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## Which Standards Are More Effective for Healthcare External Evaluation Organizations Management Systems?: ISQua 4th Ed. vs ISO 9004:2009

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### Abstract

The aim of this study; to find out which standard for institutional accreditation is more appropriate for external evaluation organizations for healthcare institutions. Data obtained from ISQua: Guidelines and Standards for External Evaluation Organizations 4th Edition Version 1.2 and ISO: Managing for the sustained success of an organization – A quality management approach.

In this study; two sets of standards that organizations can use as guide to increase their institutional quality were evaluated to find out which one is the best choice for External Evaluation Organizations for health care. Other quality systems and standard sets were not evaluated in this study.

First, the ISO standard set was examined in detail, then it was sought whether there is a matching standard or requirement in the ISQua standard set with each standard found in the ISO standard set. It was evaluated whether the sets had superiority or weakness against each other. ISQua: Guidelines and Standards for External Evaluation Organizations were found as more suitable for external evaluation organizations for healthcare institutions.

**Keywords:** Quality, Accreditation, External Evaluation Organization.

## **Introduction**

The importance of performing sustainable development and achieving the maturity level is increasing for organizations day by day. In the global marketplace, it is not possible for organizations to succeed by simply improving their business processes. In reaching the specified goal, it became necessary to make systematic assessments to continuously improve all processes and to use capacities improvement tools such as competence, ability (Moradi Moghadam, Safari ve Maleki, 2013). New management approaches assume that organizations play a critical role not only in economic, but also legal, technological and socio-economic variables, as sustainable development (Todorut, 2012). The sustainable success of an organization is related to its ability to meet the needs and expectations of its customers and other partners in a long-term and balanced manner. Continuous success can be achieved through environmental awareness and effective management of the organization and at the same time through the appropriate application of learning and improvements or innovations in the organization (ISO, 2009).

Some of the instruments used in relation to quality for performance evaluations of organizations are; ISO, Total Quality Management (TQM) and EFQM excellence models (Moradi Moghadam, Safari ve Maleki, 2013). While these tools provide valid and reliable guidance for many organizations from businesses, factories, educational institutions to healthcare facilities, certain organizations that focus on specific areas have additional needs.

## **Literature and Application**

ISO, an independent, international civil organization, aims to develop and share international standards that will support innovation and provide solutions to global problems. Following the first standard published in 1951, 22017 international standards and documents related to every sector, from technology to food safety to agriculture and health care, have been published by ISO so far ([www.iso.org](http://www.iso.org)).

ISO's first quality management system standards were published in 1987 (Murmura ve Bravi, 2017). The standards in the ISO 9000 series are the best-known and best-selling standards. The ISO 9000 Quality Management System Standards Series envisions how an effective management system can be set up, documented and maintained. The "9000" standard in this series covers the basic concept and language. While the "9001" is a certification standard, the "9004" standard provides guidance information, taking into account the effectiveness and efficiency of the quality management system. ISO 9004 guides the organization in order to constantly improving the efficiency, performance and efficiency of the organization; but, it does not provide a certification to organizations (Murmura ve Bravi, 2017; Hwang, Kim ve Jeong, 2012; Vanalle ve Lucato, 2016). While ISO 9001 aims to increase customer satisfaction by assuring product quality, ISO 9004 addresses the satisfaction of a wider stakeholder group such as employees, investors, suppliers, society.

Although, in its earliest versions of ISO 9004, it has a guiding role to ensure that the organization achieves the desired level of performance, in its version published in 2000, it plays a driving role that pushes organization toward performance excellence (Boys, Karapetrovic ve Wilcock, 2004).

The latest version, ISO 9004: 2009 - "Managing for the sustained success of an organization – A quality management approach" - moves the quality management system to a new stage, providing a more holistic approach model that defines the maturity level of the system, which will be the basis for benchmarking and improvement (Nitu, Nitu ve Solomon, 2011). The concept of maturity according to ISO 9004: 2009 is defined as the sustainable success achieved, when an organization fulfills the long-term needs and expectations of all partners in a balanced way (Vanalle, Lucato ve Rodrigues, 2016).

The basis for standardizing health care service was taken with the Flexner Report published in 1910 as a result of a research that questioned medical education in the United States. With this report, for the first time medical education was questioned and the way of standardization in health care services was opened. Standardization in medical education has also positively affected the quality of services provided in hospitals (Myers, 2012).

The American College of Surgeons published minimum standards for hospitals in 1919. When the "minimum required standards" were met by many hospitals, these standards were revised and "standards of optimal and accessible quality" were published in 1970's (Myers, 2012).

The International Society for Quality in Health Care (ISQua), which was established as a result of the World Health Organization's Training in Quality Assurance Working Group meeting in Italy in 1985, has continued to work as an international roof organization in the field of quality assurance systems especially accreditation of health care services and has organized annual international conferences.

Through the program started in 1999 with the ALPHA (Agenda for Leadership in Programs for Healthcare Accreditation) and known as the International Accreditation Program (IAP) since 2005, ISQua has accredited external evaluation organizations, their health and social care standards and their surveyor training programs. With IAP, ISQua, accreditor of accreditors, assures that health care accreditation organizations offer services to health care facilities in line with the international best practices (Shaw, 2004; ISQua, 2004).

Standards for External Evaluation Organizations, developed by ISQua, assess the external evaluation body in terms of external evaluation functions as well as core management principles such as management, human resources, risk and performance, finance, strategy.

### **Aim of the study**

In an environment where continuous change is routine, ensuring continuity in the activities that institutions carry out is an important element for sustainable success. Ensuring of the success is possible through international standards prepared by independent organizations.

This study aims at seeking an answer for the following question: "What would be the set of standards to be prioritized in practice within the scope of institutionalization processes of the organizations that carry out external evaluation activities in health care services?" Considering the resource costs like time, man power, finance, etc. within the process of standards compliance, it is of vital importance to market the right decision with regards to efficiency.

## Method

In the scope of the study ISQua 4th Ed. vs ISO 9004: 2009 standard sets are compared. ISQua 4th Ed. is a set of standards for the evaluation of external evaluation bodies under the IAP as implemented by ISQua. The ISO 9004: 2009 standard aims to achieve sustainable success for organizations through a quality management approach, but as a standard that can be applied to any organization regardless of its size, type and activity (ISQua, 2015).

As a first step of the study, ISQua standards have been translated into English. And Turkish version of ISO 9004 standard has been used. The study has been based on ISO requirements and the requirements in each section have been searched by examining which ISQua standard corresponded to, taking into consideration the aim of the relevant chapter. The requirements found are noted in the table next to the respective ISO Standard.

## Results

ISQua guide has eight (8) main chapters and ISO 9004 guide has six (6) chapters. The first three chapters in the ISO 9004 guide contain general information about the guide. The standards are explained starting from the fourth section. The main chapters of both standard sets are shown below.

**Table 1. Chapters of Standard Sets**

ISO Managing for the sustained success of an organization - A quality management approach 9004:2009	ISQua Guidelines and Standards for External Evaluation Organizations 4th Edition Version 1.2
<ol style="list-style-type: none"> <li>1. Managing for the sustained success of an organization (Chapter 4),</li> <li>2. Strategy and policy (Chapter 5)</li> <li>3. Resource management (Chapter 6)</li> <li>4. Process management (Chapter 7)</li> <li>5. Monitoring, measurement, analysis and review (Chapter 8)</li> <li>6. Improvement, innovation and learning (Chapter 9)</li> </ol>	<ol style="list-style-type: none"> <li>1. Governance</li> <li>2. Strategic, Operational and Financial Management</li> <li>3. Risk Management and Performance Improvement</li> <li>4. Human Resources Management</li> <li>5. Information Management</li> <li>6. Surveyor Management</li> <li>7. Survey and Client Management</li> <li>8. Accreditation or Certification Awards</li> </ol>

Since ISQua standards are compared with the requirements in the ISO standard set, the findings will be examined in the order of the ISO standards.

### *1. Managing for the sustained success of an organization*

The first standard (Section 4) stipulates the top management to constitute the quality management system of the organization in accordance with these principles in order for achieving sustainable success in general (4.1) The standard proceeds by listing the requirements on meeting the needs and expectations of the respective parties in the long-term and under a balanced manner for an organization to reach sustainable success (4.2) On the third section of the standard (4.3), it is emphasized for an organization to

manage the continuous changing, including the performance and risk management regardless of its environment, size, activities, products or shape. The last section of the standard (4.4) stipulates the requirements on managing the needs and expectations of the respective parties by the organization for reaching sustainable success.

Examining the ISQua standards on this ISO Standard, considering each and every criterion and guidance comments, it can be seen that the following criteria include the requirements comprising of the respective ISO standard.

Certain criteria of two standards in ISQua (stand. no. 1 and 3) correspond to the requirements in ISO 4.1 standard. This standard corresponds particularly to the third standard of ISQua, while the criteria in Standard 1 outlines the organization to adopt the ethical principles and values, including management to adopt the quality improvement. Appendix-B: Quality Management Principles within the scope of ISO will be able to be evaluated as a resource for USQua 1.6 and 1.7. Evaluating the ISQua standards within the scope of ISO 4.2 standard, it can be seen that the criteria in three standards (Stand. No.: 1, 2 and 4) correspond. ISO 4.3 requirements for risk management are included in the first 4 criteria of ISQua Standard no.: 3. ISO 4.4 standard, where all the parties and stakeholders are subjected to evaluation concerning the organization, are addressed on an individual basis in the other standards of ISQua (Stand. No.: 1, 4, 6 and 7).

## *2. Strategy and policy*

The second standard (section 5) addressed within the scope of ISO 9004 is for the top management to constitute and maintain a mission, vision and values for the organization (5.1). It is a should for the organization to set the strategies and policies clearly, while ascertaining whether the organizational environment, strategies and policies reviewed and revised in order to achieve its mission, vision and values (5.2). In order for these strategies and policies to be actualized effectively, it is of crucial importance for them to be set forth after being defined with the pre-designated systems that involve certain processes (5.3). Effective communication of strategies and policies is critical for sustainable success of the organization. The communication should be carried out purposefully, timely and continuously, as well as having the capacity to be operated both horizontally and vertically (5.4).

Comparing the ISO Standards, addressed under the topic Strategy and Policy, with ISQua standards, It can be seen that the ISO Standards, addressed under the topic Strategy and Policy, correspond to the 1<sup>st</sup>, 2<sup>nd</sup> and 3<sup>rd</sup> standards of ISQua, after being subjected to comparison. The requirements in ISO 5.1 standard are mentioned in two separate standards of ISQua (Stand. No.: 1 and 3). Similarly, ISO 5.2 is addressed under two separate standards of ISQua (Stand. 1 and 2). The requirements in ISO 5.3 correspond to the requirement no.: 2.6 of ISQua. The requirements in ISO 5.4 concerning the communication of strategy and policy correspond to the ones in ISQua Standards no.: 1 and 2.

## *3. Resource management*

The third standard of ISO 9004 book is the topic ‘‘Resource Management’’ (Section 6). This standard expects that the organization manages the internal and external sources in a manner consistent with the organizational policies and strategy in order for achieving the aims (6.1). The organization should designate the financial requirements, as well as ensuring the financial resourcing for current and future

operations, including the effective allocation and efficient utilization of these financial resources (6.2). One of the most critical resources of the organization is Human Resources. The leader is required to create and maintain an environment where relevant persons possess the capacity to be involved in the operations in the strictest sense for the organization to achieve its aims. This process also includes the qualifications, educational backgrounds of these persons, including continuous improvement, guidance and motivation provided for them (6.3). The organization should consider partnership as a specific form of relations with suppliers, thus managing its relationships based on mutual interests in a manner improving its skills. Within this scope, the respective processes should be constituted and maintained with regards to the determination, selection and evaluation of the suppliers and partners of the organization, in order to ensure continuous improvement of their skills, as well as ensuring the products and other resources provided by them to satisfy the needs and expectations of the organization (6.4). Additionally, the organization should plan, constitute and manage its infrastructure efficiently and effectively (6.5). It is important to provide and manage a suitable work environment. The suitable work environment is defined as the combination of human factor and physical factors (6.6). The organization should constitute and manager processes for managing its fund of knowledge, including the information and technology as critical resources. At this point, the organization is required to evaluate how its current knowledge base is to be determined and protected. It is critical to collect reliable and useful data, as well as turning the data into required information in decision-making processes. Efficient utilization of the technology is prioritized within these processes (6.7). Lastly, the organization should consider the risks and opportunities with regards to the usage and existence of energy and natural resource both in the short and long terms (6.8).

ISQ standard concerning Resource Management is mentioned within various requirements under six standards of ISQua. While ISO 6.1 is mentioned under three different ISQua standards (Stand. No.: 2, 3 and 5), ISO 6.2 mainly corresponds to ISQua Standard no.: 2. ISO 6.3 Management of People in the Organization is mentioned in the Human Resources Management Standard of ISQua (Stand. No.: 4). ISO 6.4 Standard concerning the suppliers and partners are mentioned in various requirements within three different standards of ISQua (Stand. No.: 1, 2 and 6). ISO 6.5 standard on infrastructure corresponds to the standards 3.1 and 4.1 of ISQua.

#### 4. Process management

The fourth standard of ISO 9004 standards is about Process Management (Section 7). In this standard, the organization is expected to ensure the proactive management of all processes, including outsourced processes, to ensure that they are effective and efficient, in order to achieve its objectives (7.1) The organization should designate and plan the respective processes, while, on the other hand, defining the functions that are required for supplying the ongoing products in order to satisfy the needs and expectations of the customers and the other interested parties (7.2). For each process, the organization should appoint a process manager with defined responsibilities and authorities to establish, maintain, control and improve the process and its interaction with other processes (7.3).

ISO Standards, in which the process management is addressed under a single section are different from the ISQua approach. ISQua standards outlines all the processes on an individual basis within each and every standard. Therefore, all eight standards of ISQua mention requirements with regards to the processes. Within this scope, ISQua standards outline the system approach, as well. The different requirements, mentioned in the ISQua Standards 2, 3, 4, 5, 6 and 8, outline the requirements for establishing a system on the areas, where the respective standard is related.

##### *5. Monitoring, measurement, analysis and review*

The fifth standard is about monitoring, measurement and analysis (Section 8). In order to achieve sustained success, it is required for the organization to regularly monitor, measure, analyse and review its performance (8.1). Top management should establish and maintain processes for monitoring the organization's environment, and for collecting and managing the information (8.2). Selection of suitable key performance indicators and monitoring method is critical for the success of measurement and analysis process. The top management should assess progress in achieving planned results against the mission, vision, policies strategies and objectives, at all levels and in all relevant processes and functions in the organization. Factors that are within the control of the organization and critical to its sustained success should be subject to performance measurement. The internal audits should assess the implementation and effectiveness of the management system. The results of internal audits are usually presented in the form of reports containing information on compliance against the given criteria, nonconformities, and improvement opportunities. Self-assessment should be used to determine the strengths and weaknesses of the organization in terms of its performance as well as its best practices. The results should be an input to management review. Assessment and Evaluation can be applied to strategies and policies, operations, processes, products and organizational structures (8.3). Top management should analyze information gathered from monitoring the organization's environment, identify risks and opportunities, and establish plans to manage them (8.4). The information obtained via monitoring, measurement and analysis should be reviewed (8.5).

Monitoring, measurement and evaluation are recognized as critical subjects within the scope of both standards. These are elaborated under the eighth section of ISO 9004 standard set. These standards are mainly addressed under the last sections of the third standard, of which topic is "ISQua Risk Management and Performance Improvement".

##### *6. Improvement, innovation and learning*

The last standard is on Improvement, Innovation and Learning (Section 9). Depending on the organization's environment, improvement (of its current products, processes, etc.) and innovation (to develop new products, processes, etc.) may be deemed required for sustained success (9.1) The organization should define objectives for the improvement of its products, processes, organizational structures and its management system through the analysis of data (9.2). Changes within the organization's environment may require innovation in order for meeting the needs and expectations of interested parties. Under such circumstances, the organization put the changes into practice in a timely manner considering the resources, where necessary. The organization should consider the management processes for ensuring sustainability

and evaluate the risks within these processes (9.3). The organization should encourage improvement and innovation through learning (9.4).

Addressing improvement, innovation and learning corresponds to the monitoring, measurement, analysis & review standards in ISO standards. This last standard corresponds to the last sections of the third standard mentioned in the ISQua standard concerning performance. Additionally, the requirements with regards to monitoring and improvement of employees are mentioned in the fourth standard of ISQua.

**Table 2.** ISQua 4th Ed. vs ISO 9004:2009 Comparison

<b>1.Managing for the sustained success of an organization</b>	
ISO Standards	Related ISQua Standards and Criteria
4.1	St 1:1.6; 1.7;1.9 St 3: 3.5; 3.6;3.7;3.8
4.2	St 1:1.9;1.10;1.11;1.13 St 2: 2.5;2.7;2.8 St 4: 4
4.3	St 3: 3.1,3.2,3.3,3.4
4.4	St 1:1.13 St 4: 4 St 6: 6 St 7 :7
<b>2.Strategy and policy</b>	
ISO Standards	Related ISQua Standards and Criteria
5.1	St 1:1.1 St 3: 3.5;3.6;3.7;3.8
5.2	St 1 St 2: 2.5
5.3	St 2: 2.6
5.4	St 1:1.1, 1.10, 1.13 St 2: 2.5
<b>3.Resource management</b>	
ISO Standards	Related ISQua Standards and Criteria
6.1	St 2:2.3, 2.5, 2.7,2.8,2.9,2.10 St 3:3.1 St 5:5.1
6.2	St 2: 2.1, 2.7, 2.8, 2.9, 2.10
6.3	St 4
6.4	St 1:1.1, 1.13 St 2: 2.1, 2.2 St 6:6.1
6.5	St 3:3.1 St 4:4.1
6.6	St 4:4.5,4.6
6.7	St 5
6.8	St 3:3.1

<b>4.Process management</b>	
ISO Standards	Related ISQua Standards and Criteria
7.1 7.2 7.3	<p>ISQua principles address the process approach separately for each relevant standard. Standards for process approach are below.</p> <p>St 1:1.3, 1.5, 1.10 St 2:2.5, 2.7, St 3:3.7, 3.12 St 4:4.2, 4.3, 4.4, 4.8, 4.11 St 5:5.1, 5.4, 6.2 St 6:6.4, St 7:7.1, 7.2, 7.8, 7.9, 7.10, 7.12, 7.14 St 8:8.1, 8.3, 8.5, 8.6, 8.9, 8.10</p> <p>ISQua standards also refer to the establishment of systems with standards that can be evaluated by the system approach.</p> <p>St 2:2.8, 2.9 St 3:3.4, 3.6, 3.11 St 4:4.5 St 5:5.3, 5.4, 5.8, 5.9 St 6:6.4 St 8:8.5, 8.6</p>
<b>5.Monitoring, measurement, analysis and review</b>	
ISO Standards	Related ISQua Standards and Criteria
8.1	St 3:3.5
8.2	St 3:3.6
8.3	St 3: 3.6,3.7, 3.8, 3.9
8.4	St 3:3.10
8.5	St 3:3.10
<b>6.Improvement, innovation and learning</b>	
ISO Standards	Related ISQua Standards and Criteria
9.1	St 3:3.5
9.2	St 3:3.5,3.6,
9.3	St 3:3.7,3.1
9.4	St 3:3.8 St 4:4.2, 4.9

### **Discussion**

While the ISQua set includes eight main topics, there are totally 6 standards in TS EN ISO 9004 set.

While ISO standards are grouped under the topics of managing for the sustained success of an organization, strategy and policy, resource management, process management, monitoring, measurement, analysis and review, Improvement, innovation

and learning, ISQua sets specific issues for external evaluation bodies and accreditation process, in addition to general institutional standards such as; surveyor management, survey and client management, and accreditation or certification awards.

Examining the ISO and ISQua standards as a whole, it attracts notice that ISO is structured in a manner covering every type of organizations, while ISQua standards focus on the organizational characteristics of particularly external evaluation bodies carrying out certification activities. ISQua standards, with this characteristic, is qualified to preferred as a more efficient tool for external evaluation bodies.

In other words, each and every ISO 9004 standard can be seen in various forms within ISQua standards, but not every ISQua standard is mentioned within the scope of ISO 9004.

### **Conclusion**

Organizations must be able to meet the needs and expectations of their customers and other partners in a long-term and balanced manner in order to achieve sustainable success. To achieve this success, international standards are important tools in guiding institutions. However, in terms of efficient use of resources, it is important that which standards will be more applicable to institutions and have effective results. In this study, from this point of view, two sets of standards (ISQua 4th Ed. with External Evaluation Organizations and TS EN ISO 9004: 2009) by which external evaluation bodies can be used to achieve sustainable success, have been compared. In conclusion, ISQua standards have been accepted to be a more effective tool in terms of external evaluation bodies.

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