SCIENTIFIC PAPERS
OF THE UNIVERSITY OF PARDUBICE
Series A
Faculty of Chemical Technology
19 (2013)

INTEGRATION OF QUALITY MANAGEMENT SYSTEMS IN CHEMICAL LABORATORY

Lenka BRANSKÁ[1] and Lukáš MARKOVIČ
Department of Economics and Management of Chemical and Food Industry,
The University of Pardubice, CZ–532 10 Pardubice

Received September 13, 2013

Given the increasing demands of customers in logistic chains for quality (of products and services), it is necessary to constantly improve business quality management systems. These can assume different forms in different businesses. In most cases, they are only based on the ISO 9000 standards, but we can often see a company that has several parallel systems of quality management built on the basis of several methodological guidelines. This allows it to obtain a few certificates and, also with the help thereof, extend the range of their customers, but it complicates their practical application in the business practice. Therefore, it is a natural tendency of managers to integrate them into a coherent quality management system that supports the daily execution of business activities. The professional literature addresses the integration of individual management systems (i.e., quality management system, environmental management system and management of health and safety at work), where however the solution is facilitated by compatibility of methodological guidelines. In principle, the problem of integrating parallel-standing quality management systems has not been

[1] To whom correspondence should be addressed.

addressed in the literature yet. Therefore, the present paper deals with this form of integration. It addresses how to integrate in a chemical laboratory several parallel quality management systems built on the basis of various methodological guidelines.

Introduction

Since the 1980s, quality systems have become an essential element in successful companies and institutions [1] because quality cannot be managed on an ad hoc basis [2]. Today those systems are indispensable to fulfill the needs of the customers and last but not least the requirements of the society [1].

Depending on the company's activities and fields of services, it is necessary to establish various quality systems [1]. Only a properly implemented quality management system (QMS) within an organization and across its supply chain can provide protection from short-term actions that do not serve long-term goals [2]. QMS enables the company to coordinate and harmonize all of the activities and processes such as quality planning, actual creation of quality, demonstrating and improvement of quality.

Organizations are increasingly implementing multiple management system standards [3] to satisfy various customer requirements as well as all the legal demands of regulators [1]. These organizations include also businesses, which incorporate a chemical laboratory and chemical laboratories as separate business entities. To build their own quality management systems, these organizations use both the requirements of ISO 9000 standards and GMP, GLP requirements as well as ISO/IEC 17025 standards. But it also became clear that these various quality systems could not be allowed to operate in isolation [1]. For a testing facility that is required to fulfill many different regulations, it is extremely important to integrate a parallel operating quality system instead of four different independently operating quality systems [1]. The difficult assignment of the management is therefore to unify these systems, although the regulations are sometimes quite conflicting. This integration had to be understandable both to the employees as well as to outside entities such as customers, auditors, accreditation and certification bodies.

Integration of quality management systems built on the basis of different concepts must be essentially the same principle as the integration of management systems (QMS, EMS, HSMS). It is actually simultaneous implementation of all requirements of the methodological guidelines (for example ISO 9000, ISO 14 000 and OHSAS 18000). But these standards (e.g., ISO 9001, ISO 14001 and OHSAS 18000) tend to use quite similar methodology with regard to their creation, structure, implementation process and monitoring by a third party [4]. Therefore, the integration of these management systems is easier. There is such a single basis

for requirements for the quality management system; neither the mutual compatibility is sought, because in principle there are no expectations for any need to harmonize them.

Generic issues of integration have been analysed in the literature, little attention has been paid to the QEM (quality, environment) framework as a single, full system [5]. The issue of integration of quality management sub-systems has been addressed in the literature only marginally. There is no satisfactory guidance on how to integrate quality management systems built on the basis of two methodological guidelines (for example, ISO 9001:2008 and GMP), while in the chemical laboratory we may witness the implementation of four concepts (ISO 9001:2008, GMP, GLP and ISO/IEC 17025:2005). In this case, the integration of sub-systems has become really difficult, though Bonk–Kassner [1] states that these quality systems are not fundamentally incompatible, so that their requirements can be combined into a unified system. Moreover integration process is not the same in all organizations, there are many possible constraints or determinants of the process and its outcome that are conditioning the level of integration of management systems [3].

An integrated quality system also produces excellent economic advantages [1]. An integrated system is less cost-intensive, more flexible, and causes less confusion among the personnel [1]. This also reduces expenses and applicable costs. Integration must be carried out not only to cut costs, but also to improve efficiency [6,7].

A single standard is also easier to implement by employees. Employees do not have the difficulties caused by having to work under and keep straight multiple different standards. Exchange of personnel between laboratories is also made simpler. The important organizational assumption for the operations of such a parallel quality system is that all locations and laboratory sections stand under one umbrella administration (or, in the sense of ISO 9001, the management representative). This is the most important condition to accomplish in a unique quality system. An important quality goal is the fulfillment of customer requirements. It can be observed already in the implementation phase of the integrated quality system that particularly customer specific requirements are comprehended more efficiently and are thereby more quickly fulfilled. It also eases cooperation with customers if they understand that all locations in the company operate under the same single quality system with a single standard [1]. In addition, costs for the addition of supplementary systems are reduced, with accompanying advantages for the customer and the company [1].

It is important that the institution of an integrated management system should not be according to a single standard or degree, but rather always according to the individual requirements of the company. That the system finally complies with a standard is only one requirement among many [1].

The main objective of this article is to propose possibilities of integration

of documentation of parallel quality management systems built in a selected chemical laboratory.

To achieve this primary objective, the following partial goals were defined:

- Define the interrelationship of quality management systems used in the chemical laboratory (i.e. the interrelationship of standards of ISO 9000 series, GMP, GLP and ISO/IEC 17025).
- Map the simultaneously used quality management systems in the selected chemical laboratory.
- Assess the possibilities of integration of quality management systems in the selected chemical laboratory.

The targets thus identified will be achieved partly on the basis of literature research (analysis of literary data sources and the subsequent synthesis of established facts) and partly using results from primary researches undertaken in spring 2013. This qualitative survey was conducted in selected chemical laboratories that are parts of the chemical company.

Theory

The basic methodological guidance to help build the quality management system in the enterprise can be seen in ISO 9000 series of standards. It is a tool generally recognized, naturally expanding as it is standardly required by customers, according to Heras-Saizarbitoria and Boiral [4] "it should be taken into account that, by late 2010, over 1,100,000 ISO 9001 certificates had been authorized in a total of 178 countries all over the world" [4,8].

ISO 9000 series of standards are designed for a wide application in terms of the size of the organizations and their focus. Naveh and Marcus [9] classified ISO 9000 standards into two major categories based on their practical uses: ISO 9000 used in daily practices and ISO 9000 used as a catalyst for change [10]. It can also be used in a self-employed chemical laboratory. In the event that the chemical laboratory is a part of the enterprise, its activity is included in the corporate quality management system constructed on the basis of ISO 9000 series of standards. TQM, another commonly used concept for building a system of quality management, is not used in chemical laboratories, as it is too general in terms of processes taking place in the laboratory.

An enterprise quality management system based on ISO 9000 series predetermines the behavior and management of the organization, providing the general framework of operation of the company (i.e. also a self-employed laboratory) and the chemical laboratory as part of it. The chemical laboratory becomes part of the system that is based on a process model approach and structures 21 elements into 4 major sections: (1) management responsibility, (2)

resource management, (3) product realization and measurement, and (4) analysis and improvement. The chemical laboratory is affected by most of these requirements, which can bring about significant changes to it.

The introduction of ISO 9000 standards for the chemical laboratory means that its activities become part of the company-wide processes. This will also affect the way they are approached in the laboratory itself. Process management implies a preventive approach to improving quality and to the reduction of process variation [11,12], with the goal of maximizing resource efficiency and reducing waste [5].

After the introduction of QMS according to ISO 9001, the laboratory should be operated in accordance with the principles of this concept (guaranteeing maximum customer satisfaction and loyalty, or that of other stakeholders, creating an environment for continuous improvement and development in the organization and guaranteeing the two previous functions with the lowest possible consumption of resources). Requirements of ISO 9000 series of standards can also be considered a basis for the shape of documentation used by the chemical laboratory, they determine the statement of policy and objectives that affect the chemical laboratory, but also the quality manual, which can show processes taking place in the chemical laboratory or refer to them. Laboratory work will be affected not only by general recommendations concerning the content of the documented procedures and rules relating to the management of documents and records, but also by the requirements for establishing responsibility of the management, approach to planning in the business and management of resources. Recommendations are important to the chemical laboratory regarding not only human resources but also infrastructure that includes workspace and associated utilities. In terms of laboratory activities, important are the requirements of Chapter 7 of ISO 9001:2008 "Product Realization". Especially important are the requirements for processes related to the customer (in the case of performing analyses for the external customer, where it is necessary to properly define his/her wishes and requirements and perform the contract review) and also requirements for the purchase (which must also provide material for laboratory work) and requirements for the production and provision of services (including the requirement for defining control conditions). The chemistry lab is also significantly affected by the requirement of the ISO 9000 standard on the identification and traceability and control of monitoring and measuring equipment. Chapter Eight "Measurement, Analysis and Improvement" gives general guidance on the method of continuous improvement of any business process, i.e. including the processes taking place in the chemical laboratory.

ISO 9000 standards focus on process control instead of product control [13], and the revised version of ISO 9000:2008 requires companies to shift from a compliance attitude to an improvement attitude [14,15]. Therefore, their implementation helps set the criteria and methods for ensuring the effective

functioning of processes and activities carried out in the laboratory and establish mechanisms for continual improvement. ISO 9000:2008 forces plants to measure many things that they may not have previously measured. These metrics are useful in both finding and solving problems. Without a proper performance measurement system it is difficult to measure, manage, and hold people accountable for their actions. The importance of performance measurement cannot be stressed enough, as good performance measurement systems facilitate a better understanding of processes and products both internally and externally [2]. Continually improving customer satisfaction is a process of increasing effectiveness in fulfilling its quality policy and objectives [2].

Some of the requirements of the ISO 9000:2008 series have no direct impact in the chemical laboratory, because they do not affect its activities (for example, design and development validation or control of design and development changes). On the other hand, it is insufficient to apply only general concepts of quality management (ISO 9000) to assure quality of laboratory activities. Therefore, selected industry standards (GMP, GLP and ISO/IEC 17025) are applied in the chemical laboratory.

Industry standards have the following characteristics:

- they are not generic, i.e. they do not apply to all sectors, but only to one sector of the economy, for example to the pharmaceutical industry, food industry, automotive industry, telecommunications, etc.
- industry standards respect the ISO 9000 series of standards, often preserving their structure and requirements, adding additional requirements that go beyond the concept of the ISO 9000 series,
- they define specific requirements for quality management systems, based on the typical characteristics of the industry and are generally more demanding than the sets of requirements of the ISO 9000 series of standards. [16,17]

Good Manufacturing Practice (GMP) regulates pharmaceutics manufacturing and its associated quality control, GLP is a highly specialized mechanism for regulating testing and ISO/IEC 17025 include "General requirements for the competence and testing of calibration and testing laboratories". This standard is the internationally recognized basic document for accreditation of laboratories [18].

Good Manufacturing Practice, Good Laboratory Practice and ISO/IEC 17025:

- they copy some of the general principles of quality management based on the ISO 9000 series of standards,
- they duplicate some elements of the ISO 9000 series or partially overlap with them,
- they develop many of the elements of the ISO 9001:2008 series and
- they define other special requirements beyond the ISO 9000 series.

It can be stated that the above-mentioned industry standards used for quality management in the chemical laboratories refine the final shape defined by the ISO 9000 series of standards. Staff requirements can be given as an example. ISO 9001:2008 generally defines that the staff must be competent and therefore their competence must be determined and required training must be defined, efficiency must be evaluated and records of their education must be maintained. GMP partially doubles these requirements (requiring regular training conducted by qualified individuals, records must be kept for training and the training should be regularly assessed). In addition, however, it requires that an adequate number be allocated of staff with appropriate education, training and/or experience and also specifies the form of training — it must cover at least particular operations that the employee performs. Another example of the overlapping requirements of the ISO 9001:2008 standards and the development thereof by GMP can be traced in determining the responsibility for carrying out activities or in reviewing the quality of products, requirements for the technical equipment, for the contents of the documentation (records) but also for storage and packaging (which fulfil the requirement of identification and traceability in more details).

Generally speaking, unlike the ISO 9000 standards, GMP regulates in more details the stage of product realization, i.e. internal company processes directly and closely connected with the manufacturing process (GMP solves manufacturing processes, for example, after mixing batches, it specifies in detail the validation process of production and relatively in detail also the process of laboratory control). It also addresses in detail the quality of pre-production operations (including the requirements for contract manufacturers) and post-production (logistics) activities such as packing and storage. GMP, unlike the ISO 9000 standards, is not limited to the company itself but it also defines the requirements for other entities of the supply chain (for example distributors and haulage contractors).

GMP also presents special requirements that the ISO 9000 series do not contain, for example, there must be a quality control unit independent of the production (and defines responsibilities of the unit, which could be regarded as a specification of the requirements of ISO 9001:2008 for determining responsibilities) or there must be appointed authorized persons designated to release intermediates and active pharmaceutical ingredients. Special requirements are also, for example, those dealing with recovery of materials and solvents, personal care of staff, they regulate the work of consultants or special instructions for medicinal substances produced from cell cultures.

At first glance, GLP is the least comparable to the ISO 9000 series of standards. It should be implemented as a complete and separately used quality management system, just as GMP is. Good Laboratory Practice specifies the ISO 9000 series of standards as well as GMP in matters of laboratory activities; it contains specific requirements for laboratories. Good Laboratory Practice (GLP)

deals with the organization, process and conditions under which laboratory studies are planned, performed, monitored, recorded and reported. GLP data are intended to promote the quality and validity of test data [18]. It addresses in detail responsibilities, place and manner of executing individual studies and records including storing thereof concerning the study. Again, GLP specifies some requirements of the ISO 9000 series, for example the requirement to determine responsibility is here developed into a requirement to determine the responsibilities of the study director, it elaborates the requirements for the personnel carrying out laboratory activities and it also specifies the documentation requirements (core documents are standard operating procedures (SOP) and documentation relating to individual studies). According to Huber [18], the most significant difference between GMP a GLP is in archiving requirements for test samples and data. GLP addresses in great detail not only areas and spaces (both areas and spaces for test systems and areas for handling test and reference items, spaces for the storage of test items and space for filing) but also the requirements for used equipment, materials and reagents. Very important appear to be Chapters 8 and 9 of GLP that address the quality of laboratory work (being related to the execution of the study, including the requirements for planning the study, implementing the study as well as reports on the results of the study). These requirements can be considered a direct development of GMP, particularly its Chapter 11. Naturally, GLP has its own specific requirements, for example for waste disposal and biological test systems. GLP and GMP regulations have a significant impact on the daily operation of an analytical laboratory [18].

If testing and calibration laboratories comply with the requirements of ISO/IEC 17025, they will operate a quality management system for their testing and calibration activities that also meets the principles of ISO 9001. ISO/IEC 17025 covers technical competence requirements that are not covered by ISO 9001 [19]. A significant linkage to the ISO 9000 series of standards is evident also from a number of common elements. For example, Chapter 4.2 “Management System” clearly reproduces the requirements of ISO 9001:2008 (they both identically state the requirement for a quality manual, quality policy setting, overall objectives, and review of the management system and management's commitment to good professional practice). Comparable are also other requirements, for example those for documentation management, review of requests, tenders and contracts, improvements and corrective actions, internal audits and management reviews, some of which are adapted to laboratory activities (for example control of nonconforming testing and/or calibration work).

Some elements of ISO/IEC 17025 are also common to GMP and GLP, for example, all dealing with the reference materials. However, it can be said that the ISO/IEC 17025 standard is the most detailed set of requirements relating to the laboratory work quality. These requirements are based on ISO 9001:2008 and in terms of laboratory activities they specify both the GMP and GLP requirements.

Technical requirements of ISO/IEC 17025 mentioned in Chapter 5 can be considered the most detailed requirements for laboratory activities and their quality. They focus on factors that bear the highest share of the accuracy and reliability of the tests performed. They include:

- requirements for persons working in the laboratory,
- accommodation and environmental conditions,
- test and calibration methods and method validation,
- requirements for laboratory equipment,
- measurement traceability (calibration a testing requirements, reference standards and reference materials),
- requirements for sampling,
- handling of test and calibration items, and
- assuring the quality of test and calibration results.

Also, ISO/IEC 17025 includes specific requirements addressing, for example, documents changes or subcontracting of tests and calibrations. They also require specific records such as test reports, calibration certificates and amendments thereto.

In conclusion of this chapter, it is thus possible to sum up that the requirements of methodological guidelines used in chemical laboratories for building the quality management system bear a certain difference, but they are of such nature that they do not contradict integration of the systems.

Experimental

Activities of the chemical laboratory, in which the research was conducted, are divided into several categories, namely: research and development of analytical and control methods, analytical, toxicological and eco toxicological testing of chemical products and components of the environment for the needs of the company itself as well as those of external customers; expertise in the evaluation of chemical substances and products. The laboratory also performs analytical testing of chemical substances implemented within the actual manufacturing activities of the company.

The aim of the company, a part of which is the chemical laboratory, is to manufacture products and provide the results of research and development so as to optimally meet the needs and requirements of existing and future customers. The aim is to meet requirements for the scope of the research and manufacturing activities, compliance of the products and services provided with the specified parameters, reliability, product safety and quality, reasonable prices, meeting deadlines to deliver achievements, all with minimal impact on the environment. The means to achieve the objectives thus defined is the maximum utilization of

new scientific and technical knowledge, expertise and experience of the company's own employees as well as the experience of customers and suppliers [17].

The chemical laboratory operates in accordance with a number of quality management systems, namely an implemented quality management system according to ČSN EN ISO 9001:2009, according to the principles of Good Manufacturing Practice, Good Laboratory Practice as well as in accordance with the accreditation system using ISO/IEC 17025 standard.

At the company-wide level, ČSN EN ISO 9001:2009 is considered a basic regulation of quality management system. In accordance with its requirements, the company has defined main business and corporate goals. The defined objectives serve as a base for description of the quality management system which is captured in the Quality Manual. It also captures the processes identified within the quality management system. The processes in the company are divided into major and minor ones. For each of the processes there are criteria of effectiveness set in the Quality Manual, by which its accuracy, effectiveness and efficiency is assessed [17].

The quality management system within the enterprise is documented by three levels of controlled documents which are subject to the principles set out in the corporate organizational guidelines "Document and Quality Records Management". Documentation of the first layer is a Quality Manual as a top business document system. The Manual contains basic information about the company and form of QMS. It is used to demonstrate compliance of the established, employed and assessed quality system with requirements of ČSN EN ISO 9001:2008. It is intended for employees of the company accredited certification organization or clients of the firm. Documentation of the second layer consists of top and implementing organizational regulations of the quality system assigned to individual elements of the cited standard. The documentation of the second layer also includes the organizational directives of general management system and the company's system of organizational management acts that are generally obligatory for all the employees of the company. The third layer of the documentation consists of controlled documents with local application, i.e., technological documentation (operational guidelines, working practices, operating instructions, analytical control procedures and standard operating procedures). Other documents of the third layer are quality records (needed for effective planning, implementation, control and process improvement). This is a specific part of the quality management system documentation. It is used to demonstrate compliance with specified quality requirements.

The supreme document in the context of Good Manufacturing Practice as the second of the applied quality management systems is "Procedure for the Testing Laboratory under Good Manufacturing Practice". This document applies to all activities of the testing laboratory, regulating their course and being

mandatory for all workers of the testing laboratory. The established GMP-based quality system is designed so as to include all activities associated with the analysis. It defines the organizational structure, including the work environment, responsibilities, structure, documentation, procedures and resources necessary to execute the contract according to customer requirements [17].

The policy objective of the work environment and areas is to identify and manage physical factors, climatic conditions and concentration of raw materials used at work so as not to adversely affect the results of tests performed, to maintain the safety rules and the rules of confidentiality in relation to customers. The laboratory working environment includes the following: the spatial arrangement of laboratory workplaces, parameters of the environment, access to individual workplaces, maintenance of order in the workplace and occupational safety.

Laboratories have introduced metrology control and metrological confirmation rules in accordance with the standard ČSN EN ISO 10 012 (Measurement Management System), which also includes calibration and qualification of equipment, reference materials, identification, registration and labelling of equipment, troubleshooting and monitoring of measuring instruments purchase, maintenance, repair, storage of apparatuses, operating competence of the staff, metrological records, responsibilities and obligations in the field of metrology and continuity of apparatuses. The requirements are set out in document with title "Control of inspection measuring and test equipment". Each apparatus has its own folder and log. The testing laboratory carries out tests according to the Czech Pharmacopoeia (CP), as currently amended, or it uses its own procedures validated with reference to the CP or methods supplied by the customer. Laboratories have developed rules (i.e. SOP) to manage test procedures to suit the customer's needs so that it is suitable for the purpose. Each analytical method used for performing analyzes is validated or verified using statistical methods and conditions specified by SOP which are referred to in the Primary Document of GMP. The testing laboratory shall maintain "records of activities" that must be archived according to the rules of GMP [17].

Within the GMP-based quality management system, internal audits are conducted. They proceed according to an approved annual program. If any discrepancies are found, corrective actions are implemented that, depending on the seriousness, include: accountability for implementing corrective measures, analysis of the causes of discrepancies, choice and design of corrective measures, approval of corrective measures, execution of corrective measures, monitoring of corrective measures (examination of implementation and effectiveness), or realization of extraordinary internal audit.

Within the implementation of Good Laboratory Practice, the following functions were established in the enterprise for the testing workplaces: senior executive of the group, research worker, administrative and operational worker

and keeper of laboratory animals. Simultaneously, rules were established for obtaining a necessary qualification of the staff in individual posts and principles of work were set for the staff executing the studies, their duties and responsibilities. Workers are familiarized with these responsibilities at regular training.

Within the quality management system, based on the principles of Good Laboratory Practice, the following controlled documentation is used in the company's chemical laboratory:

- The primary document of GLP that summarizes information about the organization, deployment of centres and staffing of the test equipment.
- Methodological standard operating procedures that contain specific procedures by which the GLP test site carries out studies described in international guidance documents.
- General standard operating procedures that contain procedures for carrying out activities that are not specified in the study plans, in guidance documents, or methodological SOPs [17].

The company has its own SOP to secure a single documentation system of study results from raw data to the final report. It also establishes rules for archiving documents created within the GLP system.

The supreme document of the Accredited Testing Laboratory (ATL) according to ČSN EN ISO/IEC 17025 is the Quality Manual. The Manual defines the competencies of employees and resources necessary to perform their duties, including the implementation, maintenance and improvement of the quality management system. Within the ATL, these job positions are performed: the head of ATL, head of the research group, researcher, technical worker and administrative operating employee. Each job has its own specific requirements for the qualification set out in the Quality Manual. A specific role is the Quality Manager.

Technical requirements according to ČSN ISO/IEC 17025 (for the staff, their qualifications and training, work environment of the ATL such as laboratory equipment, environmental parameters, elimination of environmental problems, laboratory access control and cleaning) are described in the Quality Manual and are described in more detail in each SOP or other procedures.

A very important part of the quality management system based on ISO / IEC 17025 is the security of tests performed according to documented test procedures whose validity is confirmed by validation for the given conditions. To meet customer needs through accredited tests, standardized methods or the company's own procedures are used. Accurate procedures are developed for sampling and sample handling, referred to in the Quality Manual. At the same time, procedures are used in the ATL for reporting the results and work with the results of the tests, including their transmission.

Within the QMS, it is necessary to create and maintain an effective and documented system of management, confirmation and usage of the measuring equipment so as to prevent erroneous measurements. To this end, systematic metrology control is implemented in the laboratories.

The structure of the documentation Accredited Testing Laboratory of the company is divided into four levels:

Level 0
contains external documents such as laws, government regulations, ordinances, guidelines, system standards,
Level 1
contains the ATL Quality Manual,
Level 2
contains the organizational directives of the company (selected quality management system directives of the company and directives for the activities of the laboratories),
Level 3
contains methodological standards, test methods, documents for equipment operators and manuals.

The documentation contains records. They are divided in the Quality Manual according to ČSN EN ISO/IEC 17025 for professional records (laboratory records, order, book of samples, etc.), records of metrology, administrative and personnel records and records of quality.

The policy of document management presented in the Quality Manual according to ČSN EN ISO/IEC 17025 is clearly defined. Its aim is to create, maintain and manage the documented procedures relating to the quality management system, ensure the validity and up-to-dateness of the necessary documents at workplaces, and make changes in a controlled manner. Records with an exclusive status in the quality management system must be defined by rules regulating their formation, circulation and filing.

The quality management system according to ČSN EN ISO/IEC 17025 also includes internal audits. When performing internal audits, the strengths and weaknesses are assessed of the quality management system, followed by implementation of improvements and increase in efficiency. The objective of internal audits is to determine whether the QMS conforms to the requirements of the standard and is fully implemented in practice [17].

Discussion - Possibilities of Integration of Quality Management Systems Used in Chemical Laboratory

On the basis of the literature search and outcomes of the primary research, it can be concluded that the quality management systems used in chemical laboratories can be integrated into a coherent whole, which would cover the needs of quality management in the organization.

When integrating the systems, we first need to determine the degree of integration, i.e., how many of the systems used and which of them will be the subject of integration. In terms of building the integrated system it would be easiest to integrate only two selected systems. This, however, would not bring full benefits of integration and in principle it would be wasted effort. Therefore, it is highly desirable to integrate all quality management systems of the selected company (affecting the operation of the chemical laboratory).

Subsequently, we need to decide on the level of integration. The firm must reflect on the desirable level of integration between management systems. This level of integration can be represented as a continuum with two ends: a low integration level with two independent systems; and a full integration which implies the existence of a single system. Firms are usually situated somewhere between those two points, and show various degrees of integration [5]. Wilkinson and Dale [20] describe a four-level model. The first level "applies to individual management systems, where the system is integrated into every function and activity" of the organization. The second level is a combination of "systems based on the identified linkages between management systems". Documentation is combined and "integration into every function is still required". The third level "involves integrating selected parts" of management systems "with other certificated systems, but without using identified linkages". The fourth level "is to integrate both certificated and uncertificated systems with the overall management system", with the policies and objectives "aligned to and supporting the overall strategy, policy and objectives of the business" [20,21]. For full integration, systems lose their independence [5,22]. The level of integration of management systems is denoted by the degree of integration of the system goals, resources, and processes [3].

The next step is to define how requirements for sub-systems mutually go together, in what they are in accord and in what they differ. But it is important to note that integrating standards and integrating management systems are not the same [23]. It is probably more important and useful to focus on management systems and not only on standard requirements [5]. The newly identified (i.e., integrated) quality management then displays the new documentation pyramid.

Let us now consider two extreme possibilities of integration, i.e., integration of all systems (based on ISO 9001:2008, GMP, GLP and ISO/IEC 17025) within the first level and then integration of all systems (based on ISO 9001:2008, GMP,

GLP and ISO/IEC 17025) within the highest, fourth level, which leads to full integration with the loss of autonomy of the sub-systems. The main idea, which should be maintained in both cases, lies in the fact that the quality management system according to the ISO 9000 standards becomes fundamental, and this system incorporates requirements of the applied industry standards covering specific activities in our case of the chemical laboratory. It is also possible to use the experience of practical integration as carried by Bonk–Kassner *et al*. [1]: "Elements that could be treated in the same way or in very similar ways were easily integrated and could be represented in a uniform manner *via* similar standard operating procedures (SOPs), forms, uniformly valid chapters in quality manual, etc. The elements that were only present in a single guideline had to be assessed in order to decide whether it made sense to incorporate them in other field".

Integration within the first level is merely about reconciliation of levels of documentation, not reconciliation of the actual content of individual documents. In the first layer, we create a new manual of the integrated system, defining information about the content of the integrated system (i.e., defining what will be integrated and the basic philosophy of integration) in addition to the characteristics of the company. At this level of integration, it can basically be a direct composite of sub-manuals, which is especially useful for demonstrating compliance of the established system with the sub-systems (facilitating independent verification and certification of the system).

The second layer remains to be the layer of organizational directives. All organizational directives will be, in principle, grouped in preserved systems provided by the quality management sub-systems. By all means, they will correspond to references made in the manual of the integrated system. Similarly, the third layer of documentation is created, which will contain all the documents relating to the subject area, i.e., to the individual methods (technological and working practices, control plans, test procedures, operating procedures, procedures for packaging, instructions for maintenance and all records). There is no problem to create a fourth layer (which will be placed first as the zero layer), which will include external documents such as laws, government regulations, ordinances, guidelines, system standards, etc.

When striving for full integration of the systems, resulting in the loss of independence of individual systems, it is necessary to spend much more effort. Also, independent verification and certification process will be difficult. However, all the indisputable advantages described in the introduction to this article should be reached. In case of this level of integration, it will not be only about reconciling the documentation layers but also their internal contents. The manual of the integrated system could remain essentially the same as in the previous case. Integration of the content will be applied mostly to the lower layers of documentation. This causes that the integrated system can refer to the same

documents in meeting the requirements. They must be designed so as to clearly demonstrate compliance with the requirements of several methodological instructions.

In this form of integration of systems used in the chemical laboratory, it seems appropriate for the process map to identify all the processes that are specifically modified by the requirements of the industry standards, i.e., for example:

- Management of documentation and records of quality.
- Internal audits.
- Analytical quality control in each production.
- Purchase, storage and sale.
- Management of monitoring and measuring apparatuses.
- Maintenance of production equipment.
- Training of workers.
- Computer network administration.

This will form the basis for the design of organizational directives and documentation of the third layer.

When creating documentation of the second layer, we must proceed from organizational directives resulting from compliance with the requirements of the ISO 9000 series, as they provide the basis for the general operation of the company and its parts. It will also maintain the structure of this level of the documentation pyramid containing not only organizational directives, but also operational control acts. However, each organizational directive based on the ISO 9000 series must be reviewed with regard to the adequacy of compliance with the requirements of other methodological instructions. For example, GMP requirements as well as those of ISO/IEC 17025 are demanding in terms of metrology control and metrological confirmation. In such cases, we must either specify the directive or better still develop it further in the subsequent directive (this would create 4-layer documentation pyramid) or in a document which is then moved to the third layer of the documentation pyramid. Both variants are possible. There may, of course, arise a need to integrate a specific organizational directive into the organizational guidelines based on the ISO 9000 series. It would then be added to the present system of organizational directives.

It is also necessary to solve the problem of standard operating procedures that are part of the industry standards. For example, in the quality management system based on ISO/IEC 17025 they are placed into the second layer, but it follows from the logic of the documentation system in accordance with the ISO 9000 series that they should be placed into the third layer. Variants of the solution are as follows:

1. view them as a special form of organizational directives and place them into the second layer,

2. insert them is as concretization of a general organizational directive (to the newly formed layer of documentation) or
3. place them in the logic of the ISO 9000 series into the third layer of documentation.

Then it is necessary to carry out their internal harmonization to meet the requirements of all industry standards. For example, it is possible to integrate individual measurement and testing instructions or instrumental documentation in a single methodical process.

In the last layer of documentation there will then be further methodological standards, test methods, documents for equipment operators and manuals, as well as vital records that may (laboratory book) or may not (records of the laboratory activities), depending on their nature, be subject to integration. As in the previous design, the first-level documentation may be preceded by the zero-level documentation containing external documents.

Conclusion

Because so many elements in each individual quality system (on the basis of ISO 9001:2008, GMP, GLP and ISO/IEC 17025) are comparable, they can be fulfilled at once for all systems, avoiding double or multiple documentation. However, a specific form of the quality management system in a particular company is dependent on many factors, especially the line of business and size of the company. Nevertheless, integration of parallel quality management systems can reduce the volume of documentation of systems and, consequently, streamline and accelerate activities taking place in the chemical laboratory. A unified, coordinated "documentation is the key to finding the gaps in business processes, and we would not have done this without going through the registration process" [2]. For this reason with time, it can be expected that the number of companies which integrated their standardized management systems will increase [21].

References

[1] Bonk-Kassner Ch., Ehmann J., Gallhoff G., Moore D.S., Moos B., Siegemund B.: Accred. Qual. Assur. **2**, 285 (1997).
[2] Sroufe R., Curkovic S.: J. Oper. Manag. **26**, 503 (2008).
[3] Bernardo M., Casadesus M., Karapetrovic S., Heras I.: Int. J. Oper. Prod. Manage. **32**, 291 (2012).
[4] Heras-Saizarbitoria I., Boiral O.: Int. J. Manag. Rev. **15**, 47 (2013).
[5] Molina-Azorín J.F., Tarí J.J., Claver-Cortés E., López-Gamero M.D.: Int. J.

Manag. Rev. **11**, 197 (2009).
[6] Karapetrovic S., Willborn W.: The TQM Magazine **10**, 204 (1998).
[7] Viadiu F.M., Casadesu's Fa M., Heras-Saizarbitoria I.: Int. J. Oper. Prod. Manage. **26**, 141, (2006).
[8] *The ISO Survey of Certifications 2010*. [online], 2013, [cit. 2010-08-06]. Available from http://www.iso.org/iso/home/news_index/news_archive/news.htm?refid=Ref1491
[9] Naveh E., Marcus A.: J. Oper. Manag. **24**, 1 (2005).
[10] Prajogo D., Huo B., Han Z.: Supply Chain Manag. **17**, 306 (2012).
[11] Flynn B.B., Schroeder R.G., Sakakibara S.: Decis. Sci. **26**, 659 (1995).
[12] Kaynak H.: J. Oper. Manag. **21**, 405 (2003).
[13] Tsiotras G., Gotzamani K.: Int. J. Qual. Reliab. Manag. **13**, 64 (1996).
[14] Hoyle D.: *ISO 9000 Quality Systems Handbook – ISO 9000:2000 Version*, 4th edition Butterworth-Heinemann, Oxford, 2001.
[15] Nair A., Prajogo D.: Int. J. Prod. Res. **47**, 4545 (2009).
[16] Hutyra M.: *Quality Management* (in Czech), VŠB-Technical University of Ostrava, Ostrava, 2007.
[17] Markovič L.: *Quality Management Systems in Chemical Laboratories and Possibilities of their Integration* (in Czech), Diploma Thesis, University of Pardubice, Pardubice 2013. (in Czech)
[18] Ludwig Huber: A primer Good laboratory practice and current good manufacturing practice. [online], 2013, [cit. 2010-08-06]. Available from http://www.chem.agilent.com/Library/primers/Public/59886197.pdf
[19] ČSN EN ISO/IEC 17025:2005 General requirements for the competence of testing and calibration laboratories, Czech Standardization Institute, 2005.
[20] Wilkinson G, Dale B.: J. Eng. Manufacture **213**, 275 (1999).
[21] Bernardo M., Casadesus M., Karapetrovic S., Heras I.: J. Clean. Prod. **17**, 742 (2009).
[22] Wilkinson G., Dale, B.: Manag. Serv. Qual. **11**, 318 (2001).
[23] Karapetrovic S.: Meas. Bus. Excell. **7**, 4 (2003).