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MILESTONES IN IMPLEMENTATION OF AN INTEGRATED MANAGEMENT SYSTEM IN THE HEALTH SECTOR CASE STUDY RADIOLOGISCHE NETZWERK RHEINLAND

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Abstract

Healthcare organizations in Germany exploit the benefits of the ISO 9000 family of international standards as it became compulsory to implement a quality management system in accordance with ISO 9001 requirements. Until the innovative ISO 9001:2015 proposal it was no direct connection to the other management systems like risk management, knowledge management or environmental management. So far, only few bodies ensured interconnections between different systems of management or associated the quality management system with the strategic planning process. However, healthcare encapsulates supplementary requirements which affect a number of different systems. Additionally, the financial crisis has encouraged the trend to operate integrated reporting beyond financial aspects. This paper aims at presenting the experience on the development of integrated management and reporting system integrated in an organization belonging to the health sector. The work clarifies the steps towards merging distinctly regulated management systems (quality, health or environmental management) with strategic planning and controlling, via a *Balanced Dashboard* (Balanced Scorecard - BSC) as well as integrated reporting according to the model International Integrated Reporting Initiative (IIRI) in a German medical company - Radiologische Netzwerk Rheinland - RNR AG.

Using the case study method, the paper's purpose is to highlight approaches and results of the company that could support practitioners from medical area and beyond. The literature review clarified theoretical concepts while the case study allowed converging comprehensive information and knowledge accumulated by RNR AG, thus helping to bridge the gap between literature on total integrated management reporting and reporting system in healthcare.

Keywords: ISO 9001:2015, quality management, healthcare, integrated reporting, sustainability, balanced scorecard.

JEL Classification: L2; G32; M14; I10.

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Introduction

At EU level, health expenditures have been constantly rising. Thus, while in 1990 6.85% of GDP was the average percent allocated to healthcare in the EU, in 2013, it increased to 9.52% of GDP (World Health Organization, 2016), in parallel with increasingly wider discussions concerning the need to improve performance and quality in this sector. Therefore, designing a sustainable health system represents an important topic in Europe and globally. The growing number of organizations ranging from the Sustainable Development Council (German *Rat für Nachhaltige Entwicklung*) in Germany or *European Steering Group* (ESG) on *Sustainable Healthcare* initiated by the European Commission in March 2010, is the real proof.

To achieve this level of sustainability is required both the creation of bodies to manage legal and social issues, as well as ensuring corporate profitability by introducing an integrated management and reporting system based on the new ISO 9001: 2015 standard. Since 1987, the year of issuing the first standards belonging to ISO 9000 family on quality management, there were made numerous explanations and changes to the 2008 version, to increase compatibility with other management systems.

Compared with the previous revisions, ISO 9001:2015 introduces an original configuration called "*high-level structure*" which aims to ensure identical construction for all standardized management systems. In addition to the structural changes, completely new topics appear, introduced following the latest amendments, such as risk management, change management and knowledge management.

Interestingly, compared to other areas, healthcare registered a low number of ISO certificates (figure no. 1), fact triggered by several reasons. Quality management (QM) in healthcare is a relatively young system, to which different requirements and criteria are applied, some of them occasionally competing against each other, like for example: *Kooperation für Transparenz und Qualität im Gesundheitswesen - KTQ* and *Qualität und Entwicklung in Praxen - QEP*, Germany; *European Excellence Award* or *EFQM Award*, administered by the European Foundation for Quality Management (EFQM); *Total Quality Management - TQM* as suggested by Klazinga (2000) and Count and Meurer (2001), as well as *European Health Award* (EHA). Moreover, for a long time, ISO 9001 was considered not applicable to healthcare organizations and this is why, in 2012 appeared ISO EN 15224 - *Health care services Quality management systems Basic requirements EN ISO 9001: 2008*, adapting generic requirements of ISO 9001 to the special requests of health systems and familiarizes also with risk management.

Last revision ISO 9001: 2015 introduces explicitly the concepts of "*risk-based thinking*" and "*organizational knowledge*", which leads to the implementation at organization level of both risk management and knowledge management, thus developed into integral parts of their own quality management system.

Predictably, the audit concern in the coming years will change, redirecting itself in particular towards risk management in healthcare, especially due to many quality problems recorded in this field. However, measuring the quality of health and its assessment in relation to firm requirements and criteria are just steps in the complex process of ensuring high-quality care. In our opinion, the accurate solution for recording sustainable improvements in health care is a system of management and integrated reporting - IMRS by reason of various advantages it entails, such a model being essential to fulfilling ever higher

demands from medical area: companies must operate with ever increasing costs; existence of multiple information on quality and classification of similar medical institutions available online; additional regulatory and quality risks associated to problems concerning quality; the existence of hygiene issues (such as the nosocomial infections) etc.

An integrated management and reporting model can competently facilitate the management of all aspects listed above.

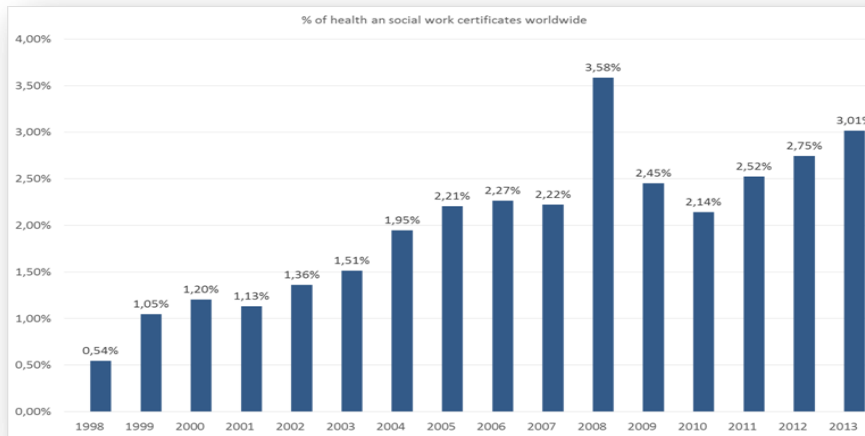


Figure no. 1. Percentage of health and social work certificates worldwide

Source: data processed from ISO Survey, 2014.

Insufficient literature on standardized integrated management system on the one hand (Jørgensen, 2006), limited use of the Balanced Scorecard as a strategic planning model (Kaplan and Norton, 1996; 2004; Kaplan, 2010) and the lack of a reference model for integrated reporting in healthcare, on the other hand (Bisbe and Barrubés, 2012) can be identified as major bottlenecks that led us to initiate our approach. Consequently, we proposed that through our research to reduce the gap in the literature on sustainable integrated management and reporting systems, using the already existing standardized management systems. The plan resulted from the analysis of the development and steps required for an IMRS implementation at a large medical company in Germany will provide answers to some pressing questions of managers and practitioners.

2. Methodological design by synthesizing quality management and integrated management state of the art

The research stems from concern of one of the largest German companies, a medical services provider, RNR AG, which can be summarized in the following question: *"How can we implement an integrated management system, simultaneously optimizing business processes, complying with the complex healthcare regulations and quality management requirements, while at the same time fulfilling our strategic objectives? "*. One of the authors as part of the management team of this company, observed the challenge and

considered appropriate to bring it to research, starting from the above question according to which the investigation methodology was established.

The literature review established some theoretical issues, including operational concepts and definitions in the context of quality management in healthcare were decisive. "Demographic change", "population aging" or "new and unforeseen healthcare problems" (Shaw, 2003) indicated a correlation with permanently increasing spending and the need for a reliable reporting system when assessing the impact of investments and quality of results in healthcare (Groene et al., 2009). Although at developing stage, the proposals for an international integrated reporting system (International Integrated Reporting Council, 2013) or "One Report" (Eccles and Krzus, 2010) could provide a solution, as a way of "*integrated thinking*", realization of decisions and actions that focus on "*value creation in the short, medium and long*" (International Integrated Reporting Council, 2013, p. 14). On the other hand, empirical studies on integrated management systems – IMS, started almost twenty years ago (Rajković and Aleks, 2009) have sparked interest both in the business sector and academic community (Olaru et al., 2014).

Secondly, an original definition for integrated management system in private healthcare was outlined, considering the German healthcare industry and its standards. To contribute beyond theoretical to the work of practitioners, the case study focused on a group of large medical German companies characterized as being in the *sustainability phase* (Kaplan and Norton, 1996) meaning that a large enterprise made significant investments and has as main objective to increase the capital effectiveness. However, profitability remains linked to increase operating capacity and nationwide coverage for the services they provide. Also, as influential is the Balanced Scorecard – BSC, namely the indicators and targets included in the financial perspective.

The opportunity to gather wide-ranging data on a large medical organization which operates both in the public and private sectors; specific knowledge on the processes of a real IMS, and making advanced research hypotheses were arguments for choosing descriptive case study (Yin, 1984) as research instrument. This involves focusing on a single aspect and analyzing its characteristics through a descriptive theory. Consequently, the findings will contribute to deriving new questions, as in the case of IMS's definition. As the case study data is relevant to a specific healthcare market, confirm the need for additional exploration in order to extend the findings to the whole European health sector. Given that most of input was qualitative, aspect sometimes subjected to criticism, the next step will be the design and implementation of a questionnaire.

3. The design of an integrative approach in a German medical company

3.1 Definition and implementation phases of an integrated management system

Norm based management systems imply certain prerequisites. They claim to have a holistic approach, but they are not part of the overall management tools used to achieve organizational success.

Most of the recognized concerns are caused by:

- Weak or nonexistent link between standardized management system and the strategic planning process or strategic financial objectives;

- The general controlling system excludes key features of standardized management systems;
- The legal constraints for healthcare increase from year to year, while the standardized management systems cover only a few. Therefore, businesses call for an integrated approach to remain effective (Berwick et al., 1990, pp. 9-10);
- The additional reporting obligations to various stakeholders in the public health sector (state, beneficiaries, health insurance companies, etc.), many of which focus on issues of quality, introducing new concepts and different reporting systems, such as: International Integrated Reporting Initiative – IIRI, social responsibility reports, Sustainability reports (Sustainability Reporting Guidelines – GRI, 2013) or Intellectual capital reports (Abeysekera, 2013). Without an integrated management system, providing different reports but interconnected, to a single entity, that cover distinct concerns and interests, will become a big challenge.

Therefore, we propose a definition of the integrated management system followed by an implementation process in several steps, applied at various organizational levels.

The first level indicates incorporating all essential elements of normed management systems of a business in the health sector into one integrated management system (figure no. 2).

The relevant management systems are:

- *Quality management* (ISO 9001:2008);
- *Risk management* (ONR 49001 or ISO 31000:2009);
- *Knowledge Management* (unregulated before by an international norm);
- *IT-Security management* (ISO 27001:2013);
- *Health and safety management* (OHSAS 18001:2007);
- *Environmental management* (ISO 14001:2007 or EMAS).

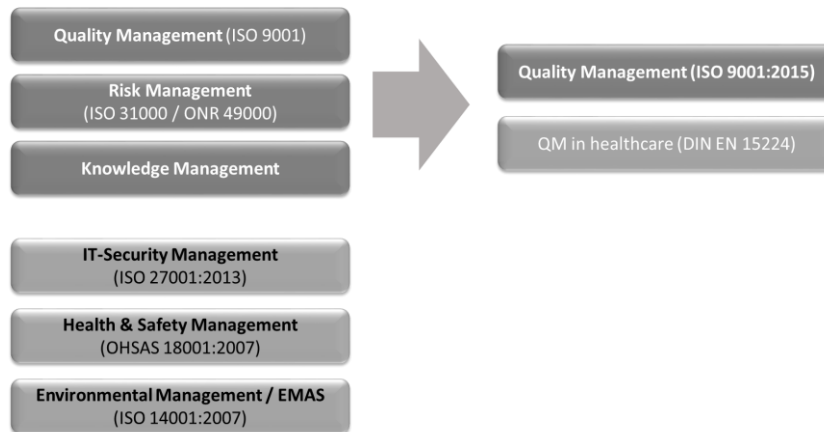


Figure no. 2. Norm-based elements of an IMS applied in the healthcare industry

The first three norms are already included in the ISO 9001:2015 proposal or DIN EN 15224 "Quality Management in Health" which concerns both patient safety and clinical risk management (TÜV SÜD, 2014). This holistic approach advanced by the new standard sets out clearly the efforts undertaken towards integration and the company's commitment to achieving long-term competitive advantage in providing medical services on the market where it operates.

The second level includes integrating a IMS model in the strategic planning process by using a BSC.

Being a complex strategic management and performance evaluation instrument, BSC links each strategic objective with the different perspectives of management. In this regard, BSC runs four dimensions: financial, internal processes, customers and learning and growing, aligning value sentences for different categories of stakeholders, with profitability and performance. Excepting the financial segment, the other sides of a BSC are components of normed management systems. Simultaneously with implementing the BSC System is recommended as a priority to define a "warehouse" for performance key indicators that will be associated to the BSC quadrants.

The source of the performance key indicators used by BSC turns at the same time in a solid foundation for internal and external reporting, updating *the third level of integration*.

In view of the above, in our opinion, an integrated management system can be defined as follows: a IMS is the system that uses the minimum of standardized management systems - quality management system, risk management system, knowledge management, IT security management, health and occupational safety management, and environmental management, interconnected through strategic planning via Balanced Scorecard and made public through an integrated reporting system. Because sustainability is a critical factor and a success one at the same time, the continuous improvement process is mandatory for all standardized management systems, in conjunction with the provision of specific components of an organization that learns, found in the learning and growth perspective of the BSC.

3.2 Overview of Radiologische Netzwerk Rheinland - RNR

RNR stands as the acronym of a group of German companies offering medical services that range from radiology, neurology and nuclear medicine, to oncology and radiation therapy. The medical network consists of RNR AG, the parent company of RNR group, organized as a limited company according to German law, and three operating companies specialized in radiology and radiotherapy. With 12 own locations where services are offered directly to patients and another 13 sites in various hospitals as part of clinical services, reliable and qualified employees make RNR one of the most significant German medical organizations in its category (Figure no. 3).

The shareholders are the management team and the physicians from the company, which began as a family business with no outside investor. This structure focuses on sustainable development of the enterprise and not on achieving short-term profits.

The administrative tasks (e.g., IT, human resources management, quality management, building management or organizational communication) are concentrated in RNR AG, its headquarters and performed about 200 employees, while the operating divisions has other

850 employees. The growth of the company transformed it considerably from 1st January 2010 when doctors organized in so-called *Gesellschaft Bürgerlichen Rechts* – GbR (Civil law partnership), and adopted the current structure of a join stock company for the group leader, reinforced by three other companies with limited liability.

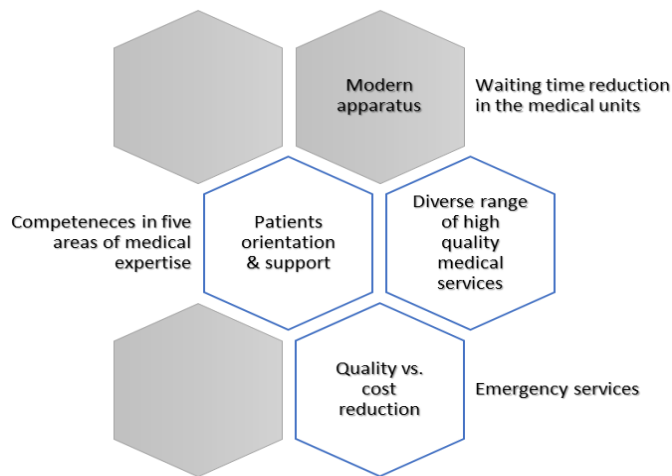


Figure no. 3. Values and strengths of RNR AG

However, rising costs for radiology and radiotherapy, in addition to the high volume and complex activities bring supplementary pressure, requiring a unique management style for pledging profitability, while complying with high quality standards.

3.3 Developing the IMRS for the RNR group

After obtaining the ISO 9001:2008 certificate, the RNR group has scheduled expanding the existing risk management system to the operative part of the company in 2014, incorporating all management systems into a single structure. Additional support for this idea came along with the new edition of ISO 9001:2015 in which the integration of risk and knowledge management is compulsory. After the Interim working draft of ISO 9001:2015 issues in december 2014, the QM team of RNR decided to start a project for implementing an IMRS, according to the steps outlined below.

• Decision of the Board of directors

To start a holisitic project is necessary to obtain full support and commitment of the Board. A key factor in accepting the proposal to implement a IMRS in February 2015 was the desire to create an instrument that will join the company's financial results with the legal requirements of standardized management systems.

Along with increasing efforts of stakeholders on relevant laws and regulations, being classified as a large company, RNR Group will be among the first organizations to be audited. As a result, the implementation of such integrated management and reporting system is an important milestone for the members of the Board in establishing a management system useful for fulfilling the legal requirements.

The condition of approval by the Board was to guarantee the implementation plan and its review and provide with analysis and revision after each stage, as well as understanding and acknowledge the conclusions. An in line requirement was that the design of processes and systems to ensure improved current activity and to minimize in parallel manual work, like for example, automated data collection and reporting. Next obligation was focusing on "flexible and agile processes" for the implementation and operation of the management system. By "agility" is understood the ability of processes to adapt to future organizational growth, a new broader structure, while "flexibility" means that RNR does not expect to hire more employees for maintaining the system effectively. Finally, the evaluation was requested to determine overall success.

- **Expanding the risk management to the operational parts**

After restructuring from 2009 and early 2010, with a joint stock company as head of the group, RNR AG Group had to develop a system of risk management, including financial and strategic ones. The requirements were met in late 2011 through the implementation and operationalization of a risk management system in accordance with ONR 49001.

In 2012 ISO 15224 (DIN EN 15224) was issued, as a general interpretation emerging the requirements of ISO 9001 standard on quality management for health care services, with concrete elements of risk management in healthcare. Moreover, in 2013 the external audit for ISO 9001 at RNR AG indicated growing interest of auditors for risk management.

Therefore, the overall progress in risk management encouraged RNR choice to extend the existing risk management to operational risks, providing a distinct advantage to start actions. Thus, it needed only an update of the Manual of risk management, risk processes and tools for financial and strategic risks in RNR AG, and also the existing quality management system which already was including elements related to operational risks, required only adapting them to comply with distinctive risk management requirements such as, for example, hygiene management, radiation protection, occupational safety management or privacy policy.

4. Results and discussions

4.1 Integration of various management systems into a single system

Each of the management systems (quality management, risk management, knowledge management, IT security management, health and safety management, and environmental management) has particular processes and applications.

For *quality management*, for example, they have been recognized:

- The online manual on quality management concerning the standard operating procedures;
- Documentation of the audit results on an online platform;
- Annual planning of internal and external audits;
- Periodical management audit.

For the risk management system, the following essential components were previously fixed:

- Online documentation of risk and assesment;
- Online documentation and management of risk management tasks;
- Annual risk report for the management team;
- Web application for risk control.

The final target was to use existing components of both management systems and combine them into a single integrated system that meets the requirements of all systems, for ensuring resource allocation and improving the acceptance of users, permitting them to operate with already familiar features.

The Risk Management Handbook for RNR AG was the foundation, adapted then to cover operational risks for all the group companies. It was also decided that for the quality management system, an online version of the manual to become available to employees. The next phase was to extend the online platform for documenting and assessing the risk and operational risks. While the old system of risk management was accessible only to RNR AG staff, the new platform was intended to be accessible to all employees. Hence, the operational risk management platform was introduced in two stages.

Primary, it was introduced an online form to document "adverse events". Then the RNR AG team assesses the risk of reported adverse events with regard to the presence or absence of a potential risk associated with each event. If the event is declared as risk after an assessment on several levels, an expert group decides on how to reduce or avoid it. All levels are documented in an online workspace where each interested employee or external auditor can track the prompt status of individual risk. This method of collecting unwanted events is later taken to build an operational risk management system, which allows a quick overview of potential risks that could arise within the organization.

Figure no. 4 captures an image of RNR platform for risk reporting and controlling. On the left once can select the companies of the group, departments and the reporting year. The risk matrix indicates then the risks to the chosen structure based on the probability of occurrence and potential damage. Risks with high probability of occurrence and damage are positioned in the top right corner of the matrix. At the bottom, can be traced the evolution of the number of risks and an indicator for the development of the potential value of the damage.

In the second stage, which requires carefully structured descriptions of each of the processes, the base business processes are analyzed for identifying potential risks. By analyzing each step of a base process and evaluating possible violations of a group of processes, the process experts describe potential risks, evaluate them according to latent damage and ultimately decide on management strategies. As previously, the measures are documented online in the risk management workspace.

The results of documenting "undesirable events" and risk analysis of the process were integrated into the internal audit checklist, and thus including operational risk management. As a novelty, now, auditors check whether employees have recognized and applied the standard operating procedures for risk management.



Figure no. 4. Risks Evaluation Matrix

A similar procedure was carried out to integrate the two management systems into the control platform. All "adverse events" were classified by themes and labeled consistent with the location where they occurred, and their list was published on the business intelligence platform. Thus, the Board of directors can obtain monthly all information on categories of undesirable events that took place in each site, unlike the former system of strategic risk management which reported to the Council at every six months. The integrated management system has kept the same reporting model, but then again with availability of daily reporting.

4.2 Connecting and aligning IMS - a strategic planning system

Before the opening of each new fiscal year, the group organizes a workshop for defining strategic business objectives for the coming year. For 2016 was discussed introducing a BSC as a tool for connecting strategic planning with the integrated management systems.

The idea of a BSC in a healthcare organization that holds an ISO 9001 certificate is not a completely new topic since many aspects of BSC are already implemented by ISO standard. Nonetheless, the BSC designed within the RNR group holds five instead of four perspectives (Figure no. 5):



Figure no. 5. Balanced Scorecard of the RNR Group within IMRS

- “Financial perspective” - exists in every company.
- “Results perspective” - is necessary in healthcare for the public sector as the number of patients/treatments does not often correlate with the financial aspects due to the fixed budget in the public sector.
- “Customer perspective” - was active in the quality management system, by addressing topics such as customer satisfaction, needs and expectations of clients of RNR AG.
- “Process perspective” - is an indispensable part of the DIN ISO 9001. The quality management handbook labelled the core processes, but most of them lacked a quality oriented description of indicators, focusing predominantly on performance indicators.
- “Resources or employees’ perspective” - is included in the DIN ISO 9001. Still, the controlling and reporting system mentioned it only for financial reasoning, missing other features.

Although that in the control and reporting system of the company, the "Financial" and "Results" perspectives were already present, while the next three have emerged as a result of the ISO 9001 certification, however, the first two perspectives were independent, while last three were not part of the control and reporting standard system.

4.3 Implementation of the integrated reporting system

RNR group has a dual reporting system, one internal and one external, the priority being the integrated reporting internal system.

By the time the project started, the members of the Board were informed about the financial situation through a monthly report, coupled with an online Business Intelligence tool, which present daily performance indicators. In addition, strategic and financial risks were reported to the Board every six months. Finally, the results of QM system were analyzed

and evaluated during the annual audit management, resulting as a challenge the strengthening of diverse existing reporting systems.

The project team had to develop a reporting structure for covering all requirements of internal stakeholders regarding frequency of reporting, the extent of the presentation of results and the balance between quantitative and qualitative indicators. At technical level, the IMRS team worked together with the in-house developer of the business intelligence solutions by defining data sources relevant to qualitative indicators and presentation techniques on the controlling online platform.

RNR Group uses the external reporting in accordance with the laws of economics and communicates the results to banks and its shareholders, but also to the main partners. In the first stage of the IMRS project, external reporting was not a priority because of the many legal restrictions involved.

Conclusions and practical implications on the incorporation of an IMS

Implementing the requirements of ISO 9001:2015 on risk management, opportunities and knowledge comes as the next logical step in building the integrated management system. The company has already organized financial risk management and the operational side extension was formerly planned because of indications included in ISO 15224 and other recommendations. An important consequence of this success for RNR AG is ISO 9001:2008 certificate which will materialize in reducing the time for applying the requirements of the new ISO 9001: 2015 version.

Another benefit is the reduction of redundant work related to management systems; therefore, future quality audits will include elements of risk and knowledge without additional checks and assessments.

It is worth mentioning the improvement of the quality of information used in decision making process, resulting from merging separate management modules which currently work unabridged. The contribution of each activity of IMS to the strategic objectives is confirmable for each BSC perspective, clarifying the connections between the IMS sub-components: strategy, mission and business objectives. We emphasize once again that ISO 9001: 2015 with its "high-level structure" and innovative components is an essential step towards an integrated management system, regardless of the activity. However, our research project goes beyond ISO 9001:2015, the success of an IRMS can be guaranteed only when there is a deep integration with strategic planning through a BSC and an integrated AND structured reporting system.

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