Metrology in industry. The mean of "*validation*" in different measurements

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Abstract. Metrology is the concurrent of the science of measurement. It is the essential part for any scientific research, industry (including manufacturing), trading, safety (environment protection, medicine, new/smart technologies) and realistically for all areas of human daily life. Nowadays society should not have any possibilities for complete functioning without it. Metrology helps to ensure high accuracy, low uncertainty measurements that are needful for now and the future. Still many industry areas needs deeper understanding of legal and industrial metrology requirements. Also it is missing some common evaluation of final result or process characterization in technical, social or natural sciences (chemistry, pharmaceutics and medicine).
High variety of measurement areas impede the common "language" and understanding. This research highlights these problems and gives some considerations about term "validation" as an example.

1. Introduction

Measurements are met in almost all human activities ranging from any production control, environmental quality evaluation, health and safety assessment, conformity assessment of products to consumer protection and fair trade assurance [1].

Measurements and measuring instruments are integral part of daily routine in every industrial enterprise and they are conscious as necessity of economic, technologic or objective evaluation. The purpose of every manufacturer is to remain competitive in European or world market. This can be achieved only ensuring high quality, modern, innovative and reliable production. Depending on the measuring instrument usage purpose and area it can be attributed to legal or industrial metrology fields. The measurements which results can have juridical consequences must have metrological control that is performed and ensured by accredited laboratories. So growing consumer's requirements for any product safety and satisfying rely on the traceability and reproducibility of measurements. The technical, documental basis of metrological supervision, also the qualification of personnel depends upon many factors such as the company politics, responsibility, activity largeness, quality assurance and financial potential [2].

Also measurements are the part of innovations. This process relies on reliable measurements and experiments. All procedure from beginning to the final product including used materials, methods, equipment, and performance of new technologies has to be validated. Wide range of industrial sectors can cause different descriptions of the same legalization sequence, for example the procedure of new

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generation medicines investigation in pharmaceutics will be named "validation" while the procedure of new measuring instrument or system creation till the step "ready for market" – will be named by some terms, such as "approved", "confirmed", "verified", "legitimated" or sometimes "validated".

Literature analysis [3 – 7] confirmed that term *validation* has well known meaning in the medicine, chemistry, food industry and computer science fields. This process comprises data collection and evaluation, from design stage throughout production, which establishes scientific evidence that whole process is capable of consistently delivering qualitative products.

2. Metrology in a wide range of industrial sectors

There is a wide variety of different measuring instruments today that belong to the industrial or legal metrology. These instruments can be used in various areas, and therefore certain requirements must be fulfilled to guarantee correct measurements. To ensure this, all instrument manufacturers in the European Economic Area (EEA) need to follow the legislation, various standards and regulations based on Directive on Measuring Instruments (MID) or other Directives or documents. Improved infrastructure and appropriate metrological supervision is essential for industry (figure 1).

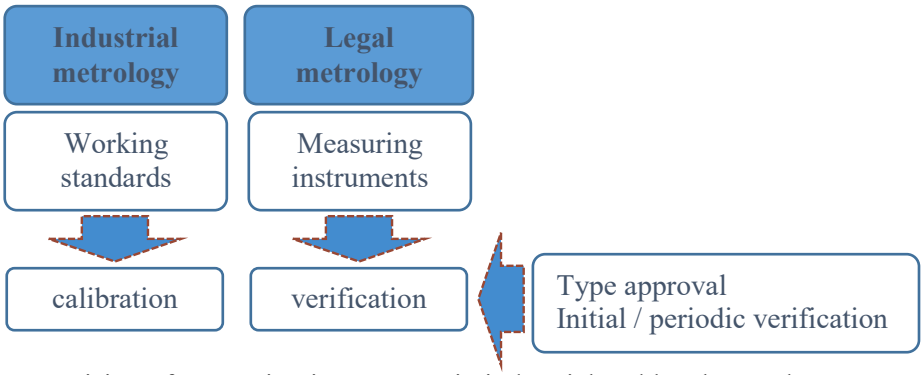

Figure 1. Supervision of measuring instruments in industrial and legal metrology

Type approval of legally controlled measuring instruments is a part of metrological control of measuring instruments. Also the innovations are necessary for competitive activity. This process relies on performance of new technologies, materials and methods, their integration in company activity. Only reliable measurement data ensures the benefits of new products and processes that can be clearly demonstrated to customers. Successful implementation of projects must follow the newest trends of metrological control (figure 2) that ensures competitiveness, reliability, and safety.

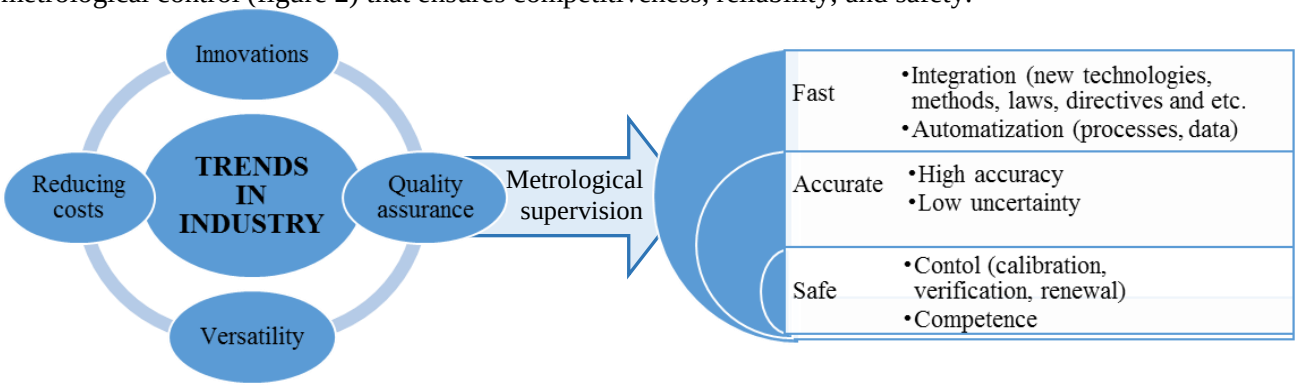

Figure 2. Competitive model of metrological control in industry

Metrology for industry is one of branches of European Metrology Programme for Innovation and Research (EMPIR) calls for the nearest future that shows the relevance of topic. The projects cover topics such as metrology for advanced manufacturing techniques, innovative materials, and next-

generation communications, electronics technologies, new possibilities in human health area (diagnostics, early and effective treatment, new innovative medicines). It looks evident to perform quality assuring procedures such as verification or calibration but sometimes it is not enough of these standard actions for some specific processes or procedures that also must be reliable (for example, creation of new generation medicines). And here appears the term "validation" that is usually met in pharmacy, bio-technologies, medicine or information technologies areas. Term validation is not used in technological areas, despite the fact that it covers whole procedures package that allows to ensure, control or check all steps from idea to final solution.

Sometimes the problems or misunderstanding can appear due to the same term usage in different sectors. The meaning is the same but the term is different – also differs the sequence of various actions that should ensure that all procedures of any process comply with the requirements, are reliable and correct. Significant and different approach of methods legalization is between technical and chemical (biological, medicine) sciences. The experts of these sciences branches use different terms describing measurements, their reliability or trueness. It seems interesting analysis of terms "validation – confirmation – approval – legitimation".

3. Validation/verification. How to ensure measurement quality?

Usually industrial enterprise (of any activity area) provides wide variety of measurements where measuring instruments are used. With the purpose to ensure the quality of final product it is needful to have a competence to evaluate whole process, control it, have basic knowledge about the supervision procedures and also have a sufficient competence to attribute instruments (including those that are used for environmental conditions control) to legal or industrial metrology (figure 3).

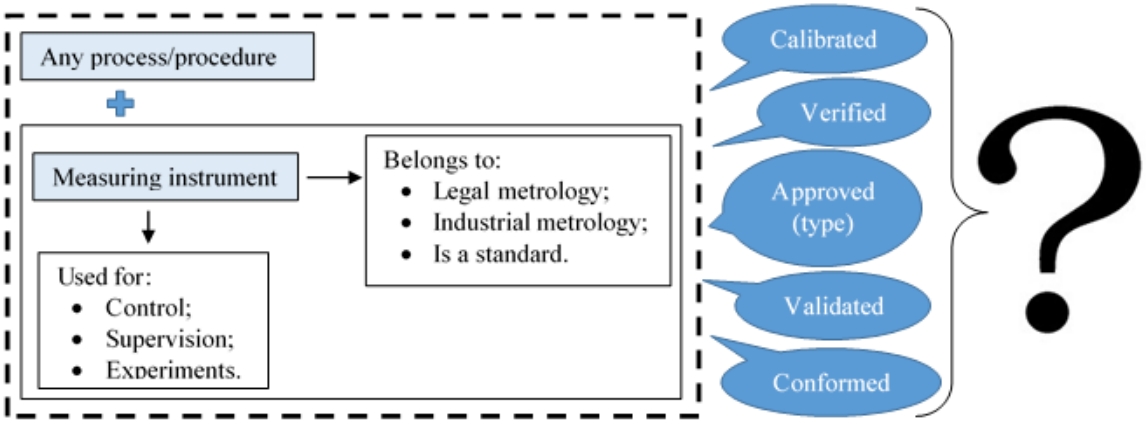

Figure 3. Measurement result quality assurance chain

Figure 3 illustrates some quality assurance actions which meaning is similar but sometimes these procedures can be confused. Calibration and verification procedures are very similar in their operation, the difference is in their application area: legal or industrial metrology. Under the law, every item that is used in regulated area has to be verified and stamped before being released for use or even sale to the user. In a type approval scheme, one or more instruments of the same pattern are subjected to rigorous tests prescribed under the law. The objective is to ensure that the instrument meets a minimum set of regulatory, technical and safety requirements and is suitable for use in the regulated area in such a way that it is expected to provide reliable measurement results over a defined period of time. If we provide any process or method where all steps must be performed strictly under the rules and every process/method step must have checking possibility, then our process/method has to be validated. Validation gives an idea of a process/method's capabilities and limitations which may be experienced in routine use while it is in control. Specific controls need to be applied to the process/method to verify that it remains in control, i.e. is performing in the way expected.

Concentrating on validation and verification terms, even International Vocabularies of Metrology (VIM) [8, 9] give obscure explanations of some terms, where misunderstanding can arise. For example: "verification – provision of objective evidence that a given item fulfils specified requirements", while "validation – verification, where the specified requirements are adequate for an intended use". And also the explanation that is given in notes "not every verification is a validation" raises doubts if every validation is a verification? Research of various processes and procedures allows such consideration: usually "validation" is concerned with checking if any system meets the exact customer's needs, while "verification" is concerned with confirmation that system meets the specifications/requirements. Sometimes used term "validation" is totally subjective process, which includes activity such as modelling (is met in IT area talking about software) or "validation" can be attributed to lawful process where verification is its integral part (pharmacy, good production practice).

Literature analysis and real examples from various fields companies confirmed that terms validation and verification sometimes are treated slightly different. Anyway these procedures are integral actions of any process or measurement quality assurance. Practical research (annual metrology personnel trainings in Lithuania; analysis of 2008 – 2018 years events) showed that medics, biologists, pharmacists, IT specialists more often use term validation or validated instead of term verification or verified while engineers, technologists, inspectors prefer term verification.

4. Conclusions

Intensive growth of innovative products in a wide range of industrial sectors needs reliable metrological methods and techniques and quality assurance improvement. Measurement science dictates a multi-disciplinary approach around themes – Energy, Environment, Health and Industry – where the spread of common attitude and knowledge is desired.

Improved novel techniques, prototypes, methods or standards have to be validated evaluating the fact that such metrological procedures as calibration, verification, type approval are the integral part of any branch.

While traditional metrology sectors centre on greater accuracy, lower uncertainty, faster methods, wider ranges, there is also a great demand for such challenges in food safety, medicine, environmental, biotechnology areas that still need more developed measurement/metrology infrastructure.

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