WELMEC 7.5
2020

WELMEC

European Cooperation in Legal Metrology

Software in NAWIs

(Non-automatic Weighing Instruments Directive 2014/31/EU)

For information:
This guide is available to the Working Group Measuring Instruments for future reference on the Europa Website.

WELMEC

European Cooperation in Legal Metrology

WELMEC is cooperation between the legal metrology authorities of the Member States of the European Union and EFTA.

This document is one of a number of Guides published by WELMEC to provide guidance to manufacturers of measuring instruments and to Notified Bodies responsible for conformity assessment of their products.

The Guides are purely advisory and do not themselves impose any restrictions or additional technical requirements beyond those contained in relevant EU Directives.

Alternative approaches may be acceptable, but the guidance provided in this document represents the considered view of WELMEC as to the best practice to be followed.

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Introduction

This document is intended to provide guidance on the software requirements in accordance with the Non-automatic Weighing Instruments Directive (NAWID) 2014/31/EU.

Produced by the WELMEC cross-sectional group WG2-WG7, the guidance provided in this document is based on the 17th resolution of the 33rd WELMEC Committee meeting 2017. There, the WELMEC Committee emphasised the fact that the software-related Essential Requirements of NAWIs could be fully covered by a subset of the software-related Essential Requirements of the Measuring Instruments Directive (MID) (2014/32/EU).

The cross-sectional group conducted a comparison between the harmonised standard used to assess the NAWID software requirements (EN 45501:2015) and the guide used to assess the Measuring Instruments Directive (MID) (2014/32/EU) software requirements, WELMEC Guide 7.2 (2019). References to WELMEC Guide 7.2 were made when it was deemed that the harmonised standard does not, or only partially covers the NAWID software-related Essential Requirements.

The right-hand column in section 3 specifies whether EN 45501:2015 covers, partially covers or does not cover the requirements of WELMEC Guide 7.2. When partially covered, the column specifies the requirements in WELMEC Guide 7.2 that are not included in EN 45501:2015. Notes have also been added to specify the requirements in EN 45501:2015 that are not covered by WELMEC Guide 7.2.

The Guide can also be used to convert NAWI software evaluations into AWI evaluations, and vice-versa. The tables in section 2 identify what additional requirements must be met to allow the conversion.

1 Preliminary Remarks

The following main points are not fully addressed in EN 45501:2015:

- Software separation for embedded systems:
  WELMEC Guide 7.2 (2019) Type P and Extension S requirements apply
- Download of legally relevant software:
  WELMEC Guide 7.2 (2019) Extension D requirements apply
- Transmission to external devices:
  WELMEC Guide 7.2 (2019) Extension T requirements apply
- Operating systems (non-embedded systems):
  WELMEC Guide 7.2 (2019) requirement U6 applies

In EN 45501:2015, “interface” includes user/software/hardware/communication interfaces.

When references to WELMEC Guide 7.2 (2019) are made, Risk Class B should be considered for instruments with embedded software and Risk Class C for other instruments.

The definition of embedded system is more restrictive in EN 45501:2015 than Type P is in WELMEC Guide 7.2 (2019):

<table>
<tr><th>EN 45501:2015</th><th>Software type</th><th>WELMEC Guide 7.2 (2019)</th></tr>
<tr><td>Embedded software (5.5.1)</td><td>Embedded software</td><td rowspan="2">Type P</td></tr>
<tr><td rowspan="2">Programmable or loadable software (5.5.2)</td><td>Programmable or loadable software with no access to the operating system and/or programs possible for the user</td></tr>
<tr><td>Programmable or loadable software with access to the operating system and/or programs for the user</td><td>Type U</td></tr>
</table>

2 Considerations for converting between NAWI and AWI applications

Software complies with EN 45501:2015; to comply with WELMEC Guide 7.2 (2019):

WELMEC Guide 7.2 (2019)		EN 45501:2015	Additional requirements in WELMEC Guide 7.2
P1: Documentation	Requirements:	5.5.1	Additional documentation is required in WELMEC Guide 7.2: b. A description of the accuracy of the measuring algorithms (e.g. price calculation and rounding algorithms). c. A description of the user interface, menus and dialogues. e. An overview of the system hardware, e.g. topology block diagram, type of computer(s), type of network, etc. f. The operating manual.
P5: Protection against accidental or unintentional changes	Requirements:	5.5.1	EN 45501 does not cover unintentional changes.
P7: Parameter protection	Requirements:	4.1.2.4	WELMEC Guide 7.2 does not have the exception “On a class I instrument, devices to adjust sensitivity (or span) may remain unsecured.” WELMEC Guide 7.2 requires documentation to “describe the device-specific parameters, whether they may be set and how they are set and how they are secured.”
U5: Protection against accidental or unintentional changes	Requirements:	5.5.2.2.a	EN 45501 does not cover unintentional changes.
U6: Protection against intentional changes	Acceptable solutions:	5.5.2.2	WELMEC Guide 7.2 requires CRC-32 instead of CRC-16 in EN 45501
U7: Parameter protection	Requirements:	4.1.2.4	WELMEC Guide 7.2 does not have the exception “On a class I instrument, devices to adjust sensitivity (or span) may remain unsecured.” WELMEC Guide 7.2 requires documentation to “describe the device-specific parameters, whether they may be set and how they are set and how they are secured.” WELMEC Guide 7.2 requires that device-specific parameters be stored in secured hardware.
L1: Completeness of measurement data stored	Acceptable solutions:	-	In addition to 5.5.3.2, WELMEC Guide 7.2 also specifies the data field “the date and time of the measurement (if applicable)”.

WELMEC Guide 7.2 (2019)		EN 45501:2015	Additional requirements in WELMEC Guide 7.2
L2: Protection against accidental or unintentional changes	Requirements:	5.5.3.3	EN 45501 does not cover unintentional changes.
L5: Confidentiality of keys	Requirements:	-	See L5 requirements if keys are used
L7: Automatic storing	Requirements:	5.5.3.5	WELMEC Guide 7.2 requires all accepted measurements to be stored even if intermediary.
T: Data transmission	Requirement	-	EN 45501 does not cover extension T.
D: Download of Legally Relevant Software	Requirement	-	EN 45501 does not cover extension D.

Software complies with WELMEC Guide 7.2 (2019); to comply with EN 45501:2015:

WELMEC Guide 7.2 (2019)		EN 45501:2015	Additional requirements in EN 45501:2015
P7: Parameter protection	Requirements:	4.1.2.4	EN 45501 specifies that the counter in case of “software sealing” must be non-resettable (4.1.2.4.a).
P8: Presentation of measurement data	Requirements:	5.3.6.1	EN 45501 also requires primary indications, as well as measurement data, are protected against falsification.
U4: Influence via communication interface	Requirements:	5.3.6. 5.5.2.2.a 5.5.2.2.b 5.5.2.2.d	EN 45501 also requires a declaration of the completeness of the set of commands.
U8: Presentation of measurement data	Requirements:	4.11.4 5.3.6.1	EN 45501 also requires primary indications, as well as measurement data, are protected against falsification.

3 Comparison of EN 45501:2015 to WELMEC Guide 7.2 (2019)

3.1 Type P

WELMEC Guide 7.2 (2019)		EN 45501:2015	Content of WELMEC Guide 7.2 covered by EN 45501:2015
P1: Documentation	Requirements:	5.5.1	**Partially covered** Additional documentation is required in WELMEC Guide 7.2: b. A description of the accuracy of the measuring algorithms (e.g. price calculation and rounding algorithms). c. A description of the user interface, menus and dialogues. e. An overview of the system hardware, e.g. topology block diagram, type of computer(s), type of network, etc. f. The operating manual.
P2: Software identification	Requirements:	5.5.1	**Covered**
	Validation Guidance:	G.1	WELMEC Guide 7.2 validation guidance may be used.
	Acceptable Solutions:	5.5.1	WELMEC Guide 7.2 acceptable solution may be used.
P3: Influence via user interface	Requirements:	5.5.1 4.1.2.4	**Covered**
	Validation Guidance:	G.1 G.2.2.1	WELMEC Guide 7.2 validation guidance may be used.
	Acceptable Solutions:	4.1.2.4	WELMEC Guide 7.2 acceptable solution may be used.
P4: Influence via communication interface	Requirements:	5.5.1 4.1.2.4 5.3.6	**Covered**
	Validation Guidance:	G.1 G.2.2.1	WELMEC Guide 7.2 validation guidance may be used.
	Acceptable Solutions:	4.1.2.4	WELMEC Guide 7.2 acceptable solution may be used.
P5: Protection against accidental or unintentional changes	Requirements:	5.5.1	**Partially covered** EN 45501 does not cover unintentional changes.
	Validation Guidance:	G.1	WELMEC Guide 7.2 validation guidance may be used.
	Acceptable Solutions:	-	WELMEC Guide 7.2 acceptable solution may be used.
P6: Protection against intentional changes	Requirements:	5.5.1	**Covered**
	Validation Guidance:	G.1	WELMEC Guide 7.2 validation guidance for risk class B may be used.
	Acceptable Solutions:	-	WELMEC Guide 7.2 acceptable solution for risk class B may be used.

WELMEC Guide 7.2 (2019)		EN 45501:2015	Content of WELMEC Guide 7.2 covered by EN 45501:2015
P7: Parameter protection	Requirements:	4.1.2.4	**Partially covered** WELMEC Guide 7.2 does not have the exception: “On a class I instrument, devices to adjust sensitivity (or span) may remain unsecured.” WELMEC Guide 7.2 requires documentation to “describe the device-specific parameters, whether they may be set and how they are set and how they are secured.” Note: EN 45501 specifies that the counter in case of “software sealing” must be non-resettable (4.1.2.4.a).
	Validation Guidance:	-	WELMEC Guide 7.2 validation guidance may be used.
	Acceptable Solutions:	4.1.2.4	Event logger in WELMEC Guide 7.2 may also be used.
P8: Presentation of measurement data	Requirements:	4.11.4 5.3.6.1	**Covered** Note: EN 45501 also requires primary indications, as well as measurement data, are protected against falsification.
	Validation Guidance:	-	WELMEC Guide 7.2 validation guidance may be used.
	Acceptable solutions:	-	WELMEC Guide 7.2 acceptable solution may be used.

3.2 Type U

WELMEC Guide 7.2 (2019)		EN 45501:2015	Content of WELMEC Guide 7.2 covered by EN 45501:2015
U1: Documentation	Requirements:	5.5.2.2.d	**Covered**
U2: Software identification	Requirements:	5.5.2.2.c	**Covered**
	Validation Guidance:	G.2.4	**Covered**
	Acceptable solutions:	5.5.2.2.c	Acceptable solutions in WELMEC Guide 7.2 may be used, provided the requirements in EN 45501 5.5.2.2 are met
U3: Influence via user interface	Requirements:	5.5.2.2.a 5.5.2.2.b T.2.3.6	**Covered**
	Validation Guidance:	G.2.2.2 G.2.3 applies when relevant	See guidance from WELMEC Guide 7.2 (U3 2nd bullet point): Check the protection measures against influences from other commands.
	Acceptable solutions:	5.5.2.2.a 5.5.2.2.b 4.1.2.4	The acceptable solution in WELMEC Guide 7.2 may be used.
U4: Influence via communication interface	Requirements:	5.3.6. 5.5.2.2.a 5.5.2.2.b 5.5.2.2.d	**Covered** Note: EN 45501 also requires a declaration of the completeness of the set of commands.
	Validation Guidance:	G.2.3	G.2.3 can be applied to communication interfaces.
	Acceptable solutions:	5.5.2.2.a 5.5.2.2.b 4.1.2.4	WELMEC Guide 7.2 acceptable solution may be used.
U5: Protection against accidental or unintentional changes	Requirements:	5.5.2.2.a	**Partially covered** EN 45501 does not cover unintentional changes. Where the operating system allows it, it is recommended that all user rights for the deletion, moving or amendment of legally relevant software is removed, and access is controlled via utility programs. Access control to legally relevant software by the use of passwords is recommended, as is the use of read-only mechanisms. The system supervisor should restore rights only when required. Note: EN 45501 also covers type-specific parameter and measurement data with this requirement.
	Validation Guidance:	G.2.2.2	WELMEC Guide 7.2 validation guidance may be used.
	Acceptable solutions:	5.5.2.2.a	WELMEC Guide 7.2 acceptable solution may be used.

WELMEC Guide 7.2 (2019)		EN 45501:2015	Content of WELMEC Guide 7.2 covered by EN 45501:2015
U6: Protection against intentional changes	Requirements:	5.5.2.2.a	**Partially covered** Features of the operating system used for the protection of legally relevant software are part of legally relevant software and secured as such
	Validation Guidance:	G.2.2.2	WELMEC Guide 7.2 validation guidance may be used.
	Acceptable solutions:	5.5.2.2.a	WELMEC Guide 7.2 requires CRC-32 instead of CRC-16 in EN 45501 WELMEC Guide 7.2 acceptable solution may be used.
U7: Parameter protection	Requirements:	4.1.2.4	**Partially covered** WELMEC Guide 7.2 does not have the exception: “On a class I instrument, devices to adjust sensitivity (or span) may remain unsecured.” WELMEC Guide 7.2 requires documentation to “describe the device-specific parameters, whether they may be set and how they are set and how they are secured.” WELMEC Guide 7.2 requires that device-specific parameters be stored in secured hardware.
	Validation Guidance:	G.2.2.3	Covered
	Acceptable solutions:	4.1.2.4	Covered
U8: Presentation of measurement data	Requirements:	4.11.4 5.3.6.1	**Covered** Note: EN 45501 also requires primary indications, as well as measurement data, are protected against falsification.
	Validation Guidance:	-	WELMEC Guide 7.2 validation guidance may be used.
	Acceptable solutions:	-	WELMEC Guide 7.2 acceptable solution may be used.
U9: Influence of other software	Requirements:	5.5.2.2.b 5.3.6.1	**Covered** For guidance on U9, see Extension S
	Validation Guidance:	- G.2.3	For guidance on U9, see Extension S.
	Acceptable solutions:	5.5.2.2.b	For guidance on U9, see Extension S.

3.3 Extension L: Long term storage of measurement data

WELMEC Guide 7.2 (2019)		EN 45501:2015	Content of WELMEC Guide 7.2 covered by EN 45501:2015
L1: Completeness of measurement data stored	Requirements:	5.5.3.2	**Covered**
	Validation Guidance:	G.3.3	G.3.3.3 specifies a checksum or other signature of the data set.
	Acceptable solutions:	-	WELMEC Guide 7.2 also specifies the data field “the date and time of the measurement (if applicable)”.
L2: Protection against accidental or unintentional changes	Requirements:	5.5.3.3	**Partially covered** EN 45501 does not cover unintentional changes.
	Validation Guidance:	G.3.2 G.3.4	WELMEC Guide 7.2 specifies “Check that a warning is issued to the user if he is about to change or delete measurement data files.”
	Acceptable solutions:	5.5.3.3	Acceptable solutions in WELMEC Guide 7.2 may also be used.
L3: Integrity of data	Requirements:	5.5.3.3	**Covered**
	Validation Guidance:	G.3.4	WELMEC Guide 7.2 validation guidance may be used.
	Acceptable solutions:	5.5.3.3	WELMEC Guide 7.2 acceptable solution may be used.
L4: Authenticity of measurement data stored	Requirements:	5.5.3.2 5.5.3.4	**Covered**
	Validation Guidance:	G.3.3	WELMEC Guide 7.2 validation guidance may be used.
	Acceptable solutions:	5.5.3.4	WELMEC Guide 7.2 acceptable solution may be used.
L5: Confidentiality of keys	Requirements:	-	Not required See L5 requirements if keys are used
	Validation Guidance:	-	Not required See L5 requirements if keys are used
	Acceptable solutions:	-	Not required See L5 requirements if keys are used
L6: Retrieval, verification, and indication of stored data	Requirements:	5.5.3.3 5.5.3.4 5.5.3.6	**Covered** WELMEC Guide 7.2 specifies that protection must cover the retrieval of data (checks for corruption before it is displayed or printed)
	Validation Guidance:	G.3.2 G.3.5	WELMEC Guide 7.2 validation guidance may be used.
	Acceptable solutions:	5.5.3.3 5.5.3.4	WELMEC Guide 7.2 acceptable solution may be used.

WELMEC Guide 7.2 (2019)		EN 45501:2015	Content of WELMEC Guide 7.2 covered by EN 45501:2015
L7: Automatic storing	Requirements:	5.5.3.5	**Partially covered** WELMEC Guide 7.2 requires all accepted measurements to be stored even if intermediary.
	Validation Guidance:	G.3.6	WELMEC Guide 7.2 validation guidance may be used.
	Acceptable solutions:	-	WELMEC Guide 7.2 acceptable solution may be used.
L8: Storage capacity and continuity	Requirements:	5.5.3.1	**Covered**
	Validation Guidance:	G.3.2	WELMEC Guide 7.2 validation guidance may be used.
	Acceptable solutions:	-	WELMEC Guide 7.2 acceptable solution (3rd bullet point) may be used.

3.4 Extension T: Data transmission

WELMEC Guide 7.2 (2019)		EN 45501:2015	Content of WELMEC Guide 7.2 covered by EN 45501:2015
T1: Completeness of transmitted data	Requirements:	5.5.3 5.5.3.2	**Not covered**
	Validation Guidance:	-	Validation guidance in WELMEC Guide 7.2 may be used.
	Acceptable solutions:	See L1 for transmission to external data storage	Acceptable solution in WELMEC Guide 7.2 may be used.
T2: Protection against accidental or unintentional changes	Requirements:	5.5.3.3	**Not covered**
	Validation Guidance:	-	Validation guidance in WELMEC Guide 7.2 may be used.
	Acceptable solutions: •	5.5.3.3	Acceptable solutions in WELMEC Guide 7.2 may be used.
T3: Integrity of data	Requirements:	4.13.9	**Not covered**
	Validation Guidance:	-	Validation guidance in WELMEC Guide 7.2 may be used.
	Acceptable solutions:	-	Acceptable solution in WELMEC Guide 7.2 may be used.
T4: Authenticity of transmitted data	Requirements:	-	**Not covered**
	Validation Guidance:	-	Validation guidance in WELMEC Guide 7.2 may be used.
	Acceptable solutions:	-	Acceptable solution in WELMEC Guide 7.2 may be used.
T5: Confidentiality of keys	Requirements:	-	Not required See T5 requirements if keys are used.
	Validation Guidance:	-	Not required See T5 requirements if keys are used.
	Acceptable solutions:	-	Not required See T5 requirements if keys are used.
T6: Handling of corrupted data	Requirements:	-	**Not covered**
	Validation Guidance:	-	Validation guidance in WELMEC Guide 7.2 may be used.
	Acceptable solutions:	-	Acceptable solution in WELMEC Guide 7.2 may be used.
T7: Transmission delay	Requirements:	-	**Not covered**
	Validation Guidance:	-	Validation guidance in WELMEC Guide 7.2 may be used.
	Acceptable solutions:	-	Acceptable solution in WELMEC Guide 7.2 may be used.
T8: Availability of transmission services	Requirements:	-	**Not covered**
	Validation Guidance:	-	Validation guidance in WELMEC Guide 7.2 may be used.
	Acceptable solutions:	-	Acceptable solution in WELMEC Guide 7.2 may be used.

3.5 Extension S: Software Separation

WELMEC Guide 7.2 (2019)		EN 45501:2015	Content of WELMEC Guide 7.2 covered by EN 45501:2015
S1: Realisation of software separation	Requirements:	5.5.2.2.b	**Covered**
	Validation Guidance:	G.2.1	Validation guidance in WELMEC Guide 7.2 may be used.
	Acceptable solutions:	-	-
S2: Mixed indication	Requirements:	4.4.4	**Covered**
	Validation Guidance:	-	WELMEC Guide 7.2 validation guidance may be used.
	Acceptable solutions:	-	WELMEC Guide 7.2 acceptable solution may be used.
S3: Protective software interface	Requirements:	5.3.6.1 5.3.6.2 5.5.2.2.b	**Covered**
	Validation Guidance:	G.2.3	WELMEC Guide 7.2 validation guidance may be used.
	Acceptable solutions:	5.5.2.2.b	WELMEC Guide 7.2 acceptable solution may be used.

3.6 Extension D: Download of Legally Relevant Software

WELMEC Guide 7.2 (2019)		EN 45501:2015	Content of WELMEC Guide 7.2 covered by EN 45501:2015
D1: Download mechanism	Requirements:	-	**Not covered**
	Validation Guidance:	-	Validation guidance in WELMEC Guide 7.2 may be used.
	Acceptable solutions:	-	Acceptable solution in WELMEC Guide 7.2 may be used.
D2: Authentication of transmitted software	Requirements:	-	**Not covered**
	Validation Guidance:	-	Validation guidance in WELMEC Guide 7.2 may be used.
	Acceptable solutions:	-	Acceptable solution in WELMEC Guide 7.2 may be used.
D3: Integrity of downloaded software	Requirements:	-	**Not covered**
	Validation Guidance:	-	Validation guidance in WELMEC Guide 7.2 may be used.
	Acceptable solutions:	-	Acceptable solution in WELMEC Guide 7.2 may be used.
D4: Traceability of legally relevant software download	Requirements:	-	**Not covered**
	Validation Guidance:	-	Validation guidance in WELMEC Guide 7.2 may be used.
	Acceptable solutions:	-	Acceptable solution in WELMEC Guide 7.2 may be used.

4 Revision History

No.	Date	Significant Changes
1	April 2020	Initial Version

Table 1-1: *Revision history*