

## **Software Version Management - Basic Rules for Legal Metrology -**

Draft

(These basic rules have been drafted by PTB and discussed with German verification authorities)

### **1. Introduction**

The precondition for the verifiability of measuring instruments which are provided with embedded software - especially for performing market surveillance - is compliance with basic, state-of-the-art rules of software version management.

This paper describes the minimum requirements for version management that have to be observed by the manufacturers of measuring devices, and on which the market surveillance authorities have to be able to rely.

The obligation to fulfil these requirements is also covered by European legal regulations [1, 2]. The identification procedures required in these regulations help to comply with an essential requirement placed on all economic operators: the requirement for traceability of the products throughout the whole supply chain.

First of all, the relation between the suggested way of proceeding for version management and the relevant European legal regulations [1, 2] is shown in section 2. In section 3, the essential basic rules for software version management are then outlined. The observance of these rules is regarded as necessary for performing market surveillance in legal metrology. These rules have to be implemented by the manufacturer of the measuring system during the entire software development process. Some recommendations for their application are listed in section 4.

The basic rules developed have been derived from the respective European legal regulations [1,2] and from the standards which characterise the state-of-the-art of software engineering [3, 4, 5, 6] and have been tailored to the specific features of legal metrology. Although these rules are tailored to software, they can, as a matter of principle, also be applied to hardware units. They are of an elementary nature and represent no additional obstacle to manufacturers who observe the standard rules of software engineering.

### **2. Legal Reference**

The REGULATION (EC) No 765/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL [1] and the DECISION No 768/2008/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL [2] regulate – within the scope of the harmonisation provisions for products – in particular the obligations of the product manufacturers. The requirements which are relevant for deriving the basic rules for software version management and which are placed on the manufacturers are as follows:

- **A1:** Manufacturers must ensure a clear and unambiguous identification of all products (see: [2], Annex 1, R2, para 5).
- **A2:** In order to make market surveillance simpler, the economic operators (the manufacturers in their sphere of action) must ensure traceability of a product throughout the whole supply chain. (see [2], Preamble, para 28).
- **A3:** Manufacturers must ensure by means of appropriate procedures that changes in product design or of the products (variants, versions) are taken into account (see [2], Annex 1, R2, para 4).
- **A4:** Manufacturers must ensure by means of appropriate procedures that conformity is always ensured in series production. (see [2], Annex 1, R2, para 4).

In the manufacture of software-controlled measuring systems, these requirements can be fulfilled by the manufacturers by realising the basic rules for version management outlined below.

### 3. Basic Rules for Version Management

In the following, we will describe four basic rules which are of special importance for version management in the field of legal metrology. The basic preconditions of version management are: the structuring of the software, and the clear and unambiguous identification of the software units (Basic Rule 1, see **A1**). An essential component of version management is the recording of relevant status information about the software units to be managed and about their changes (Basic Rule 2, see **A2, A3, A4**). Finally, for the processes in the development phase (Basic Rule 3, see **A2, A4**) as well as in the phase of archiving, delivery, installation and subsequent change (Basic Rule 4, see **A2, A3, A4**), sequences are to be determined and observed.

#### Basic Rule 1: Definition and Identification of Software Units

***All software units must be defined and identified clearly and unambiguously.***

The implementation of this rule encompasses:

- Definition of the software units as they are managed, delivered or exchanged as the smallest unit (extreme case: the whole software is one single unit);
- Description of the relations between the software units (relation as regards the content; relation within the scope of the software structure; if applicable: any relation with regard to time);
- Strategy and name conventions for a clear and unambiguous identification of the defined software units (implementation of the principle that different software units require different identifications and that further-developed versions require new identifications; distinction between delivered and non-delivered versions as well as between legally relevant and legally non-relevant software units);
- Identification of the legally relevant software parts and description of the interface with the legally non-relevant software parts.

## **Basic Rule 2: Recording of Status Information**

*The status information of the defined software units has to be recorded continuously from the very beginning and along with the creation of further-developed versions.*

The status information encompasses:

- Identifiers;
- Date of construction of the software unit and of each further-developed version;
- Date of release of the software unit and of each further-developed version;
- Date of deliveries;
- Date of subsequent changes;
- Reference to the respective documentation (e.g. instructions for use and security/safety information according to [2], Annex 1, R2, para 7);
- If applicable: Description of changed relations to other version units of further-developed versions;
- Designation of the approved software parts and of their versions ("freezing" of approved versions).

## **Basic Rule 3: Traceability of Software Units in the Development Process**

*Development processes must be organised in such a way that important sequences such as the construction, release, change or deletion of software units are comprehensible and (the different states of revision of) the software units are thus traceable.*

The implementation of this rule encompasses:

- Determination of rights and responsibilities;
- Establishment of regulated processes for the construction, storage, change and deletion of software units;
- Implementation of the determined rules, guidelines, specifications and conventions;
- Implementation of the special requirements of legal metrology (e.g. no changing of the software and of the legally relevant software part in the case of software separation after the certificate of conformity has been issued, or new order for conformity testing).

## **Basic Rule 4: Traceability of Software Units in Processes Taking Place after the Development Phase**

*Important processes which take place after the development phase (such as archiving, delivery, installation, maintenance), and in particular subsequent changes of the software, must be organised comprehensibly so that the traceability of software units is ensured.*

The implementation of this rule encompasses:

- Determination of rights and responsibilities; in particular: one person responsible for legally relevant software must be denominated (e.g. for conformity assessment module D according to the MID);
- Introduction of regulated processes for archiving, delivery, installation and maintenance;
- Establishment of regulated processes for changes carried out on already delivered software; especially by taking the regulations of legal metrology into account.

#### **4. Recommendations for the Application of the Rules**

The implementation of the four basic rules is to be effected at the manufacturer's of the measuring systems on the basis of a documented strategy (version management strategy). The documentation can be effected in a simple way in the form of short memoranda. The respective implementation can make use of the usual software development and software archiving means. For interested manufacturers, there is, however, a broad spectrum of tools for the realisation of an elaborate version management available.

#### **5. References**

- [1] REGULATION (EC) No 765/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93 of the Council.
- [2] DECISION No 768/2008/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 9 July 2008 on a common framework for the marketing of products, and repealing Council Decision 93/465/EEC of the Council.
- [3] ISO/IEC 12207:2007, Systems and Software Engineering - Software Life Cycle Processes.
- [4] ISO/IEC 15288:2007, Systems Engineering - System Life Cycle Processes.
- [5] ISO 10007:2003, Guidelines for Configuration Management.
- [6] IEEE 828:2012, Configuration Management in Systems and Software Engineering.