



National Conference on Weights and Measures

National Type Evaluation Program

Software Technical Policy



NCWM

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Amendments

Section Number	Amendment/Change	Page	Source
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Document	Second draft 5/6/21.	Document	Software Sector Repl. 2020 -> 20XX Consistent use of title 'Software Technical Policy'
Document	Second Draft reviewed and comments from 2021 Software Sector meeting incorporated	Document	Sector work session

Table of Contents

Section	Page SP
1. Definitions	4
2. Scope.....	6
3. Submission of Software	6
4. Markings	6
5. Software Identification.....	7
6. Software Update Security	8
7. Software Evaluation Checklist.....	9
8. NCWM Website Resources	9
Appendix A: Checklist for Devices with Software.....	10

National Type Evaluation Program Software Policy

1. Definitions

1.1. National Type Evaluation Program (NTEP)

A program administered by National Conference on Weights and Measures, Inc. (NCWM) in cooperation with the National Institute of Standards and Technology (NIST), state and local governments and the private sector for determining, on a uniform basis, conformance of a type, with the relevant provisions of:

- *NCWM Publication 14, National Type Evaluation Program (NTEP) Technical Policy, Checklists and Test Procedures*
- *NIST Handbook 44, Specifications, Tolerances and Other Technical Requirements for Weighing and Measuring Devices*
- Organization of International Legal Metrology (OIML) R 60, Metrological Regulation for Load Cells
- OIML R 76-1, *Non-automatic Weighing Instruments. Part 1: Metrological and Technical Requirements - Tests* (Integrate Amendment No. 1 of 1994)
- OIML R 76-2, *Non-automatic Weighing Instruments. Part 2: Pattern Evaluation Report* (Integrate Amendment No. 1 of 1995)

1.2. Appeal

An issue initiated by a party other than a state or local regulator, or member of a federal agency. An appeal may involve a third party.

1.3. Certificate of Conformance (CC) (U.S.)

NCWM issued document that constitutes evidence of conformance of a type with the requirements of *NCWM Publication 14* and *NIST Handbook 44*.

NOTE: NIST issued Certificate of Conformance until September 30, 2000.

1.4. Conformity Assessment Program

A program to ensure the continued compliance of manufactured devices with the requirements defined in the Certificate of Conformance.

1.5. Control Facility

The control facility is the facility that is in control of the product before it goes into the marketplace, which could be more than one place.

1.6. International Organization of Legal Metrology (OIML)

The OIML develops model regulations, international recommendations, which provide members with an internationally agreed upon basis for the establishment of national legislation on various categories of measuring instruments.

1.7. Measurement Canada; An Agency of Industry Canada

The legal authority in Canada to examine, test and approve devices under the Weights and Measures Act of Canada. When the term "Participating Laboratory" is used, it is understood to include the Weights and Measures Laboratory of Measurement Canada for those devices covered under the US/Canada Mutual Recognition on Type Evaluation Program.

1.8. NCWM Board of Directors (BOD)

The Board of Directors of National Conference on Weights and Measures, Inc.

1.9. National Institute of Standards and Technology (NIST) Office of Weights and Measures (OWM)

The NIST/OWM acts as Technical Advisor to NTEP.

1.10. NTEP Committee

A subcommittee of the NCWM Board of Directors, the NTEP Committee is responsible for the operation of NTEP. The Committee oversees the activities of the NTEP Administrator in all matters of policy and procedure recommendations, and the resolution of policy, technical, and appeals issues. The Committee hears appeals or reviews related to the Certificate of Conformance. The Committee hears appeals of decisions made by the NTEP Administrator. All actions of the Committee are subject to ratification by the NCWM Board of Directors.

1.11. NTEP Administrator

An individual responsible for the management of NTEP, by carrying out the policies and procedures as outlined in *NCWM Publication 14* and other policies established by the NTEP Committee and NCWM Board of Directors.

1.12. NTEP Evaluators

Individuals authorized by NCWM, either directly or by mutual recognition, to conduct NTEP evaluations. This may include state laboratories or regulators; federal laboratories, such as those at NIST, OWM or Measurement Canada; or other evaluation facilities that are recognized and/or authorized by NCWM to evaluate device types.

1.13. National Type Evaluation Program Sector (NTEP Sector)

A Committee that develops and recommends test criteria and procedures to the NTEP Administrator. Also known as a Sector, e.g. Weighing Sector.

1.14. Notice of Approval (Canada)

A document issued by Measurement Canada that constitutes evidence of conformance of a type to the Weights and Measures Act and Regulations of Canada.

1.15. OIML Certificate of Conformity

The OIML Certificate of Conformity indicates that a given instrument pattern (type) complies with the requirements of the relevant OIML International Recommendations.

1.16. OIML Issuing Authority

An identified certifying body or person in an OIML Member State that is responsible for type evaluation and that issues Certificates of Conformity in the system based on a report of examinations and tests of specified categories of measuring instruments, including families and a module or modules. NCWM is the issuing authority for the U.S. for certain OIML categories.

1.17. Participating Laboratory

A federal or state laboratory authorized by NCWM to conduct a type evaluation under NTEP.

1.18. Review

A process initiated by NCWM, NTEP, a state or local regulator, or a member of a federal agency.

1.19. Type

A model or models of a particular measurement system, instrument, element or a field standard that positively identifies the design. A specific type may vary in its measurement ranges, size, performance, and operating characteristics as specified in the Certificate of Conformance.

1.20. Type Evaluation

A process for the testing, examination, and/or evaluation of a type under NTEP.

1.21. US/Canada Mutual Recognition Arrangement on Type Evaluation

A bilateral agreement reached by the United States and Canada which allows one country to recognize the examination of tests performed by the other country for certain devices. Both the United States and Canada operate type evaluation programs for weighing and measuring devices used in commercial applications. Each country will continue to issue its own (U.S.) Certificate of Conformance or (Canada) Notice of Approval, based on an evaluation completed by only one of the countries. *See Section 7.1 for the Agreement.*

2. Scope

Any submission for type approval of a device that consists of or contains metrologically significant software, either partially or wholly, should review these guidelines. This includes stand-alone software applications, software accompanying a submitted device, and software embedded in devices (firmware). In general, this document is relevant to any device that runs metrologically significant software and is being submitted for type approval.

This document includes requirements, considerations, and test procedures common to all software-based devices, including software-only products.

It is intended to be an accompaniment to device-specific Pub. 14 documents.

3. Submission of Software

As part of the initial type evaluation submission, the following information would expedite the evaluation process of software:

- The software identification (version, revision, etc.), how to view it, and how it is tied to the software. See Section 5.
- An overview of the security aspects of the operating system, e.g. protection, user accounts, privileges, etc.
- A description of the software functions that are metrologically significant, meaning of the data, etc., e.g. an architecture diagram or flowchart.
- An overview of the system hardware, e.g. topology block diagram, type of computer(s), type of network, etc.
- For software-only products, a description of the minimum system requirements to run the software.
- A declaration of whether software separation is implemented and how it was accomplished. See Section 5.2.
- A user manual, service manual, and/or other technical documentation.
- Complete set of commands (e.g., function keys or commands via external interfaces) available, accompanied by a description of the function of each command.

4. Markings

4.1 Certificate of Conformance number (CC) marking requirements become more complicated when dealing with software that runs on a general-purpose device such as an off the shelf PC or tablet/mobile phone. Hard marking the CC (the preferred method in most cases) is not preferable if the software is installed by the user or may run on devices other than what was submitted for type approval. In these cases, it is preferable to mark the CC continuously on the display. In these cases, it should not be possible to obstruct or overwrite this information when the device is in operational mode.

If for some reason the CC can neither be hard-marked or continuously displayed, there will be allowed only a limited number of options to access the CC via the user interface (See Section 5.5).

4.2 Version Number Marking Requirements

Ideally, submitted software should continuously display the version number, similar to the CC#. Hard marking is discouraged unless “absolutely necessary” (see wording in G-S.1.d.1.i & ii) with the understanding that software is more likely to be upgraded and the original hard marking would deviate from the actual version. Navigating to the version number via directions in the CC is permitted if the process isn’t extremely convoluted and is easily understood.

See Handbook 44 General Code G-S.1. for additional marking requirements.

5. Software Identification

Marking requirements must comply with G-S.1. in Handbook 44, including requirements for version / revision. The following recommendations are intended as further guidance to satisfy the requirements regarding software identifiers.

5.1 Appropriate Means of Marking Metrologically Significant Software

5.1.1 Examples of Acceptable Software and Version / Revision Identifiers

Example 1: *Revision 1.XX.YY* – In this example, 1 is the metrologically significant version number, XX is a version number for non-metrologically significant software, and YY indicates bug fixes.

Example 2: *Ver. Number 1.XX.YYYYYYYY* – In this example, Ver. is an abbreviation for Version, 1 is the major revision, XX is the minor revision, and YYYYYYYY is the build date.

Example 3: *Ver.No. 1.XX YYYYYYYYYYYYYYYY* – In this example, Ver. is an abbreviation for Version, No. is an abbreviation for Number, 1 is the major revision, XX is the minor revision, and YYYYYYYYYYYYYYYY is a hash of the metrologically significant executable code.

Example 4: *Version 1* – In this example, the version/revision consists of a single numeric value. There is no major/minor revision and no software separation is employed. The entire software is considered metrologically significant.

The manufacturer is not limited to these examples.

5.2 Software Separation and Marking Consequences

Manufacturers may choose to separate metrologically significant software from non-metrologically significant software. Separation would allow the revision of the non-metrological portion without the need for further evaluation. In addition, non-metrologically significant software may be updated on devices without breaking the seal, if so designed.

Separation of software requires that all software modules (programs, subroutines, objects, etc.) that perform metrologically significant functions or that contain metrologically significant data domains form the metrologically significant part of a measuring instrument (device or sub-assembly).

If the separation of the software is not possible or needed, then the software is metrologically significant as a whole. In that case, any modification to the software may result in NTEP requiring further review of the modifications to the software.

Where the version revision identifier is comprised of more than one part, the manufacturer shall describe which portion represents the metrological significant software and which does not.

5.2.1 Examples of Software Identifiers When Software Separation is Employed

Example 1: *Version No. 1.XX* – In this example, No. is an abbreviation for Number, 1 is the major revision version number, XX is the minor version number. Both pertain to metrologically significant software. There would typically be an entirely separate version identifier for the non-metrologically significant software.

Example 2: *Rev. Number 1.XX* – In this example, Rev. is an abbreviation for Revision, 1 is the version number for the metrologically significant software, and XX is the version number for the non-metrologically significant software.

5.3 Relationship Between Software and Software Identifier

The manufacturer should be able to describe and possibly demonstrate how the version or revision identifier is directly and inseparably linked to the metrologically significant software.

This means that the software can't be easily changed without changing the software identifier. For example, the version identifier can't be in a text file that's easily editable, or in a variable that the user can edit.

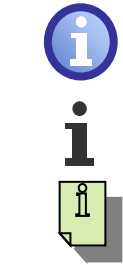

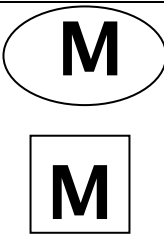

5.4 Presentation of Software Identifier

The software identifier must be easily viewed by the field inspector. It can be constantly displayed or

accessible via the display. Instructions for viewing the software identifier shall be described in the CC. The identifier must be accessible via a straightforward interaction of the interface, preferably requiring no navigation (directly from the display) or via navigation of menus or displays not more than two levels deep.

5.4.1 Example Icons and Menu Text

If the software identifier is accessible via the display, options to display it include a menu option, an icon like those in the list below, or some other method that was accepted during type approval.

<i>Menu Text examples</i>	<i>Icon examples</i>	<i>Essential characteristics</i>
Information Info		Top level menu text or icon <ul style="list-style-type: none"> • Icon text is a lower case “i” with block serifs • Text color may be light or dark but must contrast with the background color • Icon may have a circular border • Activation of this menu text/icon may invoke a second level menu text/icon that recalls metrology information.
Help ? About		Top level menu text or icon <ul style="list-style-type: none"> • Icon text is a question mark • Text color may be light or dark but must contrast with the background color • Icon may have a circular border • Activation of this menu text/icon may invoke a second level menu text/icon that recalls metrology information.
Metrology Metrological Information		Top or second level menu text or icon <ul style="list-style-type: none"> • Icon text is an upper case “M” • Text color may be light or dark but must contrast with the background color • Icon may have a circular, rectangular, or rounded rectangle border. • If present, the activation of this menu text/icon must recall at a minimum the NTEP CC number.
Weights & Measures Info	Boxes with 	Top level menu text or icon <ul style="list-style-type: none"> • W&M Info • Weights & Measures

5.4.2 Exceptions

Permanently marking the version or revision identifier shall be acceptable providing the device does not always have an integral interface to communicate the version or revision identifier.

An integral interface is one that is always present and might be a printer, remote console, display, etc.

6 Software Update Security

Updates and changes to metrologically significant software need to be protected by a sealing method, as defined in Handbook 44, G-S.9 and in the section specific to the appropriate device type.

7 Software Evaluation Checklist

When performing a type approval involving software, there is a checklist intended for the type evaluator to review with the manufacturer. See Appendix A. Many of the steps in the checklist are further clarified in this document.

8 NCWM Website Resources

NCWM website is: www.ncwm.net

Information may be printed or downloaded to individual personal computers, NTEP related information available includes:

24.1.1 Active and Inactive Certificates of Conformance issued from January 1, 1986 to present

24.1.2 NTEP Applications

24.1.3 NTEP Fees

24.1.4 List of NTEP Participating Laboratories

24.1.5 NTEP Sectors

24.1.6 International Recognition

24.1.7 Conformity Assessment

24.1.8 NTEP Logo

24.1.9 Frequently Asked Questions (FAQs)

Appendix A: Checklist for Devices with Software

1. Devices consisting of or contain metrological software

- 1.1. Is there metrologically significant software in the system? Yes No
(If No, stop. This checklist only applies to devices that have software.)
- 1.2. Is the metrological software capable of being updated in the field? **AND** Yes No N/A
- 1.3. If yes, is the metrological software protected by physical or electronic means, (i.e. can you change the software without breaking a seal?) Yes No N/A
Note: It is acceptable to break the "seal" and load new software. Audit trail (category III) is a sufficient seal.
- 1.4. The software documentation contains:
- 1.4.1. a description of all functions, designating those that are considered metrologically significant. Yes No N/A
 - 1.4.2. a description of the securing means (evidence of an intervention). Yes No N/A
 - 1.4.3. the Software Identification, including version/revision. It may also include things like name, part number, CRC, etc. Yes No N/A
 - 1.4.4. a description how to check the actual software identification. Yes No N/A
- 1.5. The software identification is:
- 1.5.1. clearly assigned to the metrologically significant software and functions. Yes No N/A
 - 1.5.2. provided by the device as documented. Yes No N/A
 - 1.5.3. directly linked to the software itself. This means that you can't easily change the software without changing the software identifier. For example, the version identifier can't be in a text file that's easily editable, or in a variable that the user can edit. Yes No N/A

2. Programmable or Loadable Metrologically Significant Software

- 2.1. The metrologically significant software is:
- 2.1.1. Documented with all relevant information (see Section 3 for list of documents). Yes No N/A
 - 2.1.2. Protected against accidental or intentional changes. Yes No N/A
- 2.2. Evidence of intervention (such as, changes, uploads, circumvention) is available until the next verification / inspection (e.g., physical seal, Checksum, Cyclical Redundancy Check (CRC), audit trail, etc. means of security). Yes No N/A

3. Software with no access to the operating system and/or programs possible for the user. This section and section 4 are intended to be mutually exclusive.

- 3.3. Check whether there is a complete set of commands (e.g., function keys or commands via external interfaces) supplied and accompanied by short descriptions. Yes No N/A

4. Operating System and / or Program(s) Accessible for the User.

- 4.4. Check whether a checksum or equivalent signature is generated over the machine code of the metrologically significant software (program module(s) subject to legal control Weights and Measures jurisdiction and type-specific parameters). This is a declaration or explanation by the manufacturer. Yes No N/A
- 4.5. Check whether the metrologically significant software will detect and act upon any unauthorized alteration of the metrologically significant software using simple software tools (e.g., text editor). This is a declaration or explanation by the manufacturer. Yes No N/A

- 4.6. Check whether the manufacturer has provided a description of the software functions that are metrologically significant, meaning of the data, etc., e.g. an architecture diagram or flowchart. Yes No N/A
- 4.7. Check that there is guidance related to the software identification (version, revision, etc.), how to view it, and how it is tied to the software. Yes No N/A
- 4.8. Check that the manufacturer has provided an overview of the security aspects of the operating system, e.g. protection, user accounts, privileges, etc. Yes No N/A

5. Software Interface(s)

- 5.9. Verify the manufacturer has documented:
- 5.9.1. If software separation is employed, the program modules of the metrologically significant software are defined and separated. Yes No N/A
- 5.9.2. The functions of the metrologically significant software that can be accessed. Yes No N/A
- 5.9.3. The metrologically significant parameters that may be exchanged are defined. Yes No N/A
- 5.9.4. The description of the functions and parameters are conclusive and complete. Yes No N/A
- 5.9.5. There are software interface instructions for the third party (external) application programmer. Yes No N/A