NATIONAL RESEARCH TOMSK POLYTECHNIC UNIVERSITY

Institute of Non-Destructive Testing COURSE OF GEP: Quality Management Department of Physical Methods of Non-Destructive Testing

MASTER'S DEGREE DISSERTATION

Theme of degree work
Improving of Internal Audit of Quality Management System of the Electric Company

Student				
Group	Name and Surname	Signature	Date	
1GM3I	Tomáš Jakubec		08.02.2016	

Scientific supervisor

Position	Name and Surname	Scientific Degree	Signature	Date
Associate Professor	Inna Plotnikova	PhD		08.02.2016

TO ALLOW TO THE PROTECTION:

Head of Department	Name and Surname	Scientific Degree	Signature	Date
Professor	Anatoly Surzhikov	DSc		08.02.2016

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Institute of Non-Destructive Testing COURSE OF GEP: Quality Management Department of Physical Methods of Non-Destructive Testing

APPROVE: Head of Department

Anatoly Surzhikov

ASSIGNMENT to execution of degree work

In form:

MASTER'S DEGREE DISSERTATION

Student

Group	Name and Surname		
1GM3I	Tomáš Jakubec		
Theme of the degree work:			
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Assignment was given by scientific supervisor:

Position	Name and Surname	Scientific Degree	Signature	Date
Associate professor	Inna Plotnikova	PhD		20.10.2014

Assignment was accepted by student:

Group	Name and Surname	Signature	Date
1GM3I	Tomáš Jakubec		20.10.2014

Abstract

The degree work is focused on the internal audit of the quality management system, especially then on the audit questionnaire, which is the useful tool for execution of the internal audits. Research object is a plant of light engineering LTD «Light of the 21st Century. Tomsk Plant of Light Engineering».

Keywords:

incandescent bulbs; audit; internal audit; standard ISO 9001:2008

Objectives:

According to the main goals of theoretical and practical parts was set the objectives, which will lead to successful fulfillment of the goals. After thorough analysis and consideration of the goals, we have defined the following objectives:

- 1) Collection, sorting, selection, study and evaluation the of the information sources.
- 2) Creation of the questionnaire draft and other necessary associated documentation.
- 3) Application of the questioner in-field during the standard operation.
- 4) Analysis of questioner and its evaluation.
- 5) Development of the process model.
- 6) Summarize benefits of using and of created documentation.

In the research process the organization can reach its aims by bringing a systematic approach to evaluate and improve the effectiveness of risk management and control processes.

Goals of the practical part were commissioned having regard to practical usage of the developed materials. After the discussion about the improvement of quality management systems in the organizations, we have decided to set the objectives of practical parts to following: Main point will be represented by creation of the Internal audit questionnaire, its evaluation based on factual information obtained by its practical usage in-field. Second part will be dedicated to creation of the process model based on the real in-field observations.

Economic efficiency of work is that the use of a questionnaire based on the methodology of quality management will identify and eliminate the causes of defective products, the consequence of this will result in a reduction of costs of improvement and replacement of the product, i.e. to reduce the "internal losses" of the enterprise, which, of course, will reduce the cost of products and increase competitiveness.

As a result of research the questionnaire of internal audit was developed.

In the future the questionnaire is planned to use to conduct an internal audit of any organization for the production of lighting products.

Foreword

We live in times in which quality represent the important factor of company success. Nowadays this aspect is not only the point of concurrence advantage, but it creates an essential border between success or a failure of the company in the competitive market environment. Therefore, it is necessary to monitor the quality on regular basis through the whole production process. It should be the matter of the whole company, because all people involved in realization of the final product can contribute to customer satisfaction. Quality management then should have the integral and inseparable function in the company. This function should connect all departments throughout the company to provide the customer with a product, which fully satisfy his requirements.

There are many tool, which can help us in monitoring of the quality. The most suitable for internal audit is the audit questionnaire. It provides us with detailed information about state of quality management system and thus the possibility for its improvement.

Acknowledgement

I would like to thank to all, who helped me to successfully complete this thesis, especially to my relatives for grammatical and factual correction, to my scientific advisor Plotnikova Inna, PhD, for her patience during consultations, provided feedback and valuable advices during thesis processing and least but not last to the management of the «Light of the 21st Century. Tomsk Plant of Light Engineering» company, where was realized practical part of my thesis.

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1 Introduction

Quality management represents the important and integral company function, which has the significant impact on the customer satisfaction. Nowadays, it creates the crucial border between success and failure of the company in the competitive environment of the market. The impact of the nonconforming product can seriously damage reputation of the company, its brand or in the extreme case send company into the bankrupt. In other words, despite the fact, that Quality management system is not the part of the company, which brings a gain to the company by direct way, it has the significant and irreplaceable role in organization structure.

One of the most important tools for the improvement of the organization's quality management system is an audit. Except the certification audit, which then entitles us to hold the certificate of proven company, and customer audit, which verifies the specific customer requirements, is most common form of the audits - Audit Internal. Internal audit is realized by a department of the quality management of the company or representative of this department. It improve the Quality management system by the continuous control of its function, submitting the remedial measures at the places of its failure or just a projection of its better performance. [1]

Audit questionnaire, as a tool for executing the internal audit, should be the integral part of the quality management system, fully integrated to the system documentation and in compliance with it. This document provide us with the information about the state of quality management system and through this gives us the opportunity to improve it.

Against all expectations, it is important to understand, that quality management system and its tools is and always will depend on the experiences, skills, liability and actions of the people, who are responsible for its functionality.

7

2 Value of internal audit is in perfection of control system of organization

2.1 General information about incandescent lamps

Incandescent lamps are light sources, which together with other lighting technologies constitute the majority of sources of light. We can meet with them in homes, offices, on the roads or simply wherever where is a need of stable and inexpensive lighting. Nowadays is this technology rather retreated from technologically newer light sources, as are halogen or LED bulbs [2].

Selection of the light source is determined by some basic criteria, that have the crucial importance for the customer. Among these most important criteria belongs: price, design, color of light, durability and quality of emitted light [2].

One of the most important criterion for selection of the light source is its durability, especially in areas, where is the often lamp replacement uncomfortable, hardly realizable or even impossible. The lifetime of the light source is the parameter which is measured in hours and depends on the technology of the light source. The average lifetime of standard incandescent bulbs is about 1000 working hours. However this time is also dependent on the number of on and off cycles [2].

Incandescent bulbs have a high quality of light and low production costs, on the other hand their disadvantage is very low energetic efficiency. That is also the reason, why they are gradually withdrawn from the sale. Incandescent lamps operate on the principle of thermal light emission. Electric current passes through a thin tungsten filament, which is heated until it emits the light. Conventional incandescent bulbs have usually a light color between 2300 and 2900 K, that's also the reason why they emit a typical "warm white" light. They have a continuous spectrum of light and high color rendering index (Ra = 100). The glass bulb protect the fiber before the oxygen, thereby destroying the fibers by oxidation. In the past the bulbs were vacuumed, but now they are usually filled with inert gas [2].

Incandescent bulb is a glass bulb, in which we can see thin tungsten filament. This filament is the most important part of the incandescent bulb. The filament is heated by passing electric current. The heated body then emits electromagnetic radiation. The color of the emitted light depends on the temperature of the body. We can observe, that the body initially emitted no light when it warms, we can feel just its heat. However the body emits electromagnetic radiation in the infrared spectrum. When the temperature of the body reaches approximately 600°C, its surface will seems to be red colored. Upon further heating approximately to 1300°C and more, light will be emitted. The composition of this light depends on the temperature of the body. It radiates the light of different wavelengths to the surroundings, but the wavelengths are not represented equally (they have a different intensity). This radiation is described by Planck's law. So inside the bulb is thus red-hot tungsten filament, which temperature is about 2500°C. Even if we can see just a white light, the Incandescent bulb emitted the light of all colors. Maximum radiation do not lie in the visible spectrum, but it is located in the infrared part of the specter. This radiation can be perceived as heat. Most of the energy is thus not emitted as light, but as a heat. Only about 5% of energy is converted on the light. [3-4].

2.1.1 History

Incandescent bulb is one of the few technical inventions, which serve the people for over a hundred years without any major modifications and retaining its original shape and function. Nevertheless, it was an incandescent bulb, which didn't find an equal opponent. Maybe it was the simplicity, elegance and sophisticated foresight of electricians, which helped it to became the queen of the light sources and guaranteed it a technical and social life for long decades [5].

It was on the First International Congress of Electrical engineering and Exhibition in Paris in 1881 after the introduction of electric arc, when the new electric light source "incandescent bulb" was discovered. It represent "a piece of the sun captured in a flask made from the glass". Unfortunately this discovery also

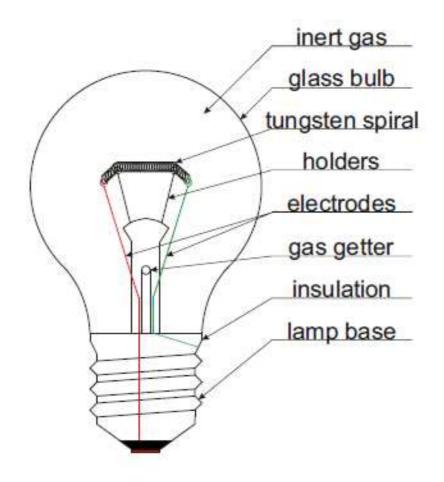
unleashed a wave of discussions, hopes, fears and protest against it. Gasworks with their current monopoly for lighting in fear about their clients and profits immediately launched a massive campaign against the electric light. However no campaign couldn't discourage engineers from their passion for electric light. Their scholarly inquiry journey has been long - lasted over half a century, but at the end it brought a fruit. The main person, which is today well known all over the world and which come first to our minds in conjunction with an incandescent bulb, is indisputably Thomas Alva Edison (1847-1931). He celebrated his longed-for success almost immediately, because he found an enthusiastic admirers and thus helped incandescent bulbs to find a way into the households of ordinary people. However, before applying of incandescent bulbs in households of ordinary people, the "artificial sun" shone in public institutions, offices, companies, shop windows and houses of wealthy people. [5].

Nowadays is the technology of incandescent bulbs slowly crowded out by more advanced technologies, such as fluorescent lamps and LED lamps [5].

2.1.2 Description

Incandescent bulb is composed of few parts. The first and visible from the first view is glass bulb. This glass bulb create a barrier between inert environment and surrounding of the bulb. It's because inside this glass bulb is an inert gas which protect the tungsten filament from the corrosion. Another visible part is lamp base. This base is connected with the glass bulb by special adhesive paste. On the surface of the base is evident screw-thread typical for electro technical purposes. On the bottom of these base is also an electrical contact for transmission of electrical power. However the most visible part, when the incandescent bulb is in operation, is tungsten spiral. Its tiny wire, which have high resistance. This wire is heated to high temperatures (up to several thousand degrees) by passing of electrical current through and emits lights. Tungsten spiral is centered in the middle of the glass bulb by using of holders. It's also connected with base by electrodes. Positive electrode - cathode is

connected with electro technical contact below the base and negative one - anode is brought simple to the base. On closer view, we can also see the inert gas getter, which is used to supply and fill the glass bulb by inert gas. The picture, which listed below, shows us an incandescent bulb with description of its main parts [6].



Pic. 1 - Scheme of incandescent bulb with descrip

2.1.3 Used materials

Since the early beginnings of incandescent bulb production, there were used many kind of materials for the filament. It was changed in 20th century after the discovery of tungsten. The filament is prepared according to the technology [6].

This kind of filaments can withstand temperatures up to 2480 degrees Celsius. The development of the tungsten filaments is considered to be the greatest advancement in light bulb production, because this production of filaments is really cheap and it can hold out longer than any of the previous materials. [6] The connection or lead-in wires are typically made of nickel-iron wire (called "du-met" because it is composite of two metals). This wire is dipped into a borax solution to make the wire more adherent to glass. The bulb itself is made of glass and contains a mixture of gases, usually argon and nitrogen, which increase the life of the filament. Air is pumped out of the bulb and replaced with the gases. A standardized base holds the entire assembly in place. The base, known as the "Edison screw base," was originally made of brass and insulated with gypsum, later, porcelain. Today, aluminum is used on the outside and glass is used to insulate the inside of the base, producing a stronger base [6].

2.1.4 Main parts

The uses of light bulbs range from street lights to automobile headlights to flashlights. For each use, the individual bulb differs in size and wattage, which determine the amount of light the bulb exudes (lumens). However, all incandescent light bulbs have the three basic parts—the filament, the bulb and the base. Originally produced by hand, the light bulb manufacture is now almost entirely automated. [6]

The tungsten filament is created by the process called "drawing". It's a procedure, in which it is mixed with a binder material and pulled through a die into a fine wire. Then the wire is wound around a metal bar called "mandrel" in order to mold it into its proper coiled shape, and then it is heated in a process known as "annealing". This process softens the wire and makes its structure more uniform. The mandrel is then dissolved in acid. The coiled filament is attached to the lead-in wires. The lead-in wires have hooks at their ends which are either pressed over the end of the filament or, in the case of larger bulbs, spot-welded. [6]

Usually the entire process of light bulb manufacturing is automated. The glass bulbs are blown by a ribbon machine, which can produce more than 50,000 bulbs every single hour. After the filament and holders are inserted into the bulb, the air inside the bulb is evacuated and an inert gas, which is typically represented by mixture of nitrogen and argon, is pumped in. After that, the base is mounted on. After heating in a furnace, a continuous ribbon of glass moves along a conveyor belt. Precisely aligned air nozzles blow the glass through holes in the conveyor belt into molds, creating the casings. After the casings are blown, they are cooled and then cut off of the ribbon mechine. Next, the inside of the bulb is coated with silica to remove the glare caused by a glowing, uncovered filament. The information about the product as are for example company mark and wattage are then stamped on the surface to the top of glass bulb [6].

The base of the bulb is also usually made from steel sheet by using of molds. It's construction is in the standardized shape of a screw and that's why can be easily fit into light socket [6].

2.2 Manufacturing process

Once the all main parts of incandescent bulb are constructed, they are put together by machines (pic.2).



Pic.2 Automat for connection of retorts

First step is mounting the filament to the stem assembly, with its ends clamped to the two lead-in wires. First step is mounting the filament to the stem assembly, with its ends clamped to the two lead-in wires.



Pic.3 Heating of socle of lamp

These gases protect the filament from the oxidation and thus guarantee it longer-life. Without the inert gas, the tungsten could evaporate and break. Typical for this process is presence of dark deposit on the glass known as "bulb-wall blackening". After that, the bulb can be seated into the base.



Pic.4 Soldering of socle of lamp

The base usually slides into the end of the glass bulb, such that no other material is needed to keep them together, or special adhesive paste can be used. Lead-in wires touching the aluminum base to ensure proper electrical contact.



Pic.5 Control of the prepared products

After control of functionality, bulbs are placed in their boxes and deported to its consumers.



Pic.6 Packing of the prepared products

3 Audit

3.1 History

The Institute of Internal Auditors Inc. (IIA) was originated in the USA In 1941, but the profession of Internal auditor seriously began to evolve in the US after World War II.

The theory of internal audit was designed primarily by Lawrence Sawyer, who is therefore often called "Father of modern internal audit". Since 2002 the value of internal audit was increased by the implementation of the Sarbanes-Oxley Act in the United States [7].

In June 1999 IIA agreed the Professional Practices Framework (PPF), which was considered one of the most significant document for internal auditing. Later, in 2006, after the revision of PPF, IIA have given International Professional Practices Framework (IPPF), which includes the most important documents such common principles and practices of auditing practice, specifically, the Definition of Internal Auditing, Code of Ethics, International Standards for the Professional Practice of Internal Auditing Recommendations for Practice, Practice tools and opinions. Nowadays the updated edition is released on every two years after the comment procedure [8].

3.2 Audits classification

There are many types of audits. Conventional classification is based on two points of view. First one is focused on the selection of committee, which carrying out the audit. The second one is then focused on a object of audit. Audits can be also classified by their scope or planning [9].

Audit's committee, can be internal, external or mediated by a certification authority.

Internal commission is set from internal employees. It usually means: person responsible for quality; higher management or managers of audited parts and other persons important for performing the audit. Internal audits, through the final reports, provide information about the current state of management systems, verify the effectiveness of the management system, ensure the detection of weak points in the tested processes and discover opportunities for improvement. [9]

In external audit, which is sometimes also called customer audit, is committee composed of customers employees or external experts paid by customer. Main objective of this kind of audit is to assess the reliability, quality and stability of supply. The conclusion of the audit may be an important or even crucial basis for selecting suppliers. (Nowadays supplier can usually proof his reliability by submitting the certification of its management systems issued by third independent organization. In that case is the external audit replaced by certification audit.) [9-10].

Certification audits are conducted by an independent accredited organization the "third side". The main purpose of these checks is the management system certification. [10]

There are many types of audits objects. For our purposes it will be sufficient, when I'll describe just basic kinds connected with quality management. These are system audit, processes audit, product audit and employee audit. Other kind of audits can be focused for example on projects, ecology, energies, finances, IT systems or others. [11]

The basic objective of system audits is to evaluate function of management system in the company. It verifies individual requirements of QMS especially their existence and applicability in practice. Usually it is realized by comparing the actual situation with the requirements of standards. Standards can be for example: ISO 9001, which is focused on quality management system; ISO 14001 - environmental management systems; OHSAS 18001 - safety management system and working conditions; respectively other standards according to requirement. [11]

We can also use combined audit, which means, that we are going to verify Integrated management system. These systems are composed of two or more parts, which are implemented in the organization and working together. For example we are verifying a quality management system according to ISO 9001 and environmental management system according to ISO 14001. If we are going to perform combined audit, we have to pay special attention to the competence of auditors during the compiling of audit team. [10-11]

When our audit is focused on processes, we monitor its eligibility, effectiveness or appropriateness of used procedures. It verifies procedures (working and production) in terms of compliance and effectiveness. Audit of this kind requires the presence of an expert from the branch (e.g. a technical expert) [10].

The content of product audit is to verify, that the product meets specified requirements (requirements defined by the customer, legislative requirements, technical regulations or others). It is possible to verify the functionality of the product, its safety, reliability or other its parameters [10].

Personnel audit verifies employees in order to increase their knowledge and working skills [10].

Classification of audits according to their scope include complex audit and partial reviews. As part of complex audit we verify and evaluate management systems within the entire company Complex audits occurs very rarely in practice, because of their time demands. We use them usually just when we are implementing new management system and need to know if single elements are in cooperation [10].

The partial audits serve us to examine specific activities in the appropriate department or its part. To verify the operational effectiveness of corrective measures we can initiate subsequent partial review, in which we verify only the effectiveness of the remedial measures set out in the previous review. Subsequent audit is one of the possibilities, which verify and evaluate the effectiveness of measures taken on the basis of recommendations from previous audits, because it examines only the activities or processes, in which were revealed major shortcomings and disagreements [10].

In terms of audit planning, we can divide audits into two groups: Planned audits, which are carried out on the basis of the audit program and extraordinary audits, which are held on the basis of sudden change, respectively immediate need to examine the behavior of the process control system, etc. They are realized for example on the basis: sudden changes in product or services quality; upon the occurrence of major or repeated customer complaints; after extensive organizational changes; after the introduction of a new information system; or after the crucial changes in the product portfolio [10].

3.3 Internal audit

3.3.1 Description

Internal audits, as we have already said before, are conducted by internal company employees or very rarely by engaging of external person. Internal audits tend to have their usual course. Everything usually starts with formation of audit schedule, which is usually prepared by the Quality Manager every single year. In smaller organizations, it is reasonable to do one internal audit per year, but larger companies tend to divide audits into sections, which don't disturb operation of the company too much. It's mainly because of audits doesn't require only the time of auditors but also audited persons. [12]

From the definition of internal audit given by The Institute of Internal Auditors (IIA), Internal auditing is "an independent, objective assurance and consulting activity designed to add value and improve an organization's operations. It helps an organization accomplish its objectives by bringing a systematic, disciplined approach to evaluate and improve the effectiveness of risk management, control, and governance processes". [1]

3.3.2 Purpose of the audit

Company management needs factual information for planning its activities and management. This information about the operation of the company can be obtained from internal audits, which provide a systematic analysis of objective facts documented in form of audit report. A team of independent auditors should guarantee, that handover record from the review won't be distorted. It should also guarantee, that presented information won't be filtered or modified at the management levels. The control of implementation and effectiveness of corrective measures is also ensured by the management if management system audits are performed correctly. The results of internal audit are considered to be inputs for further improvement of the management system, its processes and products. Internal auditors should proactively work in conjunction with audited persons to identify all problems and submit their solutions. [12]

Internal audit is, in most of the cases, implemented by internal company employees. It should contribute to the stabilization of control system and search opportunities for further improvement. The internal audit usually focuses on individual parts of the system (processes, products, etc.). [12]

3.3.3 Audit objectives

Audits are considered to be one of the most effective tools for implementing, updating and further improvement of management systems. Their basic goal is to verify compliance of the implemented management system according to standards. The outcome of the audit is report about the state of the reviewed area, thus evaluation of the management system and confirmation of its compliance with the requirements of the standard. Otherwise, the nonconformity is described and suggestions for its solution are submitted to ensure the improvement and the acceptance of corrective and preventive actions. [12]

Due to ensure the objectivity of the information, it cannot be allowed to perform the internal audit by the department leaders of the reviewed areas, who are directly responsible for the running of the departments. Audit is conducted by a team of qualified auditors, who works on the others than reviewed workplaces, i.e. They are not directly responsible for the activity under review. For large companies, it is preferable to carry out audits by employees with the same job description, but e.g. from another branch of the company. [12] To increase the efficiency of internal audits (at least in their early stages, when it is necessary to clarify the meaning of the audits and demonstrate their importance) should management representatives participate in these audits. [12]

Specific objectives of the audit have to be chosen by the client of the audit. A typical goals of auditors during the audit are [12]:

• To demonstrate the compliance rate, respectively. its disagreement for every single element of management system with the specified requirements ,which is usually represented by one of the standards, as are: ISO 9001, ISO 14001, OHSAS 18001, or others.

• To verify the effectiveness of applied management system, that can be represented for e.g. by achieving the quality objectives, fulfillment of customer requirements)

• To determine the current status of the management system, respectively to demonstrate its continual improvement (to provide a clear formulation of nonconformity and prove the status by objective evidence)

• Check the fulfillment of the requirements of technical and legislative regulations.

• Assess the readiness of management system for the certification by auditors of certification company (confirmation from practice, that documented management system meets all of the standard requirements and is applied to processes)

In addition to objectives listed above, the client can choose other specific objectives, as are for e.g. Verification of implementation of the newly established information system, implementation of new production technology and so on. [12]

3.3.4 Characteristics

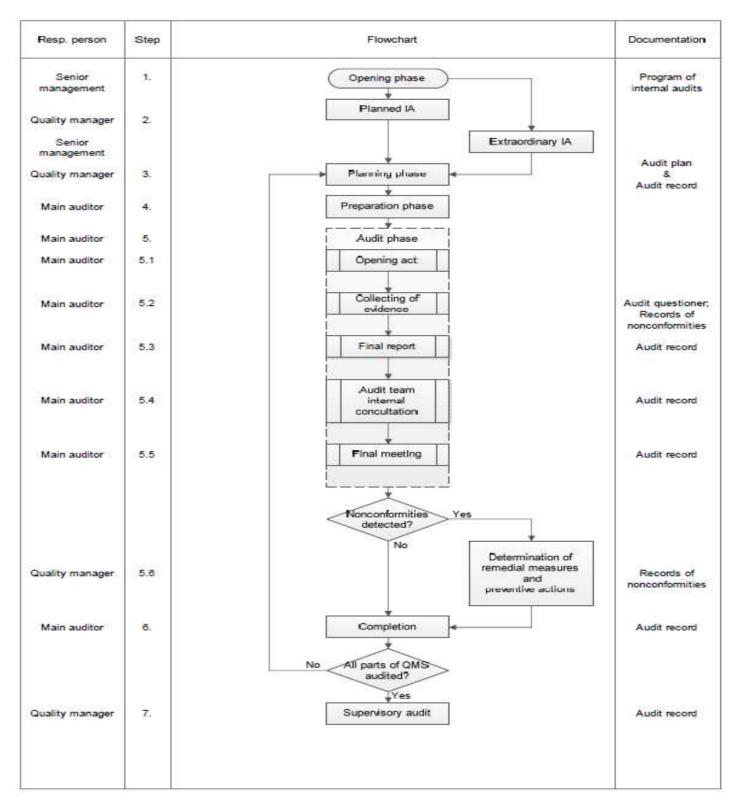
Main characteristics of processes and procedures for conducting internal audits are:

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- Internal audit verifies compliance of examined processes and their activities with documented procedures and requirements of the standard.
- Internal audit provides a permanent overview of the development, implementation, maintenance and improvement of the QMS in all departments of the company, whose activities could affect the quality assurance and the basis for continuous improvement.
- Internal audit is compulsory documented procedure, which is performed according to plan of Internal Audits, which is also recorded.
- Any findings always have to be recorded and additionally noted that are in accordance with appropriate documented procedure or are a nonconformities. In case of nonconformity it have to be clearly identified and found out the cause of this nonconformity.
- Corrective action are suggested by the person responsible for the element of QMS (process, activity)
- The audit validates the implementation of measures arising from previous audits
- Audit have to be performed by a person who is independent on the activities of examined persons [12]

3.3.5 The procedure of audit

The audit process usually has its characteristic course. First initial phase is Opening of the audit; it is followed by Audit planning; Preparation for the audit; The audit itself; Documentation of audit process and audit results; Completion of Audit; and Subsequent supervisory audit. [13]



Pic. 7 Scheme of audit flowchart with assigned responsible person and documentation

This are main phases, that can be subsequently divided into semi-phases. The additional classification of semi-phases will be mentioned during the description of individual parts. Let's look at each part in detail now.

First and initial phase of the audit is Opening. This phase is really important, because during it are designated objectives of the audit; its scope; frequency and intensity. [13]

Initial phase is usually followed by phase of planning. We should determine the specific dates and responsible persons - the auditors. Objectives of the audit are then assigned among single auditors. Allocation of the objectives should respect their skills, trainings and practical experience. Requirements for reviewed people should be also distributed in this phase to give them time for the preparations. [13]

Next phase is preparation for audit. In this phase we should study documentation provided by the company, get familiar with results of the previous audits, create a binding plan of audit and its time schedule, distribute tasks in a team (master auditor, senior auditor, minutes clerk, auditors experts). Questionnaire for audit should be also prepared in this phase. [13]

After all of this pre-phases follows the Audit itself. This phase is usually performed according to the conventional model and has some characteristic parts. First of them is opening act, which should be proportional to the size of audit. Then follows collecting of the evidence about documented procedures; responsibilities, competences and authorities; condition and suitability of equipment; and document management. All findings are usually discussed immediately right on the place during this part. After that they are evaluated and written down. All the findings are then consulted within the audit team. [13]

Now it would be appropriate to briefly mention how the collecting of evidence is realized. By the term of collecting evidence is meant, in this case, documentation of the progress and outcome of the audit and finding reliable proofs for our documentation. Outcomes of this process are usually audit records, which registers noticed nonconformities in the course of the audit. They are supported by objective proofs; and audit report, which is an inseparable part of audit documentation and is processed by master auditor. Audit report conventionally includes: name of the checked area; identification information of audit (serial number, internal designation, type of audit and so on); date of the audit; content, purpose and scope of the audit; name of auditors; names of responsible workers of reviewed areas; audit results (findings supported by objective evidence); auditor's signature; signature of the leading person of reviewed area; signature of the master auditor; and, as every record, its accessibility, time and place of archiving. [13]

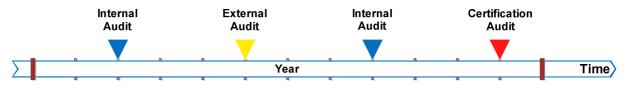
Next part is final meeting of master auditor or even the whole team of auditors with representative of senior management to thank for cooperation, summarize the objectives and scope of the audit, and finally to present all non-conformities supported by objective evidence. It's necessary to inform the representative of management, which activities or processes in the company weren't examined and state the reason why it was so. All questions of senior management representative relating to audit should be answered by relevant auditors and it should be agreed how the audit report will be distributed among all authorized person. Further on, there is only a formal farewell and meeting is over. [13]

Completion of audit is thus realized by the transmission of results from master auditor to management representative. [13]

The last phase is realization of subsequent supervisory audit. Main point of this phase is to check, if the responsible workers of reviewed areas submitted and implemented corrective measures, which led to improve the functionality of the system; quality objectives and requirements have been met; documentation of procedures, provision of resources, development, validation, verification, implementation, monitoring and testing have been ensured; to check records of evidence, which ensure processes and product requirements; to check procedures for proper clarification and understanding of customer requirements and to examination of its ability to meet product requirements (material, time and financial aspects); review of documented records; revision of customer communication and customer feedback; to ensure, that all changes of contracts and arrangements have been done accordingly to predetermined conditions. [13]

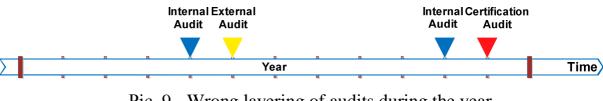
3.3.6 Audits layout

Further to classification of audits have to be noted, that audits should be properly planned and stratified in the course of time. Depending on number of audits we can speak about audits schedule during the year. Audits should be stratified equally in the course of time. Figure below shows the proper layering of audits during the year. [12-13]



Pic. 8 - Proper layering of audits during the year

It is unacceptable to establish the internal audits to be just a part of the preparation for external or certification audits. [12] [13]



Pic. 9 - Wrong layering of audits during the year

It's necessary to understand, that internal audits are equal to any other kinds of audits and their results provide the same options for improving the management system.

3.4 Auditors

3.4.1 Auditor's role in the organization

The internal auditors are persons not responsible for the management of the company. They are considered as advisory authority for higher management and the board of directors (or equivalent department of the company) to provide them with information, that are necessary for better performance of their duties.

3.4.2 Requirements for auditors

Given the wide scope of action, internal auditors should have high level of education and quality expertise. The requirements for the person of internal auditor are listed below. [14] Every auditor should:

- be independent, impartial, unprejudiced
- have necessary qualification, be well trained and experienced
- be well prepared for the audit
- be experienced in verified elements
- substantiate findings with objective evidence
- be a master in obtaining factual information
- know how to react in stressful situations
- know how to deal with people
- know how to manage time
- know how to generalize conclusions
- be persistent
- be ethical

3.4.3 The specifics of communication during the audit

It is usually not a really easy job to work as an internal auditor People are usually afraid of auditors and don't like them. It's mostly because they trust, that they are doing their job the best possible way and they are closed to make changes. Moreover audit is the process, in the course of which people of different education, character and position trying to assert and defend their views before others. That's why the internal auditor has to be a master of the communication with people, to get necessary information and stay in a friendly mood with them. He has to explain them, that changes could be positive and try to show them different possibilities of doing their job to found the optimal solution. He should ask questions in order to find out objective reality, but with honor to the counterparty at the same time. Only then we can find the understanding with others and improve the function of the system. [14]

3.5 Obtaining evidence

Records of nonconformities are the basic documentation which is used to describe problems. It provide us with a proof about nonconformity, give us a specific information about it and thereby providing us with material for improvement. To obtain the evidence auditors use various methods. From the conventional methods we can mention for example: interviews; testing; observation; comparison of data; or analysis of documentation. If we want to assign an order to obtaining of evidence , it is necessary to follow premeditated structure. Usually is this structure represented by an audit questionnaire. [15]

3.5.1 Audit Questioner

Audit questionnaire is a useful tool, which help us to follow the structure of the audit, don't forget for anything and know that main objectives have been met. It's also useful for verified people, who can prepare themselves according to specific points of the questioner. From auditor's point of view it's a preparation for discussions with verified persons. It should be customized to a specific audit, respect the scope and objectives of the audit. It have to be based on defined processes, which are subject of the audit. During the compilation of the questionnaire we should consider usage of existing quality records and other provided documents. And last but not least it provide us with necessary documentation from the audit. [15]

4 Standard ISO 9001:2008

4.1 Introduction

Due to the constantly increasing demands for the management systems in organizations, the International Organization for Standardization - ISO developed the quality management standard ISO 9000. Implementation of system according to this standard helps to identify and organize all the activities; clearly defined the responsibilities and competencies of individual workers; ensuring adequate levels of maintenance, machinery and equipment; choice of suppliers and number of other facts, which become a necessity for modern companies. [16]

4.2 Description

Standard ISO 9001 specifies requirements for a quality management system, which can organizations use for internal application, certification, or for contractual purposes with suppliers and customers. It addresses the usage of a process approach when developing, implementing and improving the effectiveness of the quality management system to enhance customer satisfaction by meeting their requirements. Application of process approach is a prerequisite for all companies, which want to introduce this system and counts with subsequent certification. The fundamental requirements, which companies have to accept is constantly monitoring and fulfilling of customer satisfaction and continuous improvement. [16-18]

4.3 Field of application

Quality management system, according to the requirements of this standard, is designed for companies of any size or focus. The ISO 9001 standard is not focused on any specific area of the business. This might include a manufacturing, sales, service, consulting company, but also educational institutions, medical facilities, government and many other fields. The Quality Management System is a very convenient tool for all companies that want to set up clear rules for their activities, to improve the functioning of processes, transparent operations and show the customer that he is a priority for the company. [18]

4.4 Compatibility with other standards

ISO 9001 is belongs to a family of international standards issued by the International Organization for Standardization - ISO. It is a standard designed for a Quality management system. ISO 9001 is highly compatible and easily combinable with standards, which will be mentioned below in next section. [17]

4.5 Related standards

Further ISO standards for management system in the organization are: ISO 10006 - Project Management System; series of ISO 14000 - Individual standards are aimed on different aspects of environmental protection in the organization; ISO 20000 - IT Service management; series of ISO 27000 - Information Security Management Systems (ISMS) standards; ISO 19439 - Enterprise integration; ISO / IEC 31000: 2009 - Risk management systems; EN 15221 - Facility Management; and others standards of ISO. Standard ISO 9001 is applicable in all sectors of the market. [17]

4.6 Integrated systems

Integrated Management System (IMS) is a system that links the requirements of two or more international standards of different areas as are for example the most common: Quality Management System (QMS); Environmental Management System (EMS); management system and occupational safety and health (HSMS) into one unit. The IMS is an important part of the overall management system of the company. IMS in comparison with three isolated - single operating systems provides simplification and time savings. Furthermore, through the synergy it effect increases clarity and performance of the entire system. All standards forming the IMS share many common features and requirements, that's why interconnections is possible. This interconnection is evident especially in terms of organization, documentation and control. [19-20]

4.7 History

4.7.1 Beginnings of this standard

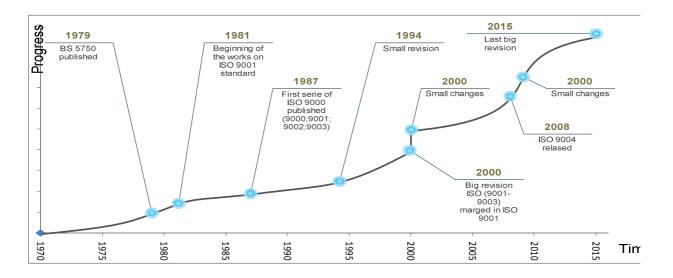
Interest about quality control rose after dramatic entry of new and technologically advanced Japanese products on the world market. Ensuring the quality of production was necessary guarantee, that the products will not be any hidden defects. [21]

In the eighties the International Organization for Standardization developed series of standards ISO 9000. These standards generalized the basic practices used by successful companies with a high level of management. Some of the national approaches were also taken into the account. [21]

In 1987, after 6 years of intensive work, through the Technical Committee TC 176 was released, the first version of standards for quality management systems ISO 9000, which was based on the British standard BS 5750 from 1979. This standard was immediately included into the national standardization systems worldwide in form of a basic series: requisite standards ISO 9001, 9002, 9003 and guidelines for choosing the appropriate ISO standard (ISO 9000) and guidelines (ISO 9004). These standards were using the defined terms from ISO 8402 - "Quality management and quality assurance - Dictionary ". Within a few years, virtually all industrialized countries took over this standard into their national systems, whether its national or new original title. [21]

4.7.2 Previous releases

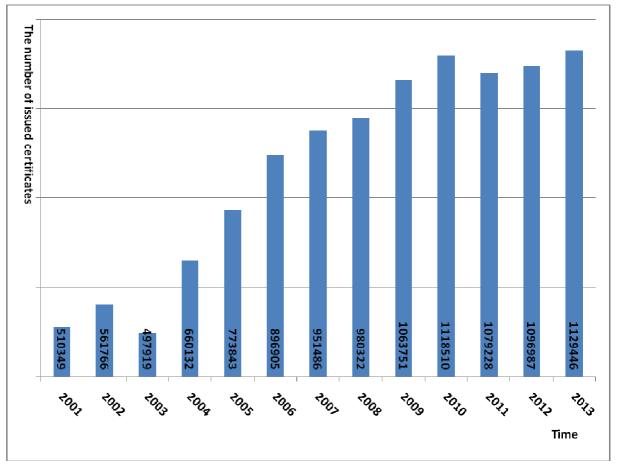
All standards have undergone two significant revisions during its existence. As was said before, in previous chapter, first ISO standard of 9000 series was based on the British standard BS 5750 from year 1979. It was published in 1987 and consist of 4 parts: ISO 9000; ISO 9001 - Model for quality assurance in design, development, production, installation, and servicing; ISO 9002 - Model for quality assurance in production, installation, and servicing; and ISO 9003 - Model for quality assurance in final inspection and test. Then in year 1994 there was a "Small revisions", which added many amendments. Second revision the "Big revision" was completed in 2000 by issuing new standards ISO 9001. Then in 2008 was released standard ISO 9004. I will describe last big revision of ISO standard which took place in 2015. The following figure shows clearly the evolution of standards ISO series 9000 in time. [22-24]



Pic.10 - Evolution of standards ISO series 9000 in time

4.7.3 ISO 9001 Nowadays

After the development in time the standard of ISO 9001:2008 gained relatively stable form. A lot of companies saw the evident benefits of implementation of this standard and that was the reason for its massive expansion. Nowadays, this standard is implemented in more than 1.1 million of companies in more than 160 states all over the world. Graf listed below shows us the number of issued certificates in time. [25]



Pic. 11 - Number of issued certificates in time

4.7.4 ISO 9001:2015

ISO 9001 standard for quality management, is now subject to a review by body of ISO (International Organization for Standardization),due to new version of ISO 9001: 2015. Its publication is planned for September 2015. This eagerly awaited release of the revision will be an important standard since the release in 2000. Revision of ISO 9001 in the state of DIS (Draft International Standard) was officially released in early May 2014 for voting in committee ISO body. The next step was the publication of FDIS version (Final Draft International Standard) in November 2014 and the final publication of the revision of ISO 9001 version 2015 will be in September 2015. Transitional period for certified organizations for implementation and adoption of new requirements for ISO 9001 will begin after the publication of the standard i.e. from September 2015 and will last for three years. [26]

Major changes of new release are: increased emphasis on the importance of establishing a quality system for the organization and its customers; it's more focused on the results of improvement; greater emphasis is also placed on considering and evaluating risks in the implementation process; it's required to consider feedback from all stakeholders and processes, not only from customers; increasing of the senior management involvement; the revised structure is aligned with the standards of most other ISO management system standards and eases integration with other management systems; the standard is more designed for use in areas of public administration and services; the standard allows for greater flexibility in terms of the documentation set, which means, that the quality manual is no longer required. Standard is simply focused only on documented procedures. [27]

Even in the new version customer still remains the main objective for the organization. [26-27]

4.8 Main principles

Standard ISO 9000 is based on the eight principles of quality management, decisive especially for top management and applicable to any type of the company. The significance of these principles consist in their determination of global goals and tools for effective quality control, both in the formulation of objectives and in their own decision-making and operational control of all processes.[28-29] Mentioned principles are:

- Customer orientation
- Leadership and management of staff
- The involvement of employees
- System approach to management
- Continuous improvement
- Decisions based on facts
- Supplier relationships
- Process approach

4.8.1 Customer orientation

Satisfying customer needs and expectations have to be the driving force behind development of the company. Its satisfaction belongs to a top priority objectives of the company. All customer's requirements for quality of the product provided, contractual conditions, obligations and commitments of the customer have to be met. Compliance of the given terms is a part of the fundamental principles of the company. Each worker should know what the customer wants, or he could want, what the customer needs or might need, what else we can offer the customer and what can be done for it from the side of organizational department, to which this person belongs. Each employee has an obligation to look for ways to continually improve operations and procedures to preserve and to enhance existing competencies, in addition to providing the necessary quality and professional level of the products offered as well as their complexity. Every worker have to do everything, what belongs to its responsibility, for the customer satisfaction. Each delivery of the product to its destination should develop recommendations for new business. [30]

4.8.2 Leadership and management of staff

Human resources play a decisive role in the successful development of the organization, therefore the personnel management is one of its key activities. Quality of human resources and its development are crucial for the functioning of the organization. Work of human resources is therefore intended to lead to the high activity of human potential across the organization and influence the quality and structure of human resources by using set of available tools to match the increasing demands of an ever-changing environment of the organization. [31]

Management of the organization determines the unified purpose and direction of development. It should create and maintain an environment in which organizational employees would be able to fully commit to fulfilling their goals. [31]

4.8.3 The involvement of employees

It is more than obvious, that to achieve a quality, which satisfies the requirements and needs of the customer is possible only if quality becomes a matter of all persons, who are responsible for its assurance during the entire process - i.e. from the phase of marketing and market research through design, sourcing, supply, planning, development of processes, manufacturing, inspection, testing, commissioning, to technical assistance and maintenance. [32-33]

Personal commitment of employees and providing adequate amount of resources provide the company with efficiency and performance of the quality management system in details of downstream processes. [33]

It's important to realize, that: human factor is a strategic factor for the development of the organization; the quality management system involves all employees at all levels of management through the process of continuous improvement, gaining ideas, their evaluation and drafting measures for improvement; organization promotes and utilizes the ability of employees to benefit of the

organization and all stakeholders; Employees are involved in continuous education system and gaining awareness of the quality importance. [32-34]

4.8.4 System approach to management

Identifying, understanding and managing interrelated processes as a system contributes to the effectiveness and efficiency of the organization in achieving its appointed objectives. [35]

In every organization are held various processes, which may be: the production of specific products and their sales, service, claims solutions, design and development of these products, provision of specific services, etc. [35]

It is important to realize, that it's necessary to start with identifying the processes, which lead to the achievement of the objectives. These processes should be designed to achieve the planned objectives in the most efficient manner. Individual processes looks separately at first glance, when they appear, but it is necessary to realize, that they affecting each other with their inputs and outputs. These processes have to be comprehended as a complex. It's also important to realize, that they have an influence not only to their results, but also to the results of the whole organization. Of course, it's possible to evaluate these processes separately one by one, but it is also necessary to evaluate them as a complex. [35]

4.8.5 Continuous improvement

The principle of continuous improvement is the main "aimed" characteristic of the quality management system (QMS), built on the basis of ISO 9001. In other words, if this principle is not met by the system, then the system has not been implemented properly. [36]

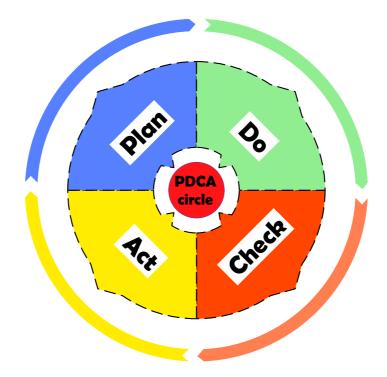
The principle of continuous improvement should inspire the company's management to the overall improvement and growth, which is the best represented by Deming's PDCA Circle. However this can only be achieved, if the company is able to fill consistently the Process control method - improvement of that kind have to be carried out already at the lowest segments of the system as are: the individual

processes; of individual workers; individual parts of the product. Only thus conceived system will be able to create a platform for continuous improvement [36-37], platform for:

- searching and elimination of reserves and wastage;
- measurement, analysis and improvement of efficiency of individual parts of the product realization;
- motivation and involvement of employees and teams to raise the performance and efficiency;
- constant improvement of the product (goods or service), and by thus long-term growth of customer satisfaction and faithfulness;
- application of progressive PDCA circle of continuous development and growth of the entire organization.

In order to achieve the main purpose of the system implementation - i.e. improvement of product quality and effectiveness of the whole organization, support processes and activities, which affect the overall performance and efficiency, have to be included in the platform of continuous improvement. [37] These include:

- management of human resources, involvement and motivation of the teams in order to increase efficiency;
- management of financial, information and logistics flows and activities;
- pre-production processes and activities (marketing research, strategy, tactics, planning, development, etc.); and
- subsequent processes and activities (especially services and care about the customer, analysis, feedback, etc.).;
- application of progressive PDCA circle of continuous improvement and growth of the entire organization; and
- infrastructure development



Pic. 12 - Deming's Plan-Do-Check-Act circle

4.8.6 Decisions based on facts

To manage the company and lead it to profit, senior management have to do effective and right decisions, which are based on facts. Logical and intuitive analysis of provided data and information is necessary. The most important facts includes: we should know the level of quality available to customers; we are able to measure the improvement only if we know the start position; right, correct and factual information for managing activities should be available to managers on all levels; decisions have to be based on these facts; process is a combination of methods, materials, labor and machinery, which results in a product or service; to achieve the quality we have to control the process and eliminate the variability. [38]

4.8.7 Supplier relationships

The organization and its suppliers are interdependent and a mutually beneficial relationship enhances the ability to create added value. [39]

4.8.8 Process approach

Combination of these two words means, that goals can be easily achieved, if the activities and related resources are managed as a process. Process management is a way of management processes within the organization, that emphasizes repetitive processes and their progress throughout the organization. Process management breaks the hierarchy caused by the organizational structure, in which is company divided into sections, departments or divisions and each organizational unit has its own responsibilities, activities and processes. Because if the organizational structure is too functionally oriented (i.e. each unit makes only its work), workers have a tendency to create barriers for processes (especially in the communication and in work transfer), which goes cross. This has a negative impact on the performance of the whole organization. [40]

Process managements priority is a process regardless of organizational structure. It also emphasizes the process customer (it does not matter whether the inner or external) and the person responsible for the whole process flow (i.e. owner of the process). This person is evaluated according to how well is the customer of the process satisfied. It also creates a simple and direct evaluation of effectiveness - if the process does not bring value to customers, or other processes, it should not exist. [40] [41]

Process approach helps improve the overall benefits especially for the customer and helps increase the overall efficiency of the company (by eliminating unnecessary processes or simplify them). [40]

Basic principles of process approach are [41] :

- Process management is used mainly for repeated and consistent processes.
- Each process has a customer
- Each process provides an added value to its customers.
- Each process can be measured with some metrics (quality outputs and other process metrics) and these can be translated into motivation system

- Each process has an owner (a person responsible for its entire course)
- All processes can be continuously improved

4.9 Structure

4.9.1 Parts

Standard ISO 9001 is divided into five elementary parts, which together form a comprehensive and arranged structure. [42]

First part, which is called "Quality management system" forms the outline for additional four parts. Outside of the introduction to the issue and general requirements are there also presented documentation requirements. [42-43]

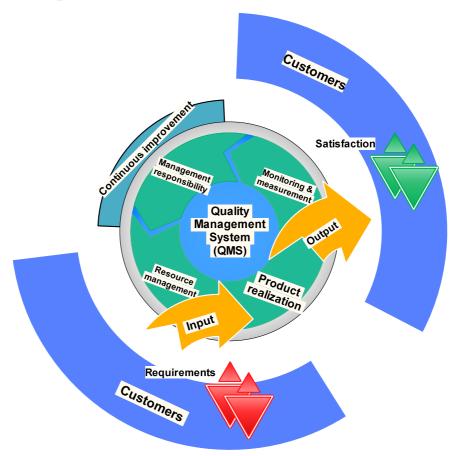
Second part from the hierarchical point of view is focused on the responsibility of management. It provide us with information about commitment of the management. Management undertakes, that it will: be actively involved in management of QMS; provide resources necessary for its proper functioning; will familiarize employees with the requirements of this standard and will take care of their observance, in order to ensure customer satisfaction; or will take any other actions prescribed in this chapter. The management should also inform the all company workers how important is fully satisfy the customer and ensure, that it is obvious from all the activities provided by the company. It should also create the policy of quality and plan of the strategic and tactical objectives. This formulated statements should be understandable, easily accessible and well known by all employees. Management is also responsible for allocation of responsibility, authority to solve tasks given and functional communication throughout the whole company. [43]

Next part is devoted to management of resources. It provide us with useful information about resources, its allocation, distribution and assignment. Kind of resources are described in subchapters. [42]

Subsequent chapter is focused on product. It provide us with important information about things necessary to its manufacturing; designing; and its improvement. It force us to select the activities which could affect the customer and secure them. As an example of this activities, we can mention services, manufacturing process, purchase of materials or goods, ensuring of usability and accuracy of equipment used for achieving the required parameters of company's products and others. [42-43]

Last chapter is focused on measurement, analysis and improvement of QMS. It provide us with overall view; specific view on monitoring and measurement of product; its control and identification of nonconforming product; principles of obtained data analysis; and improvement based on facts. [42-43]

Model of Quality management system in the figure shown below illustrates the link between the parts.



Pic. 13 - Model of ISO 9001: 2008 Quality Management System

It is obvious that the customer plays an important role in defining requirements and inputs. Monitoring of customer satisfaction requires the evaluation of information on how the customer perceives whether the organization complied with its requirements. Therefore, the acceptance of quality management system should be a strategic decision of the whole organization. [42-43]

4.9.2 Chapters

Individual parts are assigned to the chapters in this standard. Below is a list of the chapters of this standard. [42-43]

- 1.0 <u>Scope</u>
- 2.0 <u>Normative references</u>
- 3.0 Terms and definitions
- 4.0 Quality Management System (QMS)
- 4.1 General requirements
- 4.2 Documentation requirements

5.0 Management responsibility

- 5.1 Management commitment
- 5.2 Customer focus
- 5.3 Quality policy
- 5.4 Planning
- 5.5 Responsibility, authority and communication
- 5.6 Management review

6.0 <u>Resource management</u>

- 6.1 Provision of resources
- 6.2 Human resources
- 6.3 Work environment

7.0 **Product realization**

- 7.1 Planning of product realization
- 7.2 Customer-related processes

- 7.3 Design and development
- 7.4 Purchasing
- 7.5 Production and service provision
- 7.6 Control of monitoring and measuring equipment

8.0 Measurement, analysis and improvement

- 8.1 General
- 8.2 Monitoring and measurement
- 8.3 Control of nonconforming product
- 8.4 Analysis of data
- 8.5 Improvement

4.10 Requirements

Any organization, which wants to have working quality management system must establish, document, implement and maintain a quality management system and continually improve its effectiveness in accordance with the requirements of this international standard. Therefore it have to: identify the processes necessary for the quality management system and ensure their application throughout the organization; determine the sequence of these processes and mutual interaction between them; determine the criteria and methods needed to ensure the efficient operation and management of these processes; ensure the availability of resources and information necessary for the operation and monitoring of these processes; to monitor, measure and analyze these processes; implement any actions necessary to achieve planned results and continual improvement of these processes [42-44].

4.11 Function

Function of this standard is to set up the standardized order in the company; standardize all processes and optimize them; improve the quality of products and services provided by company and thus customer satisfaction; establish precise documentation system; lead the company towards continuous improvement; provide the company potential for further development; and to be a well-functioning company in general [44].

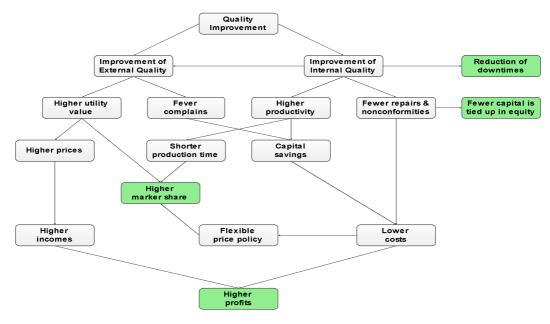
4.12 Benefits

Implementing of this standard will bring the company benefits in form of [16-18]:

- possibility of providing services even for the most demanding customers and the opportunity to gain new customers thanks to the view of increasing company's present customers satisfaction;
- opportunity to participate in tenders of large scales, particularly in public administration;
- efficiently set up processes to increase sales, profit and market share and thereby increase the satisfaction of owners, shareholders;
- demonstration of commitment to meet legal and regulatory requirements;
- guarantee of manufacturing process constancy and thus a stable and highquality services and products to customers;
- demonstration of suitability, efficiency and effectiveness of the quality management system by an independent third person;
- improvement of the management system and the organizational structure of the organization;
- improvement of order and increase efficiency throughout the organization;
- optimization of costs reduction of in operating costs, reduction of cost for nonconforming products, savings in raw materials, energy and other resources;
- increase in confidence of public and state control bodies; limitation of reclamations and thus costs arising from nonconformities findings
- better internal communication

• creation of self-controlling system responding flexibly to changes in customer requirements, legislative requirements and changes within the organization (eg. implementation of new technologies, organizational changes, etc.).

Next picture show us, how important are the quality improvements and which benefits will bring it to our company.



Pic. 14 - Benefits of quality improvements

4.13 Certification according to this standard

Certification according to standard ISO 9001 is focused on quality management systems, and is applicable to any organization in all areas of production or services. Nowadays it represents a globally used standard, of which introduction is the basis for the application of additional requirements on company management systems. [18]

A certificate issued by an independent accredited certification authority guarantees, that the quality management system is implemented, documented and used in accordance with the requirements of ISO 9001 [16].

Certification by an accredited certification authority conventionally takes place in several steps. First of them is assessment and registration of client's application for certification by a certification authority. Next step is signing a contract about performance of the certification audit (certification audit usually take place in two stages). Then the certification company will compile the audit team, which will process the audit plan. This is followed by a certification audit, in which are facts verifying in stages of reviewing the client's documentation and verifying facts in place. On the base of obtained facts is formulated a report of the results of certification audit. Next step is assessment of the audit report by certifying authority. And in the case, if all conditions are met, this authority will decide about issuance of certificate [16-18].

The supervisory audit takes place once a year during a three-year period of certificate validity. In relation with the results of supervisory audit is made a decision about the renewal of the certificate to next supervisory audit or about the suspension of the certificate. Finding of fundamental deviations from requirements of standard may results to extreme measures - withdrawal of the certificate [18].

5 Practical part

Practical part will describe everything, what was necessary to do during the competition of my thesis. All works, which was done will be presented in individual chapters and all notes and comments will be discussed, analyzed and evaluated. I divided it into three parts: First part describes everything, what preceded the audit - preparations, creation of documents, which include: audit questioner, audit map according to the standard ISO 9001:2008, record list from internal audit, record of nonconformity and the sample of process documentation. The second part describes the performance of the audit. It consists of 5 Phases - Opening phase, Planning phase, Preparation phase, Phase of auditing and Audit completion. All specifics of each phase will be described later in them. And finally the last part, which forms the finale of my work, will evaluate the current state of the organization and will give the advice to the quality manager or to the management of the organization.

5.1 Preparations

This phase was the initial phase of the whole process. Our task was to plan the whole process and to make the schedule for our future work. It's necessary to understand, that we had not to plan only the process of the audit, but also everything, what had to be realized before its beginning. So we started with creation of schedule, which describe all steps going one after another. This steps formed the first structure of our work. Without this, our work would have no system and its realization would be both time and resources increased. We considered that before the audit its necessary to create proper documentation, which will help us to fulfill in completion of audits objectives, create orientation audit time schedule and least but not last form the objectives of our audit. After that we will be ready to proceed to the next phase, which is already the audit itself.

5.2 Creation of documents

First of all we had to prepare the necessary documents, which will help us to complete the audit. Most of this documents is usual parts of internal audits documentation and create the outline for performing the audit. Their right creation is essential not just only for the right performance of the audit, but also for the proper record keeping in the organization as a whole. Without the predefined system of record keeping, there should be the disorder in documentation and thus chaos in the whole organization. Documentation should be brief and concise, written in formal language, without any unnecessary information, but mainly understandable for the other people.

After the process of brainstorming, we decided to create following documents: audit questioner, map of audit, internal audit record list, list of found nonconformity and the sample of process documentation. Let's describe now the individual parts of the documentation in detail.

5.2.1 Audit questioner

Although the audit questionnaire is not a obligatory part of company documentation, it is useful tool for audit execution, because it helps to maintain a uniformity of documentation, follow the predefined structure of the audit, don't forget for anything and know that main objectives have been met. During the completion of my questioner for internal audit of quality management system I tried to customize it to a specific kind of audit and respect the scope and objectives of the audit. I created two version of audit questioner. First one is more suitable for printing, the second one then for completion by using a computer, but in principle, they carry the common elements and are freely transferable among themselves. Let's now discuss the individual parts of the questioner.

The first column provides the association with the relevant part of the standard by numbering of chapters and its points. This link is very important, because

of easy orientation, comparison and knowing, that all requirements of the standard specified in given point have been met.

Next column is dedicated to check marking of the individual points of the standard. It provide us with visible and evident confirmation, that given point have been met. As we can see, the check marks are not spaced evenly. It's from the reason of better orientation in hierarchical structure of the questioner. Marks that are closer to the left side of the cell are considered to be hierarchically superior to the marks closer to the right side.

Then follows the questioner requirements which are based on the requirements of the standard ISO 9001:2008. These requirements have to be form properly. It couldn't be just the simple copies of the texts of the standard, because of the act of copyright, but the main idea have to be the same due to clearly formulated requirements, which are then required by the auditors.

Requirements are followed by the space designated to notes. This notes should include all information about nonconformities if they were found. In other words, they are compatible with the description of nonconformity in Record of nonconformity. It also serves as a space for notes of auditors. This notes can consist of questions for verified persons, senior management representative or notes intended to be discussed at the final meeting of auditors.

The last columns are dedicated to scoring. First of these columns specify the maximum amount of points, which can be obtained during the audit. The second row is intended for scoring granted by the auditor. In this moment we should mention, that if there is more than one auditor it means especially in audits of the big scope, the auditors should be equal in awarding points. This awarding system should be standardized to prevent inconsistencies or even different scoring. It is extremely unacceptable to choose the auditors just in order to maximize the awarded score. This act is not only the example of dishonesty, but even the crucial misunderstanding of the entire audits significance. Last column, which is visible only in the version

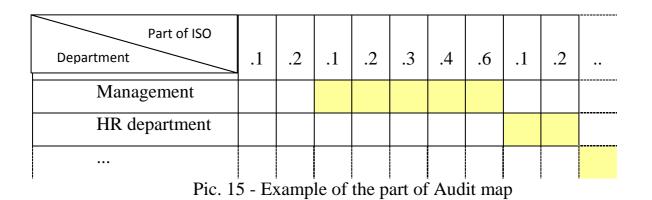
designed for computer is dedicated to percentage of the score obtained during the audit relative to maximum amount possible.

In the individual rows are then described the requirements of standard ISO 9001:2008. For the better orientation in questioner I divided individual chapters by the color markings. Green color symbolize the chapters, red color is dedicated to points of the standard and mandarin color represent the sub-points. Under these categories are then listed the requirements of the standard.

This document is as an essential part of my thesis listed in the annexes folder.

5.2.2 Audit map

Audit map is the useful tolls for execution of the audit . It helps auditors to save time during the audit by creating the structure of the audit. This structure provide auditors with system, helps them to divide the work through the audit team and can be also used as a checklist for planned system revisions. Example of the part of Audit map is listed below.



As you can see on the example given above, form of this document is uncomplicated and clear. The departments of the company, processes or parts are given in left column. The individual parts of the ISO 9001:2008 standard are given in upper row. Together they form L-shaped diagram. Cells then represent the necessity or un-necessity of verification of actual department. Necessity of verification is marked by color. Filling up of this colored cells symbolize the performance of the verification in given section. This filling can be represented by checkmark or, in better case, by the date of last revision, which will signalize us the necessity of the next revision after the given amount of time.

To better understanding of this document, I made a sample, which is enlisted in annexes.

5.2.3 Audit record

Audit record from the internal audit is the elementary part of the documentation. It provide us with general information about the audit and inform us about the state of quality management system in general.

In the baseline of this document should always be its name, that is necessary for its easy identification. Then follows the information about the audit. Number of the audit in internal company counting, its projected date and the area, which will be verified, are the basic information for identification its properties. After that comes the specific information about the audit.

I have included the persons, which will take part in audit process, at the first place into the notification. This persons are conventionally: Senior management representative, Quality management system representative, who represent the side of verified person and main auditor and other auditors, who represent the side of person authorized for verification. All this people should fill the form by their names and signatures. The date is also necessary for official documents. By the signing of this document all sides and its representatives demonstrate the intention of audit execution and accept the responsibility related to their role in audits execution.

Next part is dedicated to opening phase of the audit. Date, time and signatures of all participants of opening meeting give the basic information about this seance. In this point is good to mention, that persons participating in opening meeting have not strictly to be the same people, who are signed in notification. However in each case, there have to be at least one representative from verified side as well as the representative of side authorized for verification. Generally its better, when the main auditor and representative of companies quality system management are presented.

Following part provide us with the factually most important information from the audit, which is Total number of non-conformities identified during the audit. All of these nonconformities have to be proved by objective evidence. From the reasons of space saving and increasing of transparency are all information about the nonconformities and objective evidence related to it attached in special kind of document - The Record of nonconformity, which will be also described in next chapter. This document is unique and integral part of the Audit record.

The final meeting, which is the official part of audit phase, follows after that .The basic information about this phase are again date, time and signatures of all participants. As to the composition of the participants , we can principally apply the same rules as for the opening meeting. In this point are also mentioned all notes and questions from the representative of verification authorized side. Then the representative of verified side has the opportunity to respond all raised questions or if necessary complement any comments regarding the audit, its execution or authorized persons. All of these notes should be properly formed and documented in the place assigned to them.

If all questions raised from both sides are answered, the time for closuring of the audit will come. This phase is represented by handover of auditors final report from the side of representative of authorized side to the hands of organizations representative, which communicate the results of the audit to senior management or its representative. Most important information typical for this phase are: Signatures of authorized person side representative and company's side representative and dates of handover of the documentation.

For a better understanding I made and enclosed the example of this document as an annex.

5.2.4 Record of nonconformity

Records of nonconformity is a necessary part of documentation. Usually it's an annex of the Audit record, because of the space saving and increasing of transparency of this document. It provide us with information about the nonconformity and suggest the remedial measures. Knowing of this information and taking of the necessary actions usually leads to solution of the problem or improvement of the situation at least. In the baseline of this document should always be its name, that is necessary for its easy identification. Then follows the information about the nonconformity. Number of the audit in internal company counting, compatible with the number of audit record, number of the nonconformity and date of issue are the basic information, that identifies every nonconformity. Then follows the specific information about it.

Description of the nonconformity is naturally the first thing, which interest us. It should be brief and concise, written in formal language but mainly understandable for the other people. We should consider to which person is addressed and give all information necessary for finding remedial measures or elimination of nonconformity.

Next part is dedicated to description of point of nonconformity with the standard, regulation or et cetera. If it is possible we should give the full formulation of the point of the violation. Otherwise, the link for the relevant part of the standard or regulation will be sufficient. This link is usually represented by name of the standard or regulation, chapter, page and point of violation.

Then follows the initials of authorized person, who issued the record about the nonconformity, its signature, and date of issue. This privilege generally belongs to representative of authorized side, which means main auditor or auditor. It's conventionally followed by initials of person assuming the record of nonconformity and its signature. This is representative of company's side. It can be person responsible for non conforming process or representative of company's quality management system. The date of assumption is also stated.

After that follows planned remedial measures. It's necessary to mention, that remedial measures should be planned by person responsible for non conforming process or procedure, because this person should know the best, which remedial measures will lead to correction of nonconformity or its elimination. It should be written formally, briefly and concisely, but mainly understandable for people, who will take part in correction or elimination of nonconformity. Then follows name and signature of person, who imposed the responsibility for implementation of remedial measures to responsible person. Name and signature of responsible person is also attached. These information are complemented by a date of imposing and date of remedial measures inspection.

Before the date of inspection it's necessary to realize planned remedial measures, which means that responsible person alone, or in cooperation with other people, eliminate source of nonconformity. All realized remedial measures should be documented in predefined place of this document. This should be written formally, briefly and concisely, but mainly understandable for other people. Realization of remedial measures is confirmed by responsible person's signature. Date of realization is also stated.

Then follows the inspection of realized remedial measures. Verification of action taken is confirmed by signature of verifying person, who is conventionally the same person, who imposed the realization of remedial measures to responsible person. Otherwise the name of verifying person have to be mentioned as well.

Remaining space is reserved for the notes, that can clarify, specify or help in any other way to elimination of nonconformity.

For a better understanding I made and enclosed the example of this document as an annex.

5.2.5 Process documentation

Because of the most of the problem generally comes from a misunderstanding of the process approach, I consider essential to describe, how the proper process documentation should looks like. Firstly we should realize, that internal documentation should be written in formal language, properly formulated to prevent misunderstanding or dual interpretation. It should be also brief and include just the necessary and useful information about the process. Another important question is uniformity in time.

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In the baseline it should always be its name, that is necessary for its easy identification of this document. Then follows the name of the process and identification number, which is necessary for internal classification and faster orientation. It's good to mention, that planning of the identification numbering should be one of the first steps of documentation making. It should consider amount of documentation, its revisions, classification and other things that should have significant influence to it. It should be uniform enough to provide the integral and unifying structure, but also flexible for unplanned incoming changes.

Next important thing is main objective or objectives of the process. This part describes what are we expecting from the process and that's why it's really important, because if the result of the process is not consistent with the expectations, we can identify the problem. It should be properly and clearly formulated to eliminate misunderstanding or misinterpretation of this. Good question for proper formulation of the process objectives could also be: "What is the mission of this process?".

After that there should be given the name of person responsible for the process. This person should confirm, that it's aware of its responsibilities in their entirety and without any exception, by its signature.

Then follow the process requirements. These requirements contain both tangible and intangible items, which contribute to realization of process output. Requirements for the personnel are also contained in this part.

Next part describes the process input, wherein the input is represented by all things, which are consumed during the production of the output. It can be both tangible or intangible items. All of the input characteristics should be specified in measurable terms, in order to ensure its uniformity. In relation with process input it's also good to identify and write down the supplier of the process. This supplier should be represented by external subject or another process.

Then follows the description of the process course. This part describes all operations realized during the process. In the description, it is necessary to mention all quantified information in measurable terms. Especially times of individual steps, temperatures or amounts of necessary sources should be specified. Related to process course it's good to mention user/s of the process, who is/are represented by all persons, who assist during the course of the process. These persons are conventionally called not by their names, but in accordance to their working position.

Next part is dedicated to process output. It is represented by all things, which are produced during the consumption of inputs. Conventionally we take into the consideration only the things that we are going to use in another process or which represent the final product. Other are considered to be the waste. When we are describing the output, we should use measurable terms to provide the target values, which we want to reach. In relation with this part is also good to mention the process customer, which should be represented by external subject or another process. It should be identified, specified and written down in process documentation.

Next point, which contribute to proper process working are the criteria of the process effectiveness. They are always expressed in measurable terms and provide us with the information about the process behavior. They are usually connected to time, quality or production costs. We should monitor this criteria and try to find the optimal combination of factors to maximize required values and minimize losses and thus to optimize the process. They are based on the process objectives.

Then follows the documentation which is connected with the process. We can divide it into internal and external. Internal documentation is composed of all documents created and required by the company. It could be for example forms, records, tables or others. External documentation is represented by requirements of standards, laws, regulations or customer documentation.

Remaining space of the first page is reserved for the notes, that can clarify, specify or help in any other way to describe the process.

The second page is dedicated to process flowchart, which graphically represent the process course. This interpretation is understandable, clear and contribute to right interpretation of the process flow. It is described by standardized symbols, so it can be easily red and comprehended even by the people who don't know a lot about the process yet.

5.2.6 The Audit

After the accomplishment of all preparatory works and processes, we could proceed to the audit itself. Our intent was to try to follow the line predefined in theoretical part, but this ambition was not always possible to fill. We had to take into account the normal operation of the company and adapt to it. However, the company management was very friendly, cooperated with us and provided us with all necessary information, which we asked for.

5.3 Opening phase

First meeting was realized in a form of excursion through the company. It was an ideal opportunity to get to know with the environment of the company. The company presented us their portfolio of production, showed us the production processes and discussed all our questions. We could also discuss our question with the senior management representative and quality management representative. Our questions were directed in order to obtain necessary factual information about the organization structure, its processes and procedures. After that, we discussed and subsequently designated the audits objectives, its scope and intensity.

5.4 Planning phase

Planning phase was the integral part of the audit making. We planned the schedule of the audit with specific dates and times to ensure the all the conditions will be met with precision. Of course, we had to plan our schedule in accordance with opportunities of ordinary business operations. Against all settled conventions in selection and composition of audit team, the responsible person was represented by me. Thereby it were skipped the allocation of the objectives to the single auditors.

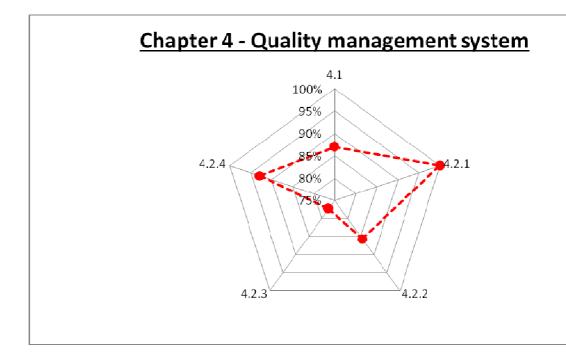
5.5 Preparation phase

During this phase we studied the documentation provided by the company. This documentation was represented by documented processes and procedures with all necessary description of its sequential relations and interactions, information about criteria and methods, which ensure that the operation and control of these processes are effectively determined, and others. Further statements of a quality objective and quality policy of the company, quality manual, various kind of records, results of the previous audits and so on. We also created the final binding plan of audit and its time schedule.

5.6 Audit phase

The culmination of preparations mentioned before was the execution of the internal audit. This phase was realized by another meeting with the quality management representative, who show us the production process once again in details. With its help we filled up the audit questionnaire and other associated documentation to confirm its suitability. We also made a photographic documentation for later usage. Filling out of the questionnaire was realized by the allocation of points to the column of scoring part dedicated to obtained points. In the case that full amount of points was not awarded, we also state the reason for it in the part of notes. Whereas we have been filling up the version designated for PC, we got the percentage of fulfillment of the standard requirements, after the allocation of points. On the base of this score was created the graphs for the fulfillment of the standard ISO 9001:2008 for its individual chapters and overall quality management system of the company. The area within the curve represents the level of conformity between the standard and the real situation. The larger the area, the better are then requirements of the standard fulfilled. The completed questionnaire with associated graphs is included in the folder with attachments. Let's now briefly discuss the results of the audit and describe the graphs.

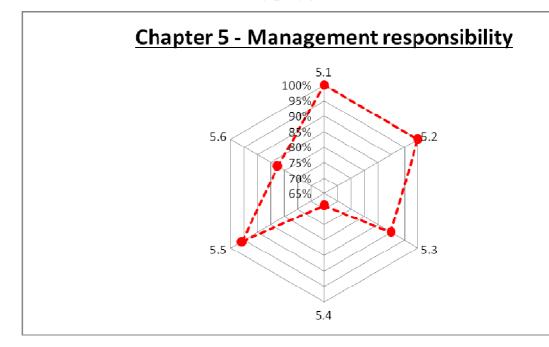
Hierarchically first and most general part of the audit was verification of quality management system in general. In ISO 9001:2008 is this part associated with chapter 4 of this standard. This part is then divided into two sections. Second section is divided into 4 subsections. The entire division describes following polygon chart of the chapter 4.



Pic. 16 - Graph of the Result of chapter 4 - Quality management system

The graph shows, that the best performance was achieved in the subsection 4.2.1 which represent general requirements for the documentation. On the other hand, subsection 4.2.3 - Document control was considered to be the worst scoring. This was caused mainly by the fact, that procedures were considered to be cluttering.

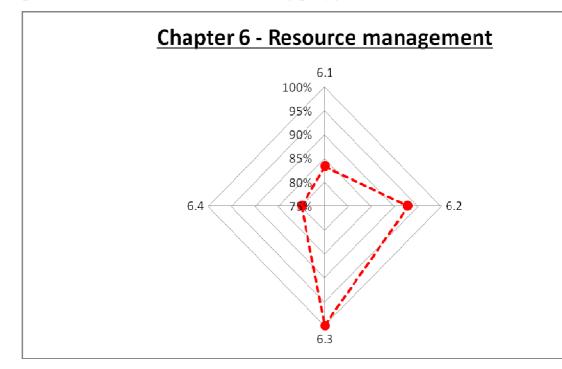
Next part of the questioner is dedicated to following chapter of this standard, fifth chapter, which is focused on the responsibility of management. This chapter has 6 sections, from which are fourth, fifth and sixth further divided into the subsections. Basic division is shown on the following polygon chart.



Pic. 17 - Graph of the Result of chapter 5 - Management responsibility

The graph show us that the best performance was achieved in sections 5.1, which represent the commitment of the management, and section 5.2 - Customer focus. Scoring of other sections was considered to be in limits except the section 5.4, which is dedicated to planning of the quality management system. This was caused mainly by the three reasons: First of them was obviousness and aims of the planning. The plans weren't clear and hardly readable. The second was insufficiencies in planning continuity and the last one the integrity of the system.

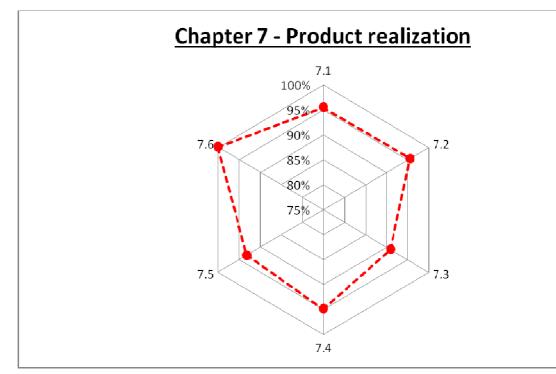
Sixth part of the questioner is focused on the verification of requirements fulfillment in the field of management of resources. It has four sections and only the second one of them is further divided into two subsections. Basic division of sixth part of questioner is shown on the following polygon chart.



Pic. 18 - Graph of the Result of chapter 6 - Resource management

From the graph is easily visible, that the main lapse of this part is both in section first and last. The main cause of this situation lies in lack of the resources necessary for ensuring the continual improvement of the quality management system and its maintenance. There were also found the lapses in the field of working environment. On the other hand, two middle sections were considered to be the higher scoring. Generally the scoring of this part is not bad and belongs rather to better average.

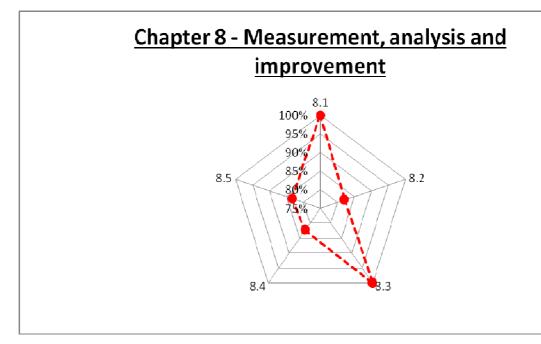
Following chapter of the questioner is as well as the chapter seven of the standard ISO 9001:2008 dedicated to the product realization. It is one of the widest and most elaborated parts of the whole system. This part has six sections, from which only the first and last are not divided into the subsections. Basic division of part seven is shown on the following polygon chart.



Pic. 19 - Graph of the Result of chapter 7 - Product realization

This part was, in comparison with others, the best scored of the entire quality management system. From the graph is easily visible, that individual sections received almost evenly scoring of higher level. All of the sections of this part were evaluated by more than 90 percent. Even better last one was evaluated by full amount of awarded points. However, the main problem of this part was, in general, out of date documentation.

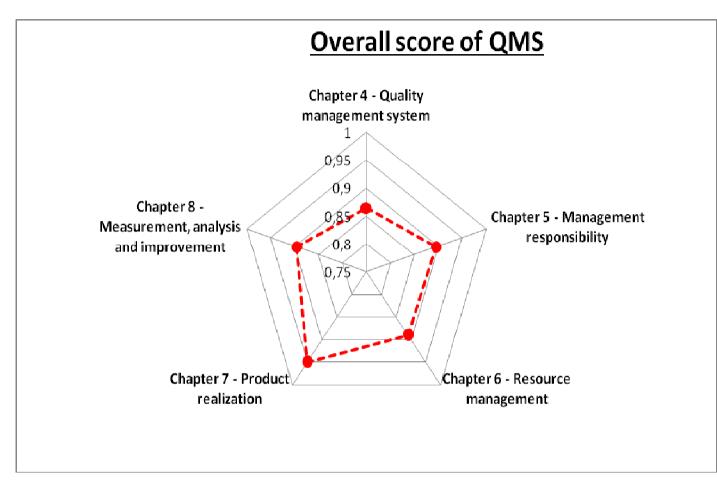
The last part of the questioner is dedicated to measurement, analysis and improvement of the quality management system. It is divided into five sections, from which are the second and fifth subsequently divided into subsections. Basic division of part eight is shown on the following polygon chart.



Pic. 20 - Graph of the Result of chapter 8 - Measurement, analysis and improvement

From the graph is visible, that first and third section got the full amount of awarded points. On the other hand, the score of the second, fourth and fifth section moved between 80 and 85 percent. Generally the scoring of this part is not bad and belongs rather to better average.

Final summary of the entire quality management system provides the graph enlisted on the following page. We can see n it, that scoring of the system is not bad, but it's necessary to focus on the problematical parts with lower scores and eliminate the nonconformities. Graph is quite symmetrical. However there is one positive exception, which is represented by part seven. Higher score of the seventh part should be the inspiration for the others. However, our audit revealed some formal nonconformities, which should be solved to improve the quality of the management system. First of all it is necessary to set the proper layout of the internal auditing and strictly follow it. Increased emphasis should be placed on keeping the documentation actual and in continuous format. It could be realized by release of revisions in some parts of the documentation or, in better case, corrections of the whole parts. Next point of the improvement should be focused on the clarity and transparency of the documentation. These remedial measures could be realized with the preparations of new documentations formed according to requirements of new version of the standard ISO 9001:2015.



Pic. 21 - Graph of the final result of QMS (overall score)

5.7 Completion

Last phase of the audit was its completion. We took all obtained evidence and evaluated documents, put them together and virtually prepare for the handover. We also met with representative of management for the last time to thank for cooperation and summarize the audit. Due to the training character of the audit, presentation of all non-conformities wasn't realized. In real situation, we should represent the final report to the representative of senior management and inform it about all activities or processes in the company, which weren't examined and state the reason why it was so. There would also be the space for the question from the side of the senior management. After that, the senior management with help of quality management representative should decide, how the audit report will be distributed among all authorized person.

5.8 Summary

In the summary part, I would like to evaluate the work with audit questioner, which I made. The questioner was quite easy to fill in, it covered all requirements of the standard and provide us with a transparent picture of the state of entire quality management system. The only one drawback I see in the form of audit questioner is lack of the space for auditors notes in printable version of the questioner. This is caused by the standardized dimension of the paper. Expansion of this space at the expense of other columns would probably lead to deterioration of transparency of these columns and thus the whole questioner. After the application of questionnaire in practice, we can find it to be suitable and recommend it for usage in real operation.

6 Conclusion

In my diploma thesis, I was focused on the process of internal audit, especially then on creation, usage and evaluation of audit questioner. The second part was then dedicated to the process model.

First of all we had to form the main goal of the thesis. We divided them into two parts - Practical and theoretical. According to the main goals of theoretical and practical parts was then set the objectives, which led to successful fulfillment of the goals.

Then we proceeded to solving of designated objectives. We started by collecting of information for the theoretical part, which provided us with introduction to the topic and gave us the basic information about the problematic of our tasks. It also defined the scope and boundaries of it. Theoretical part was divided into three sections:

First section was dedicated to production process. We introduced the final product, described its parameters, function and description in general. We also gave information about used material and history of the incandescent bulbs and described manufacturing process.

Second section was dedicated to internal audit. We mentioned some history facts and classified audits from different points of view. Then we focused on internal audits. We described it, its purpose, objectives, characteristics and gave the information about conventional procedure of the audit and its layouts. Next thing we focused on was oriented on personnel performing audit. We mentioned the role of the auditor in organization, requirements for this position and specifics of communication during the audit. Last part of second section was oriented on obtaining the evidence, in which we gave the description of audit questioner.

Third and the last section of theoretical part was focused on standard ISO 9001:2008. We introduced this standard by giving general description, field of application and compatibility with other standards. In this point we also mentioned

the conventionally used integration of these standards. Then we described history of this standard by giving basic information about its beginnings, previous releases, nowadays situation and planned release of new ISO 9001:2015. After that we mentioned and briefly introduce main principles of this standard, which are: customer orientation, leadership and management of the staff, involvement of employees, system approach to management, continuous improvement, decision based on facts, suppliers relationships and process approach. We described the structure of this standard by giving basic information about its parts and chapters. After that followed basic information about its individual requirements, function and benefits connected with implementation of this standard. At the end of the theoretical part we gave some information about certification according to this standard. By this act was part of collecting information successfully completed and we were ready to begin the practical part.

After the completion of the theoretical part f: Preparations for the audit, the audit and its summary. ollowed part practical. It was mainly focused on the audit, but before its execution, some essential preparations had to be done. We divided practical part into three sections

First part describe all processes, which preceded the audit - the preparations, creation of documents, which included: audit questioner, audit map according to standard ISO 9001:2008, record list from internal audit, record of nonconformity and the sample of process documentation.

The second part describe the performance of the audit. It was consisted of 5 phases - Opening phase, Planning phase, Preparation phase, Phase of auditing and Audit completion. All specifics of each phase have also been described. The last phase evaluate the current state of the organization and gives the advice in questions of remedial measures.

After the execution of the audit we gave a brief summary, which provide us with the description of audit questionnaire, evaluated its functionality and considered it to be suitable in real operation. This was also the last part of my thesis.

List of Pictures:

- [1] Scheme of incandescent bulb with description
- [2] Automat for connection of retorts
- [3] Heating of socle of lamp
- [4] Soldering of socle of lamp
- [5] Control of the prepared products
- [6] Packing of the prepared products
- [7] Scheme of audit flowchart with assigned responsible person and documentation
- [8] Proper layering of audits during the year
- [9] Wrong layering of audits during the year
- [10] Evolution of standards ISO series 9000 in time
- [11] Number of issued certificates in time
- [12] Deming's Plan-Do-Check-Act circle
- [13] Model of ISO 9001: 2008 Quality Management System
- [14] Benefits of quality improvements
- [15] Example of the part of Audit map
- [16] Graph of the Result of chapter 4 Quality management system
- [17] Graph of the Result of chapter 5 Management responsibility
- [18] Graph of the Result of chapter 6 Resource management
- [19] Graph of the Result of chapter 7 Product realization
- [20] Graph of the Result of chapter 8 Measurement, analysis and improvement
- [21] Graph of the final result of QMS (overall score)

List of Annexes

- [01] INTERNAL AUDIT OF QMS RECORD.doc.Provide us with general information about the audit.
- [02] RECORD OF NONCONFORMITY.docProvide us with information about nonconformity.
- [03] AUDIT MAP ISO 9001.2008.doc
 Provide us with global view of responsibility division according to parts of standard ISO 9001:2008.
- [04] Audit questionnaire Design.xlsx Draft of audit questionnaire
- [05] Audit questionnaire Filled.xlsxFilled audit questionnaire with graphical evaluation
- [06] Audit flowchart.pdfPicture of audit flowchart with assigned responsible person and documentation
- [07] Production process Flowsheet.pdf.Graphical interpretation of production process in form of flow sheet
- [08] Production process Idef0.pdf.Graphical interpretation of production process according to requirements of standard idef0
- [09] Process documentation.doc.Draft of process documentation
- [10] Process documentation Example.doc.Example of filled process documentation
- [11] Picture of iridescent bulb.pdf.Picture of iridescent bulb with description of its parts
- [12] Audits layout.pdfPicture describing right layout of the audits

- [13] Benefits of quality improvements.pdfGraphical interpretation of Benefits resulting from quality improvements
- [14] ISO 9001-2008 QMS model.pdf.Model of standard ISO 9001-2008 quality management system
- [15] PDCA cycle.pdf.Graphical interpretation of PDCA cycle

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