RIGA TECHNICAL UNIVERSITY
Faculty of Engineering Economics and Management
Institute for Quality Engineering
Department of Quality Technology

Raimonda LIEPIŅA
(doctoral student's ID No 033RMG035)

CONFORMITY ASSESSMENT SYSTEMS MANAGEMENT PROBLEMS AND SOLUTIONS

Summary of Promotion Thesis

Industry: Management
Subsector: Business management

Scientific Supervisor
Professor, Dr.sc.ing.
J.MAZAIS

Scientific Consultant
Assoc. prof., Dr.oec.
I.LAPIŅA

RTU Publishing House

Riga 2013

UDK 005.6(043.2)
Li 266 a

Liepiņa R. Conformity Assessment Systems Management Problems and Solutions. Summary of Promotion Thesis. – Riga: RTU Publishing House, 2013. - 47 pp.

Printed upon the Resolution of Riga Technical University Faculty of Engineering Economics and Management Institute of Quality Engineering Department of Quality Technology Minutes No.1-01 of January 24, 2013.

The work is developed with the support of the European Social Fund for the project "Support for the Riga Technical University for doctoral studies".

PROMOTION THESIS

PRESENTED TO QUALIFY FOR THE DEGREE OF DOCTOR OF ECONOMICS AT RIGA TECHNICAL UNIVERSITY

The Promotion Thesis has been elaborated at the Institute for Quality Engineering of the Faculty of Engineering Economics and Management of Riga Technical University. The Promotion Thesis to qualify for the degree of Doctor of Economics of the Republic of Latvia is presented for public defence on 14 June 2013, 10.00 a.m. at Riga Technical University, Faculty of Engineering Economics and Management, 6 Kalnciema St., Room 309.

REVIEWERS

Konstantīns Didenko, Professor, Dr.oec.
Riga Technical University (Latvia)

Dzintra Atstāja, Assoc. prof., Dr.oec
BA School of Business and Finance (Latvia)

Bronius Neverauskas, Professor, Dr.oec.
Kaunas technical University (Lithuania)

ACKNOWLEDGEMENT

I confirm that this Promotion Thesis is presented for public defence at Riga Technical University for being conferred the degree of Doctor of Economics. This Promotion Thesis has not been presented to any other university for obtaining the scientific degree.

Raimonda Liepiņa …….

April 4, 2013.

The Promotion Thesis is written in Latvian. It contains introduction, 3 chapters, Conclusions and Recommendations, Sources of Reference, as well as 12 Appendices. Total scope of the Promotion Thesis is 176 pages, not including the Appendices. The Thesis contains 36 figures and 5 tables. The Sources of Reference contain 204 sources.

The Promotion Thesis and its Summary are available at the Scientific Library of Riga Technical University.

References with regard to the Promotion Thesis should be sent to:
Secretary of the Riga Technical University Promotion Council P-09,
Professor, Dr.habil.oec. Anatolijs Magidenko,
Riga Technical University, 6 Kalnciema St., Riga, LV-1007, Latvia.
E-mail: rue@rtu.lv, fax: + 371 67089490, phone: + 371 67089324.

GENERAL DESCRIPTION OF PROMOTION THESIS

Substantiation of topicality of research

In order to organize and ensure the operation of the European Union internal market and promote the development of the European Union Member States, during several decades, significant measures were taken: elimination of technical barriers to trade, ensuring technical harmonization and mutual recognition. While establishing the European Union internal market, the body of Community Law (the '*acquis communautaire*') was created covering all the common rights and obligations binding to the Member States.

Each country has its own history, culture, regulatory framework, different levels of economic development, etc. Application of uniform legal and operational framework for them contributes to their development (such as international trade, investments, etc.), though, to some extent, sets restrictions to the national culture and its distinctive features being used as a competitive advantage.

The changes related to many factors: globalization, development of information technologies, intensity of competition, growth of product range, promotion of innovation, etc. have affected general market and economic trends and have created the need to develop different types of requirements. Therefore, nowadays technical harmonization is mainly used for ensuring the functioning of the European Union internal market. Its aim is to develop a uniform approach for solving specific issues across the European Union, thus ensuring that external technical barriers resulting from different national requirements have been eliminated. The influence of technical harmonization on the European Union internal market is important because a lot of requirements for the European Union products in circulation are uniform.

Over time, the number of the European Union Member States has increased, and currently it includes 27 countries, among them is Latvia (since May 1, 2004). With the increase in the number of the European Union Member States the issue of regulated, uniform requirements is becoming increasingly important. In addition, it is also influenced by the fact that technical harmonization is applied to specific products (toys, lifts, construction products, non-automatic weighings, etc.) and specific requirements related to these products (electromagnetic compliance, noise emissions, etc.), as well as requirements for specific activities and organization of elements (conformity assessment procedures, accreditation, market surveillance, etc.).

Uniform requirements are determined using a variety of technical harmonization approaches. Over time, introduction of new technical harmonization approaches does not sufficiently clearly show the set of different approaches and their consistency, the traceability of the changes is not obvious. This creates confusion for both the European Union and national government institutions in the development of requirements, as well as for entrepreneurs in their execution, which can lead to a situation when uniform operation of the European Union internal market cannot be achieved. Therefore, it is necessary to review the existing technical harmonization approaches.

In order to guarantee the functioning of the European Union internal market and mutual recognition as well as to promote international trade, the reliability of the activities carried out needs to be ensured. For this purpose conformity assessment system has been formed. Conformity assessment system is applied very extensively; its object may be products and processes, as well as people, systems, etc. Thus, nowadays conformity assessment has become a prerequisite and guarantee for using safe products, receiving appropriate services, successful operation of the processes, competences of qualified persons etc.

Conformity assessment can be ensured by knowing its processes and activities, by understanding its elements and other aspects involved, by recognizing them as a whole (a uniform system). In the European Union, there are uniform requirements for products and for conformity assessment during product design and manufacturing stages. At the same time, a uniform conformity assessment system that would include all the processes, activities, elements etc. has not been created. Today, the conformity assessment system has become a complex and fragmented system, which is difficult to manage and is not fully comprehended. As a result, parties involved in conformity assessment are confused by the amount of requirements, they have difficulties ensuring a uniform interpretation of requirements and compliance with them, taking part in laying down the requirements and improvement of the conformity assessment system. Various elements, which contribute to decision making on compliance and ensure the reliability of the decisions, are not integrated into a single system and are not uniformly managed. This creates difficulties in performing conformity assessment. At the same time, the fact that parties involved in conformity assessment and the society have different understanding of the conformity assessment system, the requirements for the products, conformity assessment activities and the terms used in this field indicates problems in the system management. This confirms the need to structure the conformity assessment system and improve its management, meanwhile improving the conformity assessment terminology base.

Conformity assessment has an important role in the safety assurance of products, services, etc., but entrepreneurs and the society very rarely think about conformity assessment during everyday activities. The Promotion Thesis is focused on the product conformity assessment, as the limited scope of the study does not allow inspecting different kinds of conformity assessment. In addition, products are things that are purchased and used every day, so there is a greater risk that they may pose a hazard to human health, life or environment.

Often in different areas conformity assessment is carried out differently, causing confusion about the conformity assessment system as a whole and the requirements used within it. It creates confusion for entrepreneurs about actions to be taken and hence a risk that the businesses will not fully meet the requirements for products, which may pose a hazard to product safety.

The requirements for conformity assessment in product design and manufacturing stages are regulated in the European Union, ensuring that compliant and safe products are placed and delivered to use on the European Union internal market. In order to protect the interests of consumers, conformity assessment of products can be also carried out during their usage where the requirements are determined at the national level. So the question arises – why uniform requirements for product conformity assessment are defined for design and manufacturing stages, but later, when the products are put into service, the requirements for the same products are different?

The goal of the Promotion Thesis is to identify management problems and offer new solutions thus improving the conformity assessment system, in order to raise awareness about conformity assessment, to make conformity assessment processes clearer for entrepreneurs and to ensure placement of safe products on the market.

The objectives set for reacing the goal of the Promotion Thesis are the following:

1. To identify and analyse theoretical issues about quality and conformity assessment, highlighting the most important aspects of their interactions, identifying the correlations between quality management and conformity assessment.

2. To evaluate the terminology and definitions used in conformity assessment field, clarifying the terms, offering new and more precise definitions and developing a system of concepts.

3. To collect and analyse information about conformity assessment in the European Union, to analyse the Latvian National Conformity Assessment System and identify problems.

4. To conduct research on conformity assessment system, identifying the views about functioning of conformity assessment system expressed by Latvian accredited conformity assessment bodies and the European Union notified bodies in order to define problems in conformity assessment system.

5. To assess technical harmonization approaches, their trends and patterns and to offer a new *Technical Harmonization Approach*.

6. To evaluate the conformity assessment system, to determine its management problems and create an interaction scheme of the parties involved in product conformity assessment, to offer solutions for the improvement of the Latvian National Conformity Assessment System.

7. To draw conclusions about the possible solutions of problems identified during the study, as well as to develop proposals for the improvement of product conformity assessment system.

The object of the research of the dissertation is the conformity assessment system.

The subject of the research is the improvement of conformity assessment system management, as well as improvement of the elements, procedures and other factors forming and influencing conformity assessment as well as enhancement of technical harmonization.

The following **hypothesis** has been put forward in the Promotion Thesis: adequate and safe products are placed on the market, understandable system for entrepreneurs and the society is established by structuring, developing and managing the conformity assessment system, by creating a common terminology base, by improving technical harmonization approaches, by forming stronger relationship with the involved parties and by promoting their responsibility.

Statements proposed for defence

1. Clarification of conformity assessment terminology and definitions, as creating and using a common terminology base promotes the organization of conformity assessment system and understanding of the parties involved.

2. Uniform, systematic and clear technical harmonization approach for product conformity assessment is one of the requirements for conformity assessment and mutual recognition.

3. A structured approach to the process of conformity assessment and the choice of the conformity assessment module enables manufacturers and conformity assessment bodies to improve their activities during product manufacturing and conformity assessment.

4. Well-organized and structurally managed conformity assessment system, which applies to the product design, manufacturing and usage stages, ensures placing compliant and safe products on the market, putting them into service and usage.

Research methods. General analysis and synthesis, induction and deduction methods, qualitative and quantitative research methods, including data collection and analysis, grouping, logical constructive, conceptual (concept) analysis, quantitative content analysis, comparative analysis, surveys, expert evaluation and other methods have been used.

The study and analysis of the conformity assessment system has been performed at three levels: a) the evaluation of the technical harmonization and the elements of the conformity assessment system in the European Union, b) the assessment of functioning of the Latvian National Conformity Assessment System, c) theoretically and practically performing conformity assessment of particular products – measuring instruments.

Theoretical and methodological basis of the research

Many foreign researchers have studied issues related to quality and quality management. The Latvian scientists have also studied issues related to quality, quality management, quality assurance, etc.: D.Solovjovs has developed a thesis about quality assurance and the management system model in transition period countries, E.Staveckis has developed a thesis about the development problems in the quality system assurance in Latvia, J.Priede has developed a thesis about Latvia's economical branches exports quality competitiveness analyses, I.Mežinska has developed a thesis about improvement methodologies of integrated management systems for production industry enterprises in Latvia and R.Greitāne has developed a thesis about economical assessment of service quality in small and medium-sized enterprises.

Relatively few Latvian and foreign authors have carried out theoretical and practical research in the field of conformity assessment. The conformity assessment field is closely connected with engineering sciences and profound research in this area has been carried out for certain products or types of measurement. For example, the Latvian scientist T.Ivanova's thesis is about research of reference weight inter laboratory comparisons.

Given that conformity assessment is necessary in order to ensure that only compliant products have free movement in the European Union regulated area, conformity assessment is

an important tool in the organization of the European Union internal market. Consequently, the thesis has some parallels with Latvian scientist O.Bogdanova's thesis on Latvia's development models in the internal market of the European Union.

The author has used the following publications of foreign authors as a theoretical basis: B.Bergman, H.I.Costin, P.Crosby, W.E.Deming, J.R.Evans, A.V.Freigenbaum, K.Ishikawa, J.M.Juran, B.Klefsjö, J.S.Oakland, V.V.Okrepilov (В.В.Окрепилов), J.Ruževičius etc. The theoretical and practical knowledge of the following Latvian authors has been used: O.Bogdanova, I.Forands, T.Ivanova, J.Mazais, I.Mežinska, J.Miķelsons, J.Priede, J.Rudzītis, D.Solovjovs etc.

The research assessed the legislative requirements of Latvian and the European Union, the documents and standards of international organizations, dictionaries, published scientific papers and studies in Latvia and abroad, materials of Latvian and foreign scholars and practitioners presented in articles, conferences and seminars, as well as the author's experience and information obtained in training courses, contacts with industry experts and long-time practical experience in the Ministry of Economics of the Republic of Latvia coordinating the Latvian National Conformity Assessment System.

The informational base for the research is formed by the data from the Latvian national accreditation, metrology and standardization bodies, international organizations active in the conformity assessment field, the data published in the European Commission database *Nando-IS*.

Limitations of the research

Conformity assessment comprises a wide range of issues and problems for study, where each of these, as well as the conformity assessment scheme of each separate product would be worth a separate scientific study. The theme of the study is many-sided and it is not possible to embrace all the issues in depth and qualitatively enough in one research, therefore limitations are set as follows:

1. Conformity assessment objects may be either products or services, or persons etc. The limited scope of the Promotion Thesis does not permit to deal with conformity assessment of different objects, therefore it is chosen to study in depth product conformity assessment, as we purchase and use them daily and thus there is a greater risk that products may pose hazards to human health, life and environment.

2. Conformity assessment is applied in the entire world defining specific requirements for it at the national level. To ensure the functioning of the European Union internal market, a

uniform conformity assessment system is created. Member States organize systems at the national level taking into consideration these requirements, wherewith they are basically similar. Taking into account that the territory of the study is the European Union, the problems related to the conformity assessment system management are considered from the aspects of methods and organization only within the framework of the European Union, and the proposals made are equally applicable in all the European Union Member States.

3. Due to the limited scope of the Promotion Thesis it is not possible to include all the issues related to conformity assessment system management. Therefore it is chosen to aim the study specifically at system management not dealing with it in the context of financing or from the economic point of view. These issues will also differ depending on the point of view of the party involved in conformity assessment, from which they are considered, simultaneously taking into consideration that the conformity assessment system is financed from different sources.

4. Taking into account the specifics of market surveillance, it is closely related to the legislation, which is not considered in depth in the present thesis. Therefore only the place and role of market surveillance in conformity assessment system are included in the study without analysing it in depth.

5. Mutual recognition is applied to both the non-regulated and the regulated area. Taking into account that the territory of the study is the European Union, in the present research the issues are dealt with as far as they relate to the regulated area.

Scientific novelty of the Promotion Thesis

1. Proposals are elaborated for improvement of conformity assessment system thus facilitating the product conformity assessment process for the entrepreneurs, more actively involving different parties in conformity assessment system, encouraging them to take responsibility, and making the process more transparent for the society.

2. Technical harmonization approaches are evaluated and their comparison is made. The necessity to use a new uniform methodology – the *Technical Harmonization Approach* that would substitute the current four different technical harmonization approaches is substantiated. The elaborated *Technical Harmonization Approach* is systematic, applicable in practice and its elements are divided into separate groups.

3. Methodology is elaborated for manufacturers for selection of the most suitable conformity assessment module in the product design and manufacturing stages. These

methods will form the manufacturers' understanding about the product conformity assessment and will facilitate performing product conformity assessment.

4. The terms of the issue under study such as: 'measuring instrument', 'notification', 'notified body' and 'harmonized standard' are defined more precisely by improving the terminology base in correspondence with the specifics of conformity assessment field. New definitions are given for the concepts of 'conformity assessment procedure', 'conformity assessment processes', 'notified body', 'harmonized standard', and the current definitions of some concepts such as 'conformity', 'conformity assessment', 'assessment', 'standardization' and 'standard' are improved.

5. Problems of conformity assessment system management and their causes are identified, and possible consequences are identified based on exhaustive study of analysis of conformity assessment system in the European Union and Latvia, according to which it has been possible to elaborate improvements for the system management.

6. Interrelationship between quality management and product conformity assessment process is established revealing their mutual relation and significance in product conformity assessment process on the basis of evaluation of the theoretical aspect of quality and quality management, thus contributing to the society's understanding of connection between quality and conformity assessment.

Approbation and practical application of the research results

The study results have been used in the legislative acts drafted by the European Commission and European Council work groups as well as by the Ministry of Economics of the Republic of Latvia (amendments to the „Law on conformity assessment", "Standardization law", the „Law Uniformity of Measurements" etc.; in elaborating the *New Legislation Framework* (European Parliament and of the Council Regulation No 765/2008 as of 9 July 2008, European Parliament and of the Council Regulation No 764/2008 as of 9 July 2008 and European Parliament and of the Council Decision No 768/2008/EC as of 9 July 2008) as well as European Parliament and of the Council Regulation No 1025/2012 as of 25 October 2012 and European Parliament and of the Council Directive as of 31 March 2004 No.2004/22/EC etc., and also legally binding documents, which are related to conformity assessment, among them elaboration of the national position of Latvia and instructions, section "Quality Assurance" of the Report on the Economic Development of Latvia, informative reports and participating in drafting other documents, as well as for surveillance

of activities of national accreditation, standardization and metrology bodies, and advising specialists in the area.

In order to practically evaluate the problems found and the solutions proposed, the author has made a research of conformity assessment in the design and manufacturing phases and during actual use of measuring instruments. Taking into consideration that there are uniform conformity assessment requirements in the European Union and making use of the method of induction the elaborated proposals can be referred to all the products in the regulated area.

The study results have been used in the following projects:

1. Leonardo da Vinci Innovation Transfer Project "Employability and Skills Anticipation Policies: a Social ROI Approach", 2012-2013. The author participates in the project as a researcher;

2. Leonardo da Vinci Mobility Project "Best Practice from Cyprus Educational System", 2012. The author elaborated the project and coordinated its implementation;

3. Comenius Multilateral Partnership Project "Health in Fun", 2011-2013. The author elaborated the project and is coordinating its implementation;

4. Leonardo da Vinci Vocational Education and Training professionals Project "Experience Exchange of Training Centres in Turkey", 2010. The author acted as an executor;

5. Ukrainian Ministry of Economic Affairs Project "Standardization System Reform: Ukrainian Perspectives and Latvian Experience when Preparing to Join the European Union", 2006. The author acted as an expert and executor.

Part of the Promotion Thesis materials have been used by the author when delivering the Bachelor level study courses "Total Quality Management" and "Market Surveillance of Conformity Assessment" of the Department of Quality Technology of the Institute for Quality Engineering, Faculty of Engineering Economics and Management of the Riga Technical University.

Scientific publications. The results of the study were presented in 12 publications, including 10 articles in cited scientific publications:

1. Liepiņa R., Lapiņa I., Mazais J. Assessment of Technical Harmonization and Conformity in the Global Market // Journal "Intellectual Economics". – 2012. – Vol 6 No 4(16). – 520-533 p. ISSN 18228011. e-ISSN 18228038.

2. Mazais J., Lapiņa I., Liepiņa R. Process Management for Quality Assurance: Case of Universities // The 8th European Conference on Management, Leadership and Governance proceedings. – Paphos, Cyprus: Neapolis University, 2012. – 522-530 p. ISBN 9781908272751 (book), ISBN 9781908272768 (CD).

3. Liepiņa R., Mazais J., Lapiņa I. Conformity Assessment: Methods for Billing water // Riga Technical University 53rd International Scientific Conference. Dedicated to the 150th Anniversary and the 1st Congress of World Engineers and Riga Polytechnical Institute / RTU

Alumni. Digest. – Riga, Latvia: Riga Technical University, 2012. – 1-7 p. ISBN 9789934103551.

4. Liepiņa R., Mazais J., Lapiņa I. Risk Management in Public Utility Service: Assessment of Water Consumption Accounting Risks // The 16th World Multi-Conference on Systemics, Cybernetics and Informatics Proceedings, Volume II. – Orlando, Florida, USA: International Institute of Informatics and Systemics, 2012. – 44-49 p. ISBN 9871936338689.

5. Liepiņa R., Mazais J., Lapiņa I. Analysis of Technical Harmonization Approaches: Comparison and Improvement // IX International Scientific and Practical Conference "Contemporary Problems of Regional Economy Management". - Saint Petersburg, Russia: Saint Petersburg State University of Engineering and Economics, 2012. – 82-86 p. ISSN 2304926X.

6. Liepiņa R., Lapiņa I., Mazais J. Social Responsibility and its Economical Impact on Society: Water Usage Reporting and Water Losses // The 7th International Scientific Conference "Business and Management '2012" Selected papers, Volume II. – Vilnius, Lithuania: Vilnius Gediminas Technical University, 2012. – 675-682 p. ISSN 20294441 (print), ISSN 2029929X (online). ISBN 9786094571169.

7. Liepiņa R., Lapiņa I., Mazais J. Role of Conformity Assessment in Global Market // International Scientific Conference "Practice and Research in Private and Public Sector - 2012": Conference Proceedings. – Vilnius, Lithuania: Mykolas Romeris University, 2012. – 453-461 p. ISSN 20297378.

8. Liepiņa R., Lapiņa I., Mazais J. Miķelsons J. Corporate Social Responsibility: Management of Reliable Water Consumption // Journal "Economics and Management". – 2012. – Vol. 17 No. 3. – 1149–1155 p. ISSN 18226515. e-ISSN20299338.

9. Liepiņa R., Mazais J., Lapiņa I. Innovative Approach in Conformity Assessment: Aspects of Public Utilities Services // Proceedings of 2011 International Conference on Business Intelligence and Financial Engineering. - Hong Kong, China: 2011 International Conference on Business Intelligence and Financial Engineering (ICBIFE 2011), 2011. – 55-62 p.

10. Liepiņa R. Public Utilities Modelling through 3D Program in Apartment Houses // Proceedings of Annual International Conference "Virtual and Augmented Reality in Education" (VARE 2011). - Valmiera, Latvia: Vidzeme University of Applied Sciences, 2011. – 54-59 p. ISBN 9789984633183.

Thesis:

1. Liepiņa R., Mazais J., Lapiņa I. Conformity Assessment: Billing Methods for Water Consumption // Riga Technical University 53rd International Scientific Conference. Dedicated to the 150th Anniversary and the 1st Congress of World Engineers and Riga Polytechnical Institute / RTU Alumni. Digest. – Riga, Latvia: Riga Technical University, 2012. – 571 p., ISBN 9789934103605. e-ISBN 9879934103551.

2. Liepiņa R. Trends of Measuring Instruments Conformity Assessment // Ventspils University College Students Scientific Conference "Current Issues in the National Economy, Translation and Technolgies" Paper Abstracts. – Ventspils, Latvia: Ventspils University College, 2011. – 12 p.

The results of the study were reported in 14 **international and local conferences** (Estonia, Latvia, Lithuania, Cyprus, the Russian Federation, China and Romania):

1. The Fourth International Conference "Future of Europe. Rethinking strategies in emerging economies", Bucharest, Romania, 9-10 November 2012. The topic of presentation – *Conformity Assessment in the European Union: Suggestions for improvement*.

2. The 8th European Conference on Management, Leadership and Governance, Paphos, Cyprus, 8-9 November 2012. The topic of presentation – *Process Management for Quality Assurance: Case of Universities*.

3. Riga Technical University 53rd International Scientific Conference. Dedicated to the 150th Anniversary and the 1st Congress of World Engineers and Riga Polytechnical Institute / RTU Alumni, Riga, Latvia, 10-12 October 2012. The topic of presentation – *Conformity Assessment: Billing Methods for Water Consumption*.

4. IX All-Russian Scientific-Practical Conference with International Participation "Contemporary Problems of Regional Economy Management", St. Petersburg, Russian Federation, 24-25 May 2012. The topic of presentation – *Analysis of Technical Harmonization Approaches: Comparison and Improvement*.

5. 7th International Scientific "Conference Business and Management – 2012", Vilnius, Lithuania, 10-11 May 2012. The topic of presentation – *Social Responsibility and its Economical Impact on Society: Water Usage Reporting and Water Losses*.

6. International Scientific Conference "Practice and Research in Private and Public Sector – 2012", Vilnius, Lithuania, 26-27 April 2012. The topic of presentation – *Role of Conformity Assessment in Global Market*.

7. 17th International Scientific Conference "Economics and Management - 2012", Tallinn, Estonia 28-30 March 2012. The topic of presentation – *Corporate Social Responsibility: Management of Reliable Water Consumption*.

8. International Conference on Business Intelligence and Financial Engineering, Hong Kong, China, 12-13 December 2011. The topic of presentation – *Innovative Approach in Conformity Assessment: Aspects of Public Utilities Services*.

9. Riga Technical University 52nd Conference "Scientific Conference on Economics and Entrepreneurship", Riga, Latvia, 7 October 2011. The topic of presentation – *Assessment of Water Consumption Accounting Accuracy Risks* and – *Modification of Formula for Improvement of Water Consumption Calculations Accuracy.*

10. The 14th International Scientific Conference "Society and Culture: Borders and New Horizons", organized by the Faculty of Natural and Social Sciences, Liepaja University. Liepaja, Latvia, 19-20 May 2011. The topic of presentation – *New Challenges for Society in Field of Measuring Instruments*.

11. Ventspils University College Students Scientific Conference "Current Issues in the National Economy, Translation and Technolgies", Ventspils, Latvia, 12 May 2012. The topic of presentation – *Trends of Measuring Instruments Conformity Assessment*.

12. International Research Conference "Changes in Global Economic Landscape - in Search for New Business Philosophy", Riga, Latvia, 29 April 2011. The topic of presentation – *Services of Latvian Conformity Assessment Institutions as Export Products*.

13. Annual International Conference "Virtual and Augmented Reality in Education", Valmiera, Latvia, 18 March 2011. The topic of presentation – *Public Utilities Modelling through 3D Program in Apartment Houses*.

14. Riga Technical University 50th International Scientific Conference, Riga, Latvia, 15 October 2010. The topic of presentation – *Conformity Assessment of Measuring Instruments within the Framework of Directive No 2004/22/EC.*

Structure and scope of the Promotion Thesis

The Promotion Thesis comprises 176 pages not including the appendices, which contain 36 figures, 5 tables. The thesis has 12 appendices. In the elaboration of the thesis 204 information sources were used, which are listed in Sources of Reference.

In the first part "Theoretical Aspects of Quality and Conformity Assessment" the theoretical aspects of quality and conformity assessment are studied. In order to improve the terminology used in the conformity assessment field, different definitions of related terms are generalized and analysed, basing on which proposals are made for translations of the terms, new definitions are given and the current definitions are made more precise. The totality of aspects characterizing product quality is evaluated, information gathered on interrelationships of quality management and product conformity assessment process.

In the second part "Development Trends, Regularities and Problems of Conformity Assessment" evaluation of technical harmonization approaches and their comparison is made, conformity assessment system in Latvia and the European Union is evaluated, conformity assessment of measuring instruments is evaluated from the theoretical and practical point of view, the main problems of conformity assessment system management and problems related to product conformity assessment are identified.

In the third part "Improvement of Conformity Assessment System Management and Technical Harmonization" solutions for elimination of the identified problems and improvement of conformity assessment system management are elaborated. The necessity to make use of uniform methodology is substantiated, and the *Technical Harmonization Approach* that would substitute the current approaches of technical harmonization is developed. Conformity assessment system scheme is improved and a method developed to be used by manufacturers when selecting the most suitable of conformity assessment modules. Proposals are made that would foster the responsibility of the involved parties and the society thus excluding use of non-conforming products.

In the conclusion the general conclusions drawn by the author are summarized and proposals are brought forward for using the results of the study.

The present thesis is elaborated in the Institute of Quality Engineering the Faculty of Engineering Economics and Management, Riga Technical University in accordance with the requirements of "Law on Scientific Activity" under the provisions of Cabinet of Minister Regulations No 1001 of 27 December 2005 "On the Procedures and Criteria for Conferral of a Doctoral Degree in Science (Promotion)", "Doctoral Degree (Thesis) Procedures and Criteria", the requirements of Latvian Council of Science and the Rules of Riga Technical University as of 29 June 2009.

The thesis has been developed with the support of the European Social Fund within the project "Support for Riga Technical University for doctoral studies".

RELEVANT SCIENTIFIC CONTRIBUTION OF THE RESEARCH

1. THEORETICAL ASPECTS OF QUALITY AND CONFORMITY ASSESSMENT

Nowadays solutions and technologies used in manufacturing are different, thus conformity assessment for design and manufacturing stages and during usage becomes more significant. Conformity assessment is carried out to ensure product compliance and safety to human health, life and the environment. Knowledge and understanding of conformity assessment and its related issues among entrepreneurs and the society is not sufficient, especially about the interrelation of quality and conformity assessment. In the first part of the Promotion Thesis the evaluation of the concepts of 'quality', 'conformity assessment' and others is made, as well as quality management and conformity assessment interrelationships are shown.

1.1. The concept of quality and its classification

The concept 'quality' in different languages describes the actual nature of the object, and most often is applied to various products. Understanding the concept of 'quality' is not ambiguous; almost every individual perceives it subjectively and describes it differently. After examining various authors and the literature where the definition of the concept of 'quality' is included (W.E.Deming, J.M.Juran, A.V.Freigenbaum, K.Ishikawa, P.Crosby etc.), it seemed that the most appropriate for the aim of the Promotion Thesis are definitions given by J.M.Juran (the original definition), F.Crosby, B.G.Dale, A. Van den Wiele, and J. van Iwaarden, which include the reference to specific requirements, their execution and evaluation, corresponding to conformity assessment activities. As a result, it is considered that conformity assessment is associated with quality and it can be used to assess the quality if explicit requirements for product quality exist.

After analysing the definition and evaluation of the opinions about the concept of 'quality', it was concluded that most frequently the quality of a particular object is assessed. Requirements are one of the key aspects characterizing the quality, without them it is not possible to perform quality assessment. Comparing the requirements with the object, its compliance is assessed. To ensure manufacturing of adequate products and reliability of the conformity assessment procedures, competent persons must be involved in the assessment process. As a result, it was concluded that the quality can be assessed objectively by taking into consideration the following aspects: object, requirements, compliance and competence.

1.2. Conformity assessment components, procedures and related concepts

To ensure that the various parties involved in the conformity assessment system (manufacturers, conformity assessment bodies, etc.) use the same terminology and the society has understanding of conformity assessment and is able to identify non-conforming products, the conformity assessment terminology database has been improved.

1.2.1. The evaluation of the conformity assessment concepts. After analysing the opinions about the concepts of 'conformity' and 'assessment' expressed in literature (dictionaries, etc.) and by different authors (J.R.Evans, W.M.Lindsay, N.Sprancmanis, etc.), it was concluded that 'conformity assessment' compares the object with the requirements and finds its compliance or non-compliance to them. To adjust these definitions to the specific area of conformity assessment, improved definitions are offered: "Conformity is the fact that the object (product, process, etc.) fulfils the requirements" and "Assessment is the process of determining the object (product, process, etc.) compliance with the requirements".

When the concept of 'conformity assessment' was evaluated, a scheme of interrelations of the related terminology was established (see Figure 1.1). And it was concluded that conformity assessment is the process of comparing the product with the requirements and on the basis of the assessment taking decision of its compliance or non-compliance.

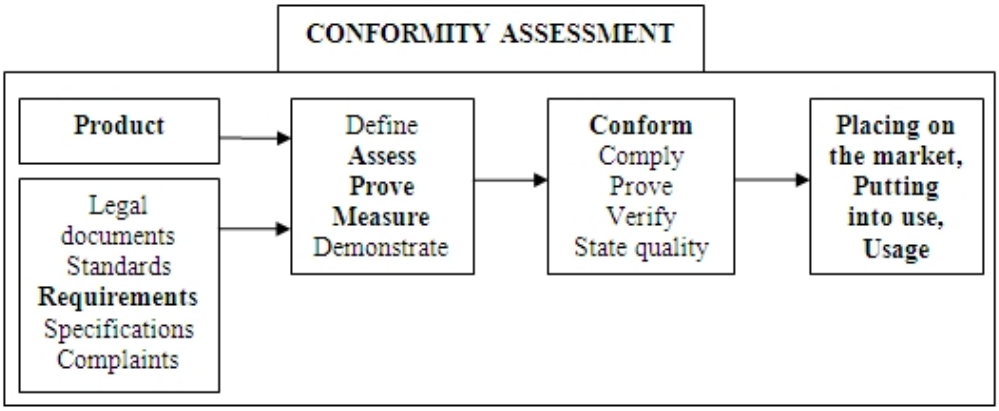

Figure 1.1. The scheme of interrelations of the terminology related to the concept of 'conformity assessment' [the author]

The concept of 'conformity assessment' is defined by the European Union and national legislation, standards, the documents of international and national organizations; also various authors (G.Strawbridge, E.Gorbashko etc.) have expressed their opinion about it. During the evaluation of the definitions and opinions of the authors, it was seen that they are very general and partly compliant and do not specify the means of conformity assessment. Consequently, the author proposes to improve the definition of the concept of 'conformity assessment' as follows: "Conformity assessment is the process by which the conformity assessment

procedures are carried out to evaluate the object (product, process, etc.) compliance with the requirements".

1.2.2. Conformity assessment procedures. In order to assess whether the product meets the requirements, conformity assessment is performed according to a specific conformity assessment process. Conformity assessment procedure is one of the important stages in conformity assessment. The concepts of 'conformity assessment process' and 'conformity assessment procedure' are widely used in conformity assessment field, but there are no precise definitions for them. The author proposes new definitions for these terms: "Conformity assessment process is a set of actions within the framework of which the object (product, process, etc.) conformity assessment is performed" and "Conformity assessment procedure is a way (action or module) in which the object (product, process, etc.) conformity assessment is performed and decision is made about issuing a certificate of conformity and/or marking". The differences of conformity assessment procedures depending on the applied approaches are shown in Figure1.2.

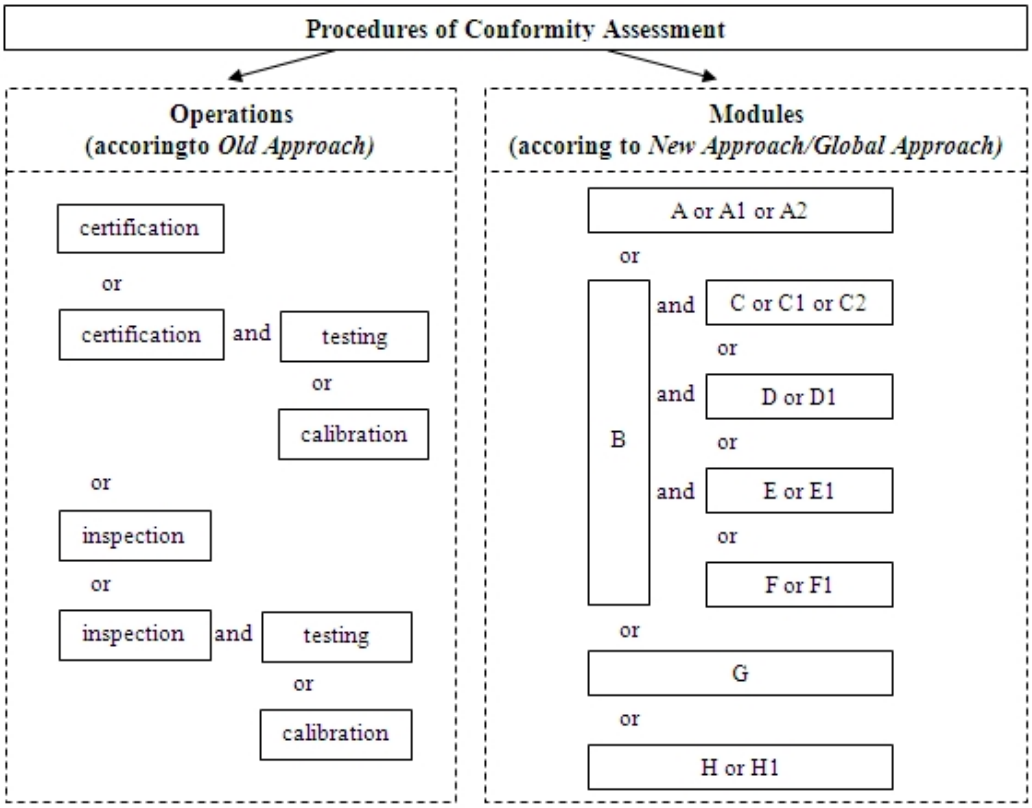

Figure 1.2. Conformity assessment procedures [the author]

Performing of conformity assessment under the *Old Approach* and the *New Approach/Global Approach* is different. In the case of the *Old Approach*, certain conformity assessment activities (inspection or certification) or support activities (calibration or testing)

are determined. In the *New Approach*/*Global Approach*, the manufacturer may choose which of the applicable conformity assessment modules or module combinations to use. The manufacturer must be sufficiently knowledgeable to be able to choose the most appropriate solution for a particular product and production process, and often prefers the more traditional solutions.

In the evaluation of conformity assessment activities – inspection, certification, calibration and testing, for each of them a scheme of interrelations of the terminology related to them has been made, and compared with the definitions and opinions of different authors found in literature. The author has also developed the representation of relationships and interactions of these activities.

The inspection of products was begun in order to ensure product control during the manufacturing process and prevent improper placement of products on the market and for use. After comparing different definitions of the concept of 'inspection', it was concluded that the „Law on Conformity Assessment" contains the most appropriate definition which describes inspection activities most precisely. It covers both the way of carrying out the inspection and indicates the possibility of performing support actions to ensure proper decision making.

The object of certification can be a product, person, process, service, etc. Certification by an independent third party is done in order to verify if the product complies with the requirements, and to confirm it by the eligibility certificate. As a result of the analysis, it was concluded that the definition in the „Law on Conformity Assessment" most accurately describes certification, covering all the main features of certification: the object, the parties involved, and the purpose of activities.

After evaluating the definitions of the concept of 'calibration', the author has identified two meanings: 1) to evaluate the accuracy of the measuring instrument or standard, 2) to adjust the operation of the device under certain circumstances. The first meaning of the calibration is used in the Promotion Thesis. It is concluded that the actual functions of the calibration are accurately described in the definition in the „Law on Conformity Assessment".

The term 'testing' also has different meanings: 1) performing testing, 2) acquisition of object characteristic values. In the thesis the author uses the second meaning. The main prerequisite for performing testing is standardized, internationally recognized or validated testing method by which objective results and their comparability are ensured. In comparison with other definitions, the definition in the „Law on Conformity Assessment" is more accurate because the activities to be performed during the testing are not specified, thus not restricting the means of testing.

Conformity assessment modules are classified according to various criteria: at what stage – design and/or manufacturing – conformity assessment is carried out, who performs the conformity assessment activities, what kind of activities are carried out to ensure product compliance: internal control, verification or quality management system is introduced. After evaluating the information related to conformity assessment modules and modular nature of the *New Approach*, it is concluded that in order to understand the activities to be performed within each module, it is necessary to provide explanations and to develop guidelines for their practical application. The expression of the modular activities in the form of a definition will not solve the uncertainty for entrepreneurs about the choice of the module and its application.

1.2.3. Conformity assessment elements. A prerequisite for successful business in the global market is the ability to recognize the importance of conformity assessment elements: accreditation, metrology, standardization, and to apply them.

Accreditation attests the competence of conformity assessment bodies to perform certain conformity assessment procedures in a particular area. It is significant for recognition of conformity assessment results and mutual recognition of products. In Latvia, accreditation is a prerequisite for the functioning of conformity assessment bodies in the regulated area. This practice is not applied in all the European Union Member States, which casts doubts on the equality of the conformity assessment results for the same product by conformity assessment bodies in different countries. In order to operate within the regulated area of the European Union, the conformity assessment body must obtain the status of a notified body. The European Union Member States apply different requirements for the notification of conformity assessment bodies. This fact can also affect the equality of the conformity assessment activities and the safety of the products in the market. After assessing the related concepts, it was concluded that the action ('notify'), in which the notification of the conformity assessment body is done, in Latvian should be translated as '*notificēt*'. The concept of 'notified body' in Latvian is '*paziņotā institūcija*' and the following definition is proposed: "Notified body is an accredited conformity assessment body, about whose competence to operate in a particular conformity assessment scheme and perform particular conformity assessment procedure the responsible institution has informed the European Commission" which has not been used in the Latvian language so far.

Essential and technical requirements, which are often standardized, are determined for products. Standardization has also contributed to the international trade. Further clarification of the definition of the concept of 'standardization' has been proposed: "Standardization is the process by which the parties involved determine the requirements and procedures that are the

best to adjust the activity of a certain area" because the current definitions are not sufficiently general and not focused on the development of standards. When developing standards, it is essential to involve all parties for the product requirements to be comprehensive, to be based on the opinions of experienced practitioners and experts, to include the latest scientific and technological solutions. After evaluating the opinions expressed by different authors (A.Klausa, N.Kozlovska, A.Vinogradova, S.R.Wilson, etc.), and definitions of 'standard' included in literature resources, there is offered an improved definition as follows: "A standard is a document that includes terminology, requirements and operating conditions and which is approved by the responsible institution with the aim to facilitate the development of a certain area" which sets the objective of the standard and highlights the most important information contained in the standard (terminology, requirements, operating conditions).

When adopting the *New Approach*, a new term 'harmonized standard' was introduced. The author proposes that the translation in Latvian is '*piemērojamais standarts*' and a new definition has been developed for it: "Harmonized standard is a national standard or adapted international standard, which can be voluntarily applied for the fulfilment of significant requirements in a specific area and about which the authorities concerned shall inform the society in a regulated way". This definition is much more concise than the one in the European Union legislation and is suitable for the Latvian situation, meanwhile emphasizing the voluntary nature of the standards in their application. In laws and regulations it is necessary to determine the procedure, in which the competent authorities shall take decisions about binding applicable standards in specific areas and inform the society.

Making measurements today is an integral part of manufacturing, conformity assessment, trade, etc. The term 'metrology' has several definitions expressed by various authors (S.C.Chappell, M.Kochsiek, I.Odītis, P.J.Potts, J.Rudzītis, K.D.Sommer, E.Šīrons etc.). The most common and most accurate definition is proposed by the International Bureau of Legal Metrology: "Metrology is the science of measurement". Measurements must have a uniform measurement system and standards: the measurement result is the value of an object with a certain uncertainty. With the Directive No 2004/22/EC coming into force in 2006, the issue of translation of the term 'measuring instrument' into the Latvian language became topical. There are two most commonly used Latvian translations of the term: '*mērīšanas līdzeklis*' and '*mērinstruments*'. After evaluation of these two terms, it was concluded that the most common Latvian term '*mērīšanas līdzeklis*' should be used.

All the terms proposed in this chapter and the new and more accurate definitions should be included in the binding laws and regulations.

1.3. The relationship between conformity assessment and quality management

In literature, quality management is described in various ways. The quality management system division defined in the Standard ISO 9000: 2005 "Quality Management Systems. Fundamentals and vocabulary" can be considered most appropriate for the present day. The author uses the Latvian translations proposed by I.Mežinska in her Promotion Thesis: '*kvalitātes plānošana*' (quality planning), '*kvalitātes kontrole*' (quality control), '*kvalitātes nodrošināšana*' (quality assurance), '*kvalitātes pilnveide*' (quality improvement).

The study evaluated each part of the quality management, meanwhile identifying the actions to be taken in each of them. The author proposes to build quality management as a sequential, continuous process where the next action after quality improvement is quality planning (see Figure 1.3).

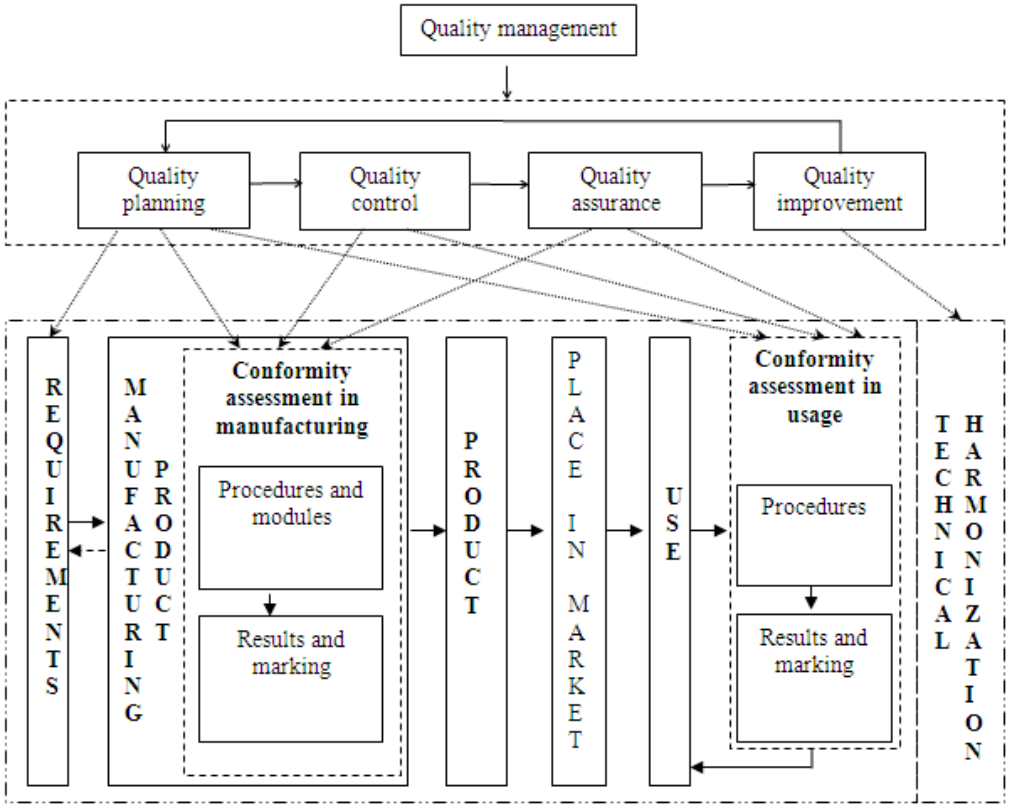

Figure 1.3. The scheme of interrelations between quality management and conformity assessment [the author]

After evaluating the elements of quality management, the activities carried out within its framework and comparing them with the product conformity assessment activities, it was concluded that conformity assessment is closely related to quality management (see Figure 1.3), ensuring that compliant and reliable products are placed on the market, delivered for use and used.

2. DEVELOPMENT TRENDS, REGULARITIES AND PROBLEMS OF CONFORMITY ASSESSMENT

In recent decades, globalization has changed the market trends and business development, increased competition among businesses, widened the range of products available on the market and the amount of them, etc. In order to comprehend the product conformity assessment system and identify the problems in its operation, technical harmonization approaches were examined, functioning of conformity assessment in the European Union was evaluated, the Latvian National Conformity Assessment System and conformity assessment of measuring instruments were analysed. The study covers two surveys, which cleared the views of Latvian accredited conformity assessment bodies and the European Union notified bodies on the requirements of conformity assessment and functioning of the conformity assessment system, as well as practical study of conformity assessment for measuring instruments. The study results confirm and complement the results of the assessment and the conclusions made during the analysis, as well as the identified problems.

2.1. The evolution of technical harmonization approaches

Technical harmonization is a process where uniform requirements are approved thus eliminating external technical barriers that could arise from different national requirements. Nowadays, technical barriers to trade are often subtly hidden in laws and regulations and technical specifications, focusing on protection of human health, life and environment, thus creating complications for entrepreneurship.

Over time, a number of technical harmonization approaches, i.e. solutions for the requirement regulatory organization, have been laid down (see Figure 2.1., the sequence of how they are laid down is numbered).

A common feature for technical harmonization approaches is setting definite requirements for products and their conformity assessment, without interference in the execution of requirements. Thus, the manufacturer is given some flexibility on how to ensure compliance and to demonstrate conformity, besides, entrepreneurs have access to a wider market, which also promotes competition among them.

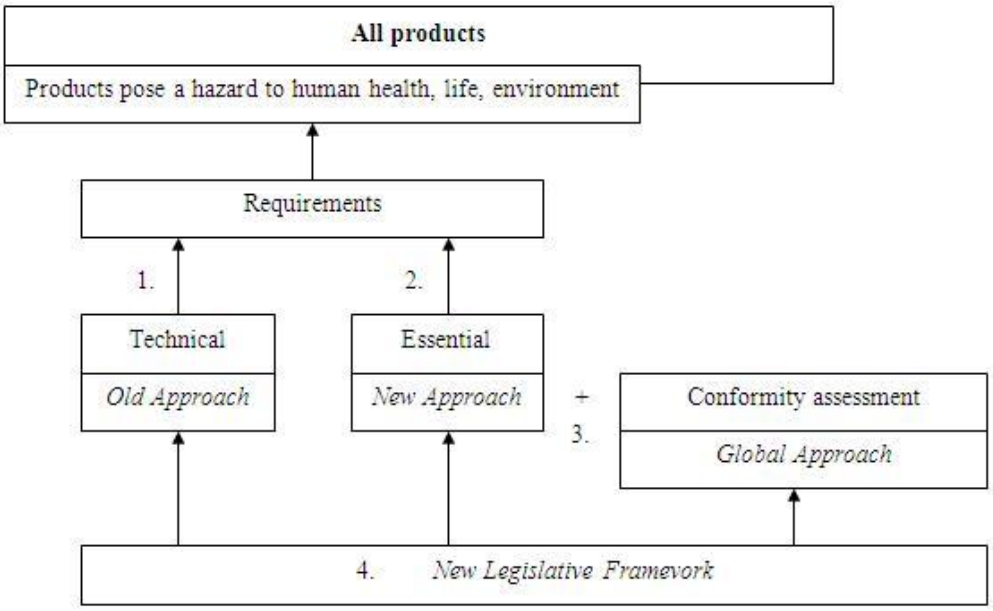

Figure 2.1. The scheme of interrelations between technical harmonisation approaches [the author]

After evaluating technical harmonization approaches and comparing them, it is concluded that the *New Approach* in comparison with the *Old Approach* is more general and flexible, while they both provide delivering compliant and reliable products for use. The *Global Approach* determines the requirements for conformity assessment and is considered as a complement to the *New Approach*. Nowadays they are integrated so well that the requirements of both approaches together are called the *New Approach.* The *New Legislative Framework* is a collection of solutions for improvement of the *New Approach* and the *Global Approach*, it contains provisions for development of market surveillance and promotes the transition from the *Old Approach* to the application of the principles of the *New Approach*. Adopting of the above technical harmonization approaches has not ensured the continuity and consistency of the changes, which has caused misunderstanding about their application in government institutions, businesses and society.

2.2. Evaluation of the Latvian National Conformity Assessment System

In order to evaluate the functioning of the conformity assessment system, and to identify the problems within it, an evaluation was made on the Latvian National Conformity Assessment System.

In the 1990s, quality-related issues became significant in Latvia, and the work on the establishment of conformity assessment system began; the reason was the desire to join the European Union, simultaneously contributing to the economic development of the state and

its competitiveness in international markets. In 1995, the national laws and regulatory acts for the regulation of conformity assessment were developed. For the functioning of conformity assessment system, a series of subsystems were established, which are essentially elements of the conformity assessment system. The coordination is done by the Ministry of Economics of the Republic of Latvia and an advisory body is organized for support of government institutions in each subsystem. The main changes in them are related to the accession of Latvia to the European Union, as well as with structural changes in the national institutions. Each of the national institutions work within international organizations to ensure the recognition of the Latvian conformity assessment activities and measurements, conformity assessment decisions adopted and the products manufactured at the international level.

National Accreditation System. The main function – accreditation and supervision of conformity assessment bodies – is carried out by the national accreditation body. In order to address unclear issues of conformity assessment, the national accreditation body may form branch technical committees. The period since 1997 witnessed a steady increase in the number of accredited conformity assessment bodies, an average of 10 conformity assessment bodies were accredited every year. Relatively more interest in accreditation of conformity assessment bodies was observed in 2002, due to the changes in the competence attestation of conformity assessment bodies. At the beginning of 2013, there were 227 accredited conformity assessment bodies. In the period of about twenty years, the number of regulated areas has decreased; thus leading to accreditation of conformity assessment bodies in non-regulated areas. With the accession to the regulated area of the European Union, the notification of conformity assessment bodies is carried out so that they can receive the status of a notified body. In Latvia, the main criterion for the notification of a conformity assessment body is its competence, attested upon accreditation. At the beginning of 2013, Latvia had 24 notified conformity assessment bodies.

National Metrology System. The main task for the national metrology institution is to provide the maintenance of basic national measurement standards. For this purpose a special national metrology institution building was erected, where it is possible to provide the appropriate conditions for the maintenance of national measurement standards. During the period from 1998 to 2006, 19 national standard measurement units were maintained in Latvia for reproduction of different physical qyantities, 11 of them are maintained at present. The next task of the national metrology body is registration of measuring instruments in the State Register where approval certificates for 88 measuring instrument types were registered at the beginning of 2013. The total measuring instruments market in Latvia is likely to increase with

each year, so to ensure the operation and reliability of measuring instruments, it is necessary to perform their conformity assessment not only in the design and manufacturing stages, but also during usage.

National Standardization System. The main task of the national standardization body is to ensure the elaboration of standards and their adaptation which is done by technical committees of standardization in different areas, by involving different parties. The main principle of standardization – the application of standards – remains voluntary. However, standards are often defined as mandatory by including references to them in regulatory acts, thus creating uncertainty for the application of the standard versions and creating restrictions for entrepreneurship. The most active standards adaptation preceded the Latvian accession to the European Union, when approximately 3500 standards were adapted every year. After joining the European Union, the process of adaptation of international standards is continued and each year international standards are adapted or amended/complemented. During recent years, the number of adapted standards has stabilized and ranges on average from about 1500 to 1700 adapted standards a year. There is a tendency that with the increase in the number of adapted international standards the number of national standards reduces, as requirements are harmonized at the international level.

As a result of the evaluation it was concluded that there is no apparent interaction among subsystems within the Latvian National Conformity Assessment System. On the whole, the system works in accordance with international requirements. Problems in each individual subsystem have been identified.

2.3. Conformity Assessment in the European Union

A notified body may be invited to carry out conformity assessment in the design and manufacturing stages for the products for which the requirements are regulated by the European Union. In Latvia, accreditation is the main criterion for the notified body competence and notification. European Union Member States apply a different approach to this matter, and there are different criteria for the notification of conformity assessment bodies. A uniform European Union regulation is not adopted, which can lead to inequalities in conformity assessment activities and decision-taking.

On the basis of the information published in the European Commission database *Nando-IS*, it was found out that at the beginning of 2013, there were 1658 notified bodies operating in the European Union. During a six months period their number decreased by 2%, which does not indicate significant problems in the European Union conformity assessment

system. The identified gaps in the information published in the database indicate the need for the European Commission to monitor it more closely and for the national authorities of the European Union Member States to be more responsible when dealing with notification of conformity assessment bodies. The majority of notified bodies work with construction products, non-automatic scales and pressure equipment. Viewing by country, the largest number of notified bodies is in Germany, the United Kingdom, Italy, Spain and France. The number of notified bodies cannot be evaluated unambiguously, in a free market, entrepreneurs have the right to choose whether to operate in the particular area, and their number is regulated by the demand for a particular conformity assessment service.

2.4. Conformity Assessment of Measuring Instruments in the European Union

The measuring instruments market is significant as a quarter of the measuring instruments are imported into the European Union. Each year, the most traded measuring instruments are material measures. At the beginning of 2013, there were 145 notified bodies for conformity assessment of measuring instruments according to the requirements of Directive No 2004/22/EC. After evaluating the modular combinations of conformity assessment of measuring instruments, it was found out that the solution proposed most often is modules B + F, modules B + D or module H1. After comparing the number of notified bodies according to the types of conformity assessment modules, it is concluded that notified bodies mostly operate with the modules F and F1. Their requirements are similar for initial verification of measuring instruments according to the principles of the *Old Approach*, which explains the large number of notified bodies.

In the European Union, uniform requirements for subsequent verification are not determined, each Member State lays down specific requirements for subsequent verification of measuring instruments at the national level. Different examples from the European Union Member States show that the frequency of subsequent verification of one type of measuring instruments can be determined according to different criteria (type of use, load, expected life cycle, etc.). The possibility of repairment and/or adjustment of measuring instruments during their use is to be limited.

2.5. Practical Aspects of Conformity Assessment of Measuring Instruments

In order to evaluate the conformity assessment system from the practical point of view, the author has carried out conformity assessment of measuring instruments in accordance with the most often used type of conformity assessment modules B + F and subsequent verification.

Conformity assessment according to module B. During the product design stage, the type assessment is carried out – the compliance of the measuring instrument sample with the technical project is assessed. For these activities the manufacturer must invite a notified body. The author has concluded that module B and other modules, where necessary, must be supplemented by an indication of the possibility that in some cases accredited subcontractors of manufacturer's choice can be attracted if this choice is motivated and the subcontractor's tasks are substantiated. The fact that the notified body does not perform the necessary tests itself cannot be evaluated unambiguously.

Conformity assessment according to module F. The type declaration of conformity based on product verification is carried out during the manufacturing stage, when the manufacturer invites a notified body. Inspection and testing can be done by the notified body itself or it can participate in inspections and tests carried out by the manufacturer, though the notified body does not always use this opportunity. To examine the module F in practice, the author carried out practical conformity assessment of measuring instruments. As a result, it was concluded that all inspected measuring instruments correspond to their values within the maximum permissible error regulated in the legislation. Thus, it can be concluded that the entire batch of the measuring instruments complies with the requirements.

Subsequent verification. When starting subsequent verification, first the visual inspection of the measuring instrument is carried out, i.e. it is assessed whether it is complete, in a usable condition and without damage. It is checked whether it conforms to the approved type and whether it has appropriate marking and seal. In order to evaluate the functioning of the measuring instrument objectively, its calibration is carried out, obtaining the measuring instrument value and assessing whether the value is within the maximum permissible error. As the result of the practical study it was concluded that all verified measuring instruments are appropriate and can be used.

3. IMPROVEMENT OF THE CONFORMITY ASSESSMENT SYSTEM MANAGEMENT AND TECHNICAL HARMONIZATION

The problems identified in second part of the Promotion Thesis are summarized and grouped; their causes and possible consequences are defined. From the established interrelationships of the problems it is concluded that the conformity assessment system management problems can be grouped as follows:

- problems related to technical harmonization (the set of the requirements for the products, understanding of the requirements, availability of non-conforming products on the market etc.);
- problems related to the conformity assessment system management (activities of conformity assessment bodies, requirements for their competency etc.)

In order to eliminate the problems, the European Union needs to improve the technical harmonization approaches, to concretize the scheme and management of the conformity assessment system and to improve the functioning of national conformity assessment system, thus ensuring that only conforming products are placed on the market.

3.1. Methodology of the *Technical Harmonization Approach*

The latest improvements of technical harmonization in the European Union were made in 2008, yet not all the problems related to product conformity assessment were eliminated. In order to deal with the problems identified in the conformity assessment system, the following information was gathered: on the set of the existing technical harmonization approaches; the requirements regulated by each approach; metrology and conformity assessment during the use of products, for which the requirements are to be regulated uniformly in the European Union in the future (see Figure 3.1).

The evaluation of the technical harmonization approaches (the *Old Approach,* the *New Approach* and the *Global Approach)* and their latest amendments (the *New Legislative Framework*) points to the need to conceptually improve the existing technical harmonization approaches. Upon accepting a uniform technical harmonization approach, which would substitute all former approaches, all the involved parties would have a clear and unambiguous understanding of the regulated requirements, the purpose of regulation, their position in the conformity assessment system and the provisions for manufacturing and conformity assessment activities, thus improving the overall understanding of conformity assessment and facilitating elaboration of specific conformity assessment schemes.

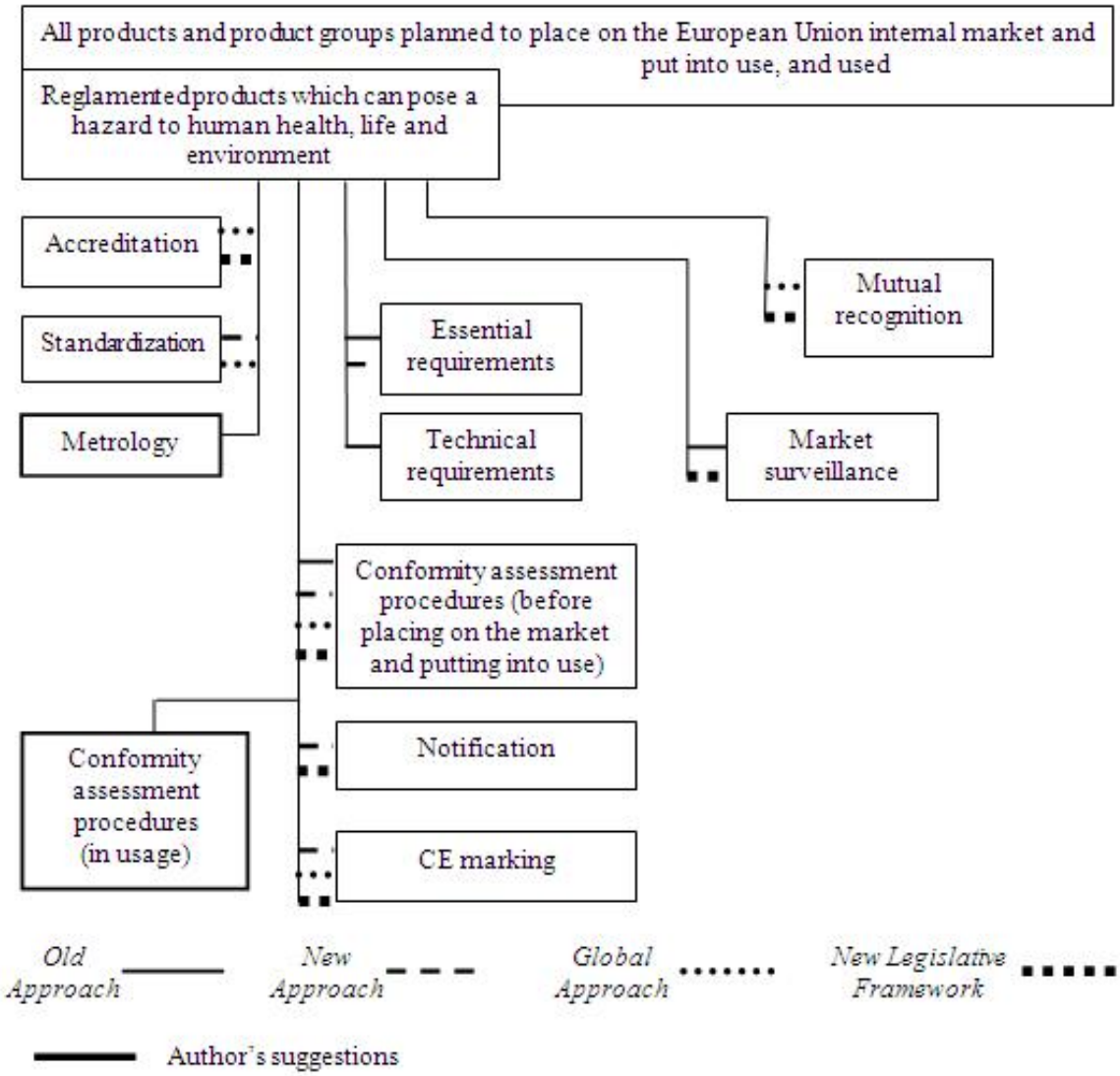

Figure 3.1. The set of technical harmonisation approaches and the regulated requirements [the author]

Taking into account the specifics and scope of the issues, it is not possible to lay down a uniform regulation for all the requirements in one legislative act. Therefore, initially it is proposed to adopt one European Union legislative act that would provide that a single *Technical Harmonization Approach* substitutes the former technical harmonization approaches, and would provide for the subdivision of regulations on specific requirements into eight groups, each of which would be regulated by a separate European Union legislative act.

The new, uniform methodology proposed by the author for laying down the requirements of technical harmonization to be applied in the European Union from now is illustrated in Figure 3.2.

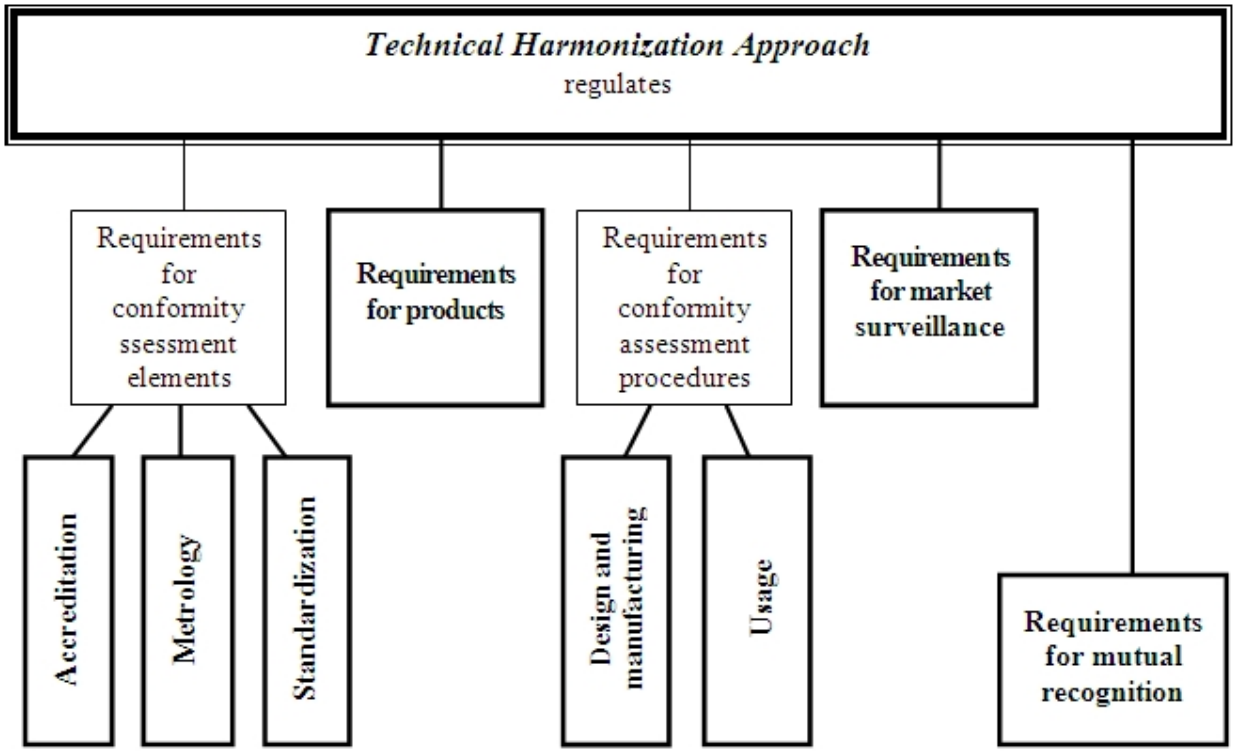

Figure 3.2. Methodology of requirements of the *Technical Harmonisation Approach* [the author]

The elaborated *Technical Harmonization Approach* is structured and within it alterations may be made consecutively and traceably.

Requirements for accreditation. A single unified international accreditation scheme has been developed at the international level; it provides for the opportunity to carry out accreditation of conformity assessment bodies on equal conditions in different countries. In the European Union, uniform requirements for accreditation were adopted in 2008 under the *New Legislation Framework* and the Regulation No 765/2008, in the drafting of which the author was involved, wherewith the competition among the national accreditation bodies of the European Union Member States has been eliminated and it is stated that only one national accreditation body may work in a Member State.

To ensure equal conformity assessment of the products on the market, accreditation must be made a mandatory prerequisite for the activities of a conformity assessment body in the regulated area at the national level and their notification in order to obtain the status of a notified body. Furthermore, the European Union needs to lay down uniform criteria for accreditation of conformity assessment bodies in order to be notified.

The proposed methods for accreditation and notification of conformity assessment bodies are shown in Figure 3.3. In order to improve the current procedure, the following activities are to be carried out: setting up of a database on the conformity assessment bodies

accredited in Latvia, to which the employees of the national body responsible for notification need remote access; if a conformity assessment body would wish to acquire the status of a notified body, it has to inform the competent institution; criteria are to be laid down for evaluation of a conformity assessment body's eligibility to become a notified body.

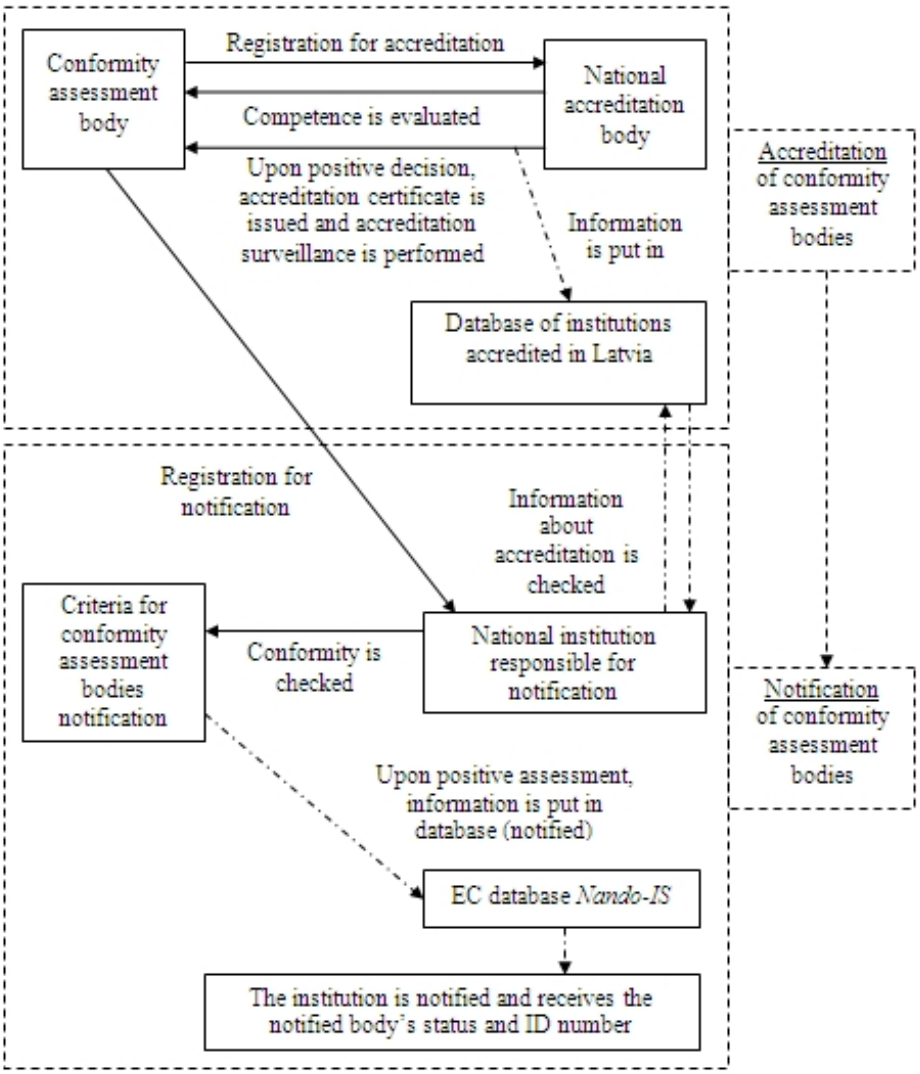

Figure 3.3. The order of accreditation and notification procedures of conformity assessment bodies [the author]

So as to make the accreditation procedure more flexible and easy for the entrepreneurs, evaluation of the whole conformity assessment body is to be performed during one audit visit.

Requirements for metrology. In order to assure the reliability of measurements and their traceability, and for conformity assessment bodies and companies to have an opportunity to reproduce their reference or work standards and measuring instruments, the national metrology body is responsible for maintenance of the national standards of units of measurement and provides for their traceability to international standards. The European Union requirements for organizing metrology scheme are not regulated, wherewith each state

has created one in accordance with its specifics. At the international level, these schemes are coordinated by international metrology organizations, which draft documents of a guiding nature in the field of metrology.

Taking into account the importance of the field, it is necessary to ensure application of a uniform metrology scheme in all the European Union Member States. For this purpose the European Union needs to lay down a legislative act on requirements for organization of metrology at the national level. Simultaneously with adoption of such a legislative act, the bases of national standards of units of measurement are to be revised adjusting them to the actual needs of national economy and granting entrepreneurs the opportunity to reproduce their standards. The states need to cooperate and jointly evaluate, which of the national metrology bodies will offer particular calibration services of standard units of measurement; it is not necessary to offer all the services in all the states.

Requirements for standardization. Upon coming into force of the *New Approach*, there are difficulties in understanding application of standards as the entrepreneurs and the society believe that standards are compulsory as they were with the *Old Approach* requirements. In order to encourage development of new products and implementation of innovative ideas in the future, voluntary application of standards needs to be stimulated. Laying down compulsory standards is to be given up, and it is advised to recommend harmonized standards. In the field of metrology, the international standardization and metrology organizations have to cooperate closely to avoid contradictions in the requirements, which are included in the standards and documents of the International Organization of Legal Metrology.

Requirements for products. In the course of time the number of products and product groups, which are subject to regulation, is decreasing and currently the requirements are applied only for the products, which may pose hazard for human health, life and the environment. The author believes that this trend needs to be developed further, gradually decreasing the number of regulated areas. At present the requirements for the products, which are subject to regulation, are divided as follows:

1) essential requirements (referring to all the products under regulation);
2) technical requirements to the products having high level of hazard.

Upon making amendments in the legislative acts, the product requirements are to be uniform as far as possible depending on the specifics of the field, and conformity assessment modules are to be applied for carrying out conformity assessment. Different involved parties (including the experts, researchers etc.) are to be invited to find better and more

comprehensive solutions. Work groups are to be organized for discussions about the requirements set for the products and their application, as well as guidelines are to be drawn up when necessary to eliminate discrepancies in the interpretation of the requirements.

Requirements for conformity assessment procedures during the stages of product design and manufacturing. A significant source of information is the Type Approval Register. During the design stage, when carrying out the procedure of measuring instrument type assessment all the information about the product is available only to the conformity assessment body, which performed the type assessment, and the manufacturer. When carrying out conformity assessment during the manufacturing stage and at subsequent verification, it is not possible for the conformity assessment body to check the type assessment of the particular product, its term of validity etc. in a simple and expedient way. It would be useful for the European Union to maintain a uniform Type Approval Register.

Over time, attempts have been made to form an understanding of the meaning of CE marking, nevertheless cases are still identified when products are marked improperly. Therefore, it is necessary to enhance the meaning of CE marking, so that customs institutions, entrepreneurs and the society would recognize improperly marked products, and on these grounds the products would not be placed on the market, or not submitted for use or purchased (see Figure 3.4).

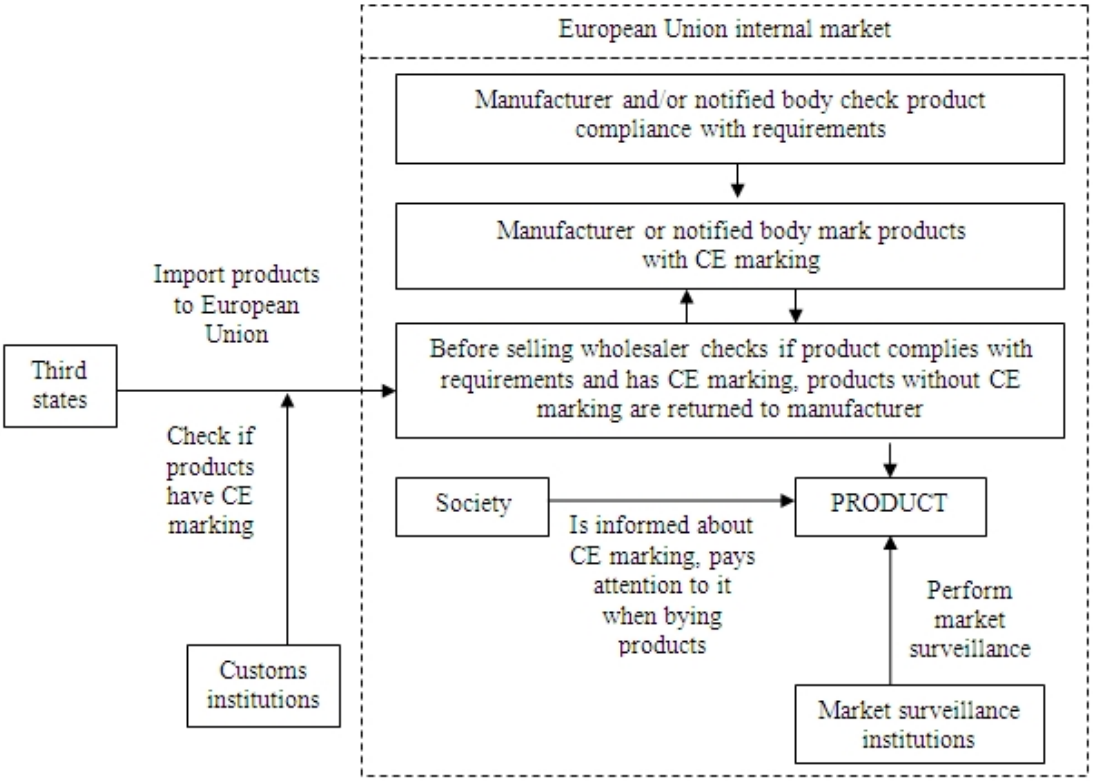

Figure 3.4. The scheme of affixing, using and monitoring CE marking [the author]

At the national level, it is necessary to take informative measures in order to inform the entrepreneurs and the society regarding the CE marking.

Conformity assessment procedures during product use. Until now conformity assessment procedures during product use were regulated only at the national level, and as a result there are different requirements for subsequent verification in each state. In order to improve this area, subsequent verification in the European Union needs to be carried out uniformly, with a prescribed periodicity for particular measuring instruments and performing verification after adjustment and repairment of the measuring instrument. For that the following requirements need to be regulated: list of measuring instruments; periodicity of verification; maximum permissible error; method to be used for carrying out subsequent verification; requirements for documentation and marking, which are issued/attached after subsequent verification.

In respect to the fact of repairment or adjustment of the measuring instrument, the entrepreneur is issued a document, which is then presented to the conformity assessment body when submitting the measuring instrument for subsequent verification. Taking into account the possible instability of the measurements, the verification period for such measuring instruments needs to be shortened.

Requirements for market surveillance. Nowadays, requirements for market surveillance are more liberal and product control is done selectively. The manufacturing and conformity assessment processes are organized in such a way as to ensure trust in the activities carried out by the manufacturers and conformity assessment bodies. In the European Union, the requirements for market surveillance are currently regulated by the Regulation No 765/2008. To avoid confusion, it is advisable to isolate them in a separate legislative act.

In order to decrease the number of non-conforming products on the market, the customs institutions have to maximize the attention when inspecting the products that the European Union imports from the third countries, and market surveillance organizations have to carry out informative campaigns to inform entrepreneurs and society regarding the meaning of CE marking. In order to improve market surveillance, the European Union needs to elaborate guidelines for explanation of the requirements and make use of uniform document forms, as well as regularly update the knowledge of employees.

Requirements for mutual recognition. At present, mutual recognition is regulated by Regulation No 764/2008. The current regulation has been improved over time and may be considered adequate and sufficient. The name of the legislative act should be changed from "Laying down procedures relating to the application of certain national technical rules to

products lawfully marketed in another Member State" to "Laying down procedures relating to mutual recognition of products" thus demonstrating unambiguously what requirements are regulated by the particular legislative act.

3.2. Improvement of the Conformity Assessment System

In order to ensure the system management, aspects to be identified and defined in each specific case are as follows:

- process to which the particular system relates (conformity assessment system);
- particular object (product) to which the process relates, when necessary;
- regulated requirements;
- harmonization level of the requirements;
- parties involved in the provision for the process activities, their functions and responsibilities;
- elements that would ensure functioning of the system and objectiveness;
- system surveillance provisions.

To ensure placement of conforming and safe products on the market and delivery for use as well as conformity to requirements of products in use, conformity assessment is carried out, thereby in the particular case the system is related to product conformity assessment. The product conformity assessment system is evaluated, structured and developed in accordance with the above mentioned aspects of system management (see Figure 3.5) in order to eliminate any inadequacies found in it.

Upon making changes in the conformity assessment system in relation to the product conformity assessment process, it is stated that in future during the product design and manufacturing stages conformity assessment is to be carried out only by making use of conformity assessment modules and uniform requirements laid down by the European Union for carrying out conformity assessment of products during their use. In order to ensure reliability of conformity assessment and its results, specific conformity assessment elements related to particular stages are identified and defined. It is determined in which stages of the process the market surveillance is made to ensure that conforming and safe products are available on the market and are used. Requirements for conformity assessment and products, conformity assessment elements and market surveillance, which are harmonized at the European Union level and allow applying mutual recognition to the products, are to be improved. It is to be applied to the non-harmonized area as well.

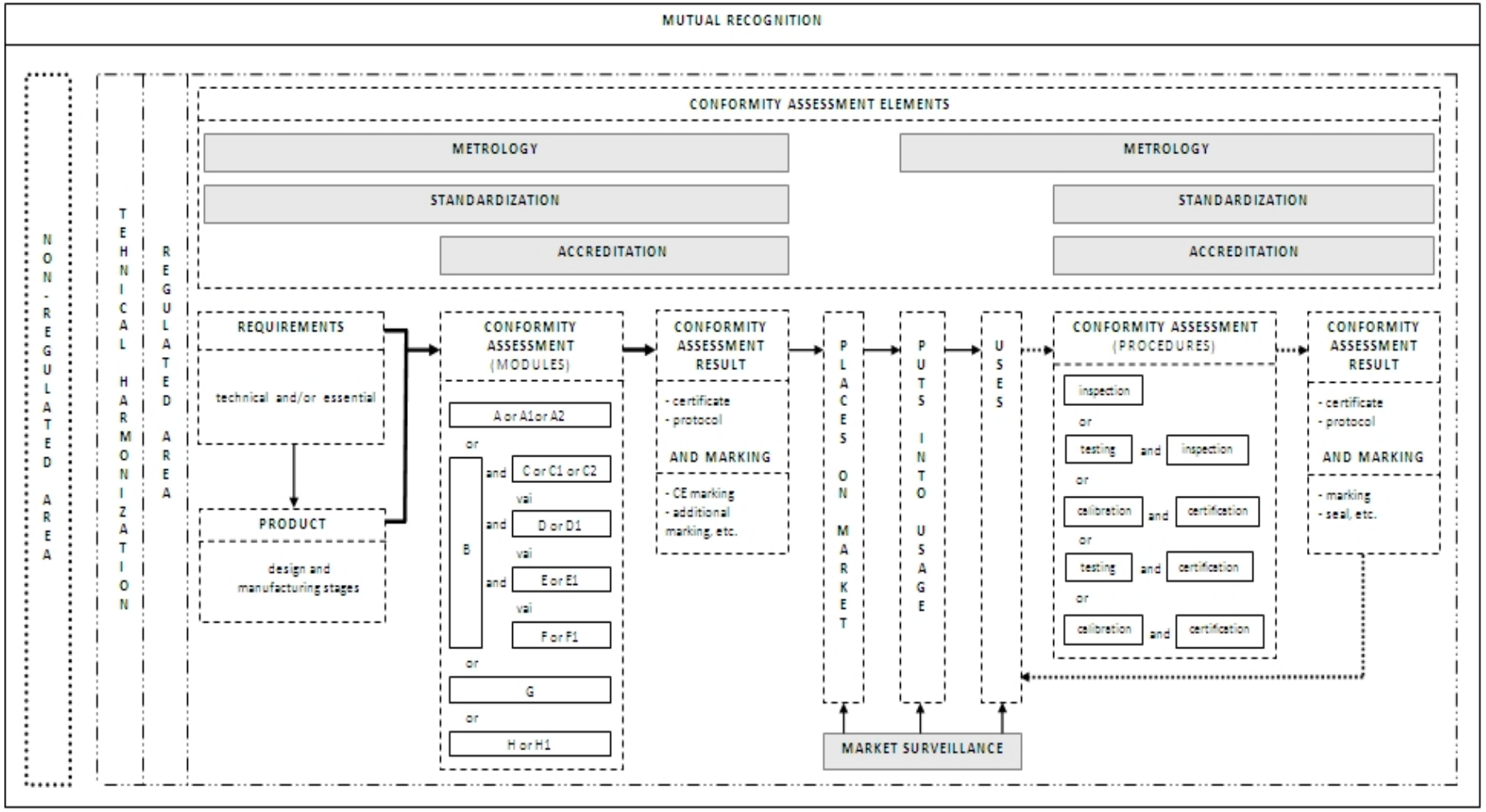

Figure 3.5. The scheme of the conformity assessment system [the author]

Parties involved in conformity assessment. To provide for the functioning of conformity assessment system, the parties involved in it are identified, their mutual relationship is established (see Figure 3.6), the parties having direct or indirect relation to the product conformity assessment or involved in the placement of the product on the market and delivery for use are depicted.

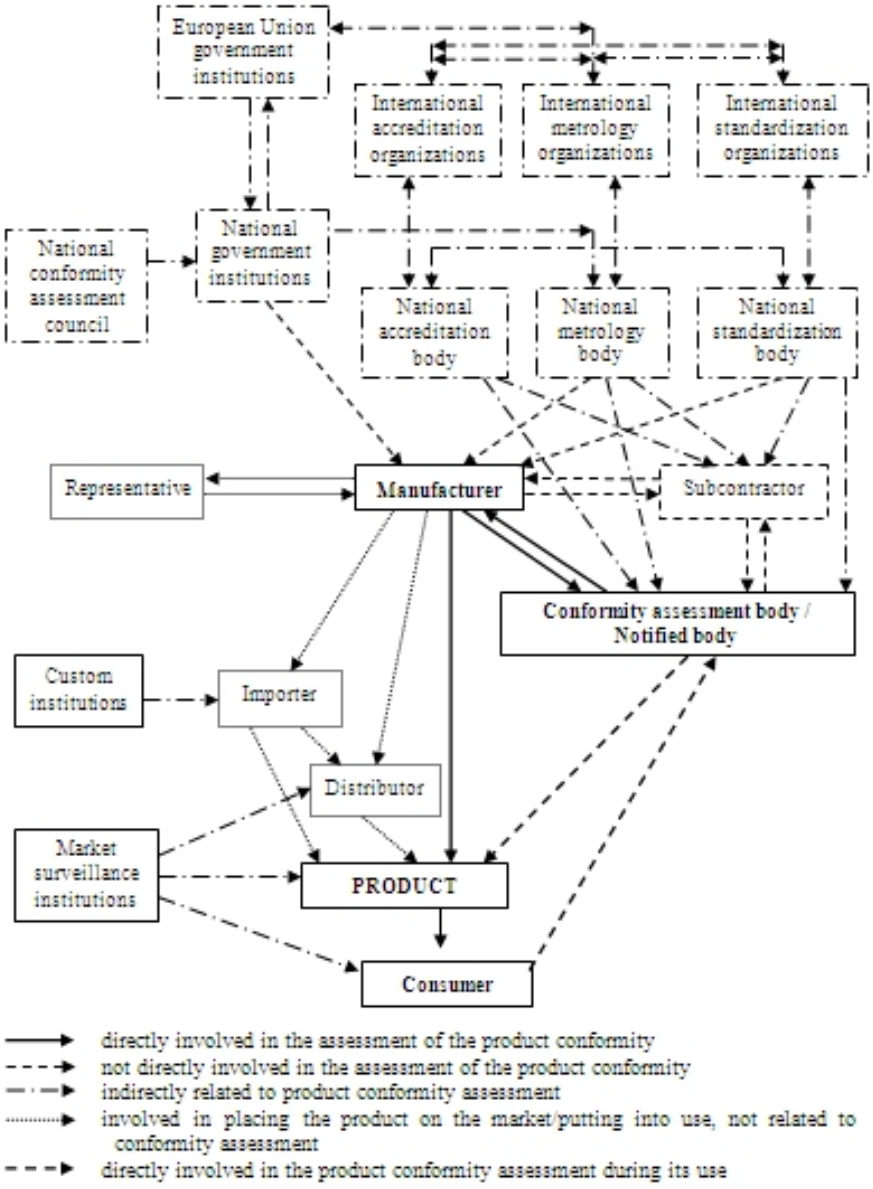

Figure 3.6. The scheme of interaction of the parties involved in product conformity assessment [the author]

The main parties, which are directly involved in the conformity assessment process, are the manufacturer and conformity assessment body on whose activities product conformity to the requirements depends. The other parties are involved either directly or indirectly, or they are involved only in placement of the products on the market/delivery for use. The consignee (user) of the product is the consumer. Product conformity assessment may be carried out

based on the consumer's opinion in order to determine its conformity to requirements during use as well. For all the involved parties to be aware of the importance of the activities carried out and to carry them out responsibly, their functions and responsibility for the activities performed should be defined clearly.

A significant aspect is attracting subcontractors, as there is a risk that products may not conform to the set requirements as a result of their actions or inactivity, wherewith non-conforming products would appear on the market. When attracting subcontractors, the following criteria are to be observed: the most part of measurements/tests are made by conformity assessment bodies; attraction of subcontractors is possible only in specific technical areas; subcontractors are not to be involved regularly over a lengthy period. Accreditation of subcontractors is to be defined as a mandatory prerequisite for their attraction.

Scheme for the selection of conformity assessment module. In order to improve conformity assessment system management and facilitate the manufacturer's selection of the conformity assessment module to be applied, a scheme for selection of conformity assessment module is suggested in the present Promotion Thesis (see Figure 3.7).

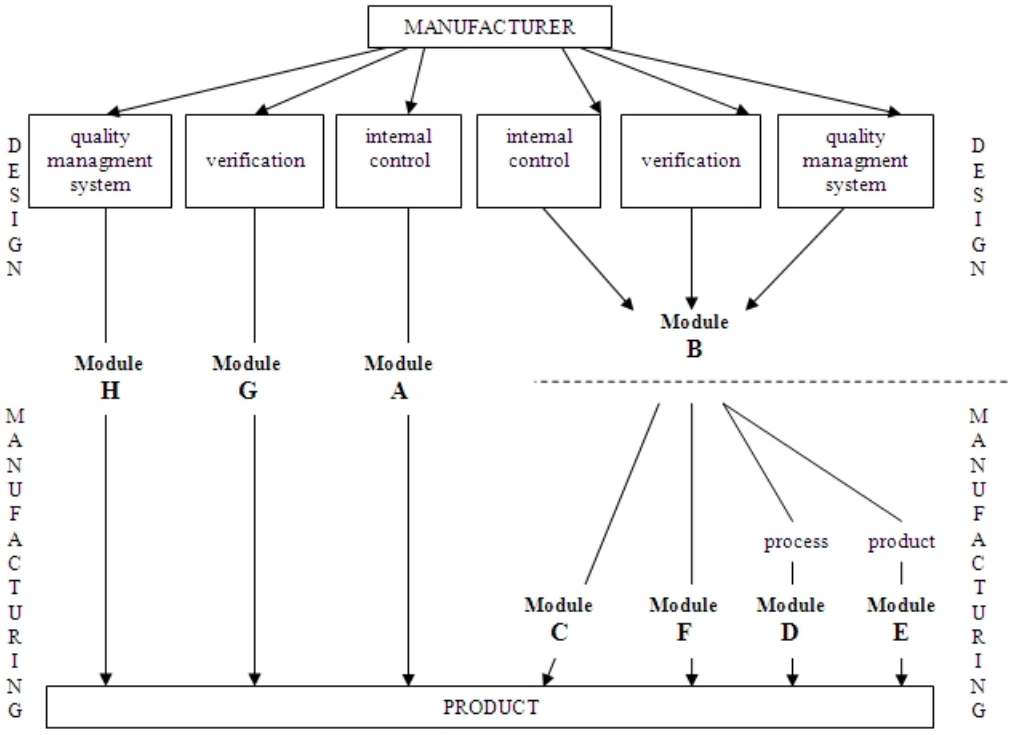

Figure 3.7. The scheme of choosing conformity assessment modules [the author]

The main criteria to be consistently considered by the manufacturer are offered, so that the most appropriate module can be selected. The choice of conformity assessment module is the manufacturer's individual decision, which is based on personal consideration. Different

application of conformity assessment modules admissible for a particular product does not influence the product conformity.

3.3 Improvement of the Latvian National Conformity Assessment System

Upon evaluation of the current Latvian National Conformity Assessment System, it is concluded that in general it functions according to international requirements. In order to make its management more effective and to satisfy the needs of the national economy, to foster entrepreneurship and to be more orientated towards the interests of the society, minor alterations and improvements are to be made to the current conformity assessment system.

In order to improve the conformity assessment system management, the task of the Ministry of Economics of the Republic of Latvia is to draw up a single document for policy planning in conformity assessment area, encourage use of common terminology base in conformity assessment area, include the involved parties in different activities more frequently and inform the society regarding the developments in the area.

It is proposed by the author to form one advisory body in the conformity assessment area – Latvian National Conformity Assessment Council that would substitute the three existing councils in the areas of accreditation, metrology and standardization. The main task of the Council would be to assess the possibility to perfect conformity assessment system and the related issues in accordance with the trends in national economy and the entrepreneurs' needs and submit its proposals to the Ministry of Economics of the Republic of Latvia.

In the course of improving the functioning of the Latvian National Conformity Assessment System, the administrative institutions and national organizations for accreditation, metrology and standardization and market surveillance are to revise and activate the following services: calibration of standards and measuring instruments; inter-laboratory comparison; dissemination of standards; organizing different work groups; elaboration of explanatory guidelines; organizing informative seminars and training.

CONCLUSIONS AND RECOMMENDATIONS

In the Promotion Thesis, the quality, management, quality management and conformity assessment issues are examined theoretically, terms and definitions related to conformity assessment are evaluated, relationship between quality management and conformity assessment is evaluated, the conformity assessment system and its management in the European Union and Latvia is analysed; the technical harmonization approach is evaluated, practical conformity assessment of measuring instruments is carried out. The research describes the actual situation in the conformity assessment field and allows drawing the following **conclusions**:

1. The concept of 'quality' nowadays is used to describe products. Not always the quality assessment is based on objective characteristics. When describing the quality, several aspects should be covered: The researched object (e.g. product), the requirements for the object (must be specific, measurable), conformity assessment (comparing objects and requirements) and the competence of involved parties (e.g. manufacturer, conformity assessment performer, etc.).

2. The definition of the concept of 'management' that refers to system management covers a set of various activities, processes, procedures, etc. to be taken to ensure the organization and development of object (such as industry, business, system, etc.) performance. The aim of the conformity assessment system management is to organize the functioning of the conformity assessment system to ensure that only compliant, safe and secure products are placed on the market, put into usage and used. It is concluded that in the current conformity assessment system not all its elements and components are interacting. Imperfections in their management are identified.

3. Quality management consists of coordinated activities that are targeted to a specific object (enterprise, system, etc.), promoting and managing it in the field of quality. In order to apply quality management as a set of consistent and continuous operations, the sequence of elements of quality management (quality planning, quality control, quality assurance and quality improvement) should be observed. Quality management and product conformity assessment process have definite interrelations, which play a role in product manufacturing and entrepreneurship.

4. Precisely defined requirements for products are a prerequisite for conformity assessment, though it is important to invite all the stakeholders in defining the requirements. Nowadays, the process of determining the requirements at the level of governing bodies has

become relatively simple; it is easier and faster to reach an agreement because consideration of specific technical questions has been directed to international and national organizations. The number of requirements for product conformity assessment has decreased. The improvement of the scope of requirements and the adoption process facilitate the development and manufacturing of new products, as companies can identify specific technical requirements for products themselves.

5. Conformity assessment is the process in which conformity assessment procedures evaluate the compliance of an object with the requirements. This process can ensure that safe and secure products are placed on the market, put into service and used. For conformity assessment to be reliable and the actions and decisions taken to be recognized by other countries, the European Union conformity assessment system is unified using the *Technical Harmonization Approach*. It is significant for the manufacturers who export products to foreign countries, and for businesses that deal with international trade.

6. Nowadays, for ensuring the operation of the European Union internal market, technical harmonization is applied. A series of technical harmonization approaches in the field of conformity assessment have been adopted (the *Old Approach,* the *New Approach,* the *Global Approach* and the *New Legislative Framework*). Taking into account the principles contained therein, product conformity assessment is carried out and placement of compliant products on the market and putting them into use in the European Union has been ensured. Upon evaluation and comparison of technical harmonization approaches, it was found out that the changes in the technical harmonization approaches have not been structured, they do not cover all the relevant elements and in the European Union there are no regulated uniform requirements for product conformity assessment during their use. Therefore, it is impossible to ensure the reliability of product conformity assessment. The solution to this problem is adoption of new uniform technical harmonization requirements (approach) to conformity assessment.

7. Conformity assessment procedures are adapted to conformity assessment schemes, depending on the nature of the product and the permissible variations of conformity assessment procedures. Currently, the European Union conformity assessment procedure requirements are unified only for the product design and manufacturing stages, by recommending to apply the same requirements for conformity assessment modules. When taking decisions about conformity assessment, specific values characterizing the products, which are obtained by support activities (testing and calibration), can be used. The reliability of conformity assessment result (decision) depends on equal interpretation and application of

requirements. The problems and current issues of conformity assessment system management need to be dealt with at the European Union level, as the development of the national economy and entrepreneurship in the long run depends on coordinated functioning of the conformity assessment system.

8. With the increasing role of conformity assessment, the issue of the competence of conformity assessment performers, their integrity and objectivity is becoming more important. Accreditation can be done to ensure their compliance with these factors. Accreditation confirms the competence and guarantees mutual recognition of conformity assessment results and products. In Latvia, accreditation is a prerequisite for performing conformity assessment. Upon evaluation of the conformity assessment field, it was found out that not in all European Union Member States accreditation is the criterion and evidence for the functioning of the conformity assessment body in the regulated area. Different requirements for notification of conformity assessment bodies have also been identified. Consequently, businesses and consumers cannot be sure that all conformity assessment performers take the same decisions and recognize the compliance of the same products.

9. Conformity assessment bodies can invite subcontractors for performing support operations, but the decisions about the product compliance with the requirements are always taken by conformity assessment bodies. Uniform requirements for the competence of the subcontractors have not been determined and their involvement is not managed, so the decisions about product conformity and the safety of products on the market cannot be reliable in cases, where subcontractors have been involved in the process of conformity assessment. This problem should be tackled simultaneously with the question of the competence of conformity assessment bodies.

10. Nowadays making measurements is an integral part of the manufacturing and marketing processes. They are also required to assess product compliance, to monitor manufacturing processes, etc. There are no uniform principles for regulation of metrology scheme.

11. In cases where the measuring instrument does not meet the requirements, it can be repaired or adjusted, followed by repeated conformity assessment. The accuracy of measurements is important, therefore, it is necessary to ensure the stability of the measurements after their repairment and adjustment. It was found out that the process of repairment and adjustment of measuring instruments is not regulated and monitored, and organized management of these activities is not ensured, so there is a risk that measurements made by measuring instruments after repairment and adjustment are inadequate.

12. The initial application of standardization and standards is different today, so there is also difference in understanding their application and mandatory nature. On the one hand, standards facilitate the conduct of business, because entrepreneurs do not have to elaborate their own requirements, methods and solutions; they can use general solutions accepted at both national and international level. On the other hand, setting standards for mandatory use creates restrictions for business activity, even the creation of innovative solutions, application and development of new products is possibly hindered. The European Union requires voluntary use of standards, and businesses are free to choose the most appropriate solution. Examination of the situation reveals that standards are sometimes defined as mandatory by referring to them in legislative acts. In order to observe the principle of voluntary application of standards, it is necessary to integrate standardization in the conformity assessment system and to promote the awareness of the entrepreneurs and the society about these issues.

13. To ensure the reliability of conformity assessment and its results, the elements of conformity assessment (accreditation, metrology and standardization) are of utmost importance. In assessing the scope of conformity assessment, the author has identified that these elements are perceived and organized as separate systems, rather than integrated into the conformity assessment system; as a result of which the functioning of the conformity assessment system is not comprehensive.

14. Thus, along with the increase in the importance of conformity assessment, manufacturers and conformity assessment performers' responsibility has also increased, and the issue of the CE marking and other markings and conformity compliance documents is more topical. Despite the opportunity of certifying product compliance in a variety of ways and the market surveillance activities, non-compliant and unsafe products, dangerous to human health, life and environment are still available on the market. Placement of non-compliant products on the market, putting them into use and using them can be related to insufficient understanding of the product requirements, conformity assessment procedures and responsibility for trading and using products among the entrepreneurs and in the society. In order to prevent putting non-compliant products into use and using them, it is necessary to improve the stakeholders and the society's awareness of the conformity assessment system.

15. The Latvian National Conformity Assessment System analysis confirms that the system is stable and its functioning is generally in line with international requirements. At the same time problems pointing to drawbacks at the national and European Union level and the need to develop the conformity assessment system management are identified. For some of them solutions were being sought for a long time, which indicates their importance and global

scale. Solutions that have not been found for a long time may hinder business development, so it is important to find a common solution to these issues.

On the basis of the research results, the author puts forward the following **proposals**:

1. To ensure organized management of the conformity assessment system and its covering all elements and activities involved in conformity assessment, a scheme for product conformity assessment system is created. The scheme depicts the sequence of activities within the product conformity assessment process and conformity assessment elements, thus facilitating the conduct of business.

2. The European Union internal market needs to follow the same requirements for products and their conformity assessment during the stages of design, manufacturing and use. On the basis of the evaluation of the current technical harmonization approaches and the conformity assessment system in the European Union and Latvia and the identified problems, a new, uniform methodology for regulations – the *Technical Harmonization Approach* – is elaborated with the aim to replace the current technical harmonization approaches. The *Technical Harmonization Approach* is divided into several groups, so that it would be more understandable for entrepreneurs and facilitate the business. The new proposed approach has to be accepted by the European Union regulatory bodies.

3. In order to ensure that products comply with the requirements, one of the conformity assessment system management tasks is to clearly define parties involved in product conformity assessment, requirements for their competence, their functions, responsibilities and surveillance procedures. Accreditation has to be a prerequisite for recognition of the competence of parties (conformity assessment bodies, notified bodies, invited subcontractors) involved in conformity assessment. In order to ensure uniform compliance in all the European Union Member States, the requirements for the competence of conformity assessment performers have to be harmonized in all the European Union. Thus, conditions for doing business would be organized and the reliability of decisions taken about conformity assessment would be ensured.

4. To facilitate the manufacturers' understanding of the differences between the conformity assessment modules and their ability to choose the most appropriate module under diversity and complexity of conformity assessment procedures, a scheme has been developed for selection of the product conformity assessment module.

5. Recognizing the importance of product conformity assessment and taking into account the need to improve accountability of the parties involved and in order to eliminate

use of non-compliant products, the national government institutions and market surveillance bodies need to promote the stakeholders and the society's understanding of the product CE marking and other marking types, their identification and compliance with conformity documents.

6. On the basis of the improved terminology database in the conformity assessment field, the government institutions of Latvia need to encourage using uniform terminology and definitions, so that entrepreneurs and the society have a common understanding of the requirements for products and for the conformity assessment process and entrepreneurs apply requirements in practice in the same way.

7. The Ministry of Economics of the Republic of Latvia needs to develop a strategic planning document – the development strategy of the Latvian National Conformity Assessment System describing the current situation and including solutions for further development of the conformity assessment system, while also ensuring compliance with international requirements and the needs of the national economy.

8. A prerequisite for the improvement of the conformity assessment system is the parties involved in conformity assessment, their competence, interest in the long-term development of the field and responsibility for the activities performed. It is therefore necessary to accept a single advisory body – the Council of Latvian National Conformity Assessment System, integrating the current three councils of accreditation, metrology and standardization, and to activate its operations. The national standardization body needs to activate the involvement of the stakeholders in technical committees of standardization, the national accreditation body – in branch technical committees and the Ministry of Economics of the Republic of Latvia has to organize and coordinate a working group of notified bodies.

After summarizing the research results, it is concluded that the theses proposed for defense in the introduction of the Promotion Thesis are valid and the hypothesis is proven.