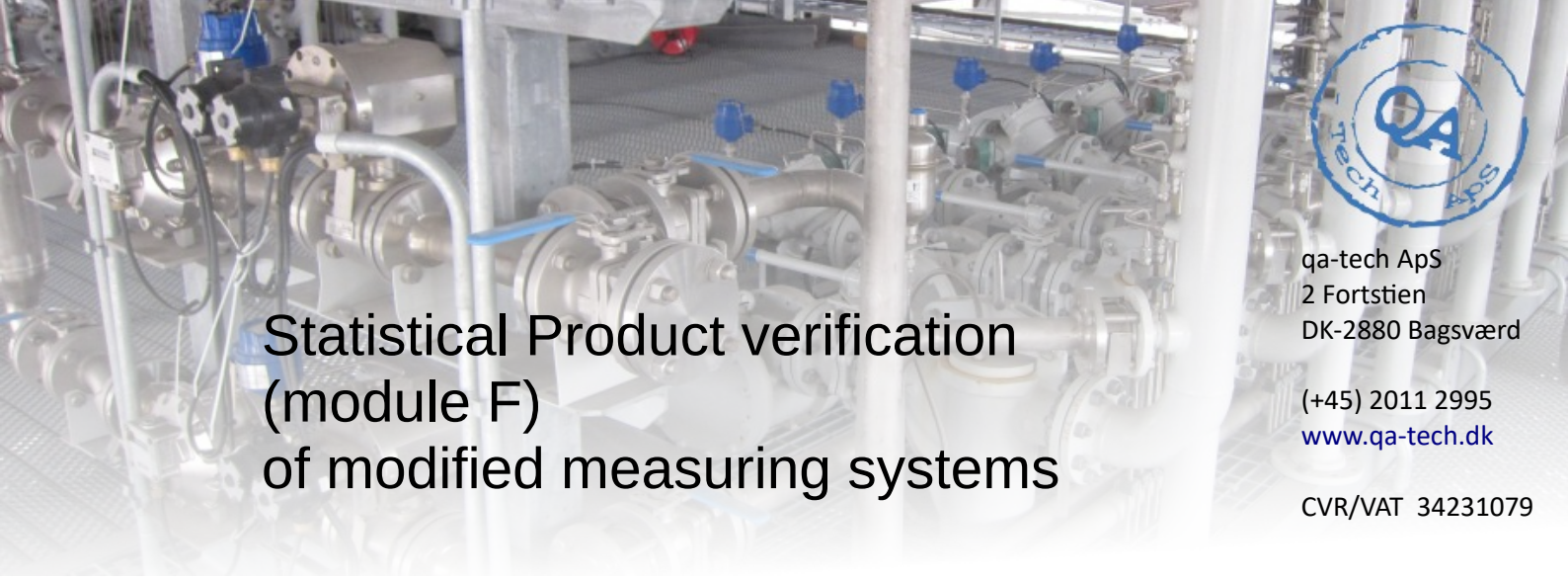

Statistical Product verification (module F) of modified measuring systems

qa-tech ApS
2 Fortstien
DK-2880 Bagsværd

(+45) 2011 2995
www.qa-tech.dk

CVR/VAT 34231079

Indhold

Summary

During the summer of 2014 the question of statistical module F on modified products was raised. Module F allows for both an individual and a statistical approach. This, however had not been used for modified measuring systems belonging to Product Directive 2014/32/EU annex VII (previously Directive 2004/22/EU annex MI-005). The article discusses some of the challenges in applying statistical product verification on such modified products.

Background

According to national legislation in Denmark, a modified CE-marked measuring system needs to undergo a re-certification process.
The CE-marking arrangement and its product directives are based on the idea, that the manufacturer takes responsibility of the product produced. Taking responsibility is displayed when the manufacturer issues a Declaration of Conformity. This is of course as the manufacturer knows the product before it is installed and put to use.

The tests

The Notified Body (NoBo) may decide what examinations and tests are appropriate for the product verification. Some tests may be described in the EU Type Examination Certificate (TEC), but this is certainly not common for measuring systems belonging to annex VII. The examinations and tests then tend to follow the national requirements for re-verification. Only a few TECs for tank truck measuring systems give full details on the examinations and tests to be carried out during verification. Only a very few TECs for dispensers give some description of the examinations and tests to be carried out during conformity assessment module D.

Module F and statistics

Annex II, section Module F, clause 5, lists the requirements for statistical verification of conformity. These make it possible for a manufacturer to save costs relative to a module F executed on each individual measuring system.
The only difference between non-statistical and statistical product verification is the sampling plan. Requirements for the sampling plan are given in clause 5.3. The sampling plan meeting the requirements may easily be designed using appropriate standards like ISO 2859.

The Homogeneity challenge

Products of the same type are required to identical to the description in their TEC and to be identical). Of course modifications need to be carried out in the same way, ensuring that the resulting product is still according to the TEC. This is also to be observed when statistical product verification is to be applied.
For smaller measuring instruments that are easily transported to the manufacturers facilities for modification, this may be rather easy to ensure. However, for measuring systems installed in the field and in operation, this seems to be quite a challenge. The manufacturer may sub-contract all or part of the physical modification and the modification may or may not all be done according to the manufacturers instructions.
Finally, the measuring instrument is under the control of the manufacturer only during the time of modification. The manufacturer will thus have difficulties in ensuring that all markings, seals and documents are as required in the TEC.
Before a Notified Body undertakes to do statistical product verification, it needs to be convinced that the population of products (the sampling lot) is homogeneous. Further, that is stays homogeneous for the duration of the product verification.
The first part is difficult, and the last part may seem almost impossible.
As the measuring systems are

- outside the control of the manufacturer
- in use and
- placed in full access to the public

chances are, that most lots will be rejected.

Acceptance of rejected products

In case a lot is accepted, the Notified Body shall issue a certificate on the examinations and tests carried out. This certificate covers the total lot. The lot now needs to be marked with the notified body identification number. The Notified Body may leave this to the manufacturer, but it is always done under the responsibility of the notified body.
During the process of placing the identification number on all measuring systems, some may be found to be in deficit of seals, other markings, or required documents. What about these? I am quite confident that a Notified Body will not place its identification number on a product which obviously does not meet the requirements.

Conclusion

I am convinced that most Notified Bodies consider module F to be applied on new products still under the full control of the manufacturer. Applying module F on modified products placed in the

field and not under the control of the manufacturer may be possible, but it gives rise to a number of questions which puts a question mark on the effort – is it really worth the while?.

21041011 Carsten Gianelli

The above is based on the text in the 2006 edition of the Measuring Instruments Directive. The Directive was updated in 2014, effective from 2016. The thoughts on applicability of Statistical Product Verification is however still valid.
Newer Danish regulations does not require a re-certifiction of a measuring instrument when modified – if, and only if – the modification is included in a TEC.

20210610 Carsten Gianelli