National Type Evaluation Technical Committee (NTETC) Grain Analyzer Sector August 25-26, 2010 - Kansas City, Missouri Meeting Agenda

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1. Report on the 2010 NCWM Interim and Annual Meetings

The 95^{th} Annual Meeting of the National Conference on Weights and Measures (NCWM) was held July 11 - 15, 2010 in St. Paul, Minnesota.

No Grain Moisture Meter (GMM) or Near Infrared (NIR) Grain Analyzer items appeared in the Specifications and Tolerances (S&T) Committee Interim Report for consideration by the NCWM at the 2010 Annual Meeting. Jim Truex, NTEP Administrator will report on other items that may be of interest to the Sector.

2. Report on NTEP Type Evaluations and OCP (Phase II) Testing

Cathy Brenner of the Grain Inspection, Packers and Stockyards Administration (GIPSA), the NTEP Participating Laboratory for Grain Analyzers, will bring us up to date on the progress of NTEP Type Evaluations and the collection and analysis of Grain Moisture Meter OCP (Phase II) data on the 2009 crop. She will also identify, for the 2010 harvest, the models enrolled in Phase II.

3. Review of Ongoing Calibration Program (Phase II) Performance Data

At the Sector's August 2005 meeting it was agreed that comparative OCP data identifying the Official Meter and listing the average bias for each NTEP meter type should be available for annual review by the Sector. Accordingly, Cathy Brenner, representing GIPSA, the NTEP Participating Laboratory for Grain Analyzers, will present data showing the performance of NTEP meters compared to the air oven. These data are based on the last three crop years (2007–2009) using calibrations updated for use during the 2010 harvest season. See the attached 2007-2009 GMM Phase II comparison graphs.

4. Report on New GIPSA/NIST Interagency Agreement for 2010 – 2014

The five-year Interagency Agreement that provides funding and defines the fee schedule for the NTEP Phase 2 Grain Moisture Meter On-going Calibration Program (OCP) expired September 30, 2009 (the end of the Federal Government's Fiscal Year 2009). At the time of the Sector's August 2009 meeting, a new Interagency Agreement was being reviewed by NIST's legal office. It was

anticipated that NIST approval would be received by the end of August 2009 so the agreement could be forwarded to GIPSA for final signatures.

Rich Pierce, GIPSA, will bring the Sector up to date on the status of the new agreement, and will point out the cost per meter type for applicable for the 2010 harvest.

The	proposed	fee schedu	le for the nev	v agreement i	s shown belo	ow:
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Proposed NTEP On-going Calibration Program Fee Schedule For Year 2010 to 2014							
(1)	(2)	(3)	(4)	Funding	g Contribut	ion From P	articipants
Total	Meters	Cost Per	Total	(5)	(6)	(7)	(8)
Meters	In NTEP	Pool	Program	NIST	GIPSA	Mfg's	Cost Per
(including	Pool	Meter	Cost			(total	Meter
official						funding	Туре
meter)						from	
						mfg's)	
2	1	22,500	22,500	7,500	7,500	7,500	3,750
3	2	22,500	45,000	15,000	15,000	15,000	5,000
4	3	22,500	67,500	22,500	22,500	22,500	5,625
5	4	22,500	90,000	30,000	30,000	30,000	6,000
6	5	22,500	112,500	30,000	30,000	52,500	8,750
7	6	22,500	135,000	30,000	30,000	75,000	10,715
8	7	22,500	157,500	30,000	30,000	97,500	12,185
9	8	22,500	180,000	30,000	30,000	120,000	13,335

Column	Explanation (or formula for calculating)
(1) Total Meters	The number of meter types (including the Official GIPSA meter) that will share in the NTEP calibration costs.
(2) Total Meters in NTEP Pool	The number of meter types other than the Official meter that will share in the NTEP calibration costs.
(3) Cost per Pool Meter	The cost associated with each pool meter in the program.
(4) Total Program Cost	A per meter type cost of \$22,500 times the number of NTEP "pool" meters.
(5) NIST Contribution	One-third the total program cost up to a maximum of \$30,000.
(6) GIPSA Contribution	One-third the total program cost up to a maximum of \$30,000.
(7) Manufacturers Contributions (total funding from manufacturers)	Total Program Cost minus NIST Contribution minus GIPSA Contribution.
(8) Cost per Meter Type	Manufacturers' Contributions divided by Total Meters (including the Official meter).

5. Item 310-1 G-S.8. Provision for Sealing Electronic Adjustable Components, G-S.8.1., Adjustment Mode Indication, and Definitions for Adjustment and Adjustment Mode

Background: This item originated from the Southern Weights and Measures Association (SWMA) and first appeared on the S&T Committee's 2008 agenda. The proposal added requirements to G-S.8. to assure that a device could not be sealed in the configuration mode and continue to operate normally. Such a condition could facilitate fraud. The proposal as submitted required that a device continuously indicate when access to the set-up mode was not disabled.

At the 2008 Interim Meeting, the S&T Committee reviewed comments received during the open hearing and discussed alternate proposals provided by WMD and SMA. At the 2008 Annual Meeting, the WMD suggested that the S&T Committee amend the recommendation to address some of the concerns noted by the CWMA, NTEP participating laboratories, and WMD since the 2008 Interim Meeting. The item remained Informational for the 2008 Annual Meeting

During the open hearings at the 2009 Interim Meeting, WMD stated that it had received comments questioning how the application of a physical seal (as recommended by the manufacturer and listed on the CC) ensures that the calibration and configuration modes are disabled. What does that presence of the physical seal (pressure sensitive or lock and wire) do to the device that disables the calibration and configuration modes? The S&T Committee agreed with the comments that the proposal *was not ready* to become a Voting item and recommended that the item remain Informational for 2009.

At the 2010 NCWM Interim Meeting, WMD stated that it remained concerned about devices which could be sealed while allowing access to calibration or configuration changes without breaking that seal. WMD agreed with the position of the NCWM S&T Committee that the current language in paragraph G-S.8. requires that a security seal be broken before a metrological change can be made to a device (or other approved means of security such as an audit trail provided). Thus, once a security seal is applied, it should not be possible to make a metrological change to the device without breaking that seal. Since this philosophy addresses provisions for protecting access to any metrological adjustment, the philosophy should be applied consistently to all device types. WMD encouraged the S&T Committee to reiterate in its Interim and Final Reports the correct interpretation of G-S.8. as the Committee and the MS have done in the past, and as demonstrated in more recent actions by the WS.

The S&T Committee agreed that a device must be equipped with an approved audit trail or that a physical seal is required to be broken before any metrological adjustments to comply with paragraph G-S.8. The Committee also believed that an indication that the adjustment mode is in operation is only necessary for devices with approved electronic methods of sealing. Additionally, the adjustment mode indicator should not be operable during normal weighing or measuring operations. The Committee agreed that if a device designed for commercial applications is capable of being "sealed" and still allows external or remote access to the calibration or configuration mode, then that device is clearly in violation of the current provisions in G-S.8. Provision for Sealing Electronic Adjustable Components and G-S.2. Facilitation of Fraud and, therefore, no change to the existing language in paragraph G-S.8. would be needed. The S&T Committee believed that type evaluation procedures have been amended in applicable sections of NCWM Publication 14 to address the issues of incorrectly applying the requirements in G-S.8. The Committee also noted that there was some confusion regarding the meaning of the terms "adjustment" and "adjustment mode" in the CWMA Annual Meeting reports.

The S&T Committee received no comments addressing potential inconsistent interpretations of the requirements by field officials, requirements for adjustment mode indications, and limitations on metrological indications while in the adjustment mode in any proposals. Consequently, the Committee developed a revised proposal that:

- 1. does not change the existing text in G-S.8.;
- 2. adds language that restates the intent of G-S.8.;
- 3. adds language to address metrological (legal for trade) measurements while in an adjustment mode;
- 4. adds a new paragraph G-S.8.1. that requires an indication and, recorded representations while in the adjustment mode (if equipped with a printer); and
- 5. adds new definitions for "adjustment" and "adjustment mode" from the white paper on the "Metrological Requirements for Audit Trails" adopted by NCWM in July 1993 to facilitate a common understanding of the terms.

The S&T Committee also recommended that the amended proposal be given Informational status to allow interested parties sufficient time to analyze and comment on the most recent language that appears in the "Item Under Consideration" below:

[See the 2008 NCWM Annual and 2009 Interim and Annual Reports for additional background information.]

Item Under Consideration:

Amend General Code paragraph G-S.8. and subsequent subparagraphs.

G-S.8. Provision for Sealing Electronic Adjustable Components. - 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 trail 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. <u>That is:</u>

- (a) <u>It shall not be possible to apply a physical security seal to the device while it is in the calibration and/or configuration mode nor to access the calibration and/or configuration (adjustment) mode when sealed, or</u>
- (b) <u>The calibration and/or configuration adjustments are protected by an approved method for providing</u> <u>security (e.g. data change audit trail).</u>

A device may be fitted with an automatic or a semi-automatic calibration mechanism. This mechanism shall be incorporated inside the device. After sealing, neither the mechanism nor the calibration process shall facilitate fraud.

During any mode of operation in which adjustments can be made, devices shall not provide indications that can be interpreted, transmitted into memory, or printed as a usable (legal) measurement value. *

(Added 1985) (Amended 1989, and 1993, and 201X) [Nonretroactive as of January 1, 1990] *[Nonretroactive as of January 1, 201X]

G-S.8.1. Adjustment Mode Indication. For electronic devices protected by an approved means for providing security (e.g. data change audit trail), the device shall clearly and continuously indicate and print, if equipped with a printer, that the calibration and configuration adjustment modes are enabled. [Nonretroactive as of January 1, 201X]

G-S.8.12. Multiple Weighing or Measuring Elements that Share a Common Provision for Sealing. – A change to any metrological parameter (calibration or configuration) of any weighing or measuring element shall be individually identified. [Nonretroactive as of January 1, 2010]

Note: For devices that utilize an electronic form of sealing, in addition to the requirements in G-S.8.42., any appropriate audit trail requirements in an applicable specific device code also apply. Examples of identification of a change to the metrological parameters of a weighing or measuring element include, but are not limited to:

- (1) a broken, missing, or replaced physical seal on an individual weighing, measuring, or indicating element or active junction box;
- (2) a change in a calibration factor or configuration setting for each weighing or measuring element;
- (3) a display of the date of calibration or configuration event for each weighing or measuring element; or
- (4) counters indicating the number of calibration and/or configuration events for each weighing or measuring element.

(Added 2007)

Add applicable definitions to Appendix D from a white paper on the "Metrological Requirements for Audit Trails" adopted by NCWM in July 1993.

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

Adjustment. A change in the value of any of a device's sealable calibration parameters or sealable configuration parameters.

Discussion: This item is a carryover from the Grain Analyzer Sector's August 2009 meeting (Agenda Item 9). At that time the changes did not appear to affect the provisions for sealing GMMs and NIR Grain Analyzers. However, if the most recent language proposed for **G-S.8**. and its sub-paragraphs, see "Item Under Consideration" above, is the version that will ultimately be accepted, changes will have to be made in both the GMM Code in HB44 and the GMM checklist in Pub 14.

The necessary changes could be addressed as follows:

 Incorporate the essence of the proposed changes to G-S.8. and applicable subparagraphs; retain the simple device categories of the existing GMM Code; broaden the scope of Category 3 by removing "remotely"; and add a note to **Table S.2.5.** to explain the meaning and scope of "Remote configuration capability". This is accomplished by amending paragraph S.2.5. Provision for Sealing and **Table S.2.5.** Categories of Device and Methods for Sealing of HB44 §5.56.(a) Grain Moisture Meters, and amending all the GMM Pub 14 checklist items under the heading Code Reference: S.2.5. Provision for Sealing to include the proposed additions/amendments to G-S.8.

The suggested HB44 changes are as follows:

S.2.5. Provision for Sealing. – Provision shall be made for applying 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 Table S.2.5. Categories of Device and Methods of Sealing) before any change that affects the metrological integrity of the device can be made to any <u>*electronic*</u> mechanism. <u>*That is:*</u>

- (a) It shall not be possible to apply a physical security seal to the device while it is in the calibration and/or configuration mode nor to access the calibration and/or configuration (adjustment) mode when sealed, or
- (b) <u>The calibration and/or configuration adjustments are protected by an approved method for providing</u> <u>security (e.g. data change audit trail).</u>

During any mode of operation in which adjustments can be made, devices shall not provide indications that can be interpreted, transmitted into memory, or printed as a usable (legal) measurement value.

(Amended <u>201X</u>)

[Nonretroactive as of January 1, 201X]

<i>Table S.2.5.</i>				
Categories of Device and Methods of Sealing				
Categories of Device	Methods of Sealing			
<i>Category 1:</i> No remote configuration capability.	Seal by physical seal or two event counters: one for calibration parameters (000 to 999) and one for configuration parameters (000 to 999). If equipped with event counters, the device must be capable of displaying, or printing through the device or through another on-site device, the contents of the counters.			
<i>Category 2: Remote configuration capability, but access is controlled by physical hardware.</i>	The hardware enabling access for remote communication must be at the device and sealed using a physical seal or two event counters: one for calibration parameters (000 to 999) and one for configuration			
A device shall clearly indicate that it is in the remote configuration mode and shall not be capable of operating in the measure mode while enabled for remote configuration.	parameters (000 to 999). If equipped with event counters, the device must be capable of displaying, or printing through the device or through another on-site device, the contents of the counters.			
Category 3: Remote configuration capability access may be unlimited or controlled through a software switch (e.g., password).	An event logger (e.g., a data change audit trail) is required in the device; it must 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 constants,			
When accessed remotely for the purpose of modifying sealable parameters, the device shall clearly <u>and continuously</u> indicate that it is in the configuration mode and shall not be capable of operating in the measuring mode.	the calibration version number may 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 of sealable parameters in the device, but not more than 1000 records are required. (Note: Does not require 1000 changes to be stored for each parameter.)			
Category 3a: No remote capability, but operator is able to make changes that affect the metrological integrity of the device (e.g., slope, bias, etc.) in normal operation.	Same as Category 3			
Category 3b: No remote capability, but access to metrological parameters is controlled through a software switch (e.g., password).	Same as Category 3			
Note: Remote configuration capability is defined in HB4 parameters from or through some other device that is no a permanent part of that device.	4 as the ability to adjust a weighing or measuring device or change its sealable of itself necessary to the operation of the weighing or measuring device or is not			
As used in this table, "remote configuration capability sealable parameters from a memory chip, external com the measuring device or connected wirelessly to the mea (Added 201X)	" also includes the ability of the measuring device to accept new or revised uputer, network, or other device plugged into a mating port (e.g., USB port) on asuring device.			

[Nonretroactive as of January 1, 1999 and January 1, 201X]

(Amended 1998)

Note: Zero-setting and test point adjustments are considered to affect metrological characteristics and must be sealed. (Added 1993) (Amended 1995 and 1997)

Any additions/changes to HB44 will also need to be made to the corresponding Sections to Pub 14.

Consideration of the suggested changes and additions depends on further discussion of this item. Please note that this proposal is an informational item on the NCWM S&T agenda.

6. Item 310-3: G-S.1. Identification. – (Software)

Purpose: This proposal is intended to amend the identification marking requirements for all electronic devices manufactured after a specified date by requiring that metrological software version or revision information be identified. Additionally, the proposal will list methods, other than "permanently marked," for providing the required information.

Background: Starting at the October 2007 meeting, the Software Sector has discussed the value and merits of required markings for software. After several iterations, the Software Sector developed a table to reflect their positions. This table was submitted to NCWM S&T Committee and was assigned Developing status in 2008. However, the Software Sector did not include a recommendation on how to incorporate the proposal into existing G-S.1. and G-S.1.1. language. In particular, WMD was concerned about properly addressing the various existing requirements and multiple non-retroactive dates.

Prior to the NCWM 2009 Interim Meeting, NIST WMD commented on S&T Item 310-3, and presented an alternate proposal with significant modifications, which were included in the Interim Meeting Agenda background for the item. There was much additional comment and various proposed versions of the table from NIST WMD, et al. (The complete background on this item can be accessed at http://ts.nist.gov/WeightsAndMeasures/Publications/upload/08-ST-10-Pub15-FINAL.pdf, the S&T Committee Interim Agenda for the 2010 NCWM Interim Meeting as it appeared in Pub 15, 2010.)

At the 2009 Software Sector Meeting, it was agreed that the proposed table had not accomplished the intended purpose of clarifying the requirements. To remove some of the confusion the Software Sector revisited this item from the beginning modifying the text of G-S.1 to match the Software Sector's original intent.

At its March 2010 meeting, the Software Sector, in response to comments heard during the 2010 Interim meeting, revised the proposed language changes described in the S&T Committee Interim Agenda **Item 310-3**. These revisions removed existing mention of "not-built-for purpose" and the differentiation between Type P and Type U software types. The first sentence of G-S.1. was restored to the current HB44 wording.

The Software Sector also initiated discussion on two new concepts, which may eventually result in additional recommendations to amend G-S.1. First, the Software Sector sees merit to requiring some "connection" between the software identifier (i.e., version/revision) and the software itself. The proposal was as follows (with the expectation that examples of acceptable means of implementing such a link would be included in Pub 14).

Add a new sub-subparagraph **G-S.1.(d)(3)**:

"The version or revision identifier shall be directly and inseparably linked to the software itself. The version or revision identifier may consist of more than one part, but at least one part shall be dedicated to the metrologically significant software."

Second, it seems that at each meeting of the Software Sector, the states reiterate the problems they have in the field locating the basic information required when the CC number is marked via the rather general current **HB 44** requirement of 'accessible through an easily recognizable menu, and if necessary a sub-menu' [**G-S.1.1.(b)(3)**]. The states have indicated that this is too vague and field inspectors often cannot find the certificate number on unfamiliar devices.

The Software Sector would like feedback on the proposal to specify a limited number of menu items/icons for accessing the CC number (if is not hard-marked or continuously displayed) in subparagraph (c) as follows:

- (b) The CC Number shall be:
 - (3) accessible through one or, at most, two levels of access.

(i) For menu-based systems, "Metrology", "System Identification", or "Help".

(*ii*) For systems using icons, a metrology symbol ("M" or "SI"), or a help symbol ("?," "I," or an "i" within a magnifying glass).

To facilitate review of the suggested amendments, additions, and changes G-S.1. and its subparagraphs the current HB44 language has been marked up to show all of the suggested modifications.

G-S.1. Identification. – All equipment, except weights and separate parts necessary to the measurement process but not having any metrological effect, shall be clearly and permanently marked for the purposes of identification with the following information:

- (a) the name, initials, or trademark of the manufacturer or distributor;
- (b) a model identifier that positively identifies the pattern or design of the device;
 - (1) The model identifier shall be prefaced by the word "Model," "Type," or "Pattern." These terms may be followed by the word "Number" or an abbreviation of that word. The abbreviation for the word "Number" shall, as a minimum, begin with the letter "N" (e.g., No or No.). The abbreviation for the word "Model" shall be "Mod" or "Mod." Prefix lettering may be initial capitals, all capitals, or all lowercase. [Nonretroactive as of January 1, 2003] (Added 2000) (Amended 2001)
- (c) a nonrepetitive serial number, except for equipment with no moving or electronic component parts and not-built-for-purpose, software-based devices;
 [Nonretroactive as of January 1, 1968]
 (Amended 2003 and 201X)
 - (1) The serial number shall be prefaced by words, an abbreviation, or a symbol, that clearly identifies the number as the required serial number. [Nonretroactive as of January 1, 1986]

- (2) Abbreviations for the word "Serial" shall, as a minimum, begin with the letter "S," and abbreviations for the word "Number" shall, as a minimum, begin with the letter "N" (e.g., S/N, SN, Ser. No., and S. No.). [Nonretroactive as of January 1, 2001]
- (d) the current software version or revision identifier for<u>not-built-for-purpose</u> <u>software-based electronic</u> devices;
 [Nonretroactive as of January 1, 2004]
 (Added 2003) (Amended 201X)
 - (1) The version or revision identifier shall be prefaced by words, an abbreviation, or a symbol, that clearly identifies the number as the required version or revision.
 [Nonretroactive as of January 1, 2007]
 (Added 2006)
 - (2) Abbreviations for the word "Version" shall, as a minimum, begin with the letter "V" and may be followed by the word "Number." Abbreviations for the word "Revision" shall, as a minimum, begin with the letter "R" and may be followed by the word "Number." The abbreviation for the word "Number" shall, as a minimum, begin with the letter "N" (e.g., No or No.). [Nonretroactive as of January 1, 2007] (Added 2006)
 - (3) The version or revision identifier shall be directly and inseparably linked to the software itself. The version or revision identifier may consist of more than one part, but at least one part shall be dedicated to the metrologically significant software. (Added 201X)
- (e) an NTEP CC number or a corresponding CC Addendum Number for devices that have a CC. The CC Number or a corresponding CC Addendum Number shall be prefaced by the terms "NTEP CC," "CC," or "Approval." These terms may be followed by the word "Number" or an abbreviation of that word. The abbreviation for the word "Number" shall, as a minimum, begin with the letter "N" (e.g., No or No.) [Nonretroactive as of January 1, 2003]

The required information shall be so located that it is readily observable without the necessity of the disassembly of a part requiring the use of any means separate from the device. (Amended 1985, 1991, 1999, 2000, 2001, 2003, and, 2006 and 201X)

G-S.1.1. Location of Marking Information for <u>Not-Built-For-Purpose</u> Software-Based <u>Electronic</u> Devices. – For not built for purpose, software-based devices either:

- (a) The required information in G-S.1. Identification. (a), (b), (d), and (e) shall be permanently marked or continuously displayed on the device; or
- (b) The Certificate of Conformance (CC) Number shall be:
 - (1) permanently marked on the device;

- (2) continuously displayed; or
- (3) accessible through an easily recognized menu and, if necessary, a submenu. Examples of menu and submenu identification include, but are not limited to, "Help," "System Identification," "G-S.1. Identification," or "Weights and Measures Identification." one or, at most, two levels of access.
 - (i) For menu-based systems, "Metrology", "System Identification", or "Help".
 - (ii) For systems using icons, a metrology symbol ("M" or "SI"), or a help symbol ("?," "I," or an "i" within a magnifying glass).

Note: For (b), clear instructions for accessing the information required in G-S.1. (a), (b), (c), and (d) shall be listed on the CC, including information necessary to identify that the software in the device is the same type that was evaluated.
[Nonretroactive as of January 1, 2004 and 201X]
(Added 2003) (Amended 2006 and 201X)

Discussion: It should be noted that these new ideas are in the developmental stage, and are included here at the request of the Software Sector, which is seeking comments from interested parties. The Sector is asked to comment on the proposed changes to G-S.1. and G-S.1.1. shown above, specifically those that will most affect Grain Analyzers:

- 1. G-S.1.(d) and its sub paragraphs will require a software version or revision identifier that is directly and inseparably linked to the software itself; and
- 2. G-S.1.1. and its sub paragraphs will allow the identifiers required in G-S.1. to be either permanently marked or continuously displayed for software-based electronic devices. This includes the software version or revision identifier.

The GMM Sector is asked to consider recommending that G-S.1.1.(b) be amended to include accessing the software version or revision identifier by menu, icon, or upon "power-up". At present all NTEP GMMs are built-for-purpose. They all have permanently marked CC numbers. Software version/revision identifiers, however, are either displayed upon "power-up" or are accessible by menu or icon. GMM displays are of limited size. Some existing devices don't have room to display the software version/revision identifier on every "screen". Hard marking of that identifier is not practical, because it precludes updating software without also replacing the hard-marked label.

3. If not either permanently marked or continuously displayed, the CC Number will have to be accessible through one or two levels of access identified by the labels, "Metrology", "System Identification", or "Help" in menu based systems, or for systems using icons, a metrology symbol ("M" or "SI"), or a help symbol ("?," "I," or an "i" within a magnifying glass). Note that this is not suggested to be the final list of valid options; the Software Sector would like to have feedback specifically on additional menu text/icon images that should be considered acceptable. The Software Sector feels that the number of acceptable options is less of an issue (within reason) than the fact that the list is finite.

GMM manufacturers are asked to recommend menu text/icon images that are applicable to their existing/future devices.

7. Other Software Requirements That May Impact Grain Analyzers

The items under this heading are mostly excerpts from the Software Sector's March 2010 meeting summary intended to keep Grain Analyzer Sector Members informed of developmental software requirements that may impact grain analyzers. For more detailed information, see the complete Software Sector meeting summary at:

http://www.ncwm.net/sites/default/files/meetings/software/2010/10_Software_Summary.pdf

a. Identification of Certified Software

[Note: This item is now partially covered by the provisional proposal to make G-S.1.(d) applicable to software-based electronic devices and by adding the following new sub-subparagraph G-S.1.(d)(3):]

"The version or revision identifier shall be directly and inseparably linked to the software itself. The version or revision identifier may consist of more than one part, but at least one part shall be dedicated to the metrologically significant software."

Also the Software Sector recommends the following information be added to Pub. 14 as explanation/examples:

- Unique identifier must be displayable/printable on command or during operation, etc.
- At a minimum, a version/revision indication (1.02.09, rev 3.0 a, etc). Could also consist of / contain checksum, etc. (crc32, for example)

Software Sector Conclusions: The item needs additional discussion and development by the Software Sector. Outstanding questions: If we allow hard-marking of the software identifier (the Sector has wavered on this in the past), does the above wording then imply that some mechanical means is required (i.e. physical seal) to 'inseparably link' the identifier to the software? Do we still have to be able to display/print the identifier if it is hard-marked?

b. Software Protection / Security

Background: The Software Sector derived a trial Pub 14 checklist based on the OIML checklist to verify that the software adequately protected against fraudulent modification as well as accidental or unintentional changes. The checklist has been distributed to current NTEP labs for use on a trial basis for new type approval applications.

Devices with embedded software TYPE P (aka built-for-purpose)				
	Declar softwa	Yes No N/A		
	canno	t be modified or uploaded by any means after securing/verification	Yes No N/A	
	Note: a suffi			
	The so			
		description of all the metrologically significant functions, designating those that are considered metrologically significant OIML states that there shall be no undocumented functions	Yes No N/A	

	description of the securing means (evidence of an intervention)	Yes No N/A
	software identification	Yes No N/A
	description how to check the actual software identification	Yes No N/A
Th	e software identification is:	
	clearly assigned to the metrologically significant software and functions	Yes No N/A
	provided by the device as documented	Yes No N/A
Personal c devices, m significant	omputers, instruments with PC components, and other instruments, odules, and elements with programmable or loadable metrologically software TYPE U (aka not built-for-purpose)	
Th	e metrologically significant software is:	
	documented with all relevant (see below for list of documents) information	Yes No N/A
	protected against accidental or intentional changes	Yes No N/A
Ev unt trai	idence of intervention (such as, changes, uploads, circumvention) is available il the next verification / inspection (e.g. physical seal, Checksum, CRC, audit il, etc. means of security)	Yes No N/A
Software v possible fo	vith closed shell (no access to the operating system and/or programs r the user)	
Ch coi	eck whether there is a complete set of commands (e.g. function keys or nmands via external interfaces) supplied and accompanied by short descriptions	Yes No N/A
Ch coi	eck whether the manufacturer has submitted a written declaration of the npleteness of the set of commands	Yes No N/A
Operating	system and / or program(s) accessible for the user:	
Ch coo con	eck whether a checksum or equivalent signature is generated over the machine de of the metrologically significant software (program module(s) subject to legal ntrol W&M jurisdiction and type-specific parameters)	Yes No N/A
Ch una sof	eck whether the metrologically significant software will detect and act upon any authorized alteration of the metrologically significant software using simple tware tools e.g. text editor.	Yes No N/A
Software i	nterface(s)	
Ve	rify the manufacturer has documented:	
	the program modules of the metrologically significant software are defined and separated	Yes No N/A
	the protective software interface itself is part of the metrologically significant software	Yes No N/A
	the <i>functions</i> of the metrologically significant software that can be accessed via the protective software interface	Yes No N/A
	the <i>parameters</i> that may be exchanged via the protective software interface are defined	Yes No N/A
	the description of the functions and parameters are conclusive and complete	Yes No N/A
	there are software interface instructions for the third party (external) application programmer.	Yes No N/A

Software Sector Discussion: The labs again indicated they had not had a chance to utilize the checklist. The list was reviewed and some minor modifications to the checklist text were incorporated as shown above.

Software Sector Conclusion: Work is ongoing on this item with the intent that it eventually be incorporated as a checklist in Pub 14; again the labs are requested to try utilizing this checklist for any evaluations on software-based electronic devices.

c. Software Maintenance and Reconfiguration

Background: The Software Sector agreed that the two definitions below for Verified update and Traced update were acceptable.

Verified Update: A verified update is the process of installing new software where the security is broken and the device must be re-verified. Checking for authenticity and integrity is the responsibility of the owner/user.

Traced Update: A traced update is the process of installing new software where the software is automatically checked for authenticity and integrity, and the update is recorded in a software update log or audit trail.

The Software Sector also worked towards language proposed for defining the requirements for a Traced Update (currently considered as relevant for Pub 14):

For a Traced Update, an event logger is required. The logger shall be capable of storing a minimum of the 10 most recent updates. An entry shall be generated for each software update.

Use of a Category 3 audit trail is required for the Traced Update. If software update is the only loggable event, then the Category 3 audit trail can be limited to only 10 entries. A log entry representing a software update shall include the software identification of the newly installed version.

Software Sector Conclusions: The general consensus of the group after considering feedback from external interested parties is that a new G-S.9. with explicit requirements [for Metrologically Significant Software] is not necessary (nor likely to be adopted by the Conference) and that this requirement belongs in the Pub. 14 lists of sealable parameters rather than in Handbook 44; i.e.,

The updating of metrologically significant software shall be considered a sealable event.

Additional work is to be done to further develop the proposed text toward inclusion in Pub 14

Grain Analyzer Sector Discussion: At its August 2009 meeting the GA Sector questioned the need for a definition of "Traced Update". The traced update was initially intended to cover cases in Europe where the National Body controls a network of devices and wants to update all the devices simultaneously from a central location. Denmark and France do this with NIR Grain Analyzers. Even though individual states may still require that a device updated via a "Traced Update" must be "returned to service" by a registered serviceperson before it can be used, the Sector may want to consider adopting "Traced Update" requirements for all Category 3 Grain Analyzers. The device is still subject to later inspection by state Weights and Measures personnel. By designing to the requirements for "traced update", states might be encouraged to allow devices updated to those requirements to be returned to service without requiring a visit by a registered serviceperson.



Software Update Procedure – from OIML D 31:2008 (E)

Notes:

- (1) In the case of a Traced Update updating is separated into two steps: "loading" and "installing/activating". This implies that the software is temporarily stored after loading without being activated because it must be possible to discard the loaded software and revert to the old version, if the checks fail.
- (2) In the case of a Verified Update, the software may also be loaded and temporarily stored before installation but depending on the technical solution loading and installation may also be accomplished in one step.
- (3) Here, only failure of the verification due to the software update is considered. Failure due to other reasons does not require re-loading and re-installing of the software, symbolized by the NO-branch.

8. Report on OIML TC17/SC1 R59 "Moisture Meters for Cereal Grains and Oilseeds"

Background: This item was included on the Sector's agenda to provide a summary of the activities of OIML TC17/SC1. In October 2008, the Secretariat of TC 17/SC 1 was jointly allocated to China and the United States. The Co-Secretariats (China and the United States) are working closely with an IWG to revise OIML R 59 "Moisture meters for cereal grains and oilseeds." The 5 CD of OIML R 59, revised to comply with OIML's Guide *Format for OIML Recommendations* and to incorporate tests for the recommended disturbances of **OIML D 11** *General Requirements for Electronic Measuring Instruments*, was distributed to the Subcommittee in February 2009. A 6 CD is being developed based on international comments received on the 5 CD. A meeting of TC17/SC1 is scheduled for September 29, 2010 in Orlando, Florida.

Diane Lee, NIST/WMD, will brief the Sector on the status of 6 CD.

9. Report on OIML TC 17/SC 8 "Quality Analysis of Agricultural Products"

Background: This item was included on the Sector's agenda to provide a summary of the activities of OIML TC17/SC8. A new subcommittee has been formed to study the issues and write a working draft document "Measuring instruments for protein determination in grains." Australia is the Secretariat for this new subcommittee. A TC 17/SC 8 meeting was hosted by NIST in September 2007 to discuss the 2 CD. Discussions on 2 CD dealt mostly with maximum permissible errors (MPEs) and harmonization of the TC 17/SC 8 Recommendation for protein with the TC 17/SC 1 Recommendation for moisture. The secretariat distributed a 2 CD of the document in February 2010. Comments were due in May 2010. A meeting of TC 17/SC8 will be held September 27-28, 2010 in Orlando, Florida to address the comments to 2 CD.

Diane Lee, NIST/WMD, will bring the Sector up to date on the status of 2 CD.

10. Standardization of Grain Moisture Meters – Traceability of GMMs used in Meter to Like-Meter testing.

Background: This item is a carry-over from the Sector's August 2009 meeting (Item 9.5). For NTEP meters Handbook 44 permits meter to like-meter testing using "Properly Standardized Reference Meters". Karl Cunningham, Illinois Department of Agriculture/Weights & Measures, asked for a definition of a "Properly Standardized Reference Meter". He also wanted to know what criteria these "Reference Meters" must meet.

He was referred to **Section VI. Standardization of Instruments** in the GMM chapter of Publication 14 that shows the relationship and maximum permissible errors between the NTEP Lab meters, Manufacturer's Laboratory Standard Meters, Manufacturer's Production Master Meter, and "As Shipped" meters. It was explained that a properly standardized reference meter for a Service

Company should have the same traceability to the NTEP Lab Meters as the Manufacturer's Production Master Meter has.

Section VI. Standardization of Instruments in the GMM chapter of Pub 14 requires manufacturers to demonstrate that their methods for standardizing units in production result in "as shipped" units which agree with the corresponding NTEP Laboratory units (path D in the accompanying Figure 1) within ± 0.3 x the Handbook 44 acceptance tolerance. They are also required to show that the mean moisture difference between Manufacturer's Laboratory Standard Meters and the corresponding NTEP Laboratory Meters (path A in the accompanying Figure 1) does not exceed ± 0.2 x the Handbook 44 acceptance tolerance.



Discussion: During a discussion of potential agenda items for the Sector's 2010 meeting, Dr. Richard Pierce, FGIS/GIPSA, representing the NTEP Participating Laboratory for Grain Analyzers, suggested that the Sector may want to explore how the NTEP program (or lab) can assist manufacturers who are asked to demonstrate traceability of field instruments back to the air oven reference method. The NTEP Lab has manufacturers' instruments in the NTEP Phase II program that are directly traceable to the GIPSA air oven reference lab. There is, however, no documentation demonstrating alignment of NTEP instruments with manufacturers' master instruments or field instruments. The NTEP lab is not involved in this process. There are no criteria for the grain types, the number of analyses, or the number of samples that should be used in side-by-side testing.

The Sector co-Technical Advisor suggested that a first step in acquiring documentation demonstrating alignment of NTEP instruments with manufacturers' master instruments or field instruments would be adding language to the NTEP Application to require submission of the documentation required by §VI., and adding a check list of the Required Documentation to the existing GMM Check List of Pub 14.

A related issue mentioned by Dr. Pierce was authorized repair facilities providing states with documentation that their "standard" instrument is traceable to the air oven reference. He was of the opinion that this was not directly an NTEP lab issue, but believed that manufacturers should be able to trace these standards back to NTEP Phase II instruments.

The Sector is asked to be prepared to discuss the questions:

- 1. How can the NTEP Program (or Lab) assist manufacturers in demonstrating the traceability of field instruments back to the air oven reference method?
- 2. Should the Grain Analyzer NTEP Application and the GMM Check List be amended as shown in the following proposal?

Proposal: Amend the Application Instructions Section of the Grain Analyzer NTEP Application as shown below:

• <u>Submit details of procedures and tests for maintaining reference meters and standardizing</u> <u>units in production to meet the requirements of §IV of the GMM Chapter of Pub 14.</u>

And insert the following Check List of Required Documentation just in front of the **General** section [but still under the "Checklist" Heading in the Table of Contents] of the GMM chapter of Pub 14:

Required (Refer to	Docu NCW	<u>mentation</u> M Publication 14, Grain Moisture Meter Chapter, §VI. Standardizatior	<u>ı of Instruments)</u>
Doc1.	<u>Manu</u> be us instru	ifacturer has submitted specific details of the proposed test procedures to ed for the comparison between their reference standard instruments and iments of like type in the NTEP Participating Laboratory.	Yes No N/A
	<u>(a)</u>	Comparisons will be made "side-by-side	Yes No N/A
	<u>(b)</u>	Comparisons will be made by an exchange of grain samples	Yes No N/A
Doc2.	<u>Manu</u> <u>Manu</u> <u>Labo</u> <u>Hanc</u>	If acturer has shown that the mean moisture difference between If acturer's Laboratory Standard Meters and the corresponding NTEP ratory Meters (path A in figure below) does not exceed ± 0.2 x the Ibook 44 acceptance tolerance.	Yes No N/A
<u>Doc3.</u>	Man produ <u>NTE</u> Hanc	If acturer has demonstrated that its methods for standardizing units in action result in "as shipped" units which agree with the corresponding P Laboratory units (path D in Figure 1 of $\$VI$) within ± 0.3 x the blook 44 acceptance tolerance.	Yes No N/A
Doc4.	Manu resul calib	ifacturer has also demonstrated that once units are standardized, moisture ts between units of like type will not exceed these tolerances when a grain ration change is made.	Yes No N/A

11. Air-Oven Collaborative Study – Analysis of results

Background: At its August 2008 meeting, the Sector agreed that a collaborative study was long overdue. It was also noted that such a study addresses the measurement traceability requirements of **ISO 17025** *General requirements for the competence of testing and calibration laboratories*. Karl Cunningham subsequently agreed that the State of Illinois Moisture Meter Laboratory would serve as the "pivot" laboratory. At the August 2009 meeting, he reported that 14 laboratories participated in this study. Participants included: USDA/GIPSA (as reference laboratory), Arkansas, Colorado, Illinois, Iowa, Maryland, Mississippi, Missouri, North Carolina, South Carolina, Wisconsin (corn only), Wyoming, and DICKEY-john. Perten was sent samples but didn't return results. With the exception of one or two outliers, results were fairly good. Histograms showing the distribution of Lab error (Participant Lab result minus Reference Lab result) for each of the grain samples were presented (see August 2009 Sector Meeting Summary).

Discussion: Karl Cunningham will present a detailed statistical analysis of the 2009 Air Oven Collaborative Study.

12. Proficiency Testing

[Submitted by Amy L. Johnson, SQT Program Manager, American Oil Chemists Society (AOCS)] **Background:** At the Sector's August 2009 Meeting Dr. Charles Hurburgh, Iowa State University, urged the representatives from the American Oil Chemists Society (AOCS) to prepare a proposal so that the collaborative (air-oven) study could be conducted on an on-going basis rather than on an ad hoc basis. He cautioned that the proposal would have to include corn and wheat as well as soybeans.

Several years ago the AOCS in conjunction with the United Soybean Board (USB) established the AOCS-USB Soybean Quality Traits Analytical Standards Program (SQT), a system of verification of analytical measurements. This program provided the infrastructure for the generation of reliable analytical results at all levels of the soybean industry by establishing industry-wide acceptance of analytical methods and protocols and their implementation under internationally accepted quality management standards. The AOCS has proposed the addition of an air-oven/grain moisture meter proficency testing (PT) series to their Analytical Standards Program (ASP). Proficency testing is a continuous program, samples are sent out in regular intervals (e.g. 2-4 times/year). Participants are able to join on a continuous basis.

Discussion: Amy Johnson, AOCS, will outline the details of the proposed air-oven/GMM proficiency testing series and its applicability to the needs of state regulators, GMM manufacturers, and GMM service companies.

13. Time and Place for Next Meeting

A tentative date and location will be selected for the next meeting. An August meeting in Kansas City is suggested. Dr. Charles Hurburgh, who will not be able to attend this year because the meeting conflicts with the beginning of classes at Iowa State, has requested that the date for the next meeting be prior to the last full week of August.