

Leaflet:

Requirements for software separation in measuring instruments and ancillary equipment in legal metrology

This leaflet sets out the legal regulations regarding the separation of legally relevant and legally non-relevant software in measuring instruments, ancillary equipment (German: Zusatzeinrichtung) and instrument components¹ (German: Teilgerät). It is aimed at the manufacturers of measuring instruments who submit their measuring instruments to the PTB Conformity Assessment Body (KBS) for software evaluation either within the frame of the European Measuring Instruments Directive (MID) [1] or of the Measures and Verification Act (MessEG) [2], according to Module B.

1 Legal requirements for software separation in a type

The legal requirements for software separation can be derived from essential requirement 7.7 of Annex 2 of the Measures and Verification Ordinance (MessEV) [3], or the identical second paragraph of essential requirement 7.6 of Annex I of the MID [1]:

“When a measuring instrument has associated software which provides other functions besides the measuring function, the software that is critical for the metrological characteristics shall be identifiable and shall not be inadmissibly influenced by the associated software.”

To facilitate conformity assessment according to module B, the terms „associated software“ and „software that is critical for the metrological characteristics“ are interpreted respectively phrased more clearly as follows:

The term “legally relevant software” is used for the entirety of all software modules that are needed to fulfil the general essential requirements according to Annex 2 MessEV / Annex I of the MID. These are all software modules, that are critical for the metrological characteristics or that realize related securing or identifications tasks. The term “legally non-relevant software” is used for all other software modules (associated software).

¹ When text refers to measuring instruments, both ancillary equipment and instrument components are included.

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In contrast to legally relevant software, which is critical for the metrological characteristics, legally non-relevant software is not part of the type and does not need to be identified. This implies that legally non-relevant software can be replaced both before placing on the market (during production of the series devices) and afterwards (in series devices on the market).

1. In the case of a change of legally non-relevant software prior to placing on the market, no new conformity assessment according to Module B is necessary, as well as no revision of the type examination certificate, as the legally non-relevant software is not part of the type.
2. If legally non-relevant software is changed after placing it on the market, this can be done without violating any technical securing means and without recalibration / verification, since the change does not affect the state of the measuring instrument, compared to that described in the type examination certificate.

Since, from a legal standpoint, legally non-relevant software is not part of the type, it can theoretically be written or respectively replaced by any market actor.

To answer the question, if the arbitrary, principally unknown, legally non-relevant software can have an influence on the legally relevant properties of the measuring instrument, an examination is performed according to Extension S (software separation) of the WELMEC Software Guide 7.2:2015 [4] which serves as a harmonized interpretation of legal requirements across Europe. The optional requirement set S is only tested if, during conformity assessment according to Module B, the manufacturer has classified part of the software as legally non-relevant and if this part does indeed not fulfil legally relevant tasks. For a measuring instrument that contains only legally relevant software during conformity assessment according to module B, requirement set S is not tested. It follows that no legally non-relevant software shall be introduced into such a measuring instrument later.

2 Technical requirements for software separation in a type

To ensure that the legally non-relevant software does not inadmissibly influence the legally relevant software, extension S of WELMEC Software Guide 7.2 requires the following. Both software parts shall be physically or logically separated (S1). Indications of both parts (if any) shall be distinguishable (S2). Finally, there shall exist a protective interface between both software parts (S3).

The principal separation of the software into two parts (associated software and software that is critical for the metrological characteristics), as described by the essential requirement, can for instance be mapped by requirement S1 of WELMEC Software Guide 7.2:2015 [4].

S1: Realisation of software separation

There shall be a part of the software that contains all legally relevant software and parameters that is clearly separated from other parts of software.

Specifying Notes:

1. *In the case of low level separation, all program units (subroutines, procedures, functions, classes, etc.) and in case of high level separation all programs and libraries
 - that contribute to the calculation of measurement values or have an impact on it,
 - that contribute to auxiliary functions such as displaying data, data security, data storage, software identification, performing software download, data transmission or storing, verifying received or stored data etc.belong to the legally relevant software.
All variables, temporary files and parameters that have an impact on measurement data or on legally relevant software also belong to the legally relevant software.*
2. *The protective software interface itself (see S3) is part of the legally relevant software.*
3. *Legally non-relevant software comprises the remaining program units, data or parameters not covered above.*

Remark: As in the next version of WELMEC Software Guide 7.2:2018 PTB's KBS no longer distinguishes between low-level software separation and high-level software separation. Instead, regardless of the actual technical implementation, requirements S1 to S3 must be met in any case. As legally non-relevant software can be classified, only such software modules, that cannot influence legally relevant software, measurement data or parameters under any circumstances and thus may be arbitrarily exchanged.

In principle, separation between legally relevant and legally non-relevant software can be achieved, e.g. by

- location on separate processors,
- location on separate memory areas of a specifically suited processor,
- Implementation as separate processes, programs or libraries.

An inadmissible influencing of the software critical for metrological characteristics can essentially occur on two levels: on the one hand by a change or imitation of the legally relevant display, on the other hand by direct or indirect influencing of the legally relevant data processing. The requirement for the protection of the legally relevant information can, for example, be mapped by the requirement S2 of the WELMEC Software Guide 7.2.

S2: Mixed indication

Information generated by the legally non-relevant software shall be shown on a display or printout in a way that confusions with the information generated by the legally relevant software are avoided.

Specifying Notes: ---²

Remark: The legally relevant software itself must ensure that no confusion of its indications with other information is possible. This means that the marking of legally non-relevant information by legally non-relevant software is not enough to fulfil the requirement. Rather, it must be assumed that the legally non-relevant software intentionally imitates the legally relevant software. It does not matter from which source (instrument manufacturer, other market actor) the legally non-relevant software comes from.

² The WELMEC Software Guide [4] does not contain any specifying notes for this requirement.

The requirement can be fulfilled e.g. in the following ways

- the legally relevant software has exclusive access to the indication hardware,
- the legally non-relevant software uses its own indication hardware that cannot be confused with the one of the legally relevant software.

The requirement for the protection of legally relevant data processing against influences from legally non-relevant software can, for example, be mapped by the requirement S3 of the WELMEC Guide 7.2 [4].

S3: Protective software interface

The data exchange between the legally relevant and legally non-relevant software shall be exclusively carried out via a protective software interface.

Specifying Notes:

1. *This requirement applies to all kind of interactions and data exchanges between the legally relevant and legally non-relevant software.*
2. *All communication shall exclusively be carried out via the defined protective interface.*
3. *There shall be only those interactions and data flows allowed that do not inadmissibly influence the measuring process, in particular the legally relevant software, device-specific parameters and measurement data.*
4. *Scheduling and runtime of the measuring process shall not be influenced by legally non-relevant software*

Remark: The protective interface must include all possible interactions between legally relevant and legally non-relevant software, especially those that may result from shared resources. It must be as small as possible. The legally relevant software must always be in control of the interface.

Concerning the interactions and all possible influences, the following must, for example, be taken into account:

- communication via physical connections, including their protocols and command sets,
- jumps and calls between separate memory areas that are not prohibited by the processor as well as interactions due to usage of shared data,
- interactions controlled by operating system or middleware, such as task managing, inter-process communication, resource allocation, priorities, common used data/files,
- interactions on source code level, such as calls, data exchanges, messages.

3 Conclusive classification as an alternative to software separation

If the technical implementation does not fulfil one of the three requirements S1, S2, S3, the entire software of the measuring instrument is classified as legally relevant. Changing one part of the software, thus, always entails a revision of the type examination certificate. Nevertheless, a modularization together with an accompanying documentation can simplify the corresponding type examination procedure. A modification of a software part on a measuring instrument in use may be made within the scope of a verification, but it is dependent on the approval of the competent verification authority, see §37 paragraph 2 no. 2 MessEG [2].

References

- [1] „Directive 2014/32/EU of the european parliament and of the council of 26 February 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of measuring instruments (recast)“, Official Journal of the European Union L96, 29.3.2014, S. 149-250
- [2] „Gesetz über das Inverkehrbringen und die Bereitstellung von Messgeräten auf dem Markt, ihre Verwendung und Eichung sowie über Fertigpackungen (Mess- und Eichgesetz – MessEG)“, Bundesgesetzblatt, Jahrgang 2013 Teil 1 Nr. 43, Juli 2013 zuletzt geändert am 11.04.2016
- [3] „Verordnung über das Inverkehrbringen und die Bereitstellung von Messgeräten auf dem Markt sowie über ihre Verwendung und Eichung (Mess- und Eichverordnung - MessEV)“, Bundesgesetzblatt Jahrgang 2014 Teil 1, Nr. 58, Dezember 2014 zuletzt geändert am 11.08.2017.
- [4] WELMEC Software Guide 7.2 (Measuring Instruments Directive 2014/32/EU), WELMEC, 2015