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Integrated management systems based on risk assessment: Methodology development and case studies

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ABSTRACT

The implementation of management systems in organizations is often based on a "blind" meeting of requirements set by the selected standard, while these requirements are not in direct relation to the risks of the organizations. Therefore, it often happens that the established management system is not operational or is not aligned with the context and real needs of the organization. This paper presents general model for the design of an integrated management system based on risk assessment of organization's processes. The model was based on the primary hypothesis that a process that has a higher risk should be described in more detail in order to be adequately realized. The presented Model was tested on three diverse companies which had already implemented management systems according to international standards. Comparing the existing with the projected documentation in three companies, it was concluded that the number, scope and structure of documented information were optimized for successful risk management, which lowers the overall costs and enables efficient management of the company. The paper provides scientific approach and methodology for designing the integrated management system in any organization, using existing risks as universal integrating factor.

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1. Introduction

The survival and prosperity of every company are closely related to the existence and control of various risks that arise in all aspects of business. Organizations are constantly forced to improve their risk management systems in order to be successful and achieve objectives in global conditions of rapid changes. Therefore, the top management of each organization must insist on adequacy and effectiveness of risk management system. As all the activities in the organization have certain risks that need to be managed, it is clear that the best way to handle those risks is to treat them within an integrated management system (IMS) [1]. This leads to a conclusion that the functional IMS must be aimed towards efficient and effective management of risks.

If the organization chooses to achieve conformance with specific standard requirements, it will reduce or eliminate some strategic and operational risks that could endanger business continuity. Those organizations that evolve faster will integrate their management systems, which should result with a competitive advantage in achieving higher added value rate and sustainability in competitive business world [2, 3]. A detailed review of management standards leads to the conclusion that every standard is bounded to the particular category of risks that can jeopardize functioning of the organization. This conclusion leads to the following:

- Implementation of standard ISO 9001 should reduce risks that can have a negative impact on customer satisfaction and quality of the processes.
- Implementation of standard ISO 14001 should reduce risks that can degrade the environment.
- Implementation of standard OHSAS 18001 should reduce risks of injuries and occupational ill health.
- Compliance with HACCP principles and standard ISO/EN 22000 provides a system that eliminates risks at all stages of the food chain.
- Standard ISO/IEC 27001 recommends the usage of appropriate mechanisms to treat information security risks, etc.

In addition to these standards that point out to specific risk categories, standard IEC/ISO 31000 defines the overall risk management principles and defines guidelines for risk management implementation. The accompanying standard IEC/ISO 31010 recommends the application of certain techniques for risk assessment that can be used in practice.

Although continual improvements are driven by internal initiative, implementation of IMS is mostly attained by external motivation [4]. The risk management process, according to [5] implies comprehensive identification of potential failures in processes, as well as risk assessment afterwards. The authors of this paper suggest that risk assessment can be used as a base for the development of appropriate IMS documentation which is aligned with the real needs of the organization. The implementation of risk based IMS is aimed to be a systematic and objective approach that involves all the basic principles used in management standards like the process approach and the PDCA cycle of improvement, as shown in section 3 of the paper.

2. Defining the problem

Generally speaking, implementation of international standards have a goal to define processes and reduce entropy level in companies, which is a prerequisite for effective risk control, but if IMS documentation is poorly designed, it can lead to duplication and vagueness [6]. Management standards are designed to be easily integrated, but in the implementation of integrated management systems, problems with compatibility are not rare. Some research results even suggest that compatibility and alignment are not crucial issues in implementing standards [7]. New versions of standards ISO 9001:2015 and ISO 14001:2015 do not have explicit requirements for the levels of documentation needed to support the management system (Manuals, Procedures, Instructions and Records). Nevertheless numerous “documented information” is inevitable for the system to function. This can be rather confusing for inexperienced users when the appropriate system documentation should be determined and there are no explicit rules defined.

Some problems that emerge in the implementation of integrated management system, as stated in [8], can be recognized in IMS complexity, reduction of the management effectiveness, increase of management costs, decrease of cultural compatibility and opposition of employees. To avoid these problems, Zeng *et al.* [8] propose a synergetic model for the integration of management standards at several levels. The first level refers to the strategic level and includes the activities of global routing (mission and vision), planning and setting goals. The second level is a synergy of resources, structures and cultural behaviours of employees, while the third level refers to the integration of IMS documentation.

Similar attitudes are shared by Zwetsloot who proposed three types of synergistic activities when establishing IMS [9]:

- synergy of common aspects,
- synergy of management systems, and
- organizational synergy.

On the other hand, an approach to integration that recognizes three levels of integration is proposed by Jørgensen *et al.* [10]:

- the increase of the compatibility of system elements,
- the coordination of generic processes,
- the awareness of the IMS of all participants through a culture of learning.

A specification PAS 99 [11] can be used as a guide for IMS integration. PAS 99 points out that, in addition to the specific requirements of each standard, there are common requirements which are divided into categories according to the following topics [11]:

- policy,
- planning,
- development and implementation,
- performance appraisal,
- improvement and
- management review.

In [12] integration can be seen as a merging of two systems into one, in a way that result in the loss of independence for at least one, if not both systems, but they agree that the integration usually leads to a stronger and more comprehensive management system.

In [13] authors suggest a two-step approach to integration:

- the creation of generic guidelines to support the integration of management systems, and
- establishment of generic guidelines for conducting audits.

According to [14] there are two ways of integration:

- implementation of individual systems, which follows their integration, and
- development and implementation of an integrated management system from the start.

Integration degree of IMS have been thoroughly analyzed by numerous researchers [15-18] however the authors' opinion is that full and effective integration is not possible without considering the risks of quality issues, environmental impacts and occupational health and safety (OH&S) risks, which can be highly related to the satisfaction of stakeholders [19] and to the development of sustainable and socially responsible organisation [20].

In [14] is also concluded that risk can be used as an integrating factor in establishing the IMS, which was a starting point for this paper.

3. Used methods

The main problem that occurs during the design of IMS documentation is the scope, which ultimately depends on the judgment of a project team. In order to determine the precise criteria that will define the required scope and type of IMS documents, a general model for the design of IMS documentation based on risk assessment of processes in organizations was developed.

The development of the presented Model was based on the hypothesis that the increased risks in processes increase the need for their more precise documenting. By increasing the extent of documentation that describes how to perform some activity of high risks, the entropy of the system should be reduced, as well as a chance for any deviation in the process.

The crucial steps needed for the development of a risk based model for IMS documentation design are presented in the further text.

3.1 Selection of a universal risk assessment method

The criteria for the selection of universal risk assessment method were as follows:

1. Convenience of application in all phases of risk assessment.
2. Convenience of application in all kinds of processes.
3. Possibility to obtain quantified results of the assessment.

IEC/ISO 31010 [21] shows the applicability of 31 techniques for risk assessment at each phase of the risk assessment process. After analyzing the presented recommendations, it has been noted that only four methods are "strongly applicable" in all phases of risk assessment.

These methods are as follows:

- environmental risk assessment,
- structure "what if" (SWIFT),
- failure mode effect analyses (FMEA),
- reliability centered maintenance.

To fulfil the second and third criteria that were set for the selection of a universal risk assessment method, the authors of this paper accepted recommendations given in [21], as shown in Table 1.

After insight into Table 1, it can be concluded that only the FMEA method meets all the criteria that were initially set for the adoption of a universal risk assessment method.

Relying on [22] the input data required for the implementation of the PROCESS FMEA method are:

- a flow chart of the observed process (see Subsection 3.2),
- parameters that can affect the outcome of the activity,
- the potential consequences of hazardous events,
- empirical data (if they exist).

Table 1 Additional criteria for the selection of a risk assessment method

Methods recommended in all phases of risk assessment	Additional criteria	
	Applicability in all kinds of processes	Quantified results
• Environmental risk assessment	-	√
• Structure "what if" (SWIFT)	√	-
• Failure mode and effect analyses (FMEA)	√	√
• Reliability centered maintenance	-	√

3.2 Modified flow chart application

The relationships of the company's processes to the environment are primarily determined by the flows of material, information and energy. If there are certain disorders in listed flows, they can cause consequences related to the operation of processes in the organization. Therefore, a flowchart used for the identification of risks in an integrated management system should display all three basic flows in the work processes.

The FMEA method emphasizes five elements of the process, which must be addressed throughout its application [22]:

- people,
- materials,
- equipment,
- work methods,
- environment.

It would be ideal to display all five listed elements in the process flow charts that will be used for risk assessment with the FMEA method. In the authors' opinion, the duration of the observed activities is also very important for risk assessment (particularly in probability assessment) so it is very useful to display that information in a modified flow chart.

The modified flowchart should present all the information necessary for an objective identification of hazards and accurate assessment of risks in analyzed activities [23]. A generic review of modified flowchart is shown in Fig. 1.

This unique way of graphic presentation is an original contribution of author's research. It displays all key elements of the process and it should be an ideal input for risk assessment using the FMEA method.

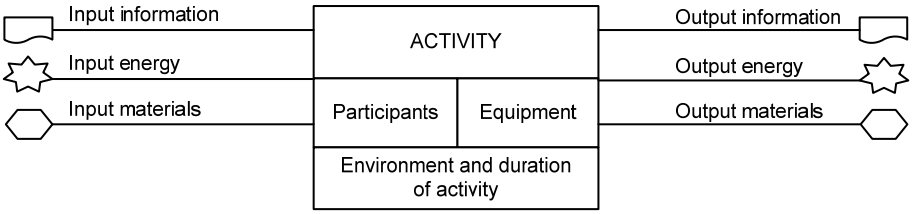

Fig. 1 Display of activity according to the modified flowchart

3.3 The application of the FMEA method

FMEA (Failure Mode and Effect Analysis) is a systematic method of identifying and preventing problems before they arise, both in products and in processes.

The main output after conducting the FMEA method is a quantified risk level that is expressed by an RPN value (Risk Priority Number). Originally, the RPN number was used for determining priorities when implementing adequate measures of risk control, while in this paper it is used as an indicator for determining the adequate type of IMS documentation.

The RPN number is determined by three factors [22]:

1. Severity – the potential consequences of failures,
2. Probability – likelihood of failure occurrence, or the frequency of its repetition,
3. Detection – the probability that the failure will be detected before the manifestation of its consequences.

Originally, each parameter should be valued on a scale that ranges from 1 to 10 for every potential type of deviation. Multiplication of the estimated values for all three factors (severity × probability × detection) determines the risk priority number (RPN).

3.4 The modification of the FMEA method

Due to specific shortcomings in FMEA method conduction, some authors suggest it can be effectively improved according to its purpose [24].

In order to facilitate risk management within an integrated management system, it is useful to classify groups of deviations (risks). The authors of this paper suggest that the number of risk groups depends on the number of management systems applied in an organization.

The modified FMEA matrix for IMS consisting of standards ISO 9001, ISO 14001 and OHSAS 18001 is shown in Table 2.

When conducting the FMEA method one must know that every activity usually has multiple risks and every consequence may have multiple causes. RPNs must be calculated for all of them.

As shown in Table 2, the authors of this paper did not consider the realization of preventive and corrective actions after the calculation of RPN number. Instead, a modified FMEA matrix results in risk ranks that define the level of IMS documentation. This modified FMEA method, together with the scale for the assessment of the severity of consequences shown in Table 3, and the scale for the detectability assessment shown in Table 5, represent an original contribution of author's research.

Table 2 Modified FMEA matrix

Process:										Date:
FMEA process										
No.	Activity	Groups of risks: Quality degradation (ISO 9001) Environment degradation (ISO 14001) Health and safety degradation (OHSAS 18001)	Possible consequences	Severity	Possible causes of failures	Probability	Possibility of detection	Detection	RPN	Risk rank

Table 3 Scale for the assessment of the severity of consequences

Rank	Effect	Severity of consequences		
		Consequences of quality degradation (ISO 9001)	Consequences of environment degradation (ISO 14001)	Consequences of OH&S degradation (ISO 18001)
10	Extremely high	Failures may lead to the loss of important operational functions for a long period of time. Lawsuits by customers and serious sanctions from the government are inevitable. Possible cessation of the company.	Permanent degradation of the environment on a large area with contamination that can be expanded by emissions into the air, water or land. The level of contamination directly threatens human health. Lawsuits and sanctions from the government are inevitable. Possible cessation of the company.	Failures may lead to emergency situations with multiple fatalities among employees and other stakeholders. Lawsuits from stakeholders and serious sanctions from the government are inevitable. Possible cessation of the company.
9	Critically high	Failures may lead to the loss of operational functions for a short period of time. Lawsuits by customers and bad publicity are inevitable. Financial losses are sometimes irrecoverable.	Permanent degradation of the environment on a small area with contamination that can be expanded by emissions into the air, water or land. Human health is indirectly affected. Sanctions from the government and bad publicity. Financial losses can be irrecoverable.	Failures may lead to fatalities among employees. Lawsuits from employees, sanctions from the government and bad publicity are inevitable. Financial losses are sometimes irrecoverable.
8	Very high	Failure leads to the suspension of supply / provision of contracted services. In addition to direct financial losses, permanent loss of customers and the market position is expected.	Local degradation of the environment with no possibility of expanding pollution. Sanctions from the government and bad publicity of the company are expected.	Significant violation of employees' health, which cannot be compensated (permanent inability to perform work-related activities). A lawsuit by employees and bad publicity are expected.
7	High	Failure leads to a brief interruption of operational functions and delays in agreed deadlines. Expected financial losses to legitimate customer complaints.	Constant degradation of the environment over a long period of time (over one year). The consequences are not fully recoverable.	Permanent violation of health and work ability of employees due to serious injuries or chronic illnesses (30% disability)
6	Moderately high	Failure leads to a number of inconsistencies in the process of work. Non-conforming products / services are delivered to end-users, which leads to their dissatisfaction.	The consequences for the environment are evident, but not fatal for wildlife. There is no possibility of spreading negative impact, but the consequences may not be fully recoverable.	Injuries / ill-health that temporarily violate work ability, but full recovery is possible (sick leave up to 3 months)
5	Medium	Systematic deviations lead to hidden defects in the product / services, leading to claims under warranty and dissatisfaction of customers.	It is necessary to make an effort to overhaul consequences for the environment after the completion of work activities.	Injuries / ill-health that temporarily violate work ability, but full recovery is possible (sick leave up to 1 month)
4	Moderate	Deviations can lead to small inconsistencies in the process. The occurrence leads to dissatisfaction of customers and financial losses.	The effects of pollution are present over a longer period of time after the cessation of activities. The environment is able to regenerate inone year period	Injury / ill-health that requires a simple and short-term medical intervention (loss of up to 1 week).
3	Low	A decline in the performance of the process, which causes the appearance of a small number of nonconformities. End users are not affected.	The effects of local pollution are present in a short period after the cessation of activities. The environment is able to regenerate in a period of one month.	Injury / ill-health that requires first aid by internally trained persons (loss to one business day)
2	Very low	Decline in performance processes causing loss of time. Adverse effects are very limited.	Environmental impact exists only as long as the current work activities.	Slight degradation of health. After little intervention of the injured person, operation continues unimpeded.
1	Insignificant	Deviations have no effect.	Deviations have no effect.	Deviations have no effect.

The severity of consequences

Assigning the values for each assessed factor can be one of the greatest problems in implementation of any risk assessment method including FMEA. Converting qualitative into quantitative values is always fraught with the subjective attitude of risk assessors. Therefore, it is recommended to establish specific guidelines for the evaluation of factors as precisely as possible.

The scale for evaluation of the severity of consequences for three groups of risks linked to the ISO 9001, ISO 14001 and OHSAS 18001 is proposed in Table 3, but every organization can define its own scale tailored to its needs.

The probability of occurrence

It is much easier to quantify probability of occurrence, especially if empirical data are available. The scale for the probability assessment is given in Table 4.

Table 4 Scale for the probability assessment

Rank	Probability of occurrence	Likelihood of failure occurrence, or frequency of its repetition
10	Extremely high	More than 1 occurrence per day / more than 3 occurrences in 10 events.
9	Critically high	1 occurrence on every 3 to 4 days / 1 occurrence in 10 events.
8	Very high	1 occurrence per a week / 5 occurrences in 100 events.
7	High	1 occurrence per a month / 1 occurrence in 100 events.
6	Moderately high	1 occurrence per 3 months / 3 occurrences in 1.000 events.
5	Medium	1 occurrence per 6 to 12 months / 5 occurrences in 10.000 events.
4	Moderate	1 occurrence per year / 6 occurrences in 100.000 events.
3	Low	1 occurrence per 3 years / 6 occurrences in 1.000.000 events.
2	Very low	1 occurrence per 3 to 5 years / 2 occurrences in 10.000.000 events.
1	Insignificant	1 occurrence in more than 5 years / less than 2 occurrences in 100.000.000 events.

The probability of detection

Since the Model should be applicable in organizations of all types and sizes, it is almost impossible to define a scale from 1 to 10 that would be applicable for every possible process. The possibility of detection is often limited by the existence of measuring equipment in the company and by the nature of the process itself. Due to these limitations and the fact that the probability and consequence are prevalent in determining any risk in most risk assessment methods [21], the matrix for detectability assessment was simplified. According to Sankar & Prabhu [25], rankings of detectability can vary even for the same type of deviation (risks), so the authors of this paper created a scale in the range of 1 to 3, which is shown in Table 5.

After defining the scales for all criteria required for conducting the FMEA method, it is clear that potential results of assessed risks (risk priority numbers – RPNs) are in a range from 1 to 300.

Table 5 Scale for the detectability assessment

Rank	Probability of detection	Description of detectability
3	Low	The process is difficult to control, and the effect of the failure is very difficult to detect.
2	Medium	Process perpetrators perform a visual process control / periodic measurements of numerical values / counting attribute values.
1	High	The failure is detected and controlled automatically or semi-automatically in a way that prevents the occurrence of deviations.

3.5 Influence of risks on IMS documentation

A common hierarchical structure of IMS documents is shown in Fig. 2. The number and scope of IMS documents that should exist in an organization and describe identified processes (according to the process approach) have not been defined by any normative references. The authors of this paper consider that the ranks of risks in the existing processes are directly aligned with the type and number of needed documentation. The exact relations between assessed risks and IMS documents are described in the further text.

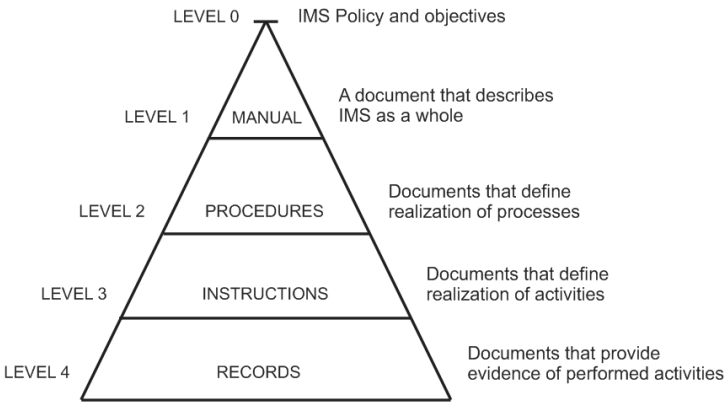

Fig. 2 Hierarchical structure of IMS documents

Level 0 – The Policy and objectives

The IMS Policy and objectives, along with the mission and vision, represent the highest level of documents in a company that are certainly affected by strategic risks.

Each management standard requires periodic management review of the system that should result in the adaptation of the policy and objectives of an organization in accordance with existing conditions. In this way, through the institution of management review, changes in operational risks indirectly reflect the changes in the policy and objectives of an organization, but the policy and objectives are not directly treated by the Model.

Level 1 – The Manual

Specification PAS 99 recommends the development of a single Manual that describes the overall management system [11]. This IMS Manual refers to the procedures and instructions of an integrated management system. Usually there is no need to describe all the processes by separate procedures because they can be very numerous and heavily burden the administration of a system. Therefore it is sufficient to describe some processes with minor risks (rank 1) just in the Manual.

Level 2 – Procedures

Some management systems insist on certain mandatory procedures but the system should be also documented with procedures that describe primary processes of the organization. The designed Model proposes that moderate risks (rank 2) must be described by procedures.

When documenting the observed process by a procedure, particular attention should be focused on those activities where the moderate risks were identified. In this way, documentation should be adapted to the risks of the organization which minimizes the possibility of deviations and errors in processes.

Level 3 – Instructions

The Model suggests that all activities with high risks (rank 3) should be described by separate instructions. The appearance of risks in rank 3 certainly implies the development of a procedure for the entire process in which risky activity occurs, but a separate instruction that will accurately describe the observed activity is also needed.

In that way, all high-risk activities would be separately described in detail, which would enable workers to adequately perform their tasks in safe manner.

Level 4 – Records

This level of documentation is actually dependent on the above-described documents of a system (especially procedures and instructions) which define the number and format of records that need to be kept. The designed Model does not foresee the changes that are directly related to the records, but their number indirectly depends on the level of estimated risks, since risks affect the quality and quantity of procedures and instructions in IMS.

Added Level 5 – Action sheets

Besides customary IMS documents, the Model introduces another level of documentation that is related to the most severe risks that can lead to disastrous consequences. Emergency situations are specially treated by ISO 14001, OHSAS 18001, ISO 22000, etc. (requiring preparedness for response in case of emergencies). The Model therefore requires the existence of special instructions called "Action sheets" which define preventive and recovery measures in case of emergency situations for all severe risks (rank 4). Action sheets should be posted in a visible location near a potential emergency spot which should enable everyone to react properly in case of emergency.

4. Results and discussion

4.1 Risk based model for the design of IMS documentation

Materials and methods used in previous chapter resulted with the universal risk based Model for IMS documentation design, which is a main result of this paper. To avoid arbitrariness in defining the scope and structure of IMS documents, the proposed Model introduces precise criteria that can be used to determine the number and types of documents required, depending on the rank of assessed risk.

The number of repetitions of all possible RPN results obtained by modified FMEA method is shown in the histogram in Fig. 3, which shows that the distribution of RPN values is far denser at the beginning of the scale where RPN values are lower.

The occurrences of high-risk deviations in practice are extremely rare, and low-risk deviations are far more common, which is in accordance with the distribution of RPN values shown in Fig. 4. The density of distribution of RPN values was taken into account when risk rankings were defined.

Since there are four levels of IMS documents that are treated by the proposed Model, the authors predicted four risk rankings within a range from 1 to 300 RPN values:

- Minor risks (Rank 1) – risks are in the interval $1 \leq RPN \leq 50$.
- Moderate risks (Rank 2) – risks are in the interval $50 < RPN \leq 100$.
- High risks (Rank 3) – risks are in the interval $100 < RPN \leq 150$.
- Severe risks (Rank 4) – risks are in the interval $150 < RPN \leq 300$.

The description of IMS documents which directly depend on the rank of estimated risks is shown in Table 6.

Risk rankings in practice can be subject to change. Each organization could define its own scale for risks according to the objectives and available resources, so rankings should be periodically reviewed and adapted to the needs of the organization.

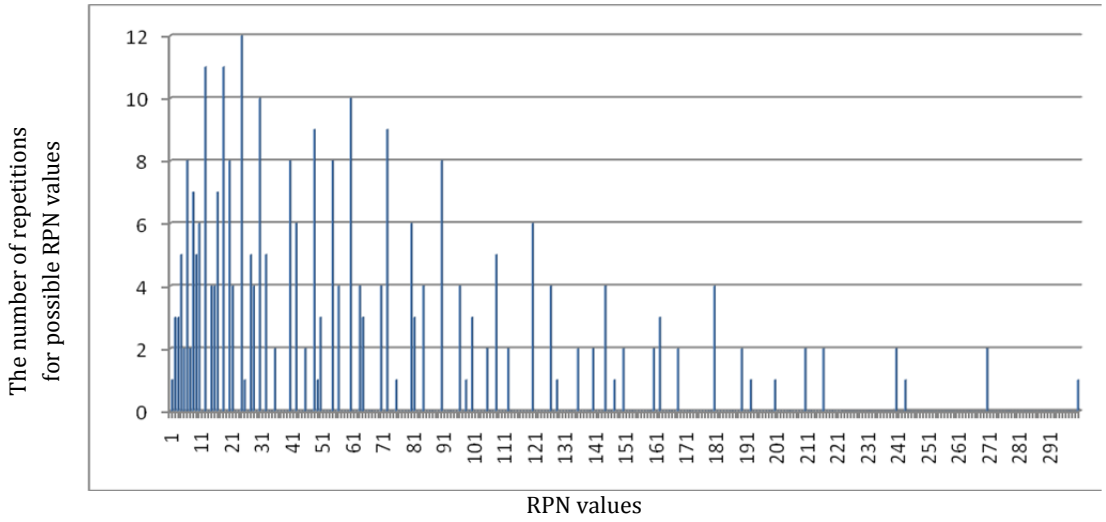

Fig. 3 The distribution of RPN values

Table 6 IMS documentation depending on the rank of the estimated risks

RPN of analyzed process/activity	RANK of risk	Description of required IMS documents
RPN ≤ 50	Minor risks (RANK 1)	Analyzed process should be described in the IMS Manual
50 < RPN ≤ 100	Moderate risks (RANK 2)	Analyzed process should be described by a Procedure and briefly described in the IMS Manual
100 < RPN ≤ 150	High risks (RANK 3)	Analyzed activity should be described by a separate instruction
150 < RPN ≤ 300	Severe risks (RANK 4)	Analyzed activity should be described by a separate instruction and by an action sheet for the prevention and treatment of possible emergency

It may be noted that, irrespective of the assessed risks, all processes should be described (at least roughly) in the Manual of the integrated management system, which is required by ISO/TR 10013:2001 [26]. The procedure is required only if the analyzed process has risks in rank 2. Risks in ranks 3 and 4 indicate that separate instructions for analyzed activities should be made. When it comes to risks in rank 4, at a first sight it could be stated that there is an overlap in the documentation for the same activities. However, the duplication of documentation does not actually exist because action sheets define just activities for the prevention and remediation of potential emergencies, but the way of carrying out the observed activities and corresponding responsibilities is defined by appropriate instructions. In addition, action sheets are designed for all present persons, regardless of their familiarity with the company processes. Unlike action sheets, the instructions are designed directly for the workers.

4.2 Case studies

The risk based Model for the design of IMS documentation has been applied in 3 various companies in Serbia:

- Company A is engaged in designing buildings and facilities and has implemented integrated management system which includes ISO 9001, ISO 14001 and OHSAS 18001.
- Company B is engaged in civil engineering, transport, asphalt production and exploitation of mineral materials. It has implemented integrated management system which includes ISO 9001, ISO 14001 and OHSAS 18001.
- Company C has implemented integrated management system which includes ISO 9001, ISO 14001, OHSAS 18001 and ISO 22000. It has three branches:
  - The first branch is engaged in the design, construction and maintenance of all types of gas, electrical and ventilation installations.
  - The second branch is engaged in the production and storage of fresh and frozen goods (food, fruit and vegetables).
  - The third branch is engaged in the production and packaging of brandies from fruits and grapes.

All three companies already had their integrated management system implemented and the comparison between the old and new IMS documentation was made. In order to facilitate the comparison and analysis of the results obtained, the following restrictions were made:

- Only the processes that have previously been identified and described in companies were analyzed and their risks were assessed (this was the only way for objective comparison between the old and new IMS documentation).
- System processes that are required to be documented in accordance with the implemented standards (such as: document control, record control, internal audit, corrective actions, etc.) were not considered by the Model.
- The categories of risk taken into account were in direct correlation to the standards applied in the organization.

Although the key performance indicators are often expressed through financial results of the company [27], the Model does not predict financial indicators for several reasons:

- The financial success of the company is not the subject of any management standard.
- Profit is just a consequence of consistent quality of the processes, products or services, which wins long-term customer satisfaction. Therefore, any deviations in the processes of the company influence its profit directly or indirectly.

After drawing flow charts for each analyzed process, the authors created corresponding FMEA tables, which resulted with a resume of IMS documents required by the proposed Model.

Comparative analysis between the documentation that existed in the companies A, B, and C in the past, and the documentation designed by new research model, showed following results:

- 9 specific processes were identified in the integrated management system of Company A. The primary system in the Company A consisted of 10 documents (6 Procedures + 4 Instructions) and the documentation designed by new model consisted of 8 documents (7 Procedures + 1 Instruction). It is obvious that number of IMS documents in Company A does not vary much depending on the approach used, but there are major differences regarding the type of designed documentation. This dispersion can be explained by the inconsistent application of the process approach when the documentation was primarily designed. Generally, Company A does not face great risks, especially when it comes to endangering health and safety at work or the environment, since the company is engaged only in the design and supervision, and not in the construction works. Therefore, the number of documents designed for this company in accordance with the proposed model is very small and covers mainly the quality aspect in accordance with ISO 9001.
- 12 specific processes were identified in the integrated management system of Company B. The primary system in the Company B consisted of 35 documents (10 Procedures + 13 Instructions + 12 action sheets) and the documentation designed by new model consisted of 48 documents (16 Procedures + 25 Instructions + 8 action sheets). There is a big difference in the size and type of business between Company A and Company B, so the IMS documentation in those two companies differs a lot, although it covers the same set of standards (ISO 9001, ISO 14001 and OHSAS 18001). It can be seen that total number of required documents designed by a risk-based model is higher by 13 than the documentation that was primarily designed. The analysis of the processes shows that unlike company A, Company B faces significant risks, especially when it comes to environment and occupational health and safety. That is why the designed documentation is "focused" on the most risky processes such as: construction, production of asphalt mass and machinery manipulation, to which most instructions and all action sheets are directed. Such a distribution of documentation was predictable, since the model was developed to be consistent with the risks of the company concerning the applied standards.
- 24 specific processes were identified in the integrated management system of Company C. The primary system in the Company C consisted of 34 documents (23 Procedures + 11 Instructions) and the documentation designed by new model consisted of 55 documents (25 Procedures + 26 Instructions + 4 action sheets). Company C has a much more complex structure and wider scope of activities than other companies analyzed in the case study. In addition, this company has the most complex management system, which comprises four standards (ISO 9001, ISO 14001, OHSAS 18001 and ISO 22000). The processes occurring in the branch which deals with the design, construction and maintenance of gas and thermo-technical installations can in some ways be compared with the processes already analyzed in companies A and B. However, other two branches have specific processes that are also subject to requirements ISO 22000, which generates a new group of risks and increases the number of required documentation. According to the set goal, the designed documentation is focused on the most risky processes such as: construction, machinery manipulation, production of frozen products, service storage of frozen products and production of brandy.
- Case studies generally showed that primary implementation of IMS was not carried out systematically and according to the process approach which is one of the core principles of quality management. This resulted with non-consistent number and types of IMS docu-

ments. For instance, that is why number of documents in the Company B was even slightly larger than in the Company C which is far more complex and even has additional standard implemented. Such omissions cannot happen when applying the proposed Model. Besides mentioned, previous documents were not aligned with existing risks in processes and by that they don't meet the needs of the organization. The practical application of the Model suggests that in some cases the same processes carry different risks in different companies. Risks vary according to an impact that the analyzed process has on the performance of the company and it should be treated and documented according to it. Therefore, there are no "a priori risky processes".

5. Conclusion

The paper presents all phases of the development and implementation of the Model for designing IMS documentation based on risk assessment in organizations.

In order to create this Model, the authors:

- Adapted flow chart, as a universal tool suitable for graphically displaying and analyzing essential process elements,
- Selected and adapted the FMEA method, as a universal tool suitable for risk assessment in the processes of the company, related to the applied management standards,
- Established a universal matrix for ranking different types of risk,
- Defined the relationship between the assessed risks and required IMS documentation.

For the purpose of practical verification of the designed Model, the following actions were performed:

- Implementation of the Model in three diverse companies that already had an integrated management system with at least three management standards implemented,
- Comparative analysis of the documentation obtained from a risk based Model and previous IMS documentation that existed in organizations.

Case studies showed that the Model can be applied in the organizations of all sizes and types in a way that the number and scope of IMS documents directly depend on the risks in the existing processes. That documentation should always be changed along with the changes of the company's risks. The risk based model for the design of IMS documentation has given precise guidelines that each company can use in creating the optimal level of IMS documentation. However, every organization can change the projected Model by adapting the scales for risk ranks in accordance with its goals and needs. Organizations that thrive in the field of risk management often desire to bring it to a higher level by reducing risk appetite.

The authors have also identified some weaknesses of the proposed approach, such as:

- Implementation of the Model depends on expertise and evaluation of FMEA team,
- Drawing the flow charts and FMEA matrix for every process can be time consuming,
- Current Model does not include financial, reputational, compliance, or similar risks,
- Current Model does not define operational actions for the reduction of assessed risks.

In order to correct recognized weaknesses, the authors anticipate following directions for further research:

- Developing adequate software would facilitate the implementation of the Model. Creating a database with all potential deviations, their consequences and associated risks, would help FMEA team to get the job done,
- Creating new types of risks related to the financial effects should broaden the use of proposed Model,
- Extending the Model with actions for the reduction of assessed risks should add operational value to the Model implementation.

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References

[1] Beckmerhagen, I.A., Berg, H.P., Karapetrovic, S.V., Willborn, W.O. (2003). Integration of management systems: Focus on safety in the nuclear industry, *International Journal of Quality & Reliability Management*, Vol. 20, No. 2, 210-228, doi: 10.1108/02656710310456626.

[2] Rebelo, M., Santos, G., Silva, R. (2013). Conception of a flexible integrator and lean model for integrated management systems, *Total Quality Management & Business Excellence*, Vol. 25, No. 5-6, 683-701, doi: 10.1080/14783363.2013.835616.

[3] Bekčić, S., Kelečević, N., Marinković, V., Tasic, L., Krajnovic, D. (2013). Approach to the integration of management systems in a pharmaceutical organization, *Indian Journal of Pharmaceutical Education and Research*, Vol. 47, Vol. 3, 19-25.

[4] Domingues, J.P.T., Sampaio, P., Arezes, P.M. (2015). Analysis of integrated management systems from various perspectives, *Total Quality Management & Business Excellence,* Vol 26, No. 11-12, 1311-1334, doi: 10.1080/14783363.2014.931064.

[5] International Organization for Standardization, ISO 31000: 2009 Risk management – Guidelines on principles and implementation of risk management, ISO Copyright Office, Geneva.

[6] Pojasek, R.B. (2006). Is your integrated management system really integrated?, *Environmental Quality Management,* Vol. 16, No. 2, 89-97, doi: 10.1002/tqem.20124.

[7] Wilkinson, G., Dale, B.G. (2006). Integrated management systems: A model based on a total quality approach, *Managing Service Quality: An International Journal*, Vol. 11, No. 5, 318-330, doi: 10.1108/09604520110404040.

[8] Zeng, S.X., Shi, J.J., Lou, G.X. (2007). A synergetic model for implementing an integrated management system: An empirical study in China, *Journal of Cleaner Production*, Vol. 15, No. 18, 1760-1767, doi: 10.1016/j.jclepro.2006.03.007.

[9] Zwetsloot, G.I.J.M. (1995). Improving cleaner production by integration into the management of quality, environment and working conditions, *Journal of Cleaner Production*, Vol. 3, No. 1-2, 61-66, doi: 10.1016/0959-6526(95)00046-H.

[10] Jørgensen, T.H., Remmen, A., Mellado, M.D. (2006). Integrated management systems – Three different levels of integration, *Journal of Cleaner Production*, Vol. 14, No, 8, 713-722, doi: 10.1016/j.jclepro.2005.04.005.

[11] British Standard Institute (BSI), (2012). PAS 99 Specification of common management systems requirements as a framework for integration, BSI Copyright Office, London.

[12] Karapetrovic, S., Willborn, W. (1998). Integration of quality and environmental management systems, *The TQM Magazine*, Vol. 10, No. 3, 204-213, doi: 10.1108/09544789810214800.

[13] Karapetrovic, S. (2002). Strategies for the integration of management systems and standards, *The TQM Magazine*, Vol. 14, No, 1, 61-67, doi: 10.1108/09544780210414254.

[14] Labodová, A. (2004). Implementing integrated management systems using a risk analysis based approach, *Journal of Cleaner Production*, Vol. 12, No. 6, 571-580, doi: 10.1016/j.jclepro.2003.08.008.

[15] Salomone, R. (2008). Integrated management systems: Experiences in Italian organizations, *Journal of Cleaner Production*, Vol. 16, No. 16, 1786-1806, doi: 10.1016/j.jclepro.2007.12.003.

[16] Asif, M., Fisscher, O.A.M., De Bruijn, E.J., Pagell, M. (2010). An examination of strategies employed for the integration of management systems, *The TQM Journal*, Vol. 22, No. 6, 648-669, doi: 10.1108/17542731011085320.

[17] Bernardo, M., Casadesus, M., Karapetrovic, S., Heras, I. (2009). How integrated are environmental, quality and other standardized management systems? An empirical study, *Journal of Cleaner Production*, Vol. 17, No. 8, 742-750, doi: 10.1016/j.jclepro.2008.11.003.

[18] Bernardo, M., Casadesus, M., Karapetrovic, S., Heras, I. (2012). Do integration difficulties influence management system integration levels?, *Journal of Cleaner Production*, Vol. 21, No. 1, 23-33, doi: 10.1016/j.jclepro.2011.09.008.

[19] Asif, M., De Bruijn, E.J., Fisscher, O.A.M., Searcy, C. (2010). Meta-management of integration of management systems. *The TQM Journal*, Vol. 22, No. 6, 570-582, doi: 10.1108/17542731011085285.

[20] Mežinska, I., Lapiņa, I., Mazais, J. (2015). Integrated management systems towards sustainable and socially responsible organisation, Vol. 26, No. 5-6, 469-481, doi: 10.1080/14783363.2013.835899.

[21] International Organization for Standardization (ISO), (2009). ISO 31010:2009 – Risk management – Risk assessment techniques, ISO Copyright Office, Geneva.

[22] McDermott, R.E., Mikulak, R.J., Beauregard, M.R. (2008). *The basics of FMEA*, *Second edition,* CRC Press, Taylor & Francis Group, New York, USA.

[23] Vulanović, S., Beker, I., Radlovački, V., Delić, M. (2012). The appliance of work flow diagram as a tool for identification and grouping of failures in processes of integrated management system, *International Journal Advanced Quality,* Vol. 40, No. 1, 23-26.

[24] Banduka, N., Veža, I., Bilić, B. (2016). An integrated lean approach to process failure mode and effect analysis (PFMEA): A case study from automotive industry, *Advances in Production Engineering & Management,* Vol. 11, No. 4, 355-365, doi: 10.14743/apem2016.4.233.
[25] Sankar, N.R., Prabhu, B.S. (2001). Modified approach for prioritization of failures in a system failure mode and effects analysis, *International Journal of Quality & Reliability Management*, Vol. 18, No. 3, 324-336, doi: 10.1108/02656710110383737.
[26] International Organization for Standardization (ISO), (2001). ISO/TR 10013:2001 Guidelines for quality management system documentation, ISO Copyright Office, Geneva.
[27] Delić, M., Radlovački, V., Kamberović, B., Maksimović, R., Pečujlija, M. (2013). Examining relationships between quality management and organisational performance in transitional economies, *Total Quality Management & Business Excellence,* Vol. 25, No. 3-4, 367-382, doi: 10.1080/14783363.2013.799331.

Appendix A

The list of the abbreviations in the paper:

FMEA	Failure mode effect analysis
IMS	Integrated management system
OH&S	Occupational health and safety
PDCA	Plan-Do-Check-Act
RPN	Risk priority number