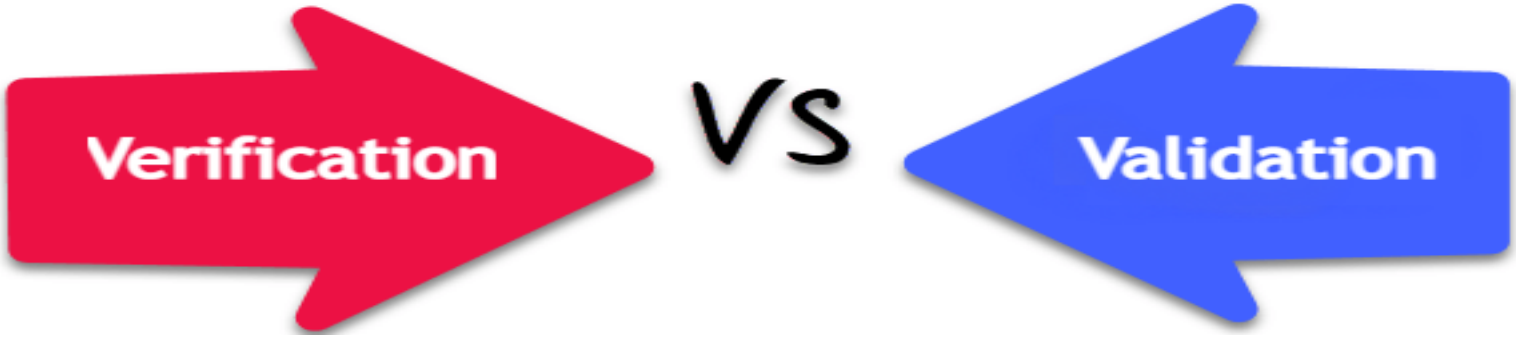
Requirements in Section 7.2 “Selection, Verification and Validation of Methods”



Presenter: Michael Kramer
PJLA Calibration/Inspection Program Manager
April 27, 2023

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Requirements in Section 7.2 “Selection, Verification and Validation of Methods”

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Requirements in Section 7.2 “Selection, Verification and Validation of Methods

The laboratory is required to use appropriate methods and procedures for activities, and when necessary, for evaluation of the measurement uncertainty as well as statistical techniques for analysis of data. Methods, procedures and supporting documentation need to be kept up to date and made available to all personnel. In addition, ISO 17025:2017 mandates that the lab stays up-to-date with methods as appropriate and when the customers do not specify a method, the lab chooses the best and latest valid version. The lab must communicate what method they are using with the customer.

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Requirements in Section 7.2 “Selection, Verification and Validation of Methods

Verification or Validation as defined in ISO/IEC 17025:2017

Verification - provision of objective evidence that a given item fulfils specified requirements

EXAMPLE 1 Confirmation that a given reference material as claimed is homogeneous for the quantity value and measurement procedure concerned, down to a measurement portion having a mass of 10 mg.
EXAMPLE 2 Confirmation that performance properties or legal requirements of a measuring system are achieved.

EXAMPLE 3 Confirmation that a target measurement uncertainty can be met.

Prior to expanding a laboratories scope into another discipline not already covered, as per 7.2.1.5, the organization needs to verify that they can achieve the required performance.

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Validation - Verification , where the specified requirements are adequate for an intended use

EXAMPLE A measurement procedure, ordinarily used for the measurement of mass concentration of nitrogen in water, may be validated also for measurement of mass concentration of nitrogen in human serum.

This covers unconventional techniques as well as conventional and laboratory-developed techniques. The methods must undergo comprehensive validation to satisfy the given application’s requirements. If modifications are made to a method that has been verified, it is essential to comprehend their impact by performing a validation test once again.

An example may be a homogeneity test (F-test) to evaluate the extent of such differences.

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Requirements in Section 7.2 “Selection, Verification and Validation of Methods

7.2.1.1 The laboratory shall use appropriate methods and procedures for all laboratory activities and, where appropriate, for evaluation of the measurement uncertainty as well as statistical techniques for analysis of data.

NOTE “Method” as used in this document can be considered synonymous with the term “measurement procedure” as defined in ISO/IEC Guide 99.

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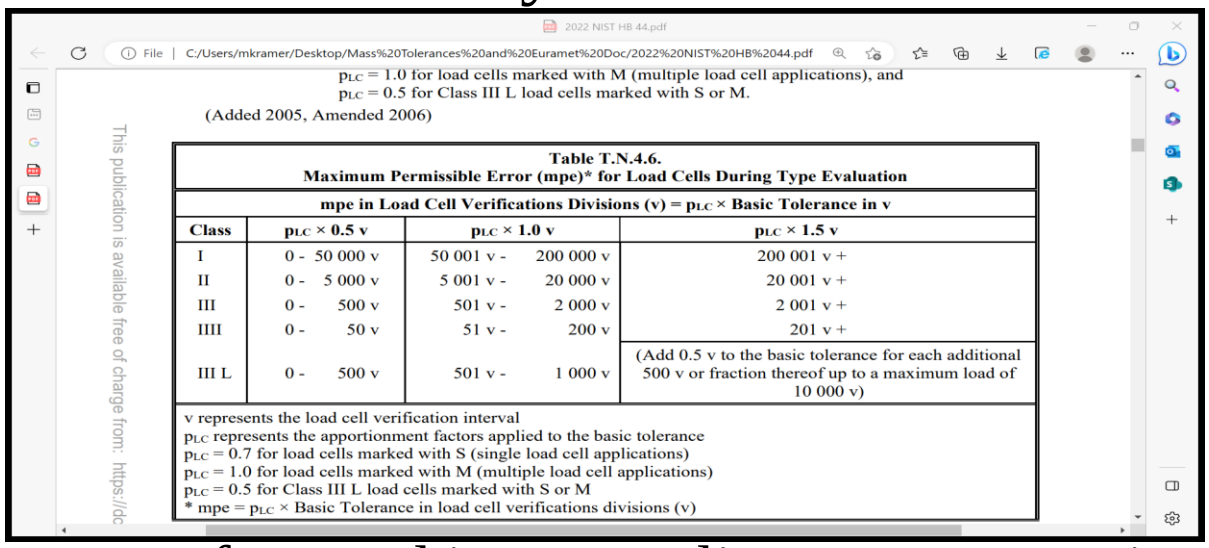
7.2.1.2 All methods, procedures and supporting documentation, such as instructions, standards, manuals and reference data relevant to the laboratory activities, shall be kept up to date and shall be made readily available to personnel (see 8.3).



2022 NIST HB 44.pdf

File | C:/Users/mkramer/Desktop/Mass%20Tolerances%20and%20Euramet%20Doc/2022%20NIST%20HB%2044.pdf

p_{LC} = 1.0 for load cells marked with M (multiple load cell applications), and
p_{LC} = 0.5 for Class III L load cells marked with S or M.

(Added 2005, Amended 2006)

Table T.N.4.6.
Maximum Permissible Error (mpe)* for Load Cells During Type Evaluation

mpe in Load Cell Verifications Divisions (v) = p_{LC} × Basic Tolerance in v			
Class	**p_{LC} × 0.5 v**	**p_{LC} × 1.0 v**	**p_{LC} × 1.5 v**
I	0 - 50 000 v	50 001 v - 200 000 v	200 001 v +
II	0 - 5 000 v	5 001 v - 20 000 v	20 001 v +
III	0 - 500 v	501 v - 2 000 v	2 001 v +
IIII	0 - 50 v	51 v - 200 v	201 v +
III L	0 - 500 v	501 v - 1 000 v	(Add 0.5 v to the basic tolerance for each additional 500 v or fraction thereof up to a maximum load of 10 000 v)

v represents the load cell verification interval
p_{LC} represents the apportionment factors applied to the basic tolerance
p_{LC} = 0.7 for load cells marked with S (single load cell applications)
p_{LC} = 1.0 for load cells marked with M (multiple load cell applications)
p_{LC} = 0.5 for Class III L load cells marked with S or M
* mpe = p_{LC} × Basic Tolerance in load cell verifications divisions (v)

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For example, assure a tolerance referenced in a compliance statement is up to date and current.

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Requirements in Section 7.2 “Selection, Verification and Validation of Methods”

7.2.1.3 The laboratory shall ensure that it uses the latest valid version of a method unless it is not appropriate or possible to do so. When necessary, the application of the method shall be supplemented with additional details to ensure consistent application.

NOTE International, regional or national standards or other recognized specifications that contain sufficient and concise information on how to perform laboratory activities do not need to be supplemented or rewritten as internal procedures if these standards are written in a way that they can be used by the operating personnel in a laboratory. It can be necessary to provide additional documentation for optional steps in the method or additional details.

8.9.2 The inputs to management review shall be recorded and shall include information related to the following:

c) suitability of policies and procedures

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Requirements in Section 7.2 “Selection, Verification and Validation of Methods”

7.2.1.4 When the customer does not specify the method to be used, the laboratory shall select an appropriate method and inform the customer of the method chosen. Methods published either in international, regional or national standards, or by reputable technical organizations, or in relevant scientific texts or journals, or as specified by the manufacturer of the equipment, are recommended. Laboratory-developed or modified methods can also be used

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Requirements in Section 7.2 “Selection, Verification and Validation of Methods”

7.2.1.5 The laboratory shall verify that it can properly perform methods before introducing them by ensuring that it can achieve the required performance. **Records** of the verification **shall** be retained. If the method is revised by the issuing body, verification shall be repeated to the extent necessary.

Standard methods and published procedures are considered to be validated. That means that the method/procedure has been proven to produce the stated measurement results when the procedure is properly followed.

However, every laboratories have different equipment, competencies, and other factors that will determine what capabilities the laboratory can maintain.

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Requirements in Section 7.2 “Selection, Verification and Validation of Methods”

The techniques used for the determination of the performance of a method can be one of, or a combination of, the following:

- calibration using reference standards or reference materials;
- comparison of results achieved with other methods;
- interlaboratory comparisons;
- systematic assessment of the factors influencing the result;
- assessment of the uncertainty of the results based on scientific understanding of the theoretical principles of the method and practical experience.

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Requirements in Section 7.2 “Selection, Verification and Validation of Methods”

7.2.1.6 When method development is required, this shall be a planned activity and shall be assigned to competent personnel equipped with adequate resources. As method development proceeds, periodic review shall be carried out to confirm that the needs of the customer are still being fulfilled. Any modifications to the development plan shall be approved and authorized.

This could be associated with product development and development of new calibration or test methods to support the product.

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7.2.1.7 Deviations from methods for all laboratory activities shall occur only if the deviation has been documented, technically justified, authorized, and accepted by the customer.

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Requirements in Section 7.2 “Selection, Verification and Validation of Methods

7.2.2 Validation of methods

7.2.2.1 The laboratory shall validate non-standard methods, laboratory-developed methods and standard methods used outside their intended scope or otherwise modified. The validation shall be as extensive as is necessary to meet the needs of the given application or field of application.

NOTE 1 Validation can include procedures for sampling, handling and transportation of test or calibration items

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Requirements in Section 7.2 “Selection, Verification and Validation of Methods”

NOTE 2 The techniques used for method validation can be one of, or a combination of, the following:

a) calibration or evaluation of bias and precision using reference standards or reference materials;

b) systematic assessment of the factors influencing the result;

c) testing method robustness through variation of controlled parameters, such as incubator temperature, volume dispensed;

d) comparison of results achieved with other validated methods;

e) interlaboratory comparisons;

f) evaluation of measurement uncertainty of the results based on an understanding of the theoretical principles of the method and practical experience of the performance of the sampling or test method.

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Requirements in Section 7.2 “Selection, Verification and Validation of Methods”

7.2.2.2 When changes are made to a validated method, the influence of such changes shall be determined and where they are found to affect the original validation, a new method validation shall be performed.

7.2.2.3 The performance characteristics of validated methods, as assessed for the intended use, shall be relevant to the customers' needs and consistent with specified requirements.

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Requirements in Section 7.2 “Selection, Verification and Validation of Methods”

NOTE Performance characteristics can include, but are not limited to, measurement range, accuracy, measurement uncertainty of the results, limit of detection, limit of quantification, selectivity of the method, linearity, repeatability or reproducibility, robustness against external influences or cross-sensitivity against interference from the matrix of the sample or test object, and bias.

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“Selection, Verification and Validation of Methods”

7.2.2.4 The laboratory shall retain the following records of validation:

a) the validation procedure used;

b) specification of the requirements;

c) determination of the performance characteristics of the method;

d) results obtained;

e) a statement on the validity of the method, detailing its fitness for the intended use

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Selection, Verification and Validation of Methods

This time is allocated for questions. You should have a space provided for submitting questions.

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If a question is not answered, please submit directly to webinar@pjlabs.com

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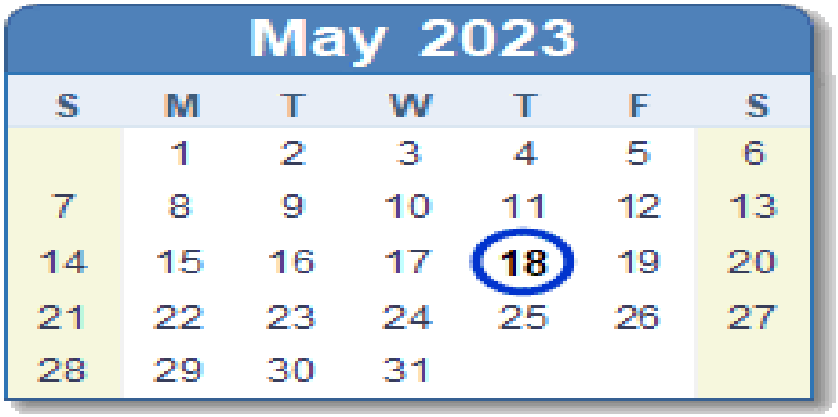

Thursday, May 18th 2023

Presented by:

Michael Kramer, PJLA Calibration/Inspection Program Manager

May 18, 2023, 1:00 PM - 2:00 PM EST

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