



European Weighing Industry

Future requirements in the relationship with notified bodies in the context of new technologies

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- The changes in technology
- The knowledge gap
- Risk Assessment
- The feedback loop

The changes in technology

- The development of the internet
- Acceleration in the growth of international trade
- Simultaneously allowed for the development of new technologies
- Cause us to rethink how we can control these instruments

The changes in technology-Industry 4.0

- The 4th Industrial Revolution
- Draws together all of the new technologies to produce the SMART Factory
- Weighing will be fundamental part of all of these processes
- “it is highly likely that the world of production will become more and more networked until everything is interlinked with everything else” – Siegfried Dias

Challenges to the weighing industry

- Future instruments
- Based around separate modules that may be in a number of countries
- May be outside the EU
- Utilizing all of the new technologies
- Will be part of smart factories and logistics chains
- Will be part of much larger interlinked networks

The Knowledge Gap

- As the technology marches on;
- The technology is fully understood by the manufacturer
- Different levels of technical understanding in different notified bodies
- Some have a high level of expertise and an ability to assess the software
- Some allow manufacturers self-declaration
- Must ensure a high level of technical understanding to ensure that systems can be properly approved

The Knowledge Gap

- Legal metrology is primarily a legislative discipline
- Many highly competent technical engineers
- Many highly competent lawyers
- Small number of people that understand in depth the relationship between software technology and the legislation
- Must ensure that notified bodies understand and agree legislative issues in conjunction with the technical requirements
- Must ensure that notified bodies understand the legal implications of their decisions
- All of this must be understood in the context of significant commercial decisions

Risk Assessment

- One method of managing the approval process is via an agreed risk assessment
- This is being worked on by WG7
- This would be agreed by WELMEC and operated by EU notified bodies
- Supported by CECIP

Risk Assessment

- Based around the concepts of ISO 27005 and ISO 15408
- “Risk is a combination of the consequences that would follow from the occurrence of an unwanted event and the likelihood of the occurrence of the event”
- Risk evaluation criteria
- “legal and regulatory requirements, and contractual obligations”

Assets and Attack Vectors

- Assets are those tangible elements of the software that will ensure the essential requirements of the Directive are met.
- Attack vectors are those things that could be threats to the assets and the consequences of such threats
- Once all assets have been defined
- Once attack vectors have been decided
- Each attack vector is subject to a vulnerability analysis
- The sum of each analysis will create a total value for the vulnerability of the instrument

Risk Assessment

- This system would be reproducible and transparent
- Very important for manufacturers
- Independent of the actual evaluator would move towards the same evaluation for the same software
- Likely that you would need to define attack vectors for a particular instrument only once

Risk Assessment-Problems

- The vulnerability analysis must include some element of attacker motivation
- The present analysis appears sufficiently sophisticated to analyse an appropriate risk once an attacker has decided to attack
- Does not attempt to analyse the likelihood of the instrument being attacked in the first place.

The Feedback Loop

- Operation of the market is made up of three main stakeholders
- Manufacturers
- Notified Bodies
- Market Surveillance Authorities

Market Surveillance Authorities

- Considered the relationship between manufacturers and notified bodies
- This must include market surveillance authorities and verification authorities
- It these authorities that will have the final say on an instrument placed on the market or in use
- Can have an instrument with a type approval that is rejected in the market place

Market Surveillance Authorities

- Must ensure that the knowledge gap for market surveillance authorities with regard to software is closed
- Must ensure that consistent interpretations are made
- Must ensure that communications between market surveillance authorities, notified bodies and manufacturers is maintained and improved.
- The Feedback loop
- Ensure that risk assessments reflect real risks not theoretical ones
- Quite often the manufacturer is in the middle of a dispute between a market surveillance authority and a notified body