

# Conformity assessment as a manner of risk optimisation in organisations

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## Industrial management and organisation

### ABSTRACT

**Purpose:** of the paper has been the revealing the dependence between conformity assessment of the implemented quality system of any kind and optimization of the system risk in typical production organisation, special organisation realising production for products supplied for the needs of arm forces as well as research and standardizing laboratory.

**Design/methodology/approach:** Methodology used for the analysis has covered the analyses of results of internal and external audits conducted in Polish organisations certified on the basis of conformity assessment with requirements of ISO 9001 standard, AQAP 2110 publication and accredited under ISO/IEC 17025 standard.

**Findings:** of analysis are as follows: estimation of number and character of nonconformities, occurring during processes of internal and external conformity assessment, has described dependences between size and branch of organisation, where the management system is implemented, phase of implementation as well as the time of the system functioning.

**Practical implications:** can be applied in case of any organisation and any kind of audit; the used procedure of conformity assessment allows for the definition of the value of the risk connected with quality assurance - in management system based on quality criterion, in services, and both production and research processes.

**Originality/value:** Value of the presented paper has been constituted by the description of different quality systems, based on requirements of ISO 9001, AQAP 2110 and ISO/IEC 17025 standards in the model of the management system using the conformity assessment in the improvement cycle of system risk minimization.

**Keywords:** Conformity assessment; System risk minimization; Quality criterion

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## 1. Introduction

Facing the contemporary competitive fight on the market only the continuous optimization of all processes risk in the organisation can assure the top and winner's position. That is why managing the risk of processes in practice requires application of

the proper methods of assessment and improvement of the risk of processes being realised. The key method applied for both: processes and system estimation and risk minimization in the organisation seems to be the conformity assessment, and one of the basic tools-internal audit and the following nonconformities proceedings.

## 2. Continuous improvement as an element of management system based on quality criterion

Continuous improvement of the processes is the ground guideline of the management based on the quality criterion. That quality policy characterises the repeatability of actions and it is pointed at gaining the further improvements of the processes based on the Deming cycle (P-plan, D-do, C-check, A-act) - on one hand. On the other hand it registers permanently in the improving the system of processes of the whole organisation by effective as well as by efficient activity and not only in the range of quality assurance, but also in the meaning of integrated quality assurance [1-5].

The improvement using the quality criterion can be realised in the largest degree with usage of the accessible technical resources, technological processes and organisational solutions. It creates the necessity of applying the quality management system based on requirements of ISO 9001 standard and - dependently on the special character of the realised processes - the other special requirements; these, for example, can be [6-8]:

- quality assurance requirements for design, development and production for products supplied for the needs of arm forces- AQAP (Allied Quality Assurance Publication),
- general demands concerning the abilities of the research and standardising laboratories - ISO/IEC 17025 standard.

Company, while accepting the requirements of both implementation of the management system and launching new products into international markets, is obliged to constant fulfilment of the external requirements. In that way company provides the conformity of the management system and constant improvement of the effectiveness of the system by the proper quality policy [1-6,9].

In the field of management based on the quality criterion one of the most popular method of examination and estimation of the system conformity seems to be auditing. It allows for elimination of the nonconformities ("non-fulfilment of a requirement") occurring in the processes [10,11].

According to ISO 9000 standard as well as ISO 19011 standard audit is defined as "systematic, independent and documented process for obtaining audit evidence and evaluating it objectively to determine the extent to which the audit criteria are fulfilled [12].

Using the most popular classification audit can be treated as [13,14]:

- internal, called first-party audit, being the internal tool for improvement of quality management system; it is conducted by or on behalf of the organisation itself for internal aims,
- external, called third-party audit or certification audit, being the tool for confirmation of the conformity of the implemented quality management system with the requirements of ISO 9001 and another formalised standards. Due to the subject audit can be classified as [15]:
- quality management system audit, which allows to confirm the conformity of the implemented system with system criterion,
- processes' quality, which allows for confirmation of the conformity of the realised processes with the assumed procedures, methods, tools,
- products' quality, allowing to confirm the conformity of product with quality, environmental and occupational safety requirements connected with product in every stage of its life-cycle,
- services' quality, allowing the confirmation of the established demands related to services.

Scheme of the general classification of audits has been shown on Fig. 1.

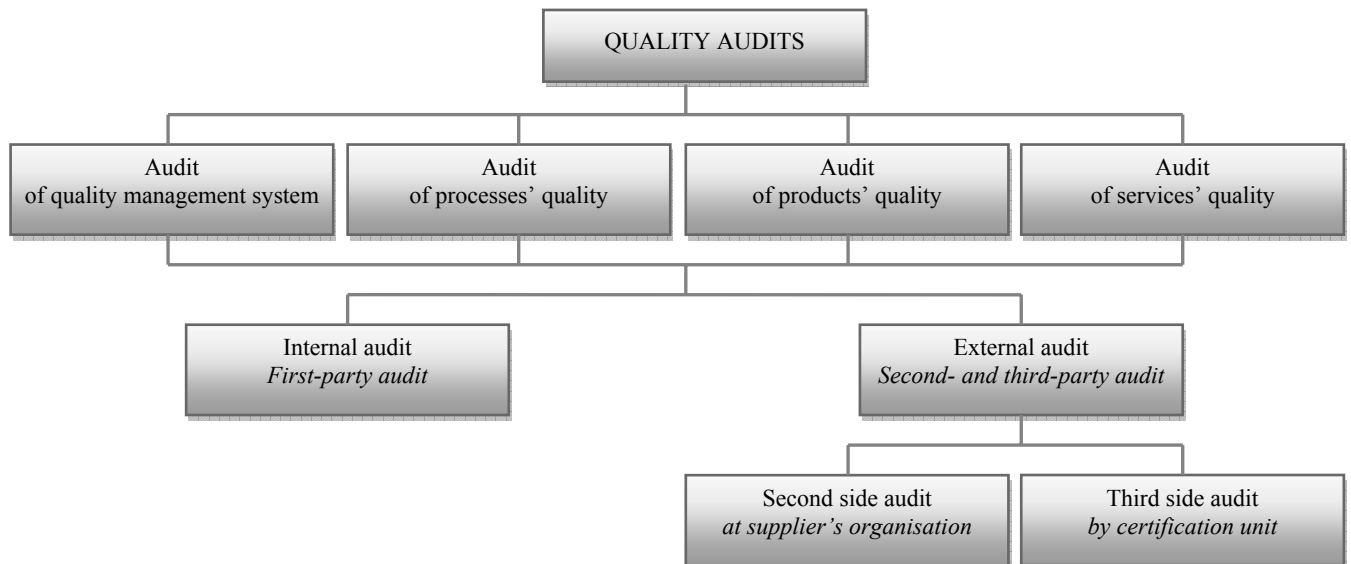


Fig. 1. Scheme of audits' classification [12]

Independently on the kind of audit, the used procedure of conformity assessment allows for defining the value of the risk connected with quality assurance - in management system based on quality criterion, in processes, products and services. Results of audit are always the basis of risk improvement in the organisation.

Results of audits can be the basis of monitoring, measurement, analysis and improvement of processes in the organisation only if they are reliable. Their reliability results from the independence of the process of obtainment of evidences as well as its objective assessment. It is possible, when auditors run the audit on the basis of the same rules [13,14,16].

### 3. Conformity assessment

Such collection of instructions for auditing is ISO 19011 standard “Guidelines for quality and/or environmental management systems auditing”. The standard has been prepared as a help in quality management system and environmental management system auditing, but the guidelines included in it can be adapted or extended properly to the application during audits realised in the ranges of the other management systems based on the quality criterion. The standard is applicable to all organisations that need to conduct any kind of audit based on the quality criterion [13-15].

The most important points in the standard define, applicable in auditing: managing an audit programme, audit activities as well as competences and evaluation of auditors. General principles assuring the reliability of audits results are: ethical conduct, fair presentation, due professional care, independence and evidence-based approach [12].

Audit activities, being the most important part of audit programme, are rather typical (Fig. 2), but dependent on the scope and complexity of the particular audit.

Reliability of audits results depends not only on the principles the audit is managed by, but also on competences of the auditors. It results from: personal attributes, knowledge and skills, education, work and audit experiences as well as maintenance and improvement of all of them. Personal attributes characterising auditors and enabling to work according to the auditing rules, are mainly: ethics, open-mindedness, diplomacy and versatility [10,12-14].

Auditor, conducting the on-site audit activities, investigates the implemented management system as well as the correctness of individual processes, looks for conformity evidences, but doesn't play the role of technical expert. Audit is characterised by [10,12-14]:

- concentration not on the procedures, but on the results,
- results creating the data for the improvement,
- verification of effectiveness and accuracy of analysis,
- assessment of real importance of nonconformities,
- focus on corrective and preventive activities for improvement of the efficiency of the organisation.

Audit applies to every process independently on the size, complexity as well as character of the realised activities. It enables the assessment of the correctness of the system solutions and indicates the possibilities of their improvement.

Every audit-assessment should give the answer to the following questions [12-14]:

- do the arrangements connected with quality and accepted by the organisation allow for the achievement of the intended aim?
- are the arrangements connected with quality and accepted by the organisation realised?
- are the achieved results consistent with the intended arrangements?

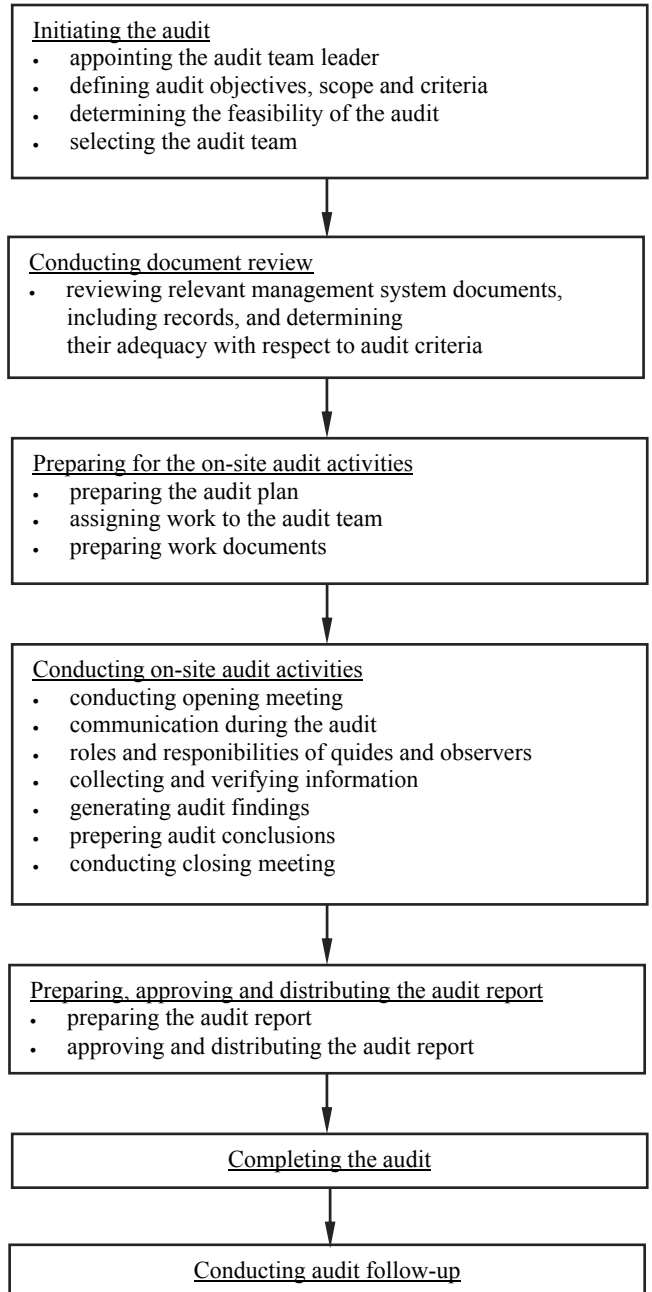


Fig. 2. Drift of typical audit activities [12]

Therefore, audit allows for the confirmation of the conformity of the input and output data with specified requirements, and at

the same time - for confirmation of the conformity with all the necessary procedures as well as the effectiveness of proceedings in the estimated processes [10,13,14].

Taking into account the listed benefits following the usage of audits, it should be stressed that audits first of all enable the assessment of the qualitative ability, compliance with the determined procedures together with the arrangement of corrective and preventive actions [10,13,14].

Approving such point of view it's not hard to spot that audit should identify direct causes of incompatibilities formation as well as to point out the places of the potential improvement of process [10,13,14].

## 4. Own research

Quality systems implemented in the analysed organisations, based on requirements of ISO 9001, AQAP 2110 and ISO/IEC 17025 standards, have been described in the model of the management system using the conformity assessment in the improvement cycle of fundamental processes (Fig. 3).

### 4.1. Methodology

Methodology used for the research has covered the analyses of results of internal and external audits conducted in Polish organisations:

- certified on the basis of requirements of ISO 9001 standard (quality management system requirements applicable to all organisations independently on their type, size and product provided) - organisation 1,
- certified on the basis of requirements of AQAP 2110 publication (quality assurance requirements for design, development and production for products supplied for the needs of arm forces) - organisation 2,
- accredited on the basis of ISO 17025 standard (general demands concerning the abilities of the research and standardising laboratories) - organisation 3.

The main aim of each audit has been the achievement of the answer to the three basic questions:

- do the accepted by the organisation settlements concerning quality permit in fact to attain the intended aim?
- are the accepted settlements in fact realised?
- are the attained results of activities in agreement with the planned settlements?

All of the realised audits have been conducted in the whole area of the organisations in all areas of their activity. The audit criteria in the conformity assessment have been the requirements of ISO 9001 standard (organisation 1), AQAP 2110 standard (organisation 2), ISO/IEC 17025 (organisation 3).

Estimation of number and character of nonconformities, occurring during internal and external audits, has described dependences between size and branch of organisation, where the management system is implemented, phase of implementation as well as the time of the system functioning.

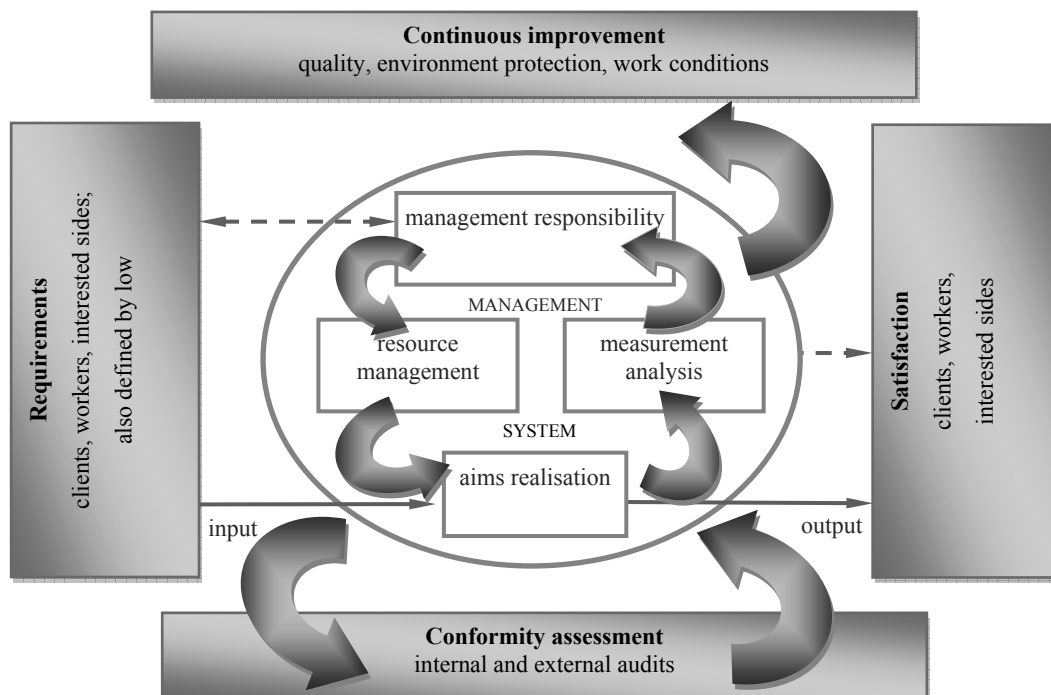


Fig. 3. Model of management system implemented in the analysed organisations and based on the requirements of ISO 9001, AQAP 2110 and ISO/IEC 17025 standards

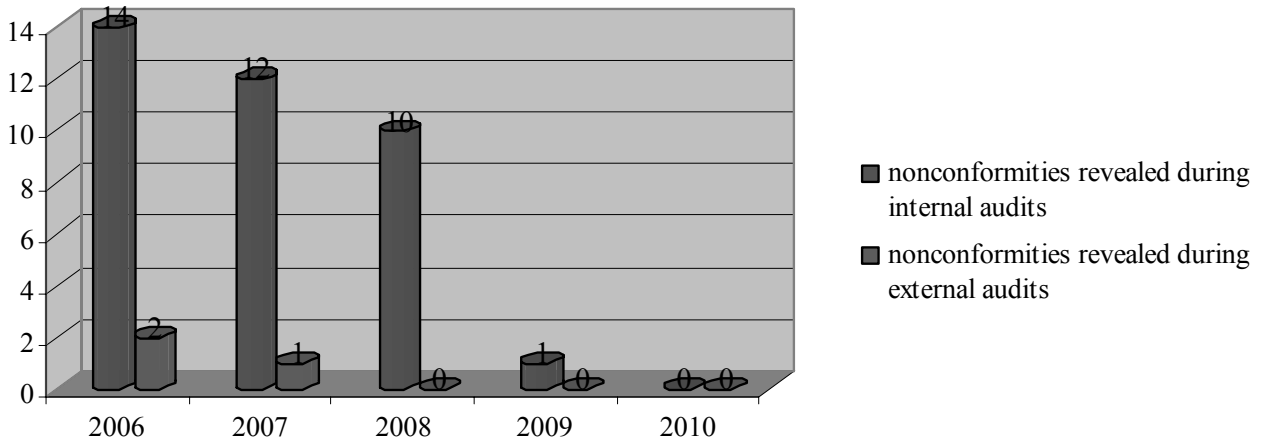


Fig. 4. The compilation of the number of nonconformities that have been proved in the organisation 1 (certified on the basis of conformity assessment with requirements of ISO 9001 standard) during internal and external audits

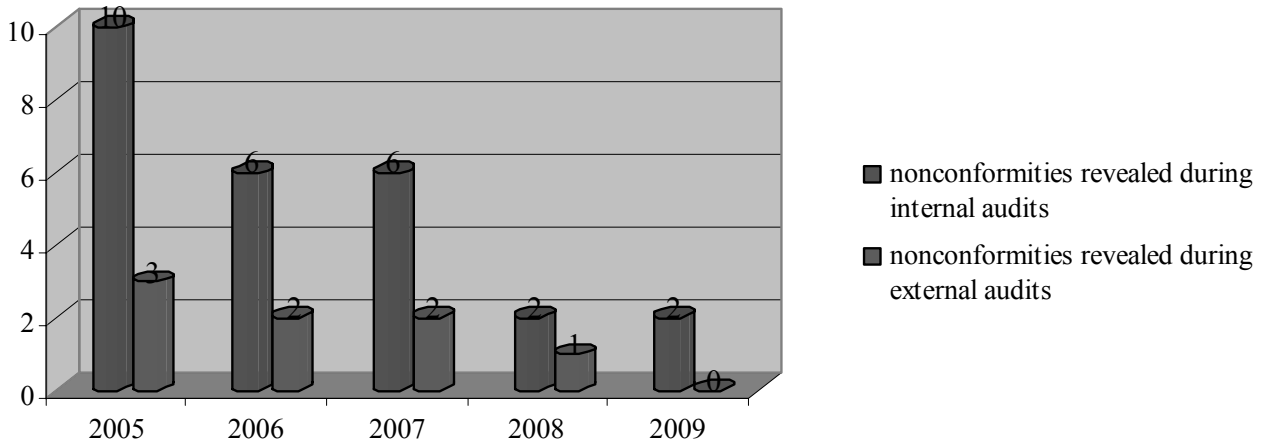


Fig. 5. The compilation of the number of nonconformities that have been proved in the organisation 2 (certified on the basis of conformity assessment with requirements of AQAP publication) during internal and external audit

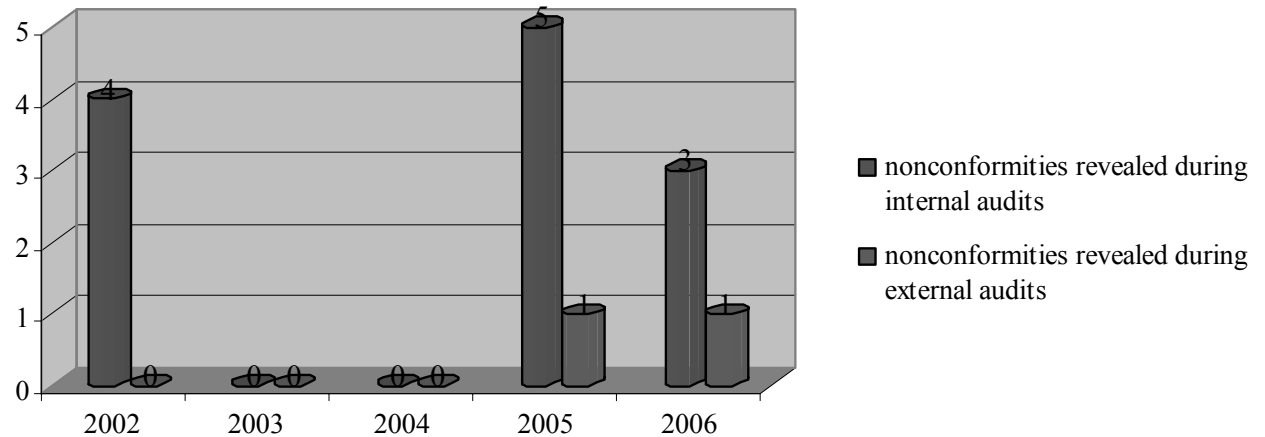


Fig. 6. The compilation of the number of nonconformities that have been proved in the organisation 3 (accredited on the basis of ISO 17025 standard requirements) during internal and external audits

## 4.2. Results and discussion

The number of nonconformities proved in the organisations within the time of 5 years has been presented on Figures 4-6.

Great differentiation in the number of nonconformities one can interpret as follows:

- during the first and the second year of the system functioning in the organisations the proved incompatibilities have been connected with the lack of experienced staff in the scope of documents management and processes realisation,
- during the following years of the system maintenance in all the organisations the decreasing number of incompatibilities have been proved, which can point out the correct implementation of the system; the exception seems to be system behaviour in the organisation 3, where the incompatibilities have been proved again (Fig. 6); it can be

explained by the implementation of the next management system and the overlap of the mature stage of the analysed system and the first stage of the new one.

The status of each nonconformity (large, medium, low) is depended on its influence on the systems functioning as well as on the quality of the carried out processes and research. Independently on the character of the organisation and type of the realised processes (typical processes, special processes, research), status of the majority of nonconformities defines a maturity of the implemented system - Figures 7 and 8. The first stage of the typical system implementation should be characterised by high amount of large nonconformities and usually small amount of low nonconformities. The mature stage of system maintenance is accompanied by absence of large nonconformities and small number of low nonconformities; what confirms the implementation of the system procedures and the system routine.

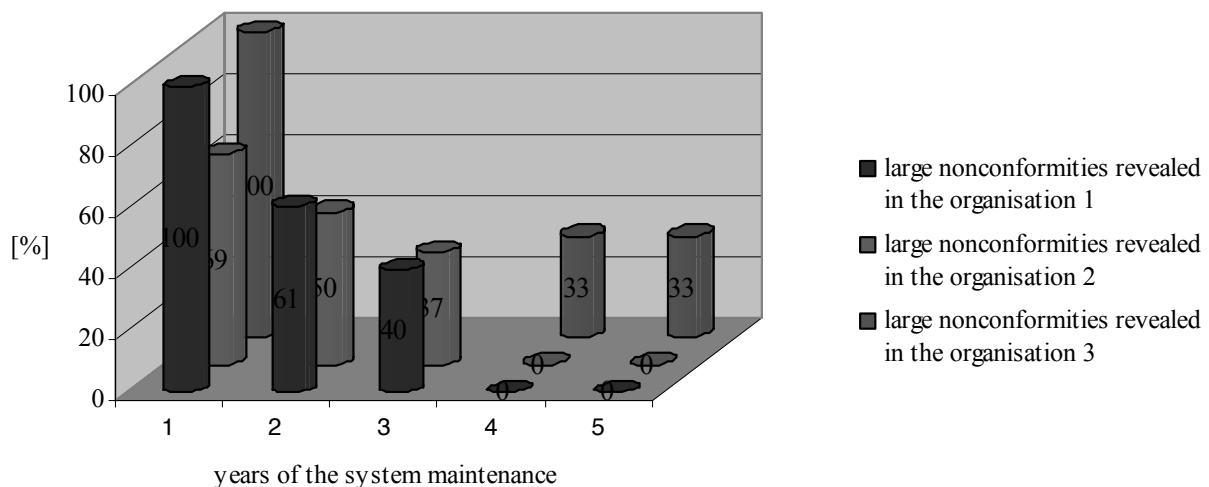


Fig. 7. The compilation of large nonconformities that have been proved in the organisations in the following years of the system maintenance

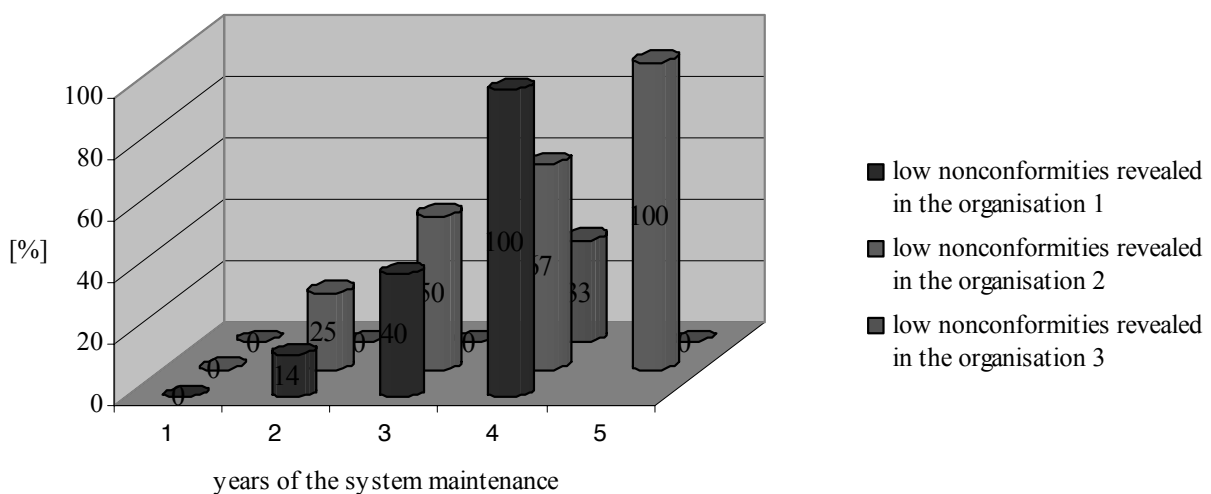


Fig. 8. The compilation of low nonconformities that have been proved in the organisations in the following years of the system maintenance

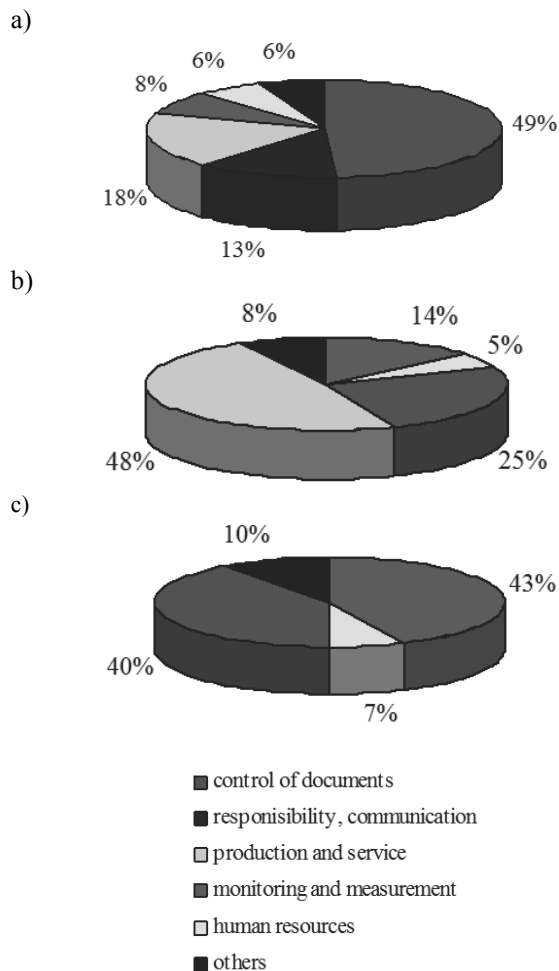


Fig. 9. Diagram of areas where nonconformities have been proved in the organisations; a) quality management system requirements for typical production organisation, b) quality assurance requirements for design, development and production for products supplied for the needs of arm forces c) general demands concerning the abilities of the research and standardising laboratories

The most often proved nonconformities concerned the control of documents (49-25%), monitoring and measurement (43-8%) and production and service (48-18%), which are the most common type of nonconformities in every organisation - Fig. 9. Areas, where nonconformities appear the most often, are dependent on the character of the analysed organisation and the realised processes which are classified as main ones.

## 5. Conclusions

The application of internal audits' results (proved nonconformities) can be surely treated as a tool for processes risk optimization by assuring the confidence and continuous

mastering in the quality management system; there is only one requirement to be met - audits should be approached as positive, not disqualifying, actions.

The status of every single nonconformity depends on its influence on the systems functioning as well as on the quality of the realised processes and research.

Number and character of nonconformities, which are exposed during internal and external audits, reveals size of organisation, where the management system is introduced, phase of implementation as well as the stage of the system maintenance - system maturity. The analysed organisations have been characterised mainly by huge nonconformities at the initial stage of the system implementation. In the course of system maintenance time the amount of enormous nonconformities has decreased in favour of low nonconformities. It has proved beneficial implementation and natural behaviour of the quality system.

Areas of the most often nonconformities are dependent on the character of organisation and processes which are classified as main ones. Nonconformities linked with control of documents, production and service provision together with the monitoring and measurement have occurred the most frequently in the analysed organisations.

The audits results and outcomes have shown the weakest links of conformity scope and have created guidelines for improvement actions and steps to be taken and applied for risk minimization in the analysed organisations.

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