Working group 8.51 „Metrological Software"   Last revision: June 16, 2020

Leaflet:
Requirements for software updates in measuring instruments and ancillary equipment in legal metrology

This leaflet sets out the legal regulations regarding the update process of legally relevant software on measuring instruments, ancillary equipment (German: Zusatzeinrichtung) and instrument components[1] (German: Teilgerät) in circulation subject to legal control. It is aimed at both manufacturers and users of measuring instruments, since they have special roles in the update process. Furthermore, this leaflet is subdivided into an organizational description of the update process (Section 1) and the technical requirements for measuring instruments and associated software for the fulfillment of legal tasks (Section 2).

1   Organizational description of the software update process

The software update process is defined by § 37 paragraph 6 of the Measures and Verification Act (MessEG) [1]. This mentions the conditions under which the Verification Authority grant permission to update:[2]

"(6) In the cases referred to in paragraph 2 number 2[3], measuring instruments whose software has been updated by a technical operation may be reused if the competent authority[4] has approved this on request pursuant to § 40 paragraph 1. The approval is to be given if:

1. *the suitability of the software and the measuring instrument has been determined for updating its software;*
2. *there is a conformity assessment for the updated software;*
3. *the actual update is recorded permanently in the measuring instrument and*
4. *an authority according to Sentence 1 has verified the existence of these conditions by means of a random sampling test.*

The reverification periods of the respective measuring instrument remain unaffected."

---

[1] When text refers to measuring instruments, both ancillary equipment and instrument components are included.
[2] From German version, translated by Dr.-Ing. Federico Grasso Toro from [1]:
„(6) In den Fällen des Absatzes 2 Nummer 2 dürfen Messgeräte, deren Software durch einen technischen Vorgang aktualisiert wurde, wieder verwendet werden, wenn die zuständige Behörde nach § 40 Absatz 1 dies auf Antrag genehmigt hat. Die Genehmigung ist zu erteilen, wenn
  1. die Eignung der Software und des Messgeräts für eine Aktualisierung seiner Software festgestellt wurde,
  2. hierfür eine Konformitätsbewertung vorliegt,
  3. die erfolgte Aktualisierung dauerhaft im Messgerät aufgezeichnet ist und
  4. eine Behörde nach Satz 1 das Vorliegen dieser Voraussetzungen durch eine Stichprobenprüfung überprüft hat.
Die Eichfristen des jeweiligen Messgeräts bleiben hiervon unberührt."
[3] The reverification period ends prematurely if the made intervention may influence the metrological properties of the measuring instrument or extend or limit its range of application.
[4] Verification authority.

Leaflet: Requirements for software updates in measuring instruments and ancillary equipment in legal metrology

Prerequisite for a successful application are therefore two conformity certificates:

1. Conformity Certificate 1: In the frame of a conformity assessment procedure, this assesses the fulfillment of the technical requirements for the suitability of the updated software of the measuring instrument (see Section 2). After a successful evaluation, the conformity assessment body issues the Conformity Certificate 1.
2. Conformity Certificate 2: In the frame of the conformity assessment body, it must check whether all the requirements of Annex 2 of the Measures and Verification Ordinance (MessEV) [2] are met by the measuring instrument with updated software (further information can be found in the leaflet "Software documentation requirements for conformity assessment" of PTB Working Group 8.51 [3]). Subsequently, the conformity assessment body issues the Conformity Certificate 2.

Once both conformity certificates have been issued, the software update application procedure for one or more measuring instruments is divided as follows:

1. The applicant (economic actors or users of measuring instruments) shall submit an application for updating the software to the competent Verification Authority. The application encloses the two conformity certificates (§ 40 paragraph 1 & 2, MessEV).
2. The authority verifies that the measuring instrument is specifically designated (§ 40 paragraph 3 No. 1 a, MessEV). It also examines the existence of both the Conformity Certificate 1 (§ 40 paragraph 3 No. 1 b, MessEV) and the Conformity Certificate 2, in accordance with § 40 paragraph 3 No. 2, MessEV, with regard to the fulfillment of the essential requirements (§ 6 paragraph 2, MessEG).
3. The software update is performed in a batch of measuring instruments. Afterwards, the authority checks the correctness of these updated measuring instruments and subsequently issues the approval (§ 40 paragraph 3 No. 3, MessEV).
4. Only after the user has consented to the software update may the measuring instrument be updated (§ 40 paragraph 5, MessEV).
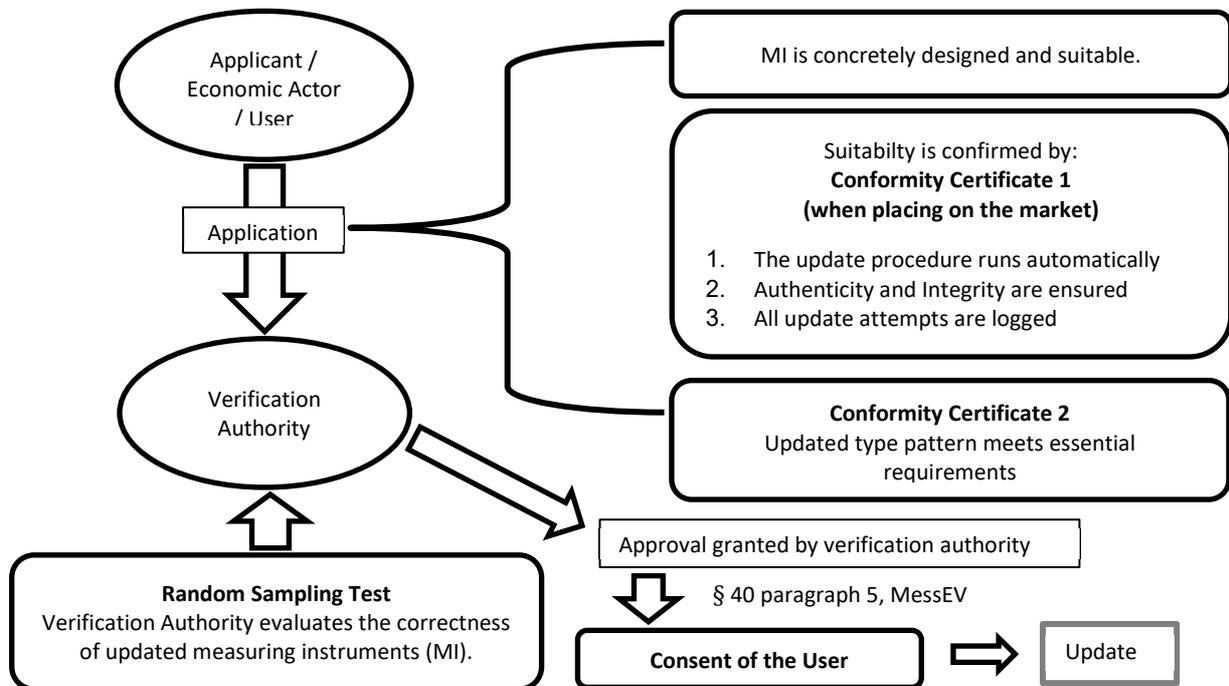

Figure 1: Sequence of events of the measuring instrument (MI) software update process and its associated application process

2 Technical requirements regarding the suitability of the type of measuring instrument for software update

The suitability of the type of measuring instrument for the software update according to § 40 paragraph 3 No. 1, MessEV [2], must be certified by a conformity assessment body with the Conformity Certificate 1. The suitability of the measuring instrument for software update required in § 40 paragraph 3 No. 1b MessEV [2] is specified by the subitems aa to cc:[5]

"(3) The approval[6] may only be granted if the following conditions are met:

1. the measuring instrument for which the updated software is intended,

   a) *is concretely specified;*
   b) *is suitable for updating software and its suitability is confirmed by a conformity certificate, in particular that:*
      aa) *the updating of the software after the start is automatic;*
      bb) *it is ensured by information technology procedures that the updated software originates from an authorized source and it has not been modified compared to the software mentioned in the conformity certificate;*
      cc) *updates and attempts to update the software are automatically logged and stored in the measuring instrument for a period of six months after the end of the reverification period, … ".*

The automatic procedure according to aa implies that the update cannot be interrupted after its start. It can be mapped, for example, onto the requirement D1 of the Europe-wide harmonized WELMEC 7.2, 2015: Software Guide [4]. Furthermore, the suitability for updating is only given if, subsequently, the protection level of the measuring instrument does not decrease.

D1: Download mechanism   *Both phases of the software download, the transmission and the subsequent installation of software, shall run automatically and not affect the protection of legally relevant software.*
Specifying Notes: 1. *The instrument shall be equipped with legally relevant software that carries out the checking functions required in D2 to D4.*   2. *The instrument shall be capable of detecting if the transmission of software or the subsequent installation fails. A warning shall be given. If the transmission or the installation is unsuccessful or has been interrupted, then the original status of the measuring instrument shall be unaffected. Alternatively, the instrument shall display a permanent error message and its metrological functioning shall be inhibited until the fault has been cleared.*   3. *On successful completion of the installation, all protective means shall be activated.*   4. *During transmission and subsequent installation of software, the measurement process shall be inhibited or correct measurement shall be appropriately guaranteed.*   5. *The number of retries of transmissions and installation attempts shall be reasonably limited.*

---

[5] From German version, translated by Dr.-Ing. Federico Grasso Toro [2]:

„(3) Die Genehmigung darf nur erteilt werden, wenn die nachfolgenden Voraussetzungen gegeben sind:

1. das Messgerät, für das die aktualisierte Software bestimmt ist,

   a) ist konkret bezeichnet,
   b) ist zur Aktualisierung von Software geeignet und die Eignung ist durch eine Konformitätsbescheinigung bestätigt, wobei dies insbesondere umfasst, dass
      aa) die Aktualisierung der Software nach dem Beginn selbsttätig abläuft,
      bb) durch informationstechnische Verfahren gewährleistet ist, dass die Software zur Aktualisierung aus einer autorisierten Quelle stammt und nicht verändert wurde gegenüber der in der Konformitätsbescheinigung genannten Software,
      cc) Aktualisierungen und Aktualisierungsversuche der Software im Messgerät automatisch protokolliert werden und für einen Zeitraum von sechs Monaten nach Ablauf der Eichfrist gespeichert werden, …".

[6] Approval for Software Update.

Leaflet: Requirements for software updates in measuring instruments and ancillary equipment in legal metrology

Remark: Ensuring a consistent level of protection includes ensuring technically that protection mechanisms can never be violated or circumvented by an update. For non-interruptible measurements such as for utility meters, it must be ensured that interrupting the measurement for updating does not cause any significant falsification of the measurement results.

Subitem bb requires that the software downloaded for updating must be from an authorized source. Due to the lack of infrastructure, instead of this, proof is required that the downloaded software is the one that has been submitted by the applicant for conformity assessment. Since the comparison with the conformity certificate cannot be done by software means, only proof of the authenticity is required here. This can be mapped onto the requirement D2 of the WELMEC Software Guide [4].

D2: Authentication of transmitted software
Means shall be employed to guarantee that the transmitted software is authentic.
Specifying Notes:
1. *Before the transmitted software is installed, it shall be checked that:* 　a. *The software is authentic.* 　b. *The software belongs to the measuring instrument on which it shall be installed.* 2. *A negative check result shall be considered as failure of transmission and treated as laid down in D1.*

Remark: If a manufacturer uses a signature process to ensure that the transferred software originated from her, then she must additionally prove in another way that the software has passed the necessary conformity assessment successfully.

In addition to the proof of origin, subitem bb requires proof of the integrity of the downloaded software. This can be implemented by the requirement D3 of the WELMEC Software Guide[4].

D3: Integrity of downloaded software
Means shall be employed to guarantee that the software has not been changed during transmission.
Specifying Notes:
1. *Before the transmitted software is installed, it shall be checked that the software has not been changed during transmission.* 2. *A negative check result shall be considered as failure of transmission and treated as laid down in D1.*

Remark: Even if the software is changed during transmission, the constant level of protection of the measuring instrument shall not be influenced or affected. If it is not possible to restore the original state of the measuring instrument after the update has been aborted, it must be ensured that the measuring instrument cannot be used for any further measurements.

A logging of updates and updating attempts (see Subitem cc) can be ensured in accordance with requirement D4 of the WELMEC Software Guide [4] as follows.

D4: Traceability of legally relevant software download
It shall be guaranteed by appropriate technical means that downloads of legally relevant software are adequately traceable within the instrument for subsequent controls.
Specifying Notes:
1. *All relevant data making a download or a download attempt traceable shall be recorded and secured. Relevant data includes date and time of download, identifier(s) of software, origin of transmission, success note.* 2. *The data recorded shall be available for an adequate period of time […].* 3. *The recorded data shall be presented on demand.* 4. *The traceability means and records are part of the legally relevant software and shall be protected as such.*

Remark: In any case, the protocol functionality (storage capacity including rules for updates, etc.) must be designed so that a record of all successful updates and update attempts is available for at least the reverification period plus six months regardless of the success or failure of the updating process with new software. Regarding the minimum storage periods of the download protocol, the respective instrument-specific reverification periods must be observed.

3 Technical requirements regarding the updated type of measuring instrument

The updated measuring instrument, according to § 40 paragraph 3 No 2, MessEV [2], must fulfill all requirements of Annex 2 MessEV [2]. This is certified as part of a conformity assessment by a conformity assessment body with the Conformity Certificate 2.

4 References

[1] Gesetz über das Inverkehrbringen und die Bereitstellung von Messgeräten auf dem Markt, ihre Verwendung und Eichung sowie über Fertigpackungen (Mess- und Eichgesetz – MessEG), Bundesgesetzblatt, Volume 2013 Part1 No. 43, July 2013, last modified on April 11, 2016

[2] 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 Part 1 No. 58, December 2014, last modified on August 11, 2017

[3] Leaflet: Software documentation requirements for conformity assessment, Physikalisch-Technische Bundesanstalt, Working group 8.51 „Metrological Software", in the current version

[4] WELMEC 7.2, 2015: Software Guide (Measuring Instruments Directive 2014/32/EU), WELMEC, 2015