

Software related Challenges in Market Surveillance

**Workshop “Software and ICT
Challenges in Legal Metrology”
June 21st/22nd, PTB Berlin, Germany**

Agenda

1. History
2. Stakeholders
3. Experiences
4. Necessary knowledge
5. Software

1. History

In former times...

- Initial verification,
- verification,
- inspection in use



Nowadays

- Declaration of conformity
- Market surveillance
- Verification
- Inspection in use

2. Stakeholders

Stakeholders

- Manufacturer
- Service
- User
- Customer

Prevention and inspection

The instruments shall have no
feature/characteristics likely
to **facilitate fraudulent use**,

...

(Annex I, No. 7.1, 2014/32/EU – MID,
Annex I, No. 8.5, 2014/31/EU - NAWI)

Essential requirements:

A measuring instrument shall be designed

- so as to allow the control of the measuring tasks after the instrument has been placed on the market and put into use...
(Annex I, No. 7.6, 2014/32/EU – MID)
- to permit ready execution of the statutory controls...
(Annex I, No. 8.6, 2014/31/EU - NAWI)

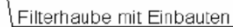
3. Experiences

Inspection in use



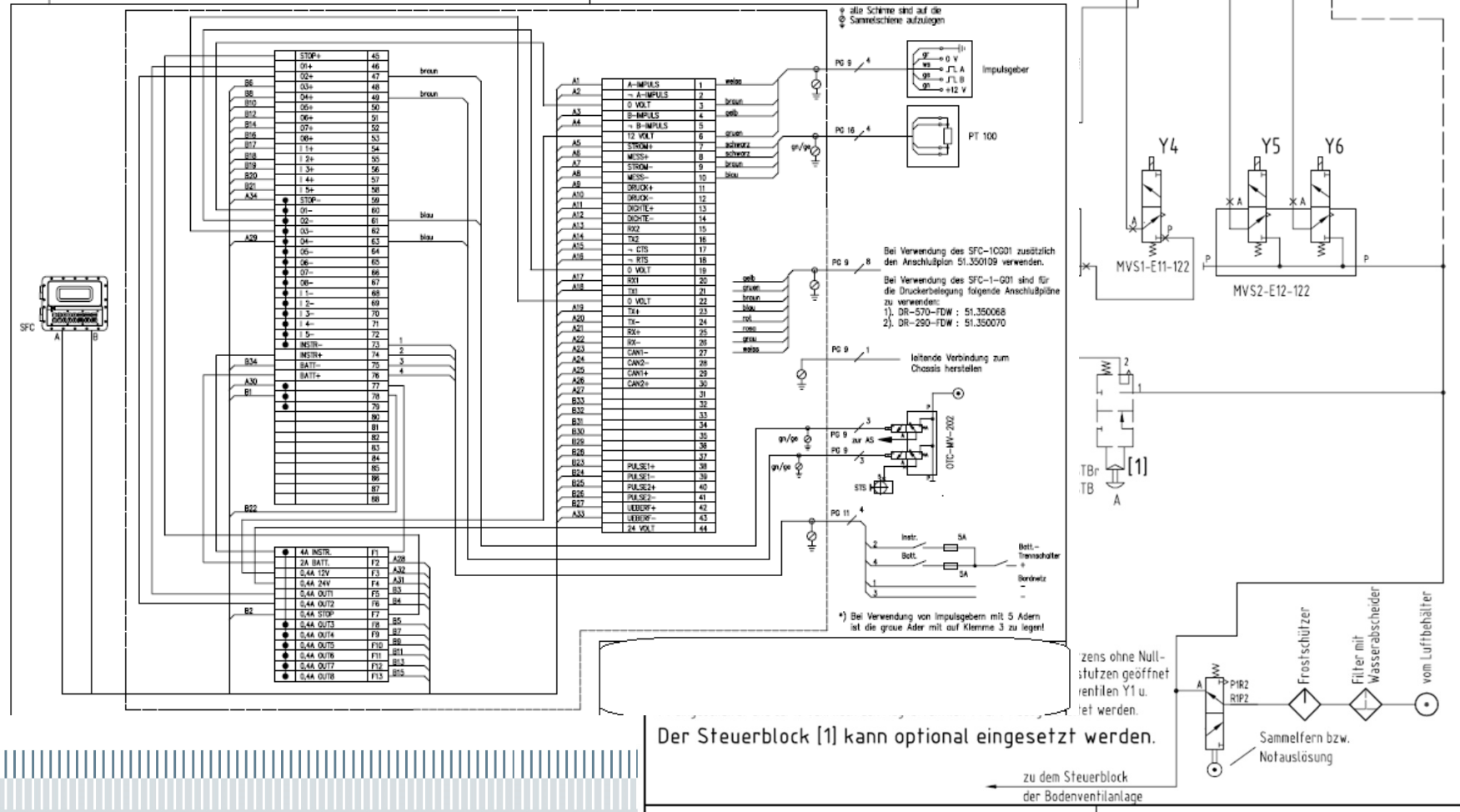
Fraudulent use (part 1)





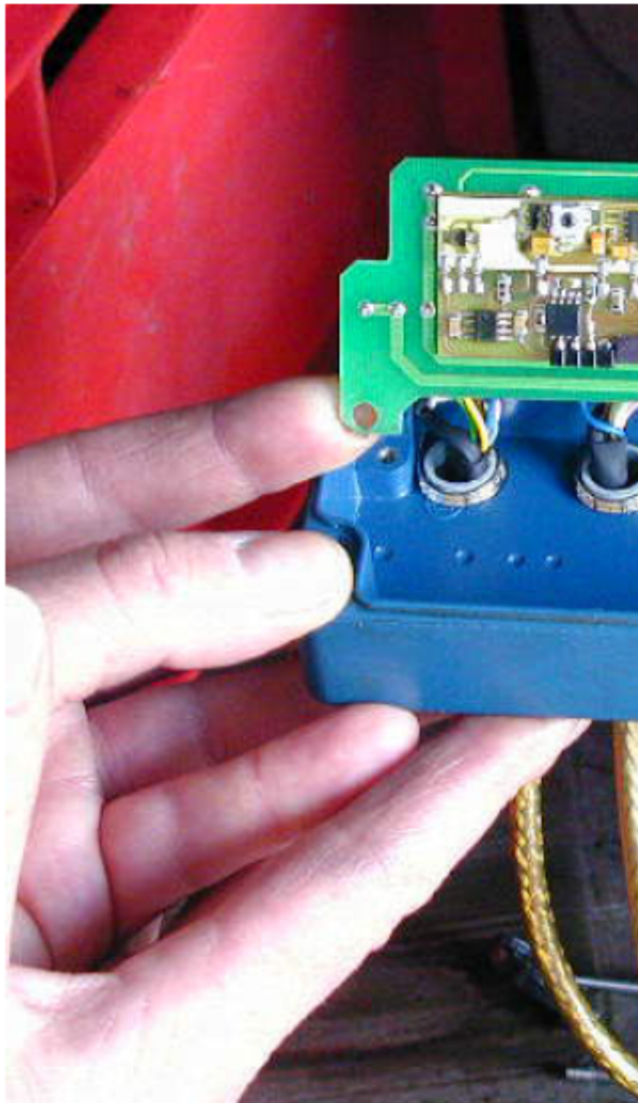
Fraudulent use (part 2)

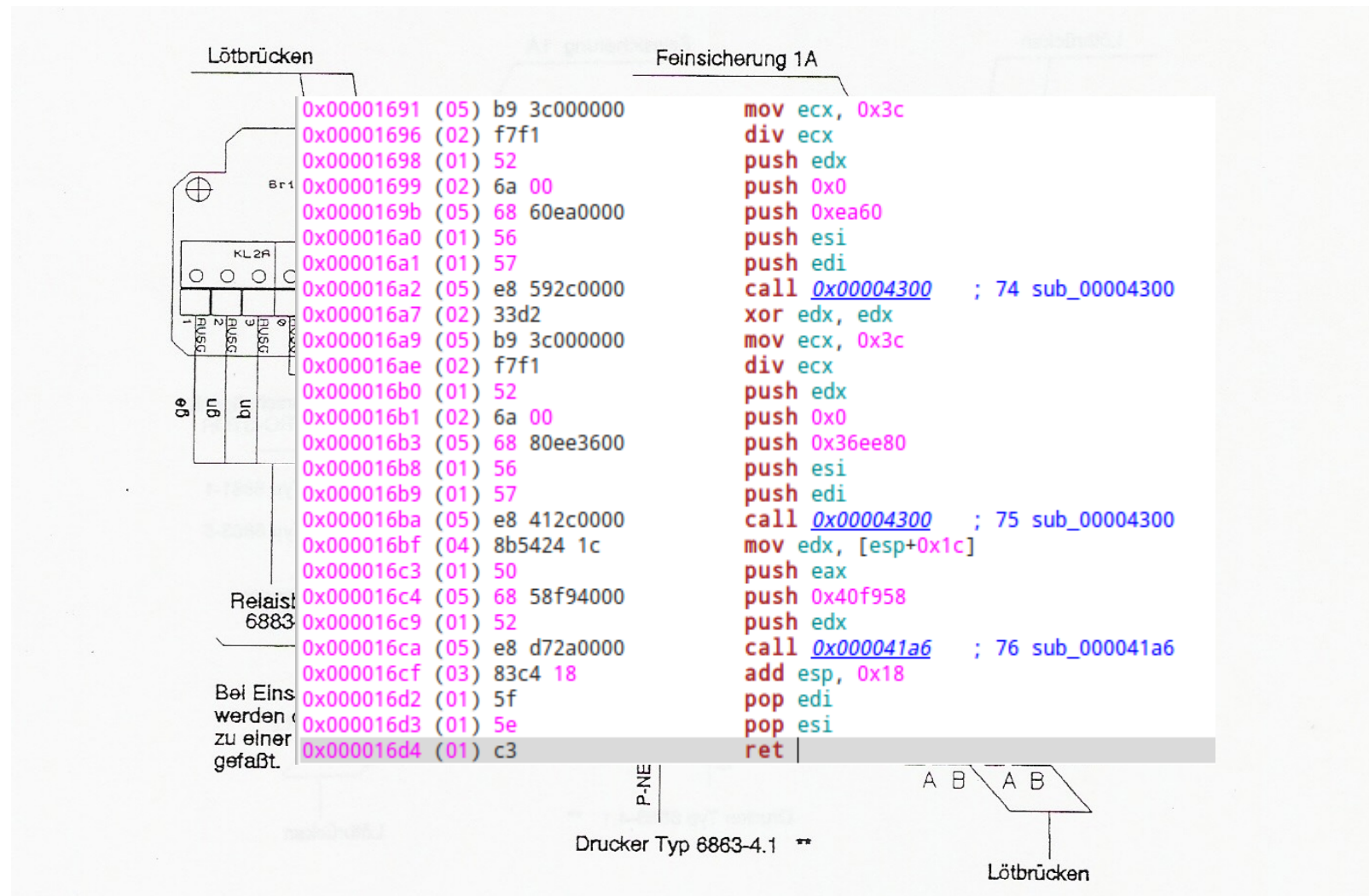




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4. Necessary knowledge

Inspector needs to know about

- Installation
- Electric concept
- Pneumatic concept
- Functioning
- = information needs to be provided by the manufacturer

5. Software

Software

essential part

important for competition

expensive development

=> Top secret

Software

- always is free of bugs,
- free of mistakes,
- never has backdoor,
- cannot be misused,
- cannot be controlled,
- cannot be attacked by others.

I disagree

⇔ **Software is safe!**

This is true?
Allways?

The WG5 sends the answer
from the subgroup on software identification
with alterations made at the meeting October 1st 2014 to WG7:

- Software has to comply with the essential requirements (NAWI, MID)
 - essential requirements (NAWI)
 - software needs to be identified (MID)
 - software has to be secured (MID)
(Directive 2014/32/EU, Annex I, No. 8.3,)

The WG5 sends the answer from the subgroup on software identification with alterations made at the meeting October 1st 2014 to WG7:

- “ Software has to comply with the essential requirements (NAWI, MID)
 - essential requirements (NAWI)
 - software needs to be identified (MID)
 - software has to be secured (MID)(Directive 2014/32/EU, Annex I, No. 8.3,)
- It is the responsibility of the manufacturer how to fulfil these requirements, i.e. acceptable technical solutions like checksum or version numbers
(2014/32/EU, Article 8. paragraph 1; 2014/31/EU, Article 6 par. 1)

Answer from WG5 (cont.)

- It is the responsibility of the MSA to check whether the instruments do fulfil these requirements
 - Market surveillance authorities shall perform appropriate checks on the characteristics of products on an adequate scale, by means of documentary checks and, where appropriate, physical and laboratory checks on the basis of adequate samples. When doing so they shall take account of established principles of risk assessment, complaints and other information.
(Regulation 765/2008/EC Art. 19 sub 1, first paragraph)

Answer from WG5 (cont.)

- The source code is one possible element of technical documentation that may need to be considered in order to evaluate whether the software meets the essential requirements.
 - Market surveillance authorities may require economic operators to make such documentation and information available as appear to them to be necessary for the purpose of carrying out their activities, and, where it is necessary and justified, enter the premises of economic operators and take the necessary samples of products.
(Regulation 765/2008/EC Art. 19 sub 1, second paragraph)”

**Software is developing very fast -
But we must not forget about the essentials!**

- Thank you for your attention!
- Any questions?