part of the network connecting the devices,

G.1.12 Seal

As a verb, to seal a device is to make a device secure so that access to adjustments and other sealable parameters will be detectable.

G.1.13 Sealable parameters

Calibration and configuration parameters that are required to be sealed.

G.1.14 Unrestricted access to sealable parameters

Unrestricted access means that a physical security seal is not present, so that access to the sealable parameters is available from a remote device at any time at the request of an authorizsed operator subject to the operating status of the receiving device.

G.2 Principles for determining features to be sealed

The need to seal some features depends upon both the following:

- The ease with which the feature or the selection of the feature can be used to facilitate fraud; and
- The likelihood that the use of the feature will result in fraud not being undetected.

Features or functions which the operator routinely uses as part of device operation, such as selecting the grain calibration to be used, are not sealable parameters and shall not be sealed.

If selection of a parameter (or set of parameters), selection would result in performance that would be obviously in error, such as the selection of parameters for different countries, then it is not necessary to seal the selection of these features.

If individual device characteristics are selectable from a "menu" or a series of programming steps, then access to the "programming mode" must be sealable.

NOTE: If an audit trail is the only means of security, then it shall update only after at least one sealable parameter has been changed; simply accessing the sealable parameters via a menu shall not update the audit trail.

The current language in NIST Handbook 44, paragraph G-s.8 states: "A device shall be designed with provision(s) for applying a security seal that must be broken, or for using other approved means of providing security (e.g. data change audit train available at the time of inspection), before any change that detrimentally affects the metrological integrity of the device can be made to any electronic mechanism." Thus, fFor parameters protected by physical means of security, once a physical security seal is applied to the deviceinstrument, it should not be possible to make a metrological change to those parameters without breaking that seal. Likewise, fFor parameters protected by electronic means of security, it should not be possible to make a metrological change to those parameters without that change being reflected in an audit trail. Since this philosophy addresses provisions for protecting access to any metrological adjustment, the philosophy should be applied consistently to all electronic device types.

If a device must undergo a physical act, such as cutting a wire and physically repairing the cut to reactivate the parameter, then this physical repair process would be considered an acceptable way to select parameters without requiring a physical seal or an audit trail.

G.3 Typical features and parameters to be sealed

The following provides examples of configuration and calibration parameters that are to be sealed. The examples are provided for guidance and are not intended to cover all possible parameters.

G.3.1 Calibration Parameters

Calibration parameters are those adjustable parameters that can affect measurement or performance accuracy; and whose values need to be updated on an ongoing basis to maintain device are expected to change as a result of accuracy adjustments. Calibration parameters can be classified into three categories:

(1) Those parameters, which are adjusted, to standardizse or normalizse instrument response to changes in the physical parameter being measured, Examples include zero-setting and test point adjustments, temperature sensing element zero and span adjustments, amplifier gain settings, optical wavelength standardizsation adjustments, etc.) These are parameters normally set by the manufacturer or a competent service representative.

(2) Those parameters, which are common to all instruments of like the same type for a given grain class and constituent type (e.g. grain constituent P_{MB} calibration coefficients). The approval certificate of conformance lists the calibration coefficients (or a unique identifier) for each grain class (or type) which has been approved for use on that a particular type of grain protein measuring instrument under the NTEP program.

(3) Those parameters, which are adjusted for each grain type to standardizse constituent P_{MB} readings on, like instruments (e.g. slope and bias settings).

G.3.2 Configuration Parameters

Configuration parameters are those adjustable or selectable parameters that can affect the accuracy of a transaction or can significantly increase the potential for fraudulent use of the device; and whose values are expected to be entered once only needs to be updated during instrument installation or upon replacement of a component and not expected to changed after all initial installation settings have been made.

(1) System date and time (only if used by an event logger as audit trail information).

(2) Constituent P_{MB} value resolution.

(3) Sample size and/or number of sub portions measured (if not determined by individual grain constituent calibrations).

(4) Password for access to sealable parameters (if used).

(5) Enable/disable display of parameters constituent values that are not legally relevant (e.g. approximate test weight).

(6) Format for results display and recording.

(7) Operating range limits (e.g. temperatures).

(8) Enable/disable display or recording of results for out-of-limits conditions.

G.4 Requirements for mMetrological audit trails

G.4.1 Scope

This discussion lists the requirements for the acceptable forms of metrological audit trail, which the NCWM recognizes as providing acceptable security for commercial grain moisture testers and near infrared grain analyzers.

The ability of users to make changes the affect the metrological integrity of the device (e.g. slope, bias, etc.) in normal operation and the remote configuration capability of commercial grain moisture meters and near infrared grain analyzersprotein measuring instruments was a major consideration in the development of the criteria ultimately adopted by the NCWM. Weights and measures officials are concerned that the use of such new features might has lead to increased fraudulent use of devices unless new, more appropriate means of sealing are also being implemented.

Categories of device

Grain measuring devices These instruments must be either physically sealed or must incorporate an approved form of audit trail. A device that allows virtually unrestricted access, whether by the operator or by a remote device, to configuration parameters or calibration parameters must have an even logger as its minimum form of audit trail.

This discussion lists Included below are the requirements for the acceptable forms of metrological audit trail, which the NCWM are recognizsesd as providing acceptable security for commercial grain moisture testers and near infrared grain analyzers.

An event logger contains detailed information on the parameters that have been changed and documents the new parameter values. An event logger requires a significant amount of memory; however, it is anticipated that any device to which unrestricted access is given, will be part of sophisticated measurement process that will have considerable memory available.

Provision for sealing near infrared analyzers

- Provision shall be made to apply a security seal in a manner that requires the security seal to be broken, or for using other approved means of providing security (e.g. audit trail available at the time of inspection as defined in part (b)), before any changes that affects the metrological integrity of the device can be made to any mechanism.
- If the operator is able to make changes that affect the metrological integrity of the device (e.g. slope, bias, etc.) in normal operation, the device shall use an audit trail. The minimum form of audit trail shall be an event logger and shall include:
- An event counter (000 to 999),
- The parameter ID,
- The date and time of the change, and
- The new value of the parameter (for calibration changes consisting of multiple calibration constants, the calibration version number is to be used rather than the calibration constants.

A printed copy of the information must be available through the device or through another on-site device. The event logger shall have a capacity to retain records equal to twenty-five (25) times the number sealable parameters in the device, but not more than 100 records are required.

NOTE: Does not require 1000 changes to be stored for each parameter.

G.4.2 Event loggers: An acceptable form of audit trails

The event logger is the minimum form of audit trail for instruments grain moisture meters and near infrared grain analyzers (those that have allows unrestricted or remote access whether by an operator or a remote device, to the configuration or calibration parameters).

(1) The event logger shall contain the following information: event counter; date and time; parameter ID; new value.

NOTE: For calibration changes consisting of multiple calibration constants, the calibration version number is to be used as the new value rather than the calibration constants

(2) This information shall be automatically entered into the event logger by the devicemeasuring instrument. Additional relevant information is permitted (e.g. the identification of the person who made the adjustment or the old value of the parameter that was changed).

(3) The date and time shall be presented in understandable format. The date shall include month, day, and year. The time shall include the hour and minutes.

NOTE: For devices incorporating an event logger, date and time are considered sealable parameters, and changes to date or time must be logged the same as any other sealable parameter.

(4) A hard-copy printout of the contents of the event logger shall be available upon demand from the instrument or an associated device on the site of the instrument installation. The printing of the event logger contents shall exclude other information not relevant to the changes logged such as transaction data, number of measurements performed, etc.

(5) An event logger shall have a capacity of at least 25 times the number of sealable parameters; however, it is not required to retain more than 1000 events for all parameters combined.

G.4.3 General requirements for metrological audit trails

The following general requirements for metrological audit trails must be satisfied:

(1) The adjustment mode shall address only sealable parameters in order to avoid entering the adjustment mode to access non-sealable parameters that must be routinely changed as part of the normal use of the device.

(2) An event counter shall have a capacity of at least 1000 values, (e.g., 000 to 999.).

(3) In the case of the event logger, the event counter will increment once for each change to a sealable parameter since each new value must be retained in the event logger. If an adjustment mode is entered but no changes are made, this does not constitute an event and the counter must not increment.

(4) When the storage memory of the event logger has been filled to capacity, any new event shall cause the oldest event to be deleted. The event counter used in the event logger shall continue to increment to its capacity, although the event logger may retain fewer records than the count capacity of the event counter. The event counter provides the necessary information to indicate the number of records that have been overwritten in the event logger as new information overwrites the old records.

(5) The audit trail data shall be:

(a) Stored in non-volatile memory and shall be retained for at least 30 days if power is removed from the device; ~~AND~~and

(b) Protected from unauthori~~z~~sed erasure, substitution, or modification.

(6) Access to the audit trail information for the purpose of printing the contents must be "convenient" for ~~the~~ an enforcement official of the national responsible body.

(a) Accessing the audit trail information for review shall be separate from the calibration mode so there is no possibility for the ~~weights and measures~~ official to change or corrupt the device configuration or the contents of the audit trail.

(b) Accessing the audit trail information shall not affect the normal operation of a device before or after accessing the information.

(c) A key (for a panel lock) may be required to gain access to the means to view the contents of the audit trail. Access may be through the supervisor's mode of operation of the device.

(d) Accessing the audit trail information shall not require the removal of any additional parts other than normal requirements to inspect the integrity of a physical seal.

(7) The printed form of the audit trail information shall be readily interpretable by ~~the inspector~~an official.

(8) The information from an event logger shall be printed in order from the most recent event to the oldest event. If a device is not capable of printing all the information for a single event on one line or at one time, the information shall be displayed in blocks of information, which are readily understandable.

PART 3: 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, outlined 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 cannot 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 1 - 5 shall be included as a minimum.

APPLICABILITY OF THIS TEST REPORT FORMAT

In the framework of the OIML Certificate System for Measuring Instruments applicable to protein measuring instruments 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.