ISO 9001: 2015 QUALITY SYSTEM MANUAL DEVELOPMENT AND IMPLEMENTATION FOR BUSINESS AND COMMERCE WITH EXPANDED EMPHASIS ON RISK MANAGEMENT

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The Supervisory Committee certifies that this ***disquisition*** complies with North Dakota State University's regulations and meets the accepted standards for the degree of

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ABSTRACT

ISO 9001: 2015 is the latest edition of the Quality Management System from the International Standard Organization. One of the most noticeable changes about the new edition is the emphasis on risk-based thinking. This study introduces a template for developing a Quality Manual and a systematic approach to Risk Assessment using a risk-based decision-making framework embedded in the Quality Management System. An extensive discussion on decision-making, risk and opportunity analysis is provided with the aim of developing a seamless integration between QMS, risk analysis, and decision-making. This study proposes a decision-making framework that aligns ISO 9001 requirements with the decision-making process. The proposed decision-making methodology is aimed specifically at product and service selection. A case study is used to demonstrate the methodology.

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DEDICATION

This thesis is dedicated to my beloved and supportive father Hesham who provided guidance for me throughout my life, my loving mother Hanaa who loved me more than anyone could and my sister Mayar who has always been my best friend and life companion. They have supported me for a decade and this work would have been impossible without them. I also would like to dedicate this work to my lovely fiancée Andreea who I am truly grateful for having in my life and who I am looking forward to spending the rest of my life with. She is the most beautiful girl in the galaxy and beyond. Her mother is nice, so I am optimistic about this. Her dad is really funny. And of course, couldn't have done this without the inspiration of the one and only; Youssef. Last but not least, I am grateful to my friend Viranga who was a continuous support and knowledgeable resource. His expertise and guidance were indispensable.

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CHAPTER 1. INTRODUCTION

ISO 9001 Quality Management System

The International Organization for Standardization (ISO) is a not-for-profit organization, recognized as an independent non-governmental international organization with memberships in 161 national standards bodies that makes International Standards. Through the contributions of its members, ISO brings experts together to develop international standards that are aimed at meeting global challenges. The standards are developed in a voluntary, consensus-based and market relevant manner. Members are divided into three categories, with varying access and influence over the ISO system.

There is a General Assembly that meets once per year. It is the principle authority and a vital organ of the organization. It consists of President, Vice-President (policy), Vice-President (technical management), Vice-President (finance), Treasurer, and Secretary-General. The body that reports to the General Assembly is the ISO Council. The council is the core governance body of the organization. It has 3 meetings per year and is occupied by only 20-member bodies at any given time. This is in addition to the ISO principle officers and the chairs of the various committees. Finally, there is the Technical Management Board (TMB), which reports to the council on the work of the many technical committees that are involved in the various specific technical aspects surrounding many industries. The technical committee responsible for the development of standards in the field of quality management and quality management systems is TC 176 Quality Management and Quality Assurance Committee. Naturally, this committee is heavily involved in the work of other committees with overlapping interests. ISO/ TC 176 is charged with an advisory role to all ISO and IEC technical committees to ensure the validity and integrity of the quality system standards and the effective adoption of the ISO policy on quality

management systems deliverables (ISO.org). Its vision is the worldwide acceptance and use of the ISO products. This would enable trading locally and globally and contribute to progress and prosperity on the individual and the organizational levels. The goals of ISO/TC 176 are centered around widening the acceptance of their standardization of the quality management principles, continuing to evolve the standards to meet the global challenges, and lead the discussion on issues related to management systems. The ISO quality management international standards are based on seven quality management principles; customer focus, leadership, engagement of people, process approach, improvement, evidence-based decision-making, and relationship management. There are other quality management frameworks; Baldridge Criteria for Performance, Excellence, The European Foundation for Quality Management Excellence Award, and Total Quality Management.

Multi-Criteria Decision-Making Methodology

A risk-based decision-making methodology is a decision-making process that integrates risk assessment in some form into the decision-maker's point of view regarding the favorability of a decision alternative so as not consider the perceived performance of the alternative as the sole basis on which to decide. Hence, risk-based decision-making considers both comparative performance and comparative risk. Multi-Criteria Decision Analysis (MCDA) is a suitable integrative decision analytic process that allows for this two-dimensional evaluation of decision alternatives. There are two broad approaches to MCDA; multiple attribute decision-making (MADM) and mathematical programming problems. The focus in this work is on MADM problems. MADM techniques have two large families; outranking and multiple attribute utility theory (MAUT). The decision-making methodology proposed in this paper is based on a MAUT technique called Analytical Hierarchical Process (AHP). Though MAUT method vary, a common

structure includes the following steps (Von Winterfeldt and Edwards, 1986, p. 273); 1) define alternatives and attributes, 2) evaluate each alternative with respect to each attribute, 3) estimate relative importance weights to the attributes, 4) aggregate weights and attributes evaluations, 5) conduct sensitivity analysis and recommend a solution. The output of a MADM problem solution is the selection of a specific decision alternative, the ranking of all decision alternatives, or some other form of screening the decision alternatives based on a value function that takes the form of $v(x) = \sum_{i=1}^{n} w_i v_i(x_i)$, where $v_i(x_i)$ is the value of alternative *x* with respect to the *i*th attribute, w_i is the importance weight of the *i*th attribute, and *n* is the number of attributes.

AHP is used for setting up a performance criteria tree and determining their importance and utilizes pairwise comparison which allows for comparing pairs of alternatives on a 1-9 scale with regards to each criterion. AHP transforms value preferences into ratio scale weights that are combined into a linear additive weight for each alternative. AHP has three functions. The first is structuring complexity. AHP uses hierarchy to structure the factors that are relevant to the decision problem. This is in-line with how people classify information and naturally structure problems. The second function is measuring on a ratio scale, which are higher than other measurement scales and is also used by MAUT. The third function is synthesizing a decision analysis of multiple dimensions (Forman and Gass, 2001). Furthermore, AHP has three basic principles. The first principle is decomposition, which refers to decomposing the decision problem into a structure of hierarchy of clusters, sub clusters, and so on. The second principle is comparative judgments, which is the utilization of pairwise comparison to compare each pair of criteria and derive local priorities in their level of the hierarchy with respect to their parent in the higher level. Finally, AHP has three axioms. The first axiom is reciprocity of comparison pairs. This means that if A has 5 times the value that B has, then B has 1/5 the value that A has. The

second axiom is homogeneity, which means that the elements being locally compared in terms of importance or value should not differ by more than an order of magnitude. The third and final axiom is that the judgement made regarding the value or importance of an element, does not depend on its child elements, but on the elements within its cluster, and with regards to their parent element (Forman and Gass, 2001). Zahedi (1986) conducted a study that shows that utilizing AHP's pairwise comparison and MAUT's value functions can be compatible and coherent as long as the interpretation of the DM's preferences regarding the attributes and their weights is coherent. The implication of Zahedi's work is that it is possible to utilize pairwise comparison and value functions within the same framework in an integrated way. Furthermore, based on the identified performance criteria and their importance, risk assessment is conducted, and a comparative risk score is determined for the decision alternatives.

Decision-Making in ISO 9001

The QMS is a framework that governs the processes of an organization. Hence, it should also govern and be relevant for the organization during a decision-making process. Particularly, the decision problem that is most relevant to ISO 9001 and the strategic direction of the organization is products and services selection. The proposed methodology discusses the integration of ISO 9001 with the decision-making process. Specifically, three points will be discussed in the context of developing a process that supports factual-based decision-making within ISO 9001; extracting data and information from QMS for developing a decision-making process, the documentation of the decision process in an ISO 9001 compatible way, and strategic mapping of the decision performance criteria and the organizational context. The decision-making methodology proposed in this study is based on Analytical Hierarchical Process (AHP) and the Multi-Attribute Utility Method (MAUT).

MAUT is a technique for measuring values of a set of important attributes for a set of alternatives and weighing the relative importance of these attributes from the decision-maker's perspective to generate a multi-attribute utility score. It has 5 steps (Jansen, 2012);

a) Define alternatives and attributes

b) Evaluate value of each alternative

c) Assign importance weights

d) Aggregate weights and values to obtain overall utility evaluation of alternatives

e) Sensitivity analysis

Risk Assessment in ISO 9001

Risk assessment holds a central place in ISO 9001, with the requirement of adopting "risk-based thinking" as the hallmark of the role risk assessment plays in the new ISO 9001 edition. This paper will discuss the role of risk assessment in QMS that is mandated by ISO 9001 and how this role needs to also be present when making decisions. The terminology and conceptualization of risk assessment will be based on ISO 9001 as well as ISO 31000, which is a designated risk management framework that is referenced by ISO 9001.

Organization of The Study

This thesis is divided into seven chapters. Chapter 1 introduces the topics of ISO 9001: 2015 Quality Management Systems, Decision-Making, and Risk Assessment. Chapter 2 provides literature review detailing the new changes seen in the 2015 edition of ISO 9001 and their implications. Chapter 3 outlines and explains the methodology used to achieve the objective of this thesis. It also presents literature review and discussion on risk-based thinking in ISO 9001: 2015 and integrating risk management and quality management. Finally, Chapter 3 presents literature and discussion in decision-making. Chapter 4 presents a Quality Manual for ISO 9001

to outline the Quality Management System. It also details the proposed framework for a risk-based decision-making process for ISO 9001: 2015. Chapter 5 presents a case study where the decision-making framework is utilized by a medium-sized manufacturing company that uses the framework to support the critical yearly process they go through for selecting the projects they will accept from their clients. Chapter 6 summarizes lessons learned and conclusion is provided.

CHAPTER 2. LITERATURE REVIEW

New Changes in ISO 9001

Medic et al. (2016) discusses the main changes introduced in the new edition of ISO 9001, especially requirements related to context of organization, risk-based thinking, knowledge as resource and leadership. Shulyar and Reverenda (2017) identified the most significant changes in the new edition of international standards of quality management ISO 9001: 2015 concerning requirements to adaptability and flexibility of quality management in an enterprise. Reid (2015) discusses the requirement of determining the context of organization, sub clause 4.1, in depth. Liebesman, S. (2014) discusses risk-based thinking in the new international standard, while Hrbackova (2016) talked about methods for implementing risk-based thinking in the production process and recommended utilizing FMEA for risk assessment. Murray, W. (2016) also discusses risk-based thinking in the new standard. Hampton, D. M. H. (2014) discussed the changes to the new international standard, particularly with regards to risk identification and process approach. "Jack" West, J. E., & Cianfrani, C. A. (2016) emphasize preventive action through risk-based thinking, referencing clause 6.1 of the new international standard. They also published another article where they discuss significant changes in the new edition that transitions organizations to the position of benefiting from ISO implementation for operational excellence instead of mere compliance and conformance.

Hunt (2017) discusses topic management commitment required in clause 5.1 in the new international standard. Palmes, P. (2016) focuses the discussion on clause 5.3 of the new international standard in which the organizational roles, responsibilities and authorities are required. Gorny (2017) discusses occupational safety in terms of working conditions and damage caused by failures, in the context of complying with ISO 9001: 2015. Harpster (2016) argues that

Design FMEA and process FMEA can be a foundation for risk-based and fully compliant ISO/DIS 9001: 2015 QMS.

The context of the organization is a newly introduced concept in ISO 9001. This new concept is concerned with understanding the organization's business and operations conditions that are relevant to the organization. For example, the organization's specific objectives, needs, process complexity, size and structure are all considered to be part of the organization's context. (Medic et al, 2016). On a more fundamental level, the issues that need to be defined and addressed for demonstrating understanding of context requirement are issues that are relevant to the organization's purpose and strategic direction and have an impact on the organization's ability to achieve the objectives of the Quality Management System (QMS). These issues can be categorized as External issues, such as technology, competition and regulations, and Internal issues, such as resources, organizational structure and the needs and expectations of the interested parties (Reid, 2015). Defining and understanding the context of the organization is a critical step that has been added to the new ISO 9001: 2015 for a reason. In the 2008 version of the ISO 9001, it has been stated that the elements of the organization's context that has been discussed above are factors that influence the design and implementation of the organization's quality management system. (Medic et al, 2016). Hence, making it an explicit requirement serves to ensure a solid foundation for the QMS of an organization. Furthermore, this requirement also ties into another new requirement that has been one of the hallmarks of this new edition, which is "Risk-based thinking". In the new 2015 edition, clause 4.1 indicates that part of the understanding of the organizational context is the understanding and determination of the risks and opportunities of the organization (Hampton (2014)), which is the corner stone for risk-based thinking. This is because it is concerned with the organization's business strategy. Risk-based

thinking is a newly introduced concept in ISO 9001, however, it has been introduced previously in ISO 14001: 2015, ISO 31000 and ISO 9000: 2015. Risk has been defined in the new ISO as "effect of uncertainty" and as "deviation from the expected, either positive or negative". This is worded slightly differently than in ISO 31000 where it is defined as the "effect of uncertainty on objectives". While in ISO 9001: 2015, risk is defined as the "effect of uncertainty on an expected result." (Liebesman, 2014). Any tool that might be used for risk-based thinking must then include preventive action. Preventive action then becomes part of strategic and operational planning, which in turn, transforms the management system into a preventive planning tool. (Murray, 2016). Although previous versions of the ISO 9001 explicitly required "correction", "corrective action", and "preventive action", the term is not used in ISO 9001: 2015 (West, 2016). Organizations can check for the effective of actions aimed for formulating preventing action through certain methods such as audit and internal reviews, KPI analysis or project evaluation (Medic et al, 2016). There are multiple types or risk; organizational-level risk, activity-level risk, strategic risk, compliance risk, operational risk, and customer satisfaction risk (Liebesman, 2014).

Another notable change is the requirement of the viewing of Knowledge as a resource. To comply with the new ISO 2001: 2015, it is important to identify the needed knowledge to carry out an activity in accordance with the quality management system. It is recommended to maintain and protect knowledge and to make it available when and where needed. Changes in knowledge needs should be anticipated and the associated risk should be (Medic et al, 2016).

The new edition of ISO 9001 is emphasizing the key role that upper management plays in the success of the implementation of the QMS and presents the leadership requirements in a more prescriptive way. There is an attempt in the new edition to create integration and

harmonization between business processes and business strategies (Medic et al, 2016). In the previous versions of ISO 9001, this was the responsibility of the Quality Manager. However, management now is required to be active in leading the quality management efforts. Top management are now expected to show that they are taking responsibility for demonstrating leadership and commitment. This serves to integrate QMS requirements into the organization's business (Yasenhak, 2016). This integration occurs on many levels, from the staff's sense of purpose to the development of common terminologies and behavioral systems that are well seated in the organization's culture that are oriented towards quality awareness and the implementation of the QMS of the organization on all levels of personnel. Management will need to lead by example, which will first require management to be very familiar with the basics of quality management such as the seven foundations of quality and a good understanding of the ISO requirements (Hunt, 2017). Clause 5.1.1 contains an extensive list of 11 requires on how to demonstrate leadership (Managing the system). It is not required to document management's commitment. Management commitment should be demonstrated by attending key meetings, management reviews, providing meeting minutes or presentations to employees to announce the actions that are in place that demonstrate commitment (Hunt, 2017).

A process approach is required in the new edition of ISO 9001. The processes that require attention in this case are the ones needed for the quality management system as well as the application of these processes throughout the organization (Liebesman, 2014). Clause 4.4.2 requires the determination of the "inputs required, and the outputs expected, risks of conformity of goods and services, and customer satisfaction" (Hampton, 2014).

A Quality Manual is not a requirement anymore for ISO 9001. The only information that needs to be documented are the ones necessary for the effectiveness of the QMS

(Hampton ,2014). A couple of other terms changes include “product” being replaced with “good and services” when referring to the organization’s products or services. “Control of external provision of goods and services” replaced “purchasing requirements”. Development of good and services has replaced “design and development”. “Production of good and provision of services” has replaced “product realization”, in accordance with the previously mentioned terminology changes. “Preventive action” was replaced with “Actions to address risks and opportunities” (Murray, 2016). “Improvement” has replaced “continuous improvement”.

The new ISO 2015 edition is expected to provide more flexibility for top management, allow more applicability in the service sector, and assist in making ISO certification more relevant to all types of companies globally, by encouraging them to managing their risk, improve their quality and better serve their customers. Furthermore, the new edition has put into consideration the other ISO standards and so it created a better alignment in the new edition with other new editions of related standards (Yasenchak, 2016)

Integrating Risk Management and Quality Management

Paraschivescu (2016) discussed an integrated approach to risk management and quality management. The author calls for including a systemic process to design, coordinate and facilitate decision-making with respect to risk when conducting quality risk management. The author proposes a quality risk management process that includes; defining the problem, assemble background information, identify a leader and critical resources, specify a timeline, deliverables, and appropriate level of decision-making for the risk management process (Paraschivescu, 2016).

Popescu and Dascalu (2011) highlight the relation between risk management and quality management and the potential for an integrated Quality-Risk approach. Some of the levers of

quality management that drive risk prevention and mitigation mentioned by the authors are integrated databases that incorporate approach. One of the major challenges identified by Popescu and Dascalu (2011) is that quality management systems and risk management systems are usually set up separately due to being utilized by two distinct functional teams; quality engineers, and risk auditors, respectively. The authors call for several rules for a hypothesized integrated system; utilizing the phases of risk management that are listed in ISO 31000; establishing context, risk assessment and risk treatment, and encouraging teamwork for solving complex problems by utilizing individuals and specialists in the domain of quality management and risk management. Furthermore, the authors call for the establishment of structures and distinct functions in the two areas of risk management and quality management by the top management. However, the authors do not detail the mechanism through which the two functions integrate and provide a seamless framework for a quality-risk management. Samani et al. (2014) consider QM to be concerned with measuring satisfaction in requirements, and on the other hand, RM is concerned with unfavorable situations and deviations from requirements. Some of the crucial benefits of integrating QMS and RMS are; improved joined operational performance, improved internal management methods, cross-functional teamwork, multiple audits reduced and streamlined, reduced cost, and more efficient reengineering (Samani et al., 2014). Hrbackova (2016) proposed utilizing FMEA to analyze production process risk within the framework of ISO 9001.

Multi-Criteria Decision Analysis

Multi Criteria Analysis (MCA) (also sometimes referred to as Multi Criteria Decision Analysis (MCDA)) is a family of decision analysis techniques that incorporate various evaluation criteria in a systemic way to make decisions. Some of the most prominent among

them are AHP (Analytical Hierarchical process) and MAUT (Multi Attribute Utility Theory). Jansen (2012) implemented MAUT in the domain of Housing through a number of examples that demonstrated the effectiveness of the technique. Pergher and De Almeida (2017) applied MAUT in the domain of production planning by selecting production values for the critical production parameters. The application was for a multi-product assembly line and the usefulness of the proposed decision model was discussed. The authors noted the lengthy time it takes to apply the decision methodology but also noted its high utility value when combined with discrete event simulation. Kiker et al. (2005) provided a review of the application of MCDA in environmental management and provide recommendations for such applications. Konidari and Macrakis (2007) combined MAUT, AHP, and SMART to evaluate the performance of a number of EU emission trading schemes across Europe. The proposed tool proved to be useful as it provided the decision makers with a rank of value indexes for the additive aggregated performance of climate policy instruments. In the presence of data MAUT was used while in the absence of data SMART was used. AHP was used to hierarchically structure the performance criteria. Canbolat et al. (2005) applied MAUT in combination with a decision tree to a location problem on a global scale for a manufacturing facility. They highlighted the ability of MAUT to explicitly incorporate the quantification of uncertainty, which was measured separately by formulating risk profiles for each of the candidate countries that represent the decision alternatives. Linkov et al. (2006) proposed a decision framework that combines MCDA techniques with adaptive management, considering public participation and diverse stakeholder values in the domain of environmental projects. Dai and Blackhurst (2011) combined AHP and QDF in a decision analysis methodology for supplier assessment. Utilizing QDF enabled the alignment of the organization's strategy and customer requirements, while AHP sets the structure of the linkage

between the organizational strategy and the supplier assessment and the determination of the importance of the various organizational objectives. The methodology results in a decision analysis that includes the proportional impact of the organizational strategy on the technical assessment of suppliers.

Multi Attribute-Based Risk Assessment Methodologies

Comparative Risk Assessment (CRA) is the utilization of multi-attribute analysis for risk assessment where the decision-maker is faced with multiple alternatives that are described by multiple attributes with regards to risk. NAL Thesaurus (2014) defines CRA as "the process of comparing and ranking various types of risks to identify priorities and influence resource allocation". CRA is commonly used in domains where decision and risk are highly intertwined, in particular, environmental and health domains. Kang and Feng (2009) used MAUT to conduct project risk assessment with the purpose of identifying uncertainty factors that are risky as well as identify primary and secondary risk factors. Ananda and Herath (2005) analyzed stake holders' risk preferences regarding public forest land-use attributes using MAUT. The authors were able to deduce risk attitudes towards native timber extraction and forest land-use option. Bedford and Atherton (2007) combined MAUT and cost benefit analysis to support ALARP decision-making and found that utilizing MAUT strengths the traditional cost benefit analysis when the decision process attempts to incorporate multiple perspectives. Borgonovo et al. (2018) introduced a framework that integrates decision theory with operational risk analysis. The authors' focus was on decision theoretic modeling as it relates to risk analysis. Linkov et al. (2006) reviewed various studies that utilize multi-criteria decision analysis for decision-making and risk assessment for regulatory agencies in the United States and Europe to apply to environmental policies. They also develop a decision analysis framework that combines multi

criteria decision analysis with adaptive management that incorporates public and stakeholders perspectives.

Other domains have also seen the utilization of multi attribute decision methodologies in risk assessment. Pacaiova et al. (2017) developed a generic risk assessment framework for emergent or existing hazards related to the individual as well as the society. The end result of the framework "the foundations of decision analysis revisited" is the evaluation of risk to determine whether it is acceptable or not. Garbuzova-Schlifter and Madlener (2016) developed an AHP-based risk assessment methodology that they applied to energy performance contracting projects in Russia. This methodology explored risk sources through developing risk hierarchies consisting of a risk assessment goal, risk factors, and causes of risk. A questionnaire was used to compare the importance of the risk sources and risk factors and the result was a ranking of risk sources with regards to criticality. Hyun et al. (2015) developed a risk analysis methodology that incorporates fault-tree analysis (FTA) and AHP and applied it to a shield tunnel boring machine (TBM). AHP was used for comparing and determining the relative magnitude of risk impact from expert's perspective and FTA was used for determining the probability of the impact. By combining the impact magnitude and impact probability, the authors presented a risk evaluation map that allows the decision maker to prioritize the most critical risk factors and risk sources. An et al. (2015) developed a fuzzy AHP technique for risk decision-making when dealing with incomplete or uncertain data. Silvestri et al. (2011) integrated an AHP/ANP with failure mode, effects, and criticality analysis (FMECA) for risk assessment of safety in manufacturing systems.

CHAPTER 3. RESEARCH METHODOLOGY

Research Motivation

This research was motivated by a lack of a decision-making framework within ISO 9001. Having a systemic decision-making process that includes both the evaluation of performance and risk is extremely valuable when considering that QMS is intended to be a mechanism that enables the organization to assure quality and control over its processes. Without a decision-making process that takes into account the various factors that must be considered by ISO 9001 , there will be a disconnect between the basis of the design decision-making and the requirements of ISO 9001. A decision framework that is integrated into ISO 9001 would enable the realization of the benefits of ISO 9001 as it will act as a proxy to the ISO 9001 itself within the scope of the specific decision problem that is being explored. One of the most important and critical decisions that are relevant to ISO 9001 is the products and services selection decision. This is not only one of the most influential decisions an organization can make to affect its business strategy, but it's also one of the most extensively discussed issues in ISO 9001 guidelines. The guidelines detail product and service designing because it is at the core of the organization's business. Though there are a lot of decision-making frameworks and methodologies that can help in product and service design decisions, they are not specific to ISO 9001. The requirements, objectives, constraints, and factors involved in the product design process must all adhere to ISO 9001 guidelines, and hence, they must be included in the decision-making process. At this point in time, there are no decision-making frameworks that can claim to be able to act as a proxy for ISO 9001 when facing products and services selection problem. Furthermore, ISO 9001 guidelines intertwine the product and service selection with not only quality factors to consider but also risk factors that should be considered. in addition, two of the most important success

factors for ISO 9001 certified organizations are implementation level of quality management practices, management commitment, and the culture of the organization. A lack of an integrated decision-making process that is tied to ISO 9001 causes management to make decisions in isolation of ISO 9001 requirements. Implementation level could be low because of the lack of linking the implementation of ISO 9001 to the information management system of the company and the lack of the utilization of its requirements in analyzing and measuring products and services design quality. The culture of the organization is possibly not changed by merely adopting ISO 9001 because of lack of mechanisms that allow the constant referencing and utilization of ISO 9001 requirements.

The decision-making process must incorporate risk assessment and risk planning in a way that allows for a benefit-risk assessment of each of the potential designs. A decision-making framework that aligns ISO 9001 requirements with decision-making is needed. This decision-making framework must incorporate all relevant ISO 9001 requirements in terms of the quality management and risk management of product and service designing. Without such decision-making framework, factors and requirements that are demanded by ISO 9001 might not be incorporated in the decision-making as it would be up to the decision maker to analyze and interpret ISO 9001 requirements and attempt to make sense of it when making design decisions of the products and services offered by the organization. A coherent framework that acts as a proxy to ISO 9001 will enable not only selecting the best design but would also simultaneously benefit from abiding by ISO 9001 requirements and enable the justification of the decision that was made by tracing it to these requirements and demonstrate the organization's compliance with the international standard. A decision-making framework is needed to increase possibility of

having the critical success factors of ISO 9001, particularly, the implementation level and management commitment.

Research Methodology

The purpose of this study is to propose a risk-based decision-making framework for implementation with ISO 9001 QMS framework. This framework bridges the gap between utilizing a QMS for process control and making critical decisions. The framework was developed by studying the domains of risk management and decision-making. Furthermore, the framework is further integrated into ISO 9001 QMS framework through interfacing the QMS to the decision-making framework. The applicability and the benefits gained from the proposed framework are discussed as a case study experience in an e-commerce business. The information needed for this study was obtained from the company's various information databases as well as through interviews with managers and employees of the company. The framework was implemented at the company to develop and utilize a decision-making process for a critical recurring decision faced by the company, which is product selection.

Original Contribution and Significance of The Study

This is the first study that provides a comprehensive detailing of the implementation of risk-based decision-making based on ISO 9001 requirements for product and service selection. Methodologies and tools were developed to incorporate ISO 9001 requirements within the decision-making process. The study describes a decision-making full cycle which incorporates systems thinking, risk-based thinking, and knowledge management, all of which are concepts that are taking front-and-center stage in the new edition of ISO 9001. The relationship between ISO 9001 clauses and product and service selection is identified and is accordingly considered in the evaluation of the new products launching alternatives. The decision methodology will enable

the realization of a number of success factors for ISO 9001; management commitment and implementation level. Management commitment is realized through the utilization of ISO 9001 requirements in the strategic decision of products and services designs selection. The implementation level is also increased through mandating a decision-making process that adheres to ISO 9001 requirements. In this study, products and services selection is the decision process that is being considered but the approach is applicable to other critical decisions as well, such as supplier selection and quality control mechanisms selection.

Quality Procedures Manual

Quality procedures are the activities and processes that are the building blocks of the quality management system. These activities and processes are intended to fulfill the requirements of the Quality Management System. Company XYZ will ensure that relevant documented quality procedures are available, utilized and adhered to by all its employees in all processes and activities that are relevant to the Quality System.

NAME OF COMPANY		Effective Date
DOCUMENT TYPE	Rev X	DD Mmm YY
QUALITY SYSTEM MANUAL DOCUMENT		
	Chg X	Page
CONTROL NUMBER, DOCUMENT TITLE		X of X

Figure 1. Header for QMS Document

Quality System

Company XYZ has developed and implemented a Quality Management System (QMS), based on ISO 9001: 2015 framework that allows the organization to improve its practices through a structured documented system. This will allow the organization to better satisfy the

needs and expectations of customers, stakeholders, and interested parties. This Quality Manual describes the quality management system, defines and delegates authorities and responsibilities, familiarize relevant parties with the controls and structure that have been implemented within the QMS architecture.

Company XYZ's quality management system used Plan, Do, Check, Act approach (PDCA). Our QMS addresses and supports our strategies for designing our services and meeting the high-quality standards that distinguishes us from the competition. Our organization provides administrative services for governmental and non-governmental clients.

Quality Policy

Company XYZ has established a set of processes within the framework of an ISO 9001: 2015 compliant Quality Management System (QMS). This is aimed for ensuring quality will be consistently met in all aspects of the administrative services provided. This QMS will also support improvement efforts with a continuous improvement mindset. Our Quality Policy is 100% customer satisfaction; delivery of services will not exceed the agreed upon time period that was specified in the service contract and rules. Furthermore, services will be carried out with the utmost diligence in observing rules and regulations that are mandated by our clients as well as by our internal quality control system and internal regulations.

Quality Objectives

The Quality Objectives of Company XYZ:

a) Close cases in under 30 days 100% of the time.

b) Achieve at least 90% confidence in the compliance of the administrative service to the requirements and guidelines.

c) Reduce the amount of paperwork that needs rework by 50%.

The progress towards achieving these quality objectives will be incorporated in the management review. Quality objectives may vary based on status and any changes to the company's mission and goals.

Quality Manager

Designated Quality Manager (QM) in charge of the Quality of work in the company with the final approval authority for all Quality Documents is identified.

Quality Manager's Approval Page

This procedure is a Quality System document. It is the holder's responsibility to ensure that any printed copies are the most current version available. The final approval is made by the QM.

Quality System Manual

The purpose of this Quality System Manual (QSM) is to outline the Quality Management System (QMS) of our company. This is a level 1 document and all changes are controlled and approved by the QM. QSM is a document stating the Quality Policy and describing the QMS of the company. The QSM outlines the importance of compliance with customer and regulatory requirements. QMS is complete and responsive to the requirements of International Organization for Standardization (ISO) 9001:2015.

Company Profile

Company XYZ performs administrative tasks on behalf of its clients. The biggest client that the organization has is Center for Medicare and Medicaid (CMS), a governmental agency responsible for administering Medicare and Medicaid programs. Company XYZ is responsible for administering Medicare and Medicaid claims on behalf of CMS in 13 states.

Scope

The QSM specifies requirements for a quality management system that consistently provides products and services that meet customer requirements and enhances customer satisfaction through the effective application of QMS and processes for continuous improvement of the system and the assurance of conformity to customer and any legal *and authority* requirements.

Application

This Quality Manual was created to enable the successful implementation of a quality management system, to enable the demonstration of the organization's ability to consistently provide services that meet customer and applicable statutory and regulatory requirements. Managers and team leaders within Company XYZ will find valuable information about our organization's quality policy.

Organization Map

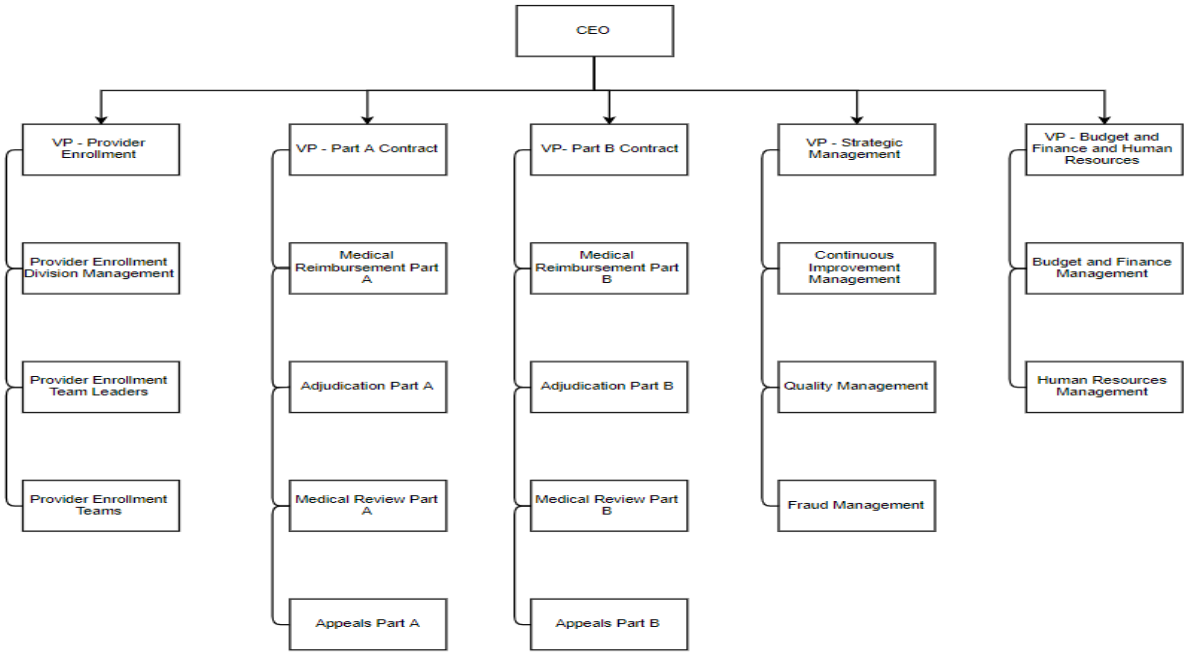


Figure 2. Organization Map

Major Products & Services

Company XYZ provides the following services;

a) Administrative services such as claims processing, electronic data interchange, provider enrollment and call centers

b) Analysis on the populations healthcare needs

c) Anti-fraud services

Normative References

ISO 9000:2015, Quality management systems — Fundamentals and vocabulary

Definitions/Acronyms

For the purposes of this document, the terms and definitions given in ISO 9000:2015 apply.

Organizational Context of Company XYZ

The top management of Company XYZ shall determine external and internal issues that are relevant to its purpose and its strategic direction and that affect its ability to achieve the intended results of its quality management system. External issues are to include, but not be limited to legal, technological, competitive, market, cultural, social and economic environments, whether international, national, regional or local. On the other hand, Internal issues are to include, not be limited to values, culture, knowledge and performance of organization. Internal and external issues are to be viewed considering risk-based thinking.

Company XYZ's external issues were identified as; relevant state and government regulations, market competition risks and opportunities, cultural and social issues, the outlook of the country's economy and technological breakthroughs that enable higher level of competition, and healthcare laws and regulations. The internal issues that shape the context of Company XYZ is its organizational structure, its culture, its employees' talents, skillsets and expertise, and the

performance of its systems. The output of this exercise is used as an input when considering risks and opportunities and the actions needed to address them.

The organizational context is derived from:

a) Business plans, strategies, and statutory and regulatory commitments;

b) Technology and competitors;

c) Economic reports from relevant business sectors;

d) Technical reports from experts and consultants;

e) SWOT analysis reports;

f) Meetings minutes;

g) Process maps and reports.

Understanding the Needs and Expectations of Interested Parties

Due to their effect or potential effect on Company XYZ's ability to consistently provide best services that meet customer and applicable statutory and regulatory requirements, the top management of Company XYZ shall determine the relevant interested parties and their requirements that are necessary for the quality management system. The information about these interested parties and their relevant requirements shall be periodically monitored and reviewed. To keep our QMS aligned with our strategy, internal and external factors will be taken into consideration in order to determine potential impact on our context.

The internal interested parties of Company XYZ are:

a) front-line staff

b) support staff

c) Middle and upper management.

External interested parties of Company XYZ are:

a) Vendors.

b) Contractors, such as IT contractors and contractors for other supportive services.

c) Customers.

d) State and government.

Scope of Quality Management System

The top management of Company XYZ shall determine the boundaries and applicability of the quality management system to establish its scope. Factors to consider when considering the scope of the QMS are;

a) the external and internal issues referred to in clause 1.1

b) the determination of the interested parties referred to in 1.2 and their requirements

c) Company XYZ's products and services.

The scope of this QMS shall be available and maintained as documented information. The requirements of this QMS shall all be applied unless otherwise stated and justified by the top management of the organization. To justify the irrelevance of any of the requirements stated in this QMS, top management shall show that the requirements in question do not affect the organization's ability or responsibility to ensure the conformity of the its products and services and the enhancement of customer satisfaction.

Quality Management System and Processes

The organization shall establish, implement, maintain and continually improve a quality management system, including the processes needed and their interactions, in accordance with the requirements of the International Standard. There are a number of elements that need to be present in order to systematically establish business processes in a way that is compliant with the Quality Standard;

a) clause 6 of the Quality Standard. Determine the required process input and the expected process output as well as their sequencing and interactions. This can be accomplished through utilizing methods such as Business Process Mapping and Project Management Process Sequence.

b) Determine and apply the criteria and method of these processes.

c) Determine the resources required to carry out these processes.

d) Assign responsibilities and authorities for these processes.

e) Address risk and opportunities according to the risk-based thinking found in

f) Evaluate the processes and implement any required changes to ensure the objectives of these processes.

g) Continuously improve these processes as well as the QMS itself.

Supporting documentation with relevance to the QMS processes shall be available in order to support these processes and provide confidence in their value. Company XYZ has adopted a process approach to its QMS. The key process groups are;

a) Leadership and planning processes;

b) Customer and stakeholder processes;

c) Service development processes;

d) Evaluation and improvement processes.

We utilize key performance indicators (KPI) that reflect our objectives to control and monitor our processes. KPI also enable assessments that help in determining risks and opportunities inherent to each process. Furthermore, we utilize trends analysis and various indicators with regards to nonconformities. Other relevant data that influence our assessment of

our processes are audit results, customer satisfaction data, process performance and the conformity of our services.

Leadership

Leadership General Requirements

Top management of company XYZ shall demonstrate its leadership and commitment regarding the quality management system by;

a) Assuming accountability for the effectiveness of the quality management system.

b) Verify the existence of a quality policy and quality objectives for the quality management system and continue to ensure their alignment and compatibility with the organization's context and strategic direction.

c) Assuming accountability for integrating the requirements of the QMS into the organization's business processes.

d) Advocating and setting expectations for utilizing process approach and risk-based thinking.

e) Provisioning the required resources for the quality management system.

f) Stressing the prioritization of an effective quality management and the importance of conforming and adhering to the quality management requirements.

g) Verify that the quality management system is achieving its specified results.

h) Continuously engage, direct and support individuals who can contribute to the effectiveness of the quality management system.

i) Nourishing a culture of improvement.

j) Demonstrating leadership through supporting other relevant management roles as it applies to their area of responsibility.

Leadership Customer Focus

The customer is the primary priority of the QMS. Hence, top management will demonstrate leadership and commitment in regard to the customer by:

a) Determining, comprehending and consistently meeting all customer requirements as well as applicable statutory and regulatory requirements.

b) Determining and addressing risks and opportunities that can affect conformity of products and services and the ability to enhance customer satisfaction.

c) Maintaining the focus on enhancing customer satisfaction.

Policy

Establishing the Quality Policy

Top management shall set, implement and maintain a quality policy that:

a) Suitable for the purpose, context and strategic direction of the organization.

b) Can be used as a framework for setting quality objectives.

c) Includes a commitment to satisfy applicable requirements.

d) Includes a commitment to continual improvement of the quality management system.

The Quality Policy Statement of Company XYZ

Company XYZ aspires to be the leading and professional services administrator in achieving customer satisfaction by:

a) Providing excellent standard of quality administrative services which exceeds customer requirements.

b) Continuously monitor and fulfill customer required projects deadlines.

c) And we are committed to continuously improve the effectiveness of our services by implementing and complying to all requirements required by ISO 9001: 2015 standard.

Communicating the Quality Policy

The quality policy is a document that is:

a) Available and maintained as documented information according to clause 4.5 Documented Information of this Quality Manual.

b) Communicated, understood and implemented within the organization according to clause 4.3 Awareness of ISO 9001 guidelines.

c) Available to relevant interested parties, identified in 1.2 of ISO 9001 guidelines.

Organizational Roles, Responsibilities and Authorities

Top management shall:

a) Assign roles, responsibilities and authorities and ;

b) Ensure that they are communicated and understood within the organization.

c) Ensure the conformity of the quality management system to the requirements of the ISO 9001 Internal Standard.

Conformity of the quality management system to the requirements of the ISO 9001 Internal Standard will be achieved through;

a) Internal auditing according to clause 6.2 Internal Audit of this Quality Manual.

b) conducting management reviews according to clause 6.3 Management Review of ISO 9001 guidelines

c) being aware of every staff according to clause 4.3 Awareness of ISO 9001 guidelines.

d) Ensure that the processes are delivering their intended outputs. This will be achieved through Business Process Mapping, Project Management Process Sequence. The planning of these processes should be according to clause 5.1 Project Planning of this Quality Manual and Clause 5.5.1 Project management control of ISO 9001 guidelines

d) Ensure that the processes are delivering their intended outputs.

e) Report on the performance of the quality management system and on opportunities for improvement according to clause 7.1 of ISO 9001 guidelines

f) Ensure the promotion of customer focus throughout the organization.

g) Ensure that the integrity of the quality management system is valid and maintained when changes to the quality management system are planned and implemented.

Planning

Actions to Address Risks and Opportunities

Plan for the Quality Management System

Company XYZ shall plan for the Quality Management System according to clauses 1.1 and 1.2 of ISO 9001 guidelines. The considerations to the issues and requirements that are relevant to the planning of the QMS allows the organization to:

a) Provide assurance that the QMS will be able to achieve its intended results.

b) Enhance the desirable effects.

c) Prevent, or reduce, undesirable effects.

d) Achieve improvement.

The organization shall plan actions needed to address the relevant risk and opportunities. The organization shall also determine and plan the integration and implementation of these actions into its quality management system processes according to clause 1.4 of ISO 9001 guidelines. The planned actions shall be proportionate to the anticipated impact on the conformity of products and service.

Quality Objectives and Planning to Achieve Them

Company XYZ shall determine and establish quality objectives at the relevant functions, levels and processes needed for the quality management system. The organization shall maintain the quality objectives as documented information.

The quality objectives of Company XYZ are:

a) Improve on-time delivery by 20%

b) Reduce re-work by 30%

c) Improve decision accuracy by 15%

The quality objectives of Company XYZ must be:

a) Consistent with the quality policy.

b) Measurable.

c) Considerate of the applicable requirements.

d) Relevant to conformity of products and services and to enhancement of customer satisfaction.

e) Monitored.

f) Communicated.

g) Updated as appropriate.

The planning of achieving the quality objectives of the organization shall determine;

a) What will be done.

b) The resources that will be required.

c) The persons responsible.

d) The timeline of completion.

e) How the results will be evaluated.

Planning of Changes

The organization shall carry out changes to the quality management system when necessary in a planned manner according to clause 1.4 of ISO 9001 guidelines When planning for changes, the organization shall consider:

a) The purpose of the changes and their potential consequences.

b) The integrity of the quality management system.

c) The availability of resources.

d) The allocation or reallocation of responsibilities and authorities.

Support

Resources

General

The resources needed for establishing, maintaining and continually improving the quality manual system shall be determined by the organization. The organization shall consider capabilities and constraints related to the existing internal resources and what is needed from external providers.

People

The organization shall determine and provide the required personnel for the effective implementation of its quality management system and for the operation and control of its processes. The required qualifications of the personnel will be addressed in clause 4.2 of ISO 9001 guidelines. The detailed parameters of the required personnel shall be determined based on both anticipated demand and processing time. The decision support framework shall retain information regarding the methodology and context of the decision on the detailed parameters of

required personnel. Decision on staffing level shall be connected to and affected by a larger resource allocation strategy.

Infrastructure

Company XYZ shall ensure that the infrastructure that is determined to be necessary for the operation of its processes and for the achievement of conformity of products and services is provided and maintained. This will facilitate process control as defined in clause 5.5.1 project management control of ISO 9001 guidelines

The infrastructure of Company XYZ includes:

a) Buildings and associated utilities;

b) All equipment, including hardware and software;

c) Transportation resources available from within the company or through a third party that the company contracts with.

d) Information and communication technology.

The decision support framework shall retain information regarding:

a) Information related to the organization's infrastructure in its various forms, including but not limited to percentage of utilization, operability status or condition, criticality to business, value, value depreciation rate, etc.

b) Standardized procurement decision processes.

c) Risk mitigation through maintenance and contingency plans.

Environment for the Operation of Processes

The necessary environment for the operation of the organization's processes shall be determined and provided by upper management with the purpose of achieving conformity of products and services. The necessary social environment is non-discriminatory, calm, non-

confrontational, and team orientated. The necessary psychological environment is stress-reducing, non-threatening or intimidating. The necessary physical environment at company xyz in all its buildings is balanced temperature, heat, humidity, light, airflow.

Monitoring and Measuring Resources

Company XYZ shall determine and provide the resources needed to ensure valid and reliable results when monitoring or measuring is used to verify the conformity of products and services to requirements. These resources that are provided for monitoring and measurement will be:

a) Suitable for the specific type of monitoring and measurement activities being undertaken;

b) Maintained to ensure their continuing fitness for their purpose.

Appropriate evidence of fitness of the monitoring and measurement shall be retained as documented information according to Documented Information Control Procedure.

The decision support framework shall retain information regarding;

a) the context and methodology based on which monitoring and measuring resources were determined.

b) Relevant parameters such as, but not limited to, effectiveness, criticality, risk of type I and type II errors and capacity,

Measurement Traceability

Measurement traceability is required internally within company XYZ for the purpose of tracking labor efficiency, tracking service quality and determining performance trends. The measurement of labor efficiency occurs through employee submitted information regarding the process or service time. Measurement of quality of service occurs through sampling by a quality auditor of results of finished processes. There are clear and written checklists that the quality

auditor goas through to verify the quality of work. Whether the measurement is self-reported, automated or performed through an auditor, all measurement equipment and processes shall be calibrated or verified or both, at specified intervals, and prior to use, against measurement standards traceable to:

a) Customer requirements;

b) Internal quality requirements;

c) Relevant International Standards.

The relevant requirements or standards that are being traced to shall be retained as documented information. Measuring equipment and processes shall be identified and their status shall be clearly determined. Safeguards shall be in place to prevent any adjustments, malfunctioning, damage or deterioration in measurement equipment of processes so as to protect the validity and verifiability of the measurement results.

Organizational Knowledge

The organization shall determine the knowledge necessary for the operation of its processes and to achieve conformity of products and services. This knowledge will be available to the relevant parties and maintained in a specified repository. In order to address changing needs and trends, the organization shall consider its current knowledge and determine how to acquire or access any necessary additional knowledge and required updates. ISO 9001: 2015 International Standard defines Organizational Knowledge as “knowledge specific to the organization; it is generally gained by experience. It is information that is used and shared to achieve the organization’s objectives”. Furthermore, organizational knowledge can be drawn from internal sources or external sources. The decision support framework is an integral part of the organizational knowledge.

Competence

Competence shall be determined based on the respective Job Description. The JD shall elaborate the qualifications needed for staff performing work under their control that affects the performance and effectiveness of the quality management system. The subject of Competence is related to other clauses in this Quality Manual; Clause 2.3 Organizational Roles, Responsibility and Authorities, Clause 4.1.2 People, Clause 4.1.6 Organizational Knowledge and Clause 4.3 Awareness. Competence shall be determined and revised in the event that an issue has been raised from Control of Non-Conformity Procedure.

The organization shall:

a) Determine the necessary competence for each position for achieving the required level of performance and effectiveness of the quality management system.

b) Ensure that the individuals currently performing work, will be assigned work in the future or engaging the QMS in other ways are competent on the basis of appropriate education, training, or experience;

c) Take actions to acquire the necessary competence when necessary. This will be followed by an evaluation for the effectiveness of the actions taken. Applicable actions can include the provision of training to, the mentoring of, or the reassignment of currently employed persons, or the hiring or contracting of competent persons.

d) Retain evidence of competence as documented information.

Awareness

The organization shall ensure that persons doing work under the organization's control are aware of:

a) The quality policy;

b) Relevant quality objectives;

c) Their contribution to the effectiveness of the quality management system, including the benefits of improved performance;

d) The implications of not conforming with the quality management system requirements.

Communication

Top management of the organization will determine the required internal and external communications relevant to the quality management system, including; subject of communication, time of communication, recipients of the communication, method of communication, and the issuer or initiator of communication. Communication of the quality policy will be the responsibility of top management as mentioned in clause 2.2.2 of ISO 9001 guidelines Interested parties internally and externally will be considered when determining the required communications. Communication directed from an employee could be directed with to another employee, a customer, or a stakeholder. This form of communication is usually managed through emails, Memos, CAR, and Notice Boards. Communications initiated by customers will usually be directed to employees through emails or written official letters/notices. Similarly, stakeholders initiate communications to employees through also emails or written letter.

Documented Information

General

Company XYZ's QMS includes documented information that is required by the International Standard ISO 9001 as well as documented information that is determined to be necessary by the organization for the effectiveness of the quality management system. The extent to which information has been documented is dependent on the size of the organization, the type

of activities, processes and services, the complexity of its processes and their interactions, and the competence of individuals documenting the information.

Creating and Updating

Company XYZ shall ensure that creating and updating documented information is done with the appropriate identification, description, format, and is reviewed and approved for suitability and adequacy.

Control of Documented Information

Information required by the QMS and by the International Standard shall be documented and controlled to ensure its availability for relevant parties, its suitability for usage wherever and whenever it is needed. Furthermore, documented information shall be sufficiently protected from loss, improper use, or loss of integrity.

For controlling documented information, Company XYZ shall:

a) Address the distribution, access, retrieval and use of documented information. This will be achieved through accordingly managing our internal network for internal interested parties as well as the information dispatched for external interested parties.

b) Ensure safe storage and preserve the legibility of the documented information as well as preserve the integrity of the information in relation to updated policies, processes, etc.

c) Control changes to documented information through implementing version control principles.

d) Follow specified rules for retention and disposition.

e) Identify and control documented information of external origin that is deemed by the organization to be necessary for planning and operation of the quality management system.

Company XYZ has determined its required documented information to be:

a) Quality policy;

b) Quality objectives;

c) Process input

d) Process Control

e) Process output

f) Process change.

Operation

Operational Planning and Control

Company XYZ will plan, implement and control the needed processes and their interactions for establishing, implementing, maintaining and continually improve the QMS. Planning will include determining inputs, outputs, sequencing, criteria and methods, resources, responsibilities, and authorities, according to Clause 4.4 of the International Standard. Furthermore, when planning for the QMS, Company XYZ shall consider the risks and opportunities that need to be addressed according to clause 6.1 of the International Standard.

This will be accomplished through:

a) Determining the requirements for the services.

b) Establishing criteria for the processes and the criteria for acceptance of services.

c) Determine the resources needed according to clause 7.1 of ISO 9001 guidelines

d) Implement control of the processes based on the criteria.

e) Creating and managing all necessary documentation to ensure that the processes have been carried out as planned, and to demonstrate the conformity of services to their requirements.

Requirements for Services

Customer Communication

Customer communication will follow the guidelines previously established under clause 7.4 in the International Standard. Following the guidelines will ensure that Company XYZ:

a) provides the necessary information regarding services it offers; during bidding process.

b) Helps its customers adapt to major changes introduced by internal or external factors.

c) Handles enquiries, contracts or special requests;

d) Obtains customer feedback regarding its services. A solution process shall follow according to clause 10.2 Nonconformity and corrective action of ISO 9001 guidelines

e) Handles customer information appropriately.

f) Establishes specific requirements for contingency actions, when relevant.

The decision support framework shall retain the information on information gathered through customer communication relevant to decision-making. In particular, information related to;

a) Feedback regarding services offered.

b) Specific requirements for contingency actions.

c) Customer special requests.

Determine the Requirements for Services

Company XYZ shall determine the requirements for services, including any applicable statutory and regulatory requirements, as well as those considered necessary by the organization. The organization shall ensure that it is able to meet the claims for services it offers as defined in the Contract Document.

Review of the Requirements for Services

Th**e** organization will conduct a review regarding its ability to meet the requirements for services before committing to supply services to customers. This review will include:

a) Requirements specified by the customer and outlined in the Contract Document;

b) Requirements that are necessary for legally carrying out services but is not required by the customer;

c) Requirements specified by the organization as discussed in clause 8.0 of this Quality Manual;

d) statutory and regulatory requirements applicable to the services, especially new government regulations regarding universal healthcare.

The results of the review shall be documented according to clause 7.5 Documented Information of this Quality Manual and in this Decision Support framework. If there are new requirements for services, this documentation shall be updated accordingly. Changes made to the requirements of services will also be communicated to the relevant team members according to clause 7.4 Communication of ISO 9001 guidelines

Design and Development of Services

General

Company XYZ will establish, implement and maintain a design and development process that is appropriate to ensure the subsequent provision of products and services.

Design and Development Planning

For determining the stages and controls for design and development, Company XYZ will consider:

a) The nature, duration and complexity of the design and development activities;

b) The required process stages, including applicable design and development reviews;

c) verification and validation activities for the required design and development;

d) the responsibilities and authorities involved in the design and development process.

e) The internal and external resources required for the design and development of services;

f) The adequacy of the interfaces between individuals and teams involved in the design and development process;

g) The requirements for subsequent provision of products and services;

h) The level of control expected to be given to the relevant interested parties for the design and development process;

i) Meeting the requirements for documentation according to clause xx Documented Information of ISO 9001 guidelines

The decision support framework shall retain the information on the parameters and specifications of the planned design and development processes. This information will be most relevant when a decision needs to be made in relation to the design and development of services. Furthermore, the following information needs to be explicitly extracted in order to streamline potential decision analysis in the context of design and development:

a) Viable Alternate designs corresponding to current organizational strategy as well as potential variants of the current organizational strategy.

b) Analysis of the associated internal and external resources in terms of time, cost, capital, and manpower.

Design and Development Inputs

The organization shall determine the requirements necessary for the specific types of services to be designed and developed. The organization will consider:

a) The functionality and performance required from the service being designed.

b) Previous design and development activities.

c) Statutory and regulatory requirements.

d) Standards of practice that the organization has committed to.

e) Consequences of failure considering the nature of services. For example, delays are one of the major consequences to failures in the primary services provided by our organization.

The organization will retain documented information on the design and development inputs in accordance with the Documented Information clause of ISO 9001 guidelines The decision support framework will retain the information on the design and development inputs as well.

Design and Development Controls

The organization shall ensure that controls are applied to the process of design and development. This will ensure that:

a) The results expected to be achieved are defined;

b) Reviewing is possible for evaluating the ability of the process of design and development to meet requirements;

c) Verification took place for the output of the process of design and development;

d) Necessary action is taken on problems determined during the reviews, validations and verifications of the process.

e) Documented information is retained for the design and development process.

The decision support framework shall retain the information on the controls applied to the process of design and development. This information will be relevant when making decisions related to the process of design and development.

Design and Development Outputs

The organization will ensure the adequacy of the outputs of the design and development process through:

a) Verifying its compliance with the input requirements;

b) Ensuring that they are adequate for the subsequent processes for provision of services;

c) Including the monitoring and measuring requirements as well as the acceptance criteria;

d) Specifying the standard characteristics for the services that are essential for their intended purpose.

e) Retaining documented information.

The decision support framework will retain information regarding the mechanisms utilized for monitoring and measuring the adherence of the output of the design and development process to the requirements and the acceptance criteria.

Design and Development Changes

The organization will manage changes made during, or subsequent to, the design and development of services to ensure that there is no adverse impact on conformity to requirements. The changes, review results, authorization of the changes, and actions taken as countermeasures to prevent adverse impacts will be retained as documented information.

Control of Externally Provided Processes and Services

The organization does not receive products or services from external sources that are relevant to the quality management system.

Production and Service Provision

Control of Production and Service Provision

Company XYZ shall ensure the control of production and service provision through:

a) Ensuring the availability of documented information that defines that characteristics of the process output, the services to be provided, or the activities to be performed as well as the results to be achieved.

b) Measuring and monitoring the production and service provision using adequate resources.

c) Implementing control activities as appropriate stages to apply acceptance criteria;

d) Utilizing adequate infrastructure and environment for providing services;

e) Assigning responsibilities and authorities based on competency;

f) Validation and periodic revalidation of the process's ability to achieve the planned results, whenever the resulting output cannot be verified by subsequent monitoring or measurement;

g) Implementation of error-averting actions;

h) The implementation of release, delivery and post-delivery activities.

The decision support framework shall retain the information on the controls applied to production and service provision. Decisions made in relation to production and service provision should utilize control activities and error-averting actions, integrated into a control plan.

Identification and Traceability

The organization shall verify the conformity of its services whenever applicable with respect to monitoring and measurement requirements. Unique identification of the outputs will be controlled and retained as documented information with the purpose of enabling traceability.

Property Belonging to Customers or External Providers

The organization will exercise care when handling property that belongs to customers or external providers, and its loss shall be reported and retained as documented information.

Preservation

Preservation shall be applied to outputs during production and service provision, to verify and demonstrate conformity of services

Post-Delivery Activities

The organization is responsible for meeting post-delivery requirements associated with products and services. The organization shall ensure that it is meeting its post-delivery commitments by considering:

a) Statutory and regulatory requirements

b) The potential unintended consequences associated with its products and services

c) The life span of its products and services

d) Customer requirements

e) Customer feedback.

Control of Changes

Changes in production and services provision will be managed, for ensuring and maintaining conformity with requirements. The results of change reviews, authorizing personnel, and actions taken will be retained as documented information.

Release of Products and Services

The organization shall release its products and services only when planned arrangements associated with these products and services, have been satisfactorily completed at the appropriate stages.

Control of Nonconforming Outputs

The organization will ensure the conformity of its products and services to the applicable requirements. Products and services that do not conform the requirements will be identified and controlled to prevent their unintended use or delivery. The organization will take the necessary actions while considering the nature of the nonconformity and the stage it was detected at. Possible actions that are available for the organization to take regarding nonconformity:

a) correction;

b) segregation, containment, re-work or dismissal.

c) informing the customer;

d) obtaining necessary authorization for acceptance under concession

Documented information will be retained in the event of nonconformity. The retained documented information will be:

a) description of the non-conformity;

b) description of the action taken to deal with the non-conformity;

c) concessions obtained when applicable;

d) authorizing personnel.

Performance Evaluation

Monitoring, Measurement, Analysis and Evaluation

General

In order to evaluate performance, the organization will collect and retain data that can be turned into critical information on the performance of processes, products and services. The organization will determine what will be monitored and measured, when those activities shall be performed, and when the results of the monitoring and measurement shall be analyzed and

evaluated. Through the analysis of such data, the organization is committed to reviewing and evaluating the performance and effectiveness of its quality management system.

Customer Satisfaction

The organization is primarily concerned with customer satisfaction. To this end, the organization will monitor customers' perception of company XYZ, their needs and expectations.

Analysis and Evaluation

Data gathered through monitoring and measurements carried out by the QMS will be used to evaluate the conformity levels of products and services, the degree of customer satisfaction, performance and effectiveness of the quality management system, effectiveness of the planning phase, effectiveness of risk and opportunity management, performance of external providers, and the need for improving the quality management system.

Internal Audit

Internal audits shall be conducted annually to provide information on the conformity of the quality management system to the organization's own requirements and to the requirements of the International Standard ISO 9001: 2015. The audit will also provide information on the effectiveness of the implementation and maintenance of the system.

An audit program will be established by our internal auditors who will establish frequency, methods, and reporting. The importance of a process will influence the reporting needs and frequency. The organization's internal auditors are tasked with defining an audit criteria and scope for each audit. Our auditors have in-depth understanding of our organization, which enables them to communicate effectively with management regarding the criteria and scope of the internal auditing process. Our internal auditors know how to communicate effectively about a certain situation that needs upper management's attention, and they usually

enabled and given the tools necessary to take appropriate correction and corrective action with no delay. The organization's internal audit information and results will be retained by our internal auditors as documented information.

Management Review

General

Top management will be responsible for reviewing the quality management system on a quarterly schedule, to verify and ensure that it continues to be suitable, adequate, effective, and aligned with the strategic direction of the organization.

Management Review Inputs

Management will consider multiple streams of information when reviewing the quality management system. Previous actions planned in the previous management reviews are investigated to determine their status. Management also looks at the changes that occurred to the internal or external issues that face the organization. Management will look into developing trends in customer satisfaction, process performance, corrective action, monitoring and measurement results, internal audit results, performance of external providers, adequacy of resources, effectiveness of risk management, and discuss opportunities for improvement.

Management Review Outputs

Management reviews will, through the RBDM process, result in decisions and actions related to:

a) Opportunities for improvement;

b) Any need for changes to the quality management system;

c) Resource needs.

Management reviews outputs will be retained as documented information as evidence for management reviews and their results.

Improvement

General

The organization will actively, continuously and rigorously explore, determine and select opportunities for improvement. The organization will strive to implement any necessary actions that enables it to meet customer requirements and increase customer satisfaction. This will include:

a) Improving products and services;

b) Correcting, preventing or reducing undesired effects;

c) Improving the performance and effectiveness of the QMS.

Nonconformity and Corrective Action

The organization shall react to nonconformity when it occurs by:

a) acting to control and correct it;

b) deal with the consequences.

The organization shall evaluate the need for action to eliminate the root cause(s) of the nonconformity by:

a) Reviewing and analyzing the nonconformity;

b) Determining the causes of the nonconformity;

c) Determining if similar nonconformities exist or have the potential for occurring.

The organization shall implement any actions necessary to deal with the nonconformity. The actions taken will be reviewed for their effectiveness. Risk and opportunities associated with the nonconformity will be updated. The quality management system will be updated if needed.

The organization will retain documented information regarding the nature of the nonconformities and any subsequent actions taken, and the results of any corrective action.

Continual Improvement

The organization shall continually improve the suitability, adequacy and effectiveness of the quality management system. The organization shall consider the results of analysis and evaluation, and the outputs from management review, to determine if there are needs or opportunities that shall be addressed as part of continual improvement.

Discussion on Implementation for a Company New to ISO Certification

Sawant (2016) developed a 7 steps framework for implementing ISO 9001 in small and medium organizations. Domain-specific implementation frameworks have also been developed for Manufacturing, railway, textile, and other large complex enterprises (S. Aniyan, 2002; Lee and Lam, 1997; Garza-Reyes et al, 2015). Development and implementation steps for ISO 9001 can be summarized in the following list;

a) Determine the organization's needs with respect to the organization's quality needs through assessing the strong and weak areas, SWOT analysis and hiring external consultants.

b) Strategic planning through business analysis and organizational strategy formulation of mission, vision and objectives, and developing models for decision-making such as cost/benefit analysis, business process models and quality improvement models.

c) Develop QMS infrastructure through ensuring five pillars; corrective and preventive actions, management commitment, internal audits, control documents, and control of nonconformance.

d) Identify critical processes through risk assessment and gap analysis.

e) Prepare for implementation through fulfilling the requirement of ISO 9001 guidelines for planning and designing of processes, products, and services, control mechanisms, training the workforce, and documenting the planned system.

f) Implement QMS for the critical processes by actualizing the QMS processes and controls.

g) Evaluate the QMS and business processes through collecting information from customer feedback and measuring and monitoring variation in conformity and performance.

h) Maintain and improve the QMS through acting on feedback provided by the customer, implementing corrective and preventive actions, and conducting internal audits.

i) Expand the QMS through re-implementing step 3.

j) Maintain and improve the QMS through reacting to lessons learnt from implementing all the prior steps and utilize these lessons in expanding the QMS.

Discussion on Implementation for a Company that Adopts the Older Version of ISO 9001 Certification

The most important changes to look out for are summarized below along with their implementation in ISO 9001 guidelines

Context of the Organization

Understanding the context of the organization is one of the major new requirements. This requirement has been fulfilled in Clause 4.0 in the Quality Manual. The extent of the internal and external issues has been specified. Furthermore, the resources that can be drawn upon in a practical manner to put together and paint the understanding of the organizational context have been listed. These resources, as a whole, contribute to the management's understanding of the organizational context. In addition to that, the internal and external interested parties have been

listed, enhancing the management's focus on the parties that matter and who should be aware of our quality policy listed in this manual and who also should be in the focal point when we talk about the organizational context, as these parties all play a role in shaping it as well.

Risk-Based Thinking

This requirement is addressed in multiple ways in the Quality Manual. In clause 6.1, 'actins to address risks and opportunities' are mentioned but the actions themselves are listed in the Discussion on Risk Management Methodology, which is a separate document that addresses specific actions that need to be taken to address risks and opportunities. Planning for all processes as well as planning for changes is listed as a set of actions in clauses 6.2 and 6.3.

Viewing of Knowledge as a Resource

Under the clause 7 'Support', there is sub clause 7.1.5 'Organizational Knowledge', which is a sub clause of the Resources aspect of Support. Others required Resources are People, Infrastructure, Environment of the operation of processes, Monitoring and measuring resources, measurement traceability.

Top Management Commitment

The Management's responsibilities are outlined in sub clause 5.1.1 of the Quality Manual. Furthermore, in sub clause 5.2, the Quality Policy is stated as evidence for the commitment of top management to a certain policy. Furthermore, top management is committed to certain specific roles in ensuring the success Quality Management System (QMS).

Risk-Based Thinking

Top management shall plan and implement actions to address risks and opportunities. Opportunities emerge from a favorable situation that allows for achieving an intended result. Risk can be positive or negative, as it is merely the effect of uncertainty. Risk management is set

of coordinated activities to direct and control an organization with regards to risk (ISO Guide 73: 2009, 3.1). Effective and efficient risk management should abide by certain principles that ensure its intended purpose such as value creation and protection, integration, structure, customizability, inclusiveness, dynamism and responsiveness, highest quality of data, consideration of human and culture factors and continual improvement. The guidelines for ISO 9001: 2015 require risk-based thinking to be a part of the Quality Management System. In the prior version of ISO 9001 required designing procedures of preventive actions. The issue with how preventive actions were described is that the ISO 9001 standard did not discuss their sources and where and how to find them. The new edition requires establishing risk management processes, which are integrated into the QMS framework (Wawak, 2015). Risk and opportunities should be planned for, and actions to deal with them should be implemented, but much needs to be determined in order to achieve this requirement in an integrated manner. The internal and external organization's context could pose complexity, uncertainty, ambiguity or a combination of them. The organization's internal and external environments is usually an extremely complex system that involves too many factors from the legal and organizational aspects along with changes in the letter of the laws devised in it, the shift in political power, popularity of certain public opinions to the potential for the occurrence of disasters to the introduction of new industry disrupting technologies. The nature of the industry that the organization is involved in could be a low risk routine one or a highly risky industry in which failure could mean hundreds of thousands of fatalities. In a complex system, customer requirements of a dynamic nature could pose serious risk on the system. Quality Management System processes are the engine that drives the quality management system. These processes need to be determined, their interaction defined, their criteria, resources and responsibilities assigned, and the risk and opportunities associated with

them addressed (ISO 9001: 2015 sub-clause 4.4.1). The risk-based decision-making methodology proposed in this paper can be utilized in a standardized way to make decisions for addressing the system's complexity. Any action or process that is intended to achieve a certain quality objective will naturally have risk associated with it, decision-making is no exception. Furthermore, ISO 9001: 2015 refers to addressing of risk and risk-based thinking on multiple occasions in the standard;

- Clause 0.3.3 requires using risk-based thinking through addressing risks and opportunities present in every aspect that could be related to the effectiveness of the quality management system and the achievement of improved results and mitigation of negative effects.
- Clause 4.4.1 considers addressing risks and opportunities to be an integral part of the quality management system and acts as a supporting activity for the quality management processes.
- Clause 5.1.2 requires addressing risks and opportunities that can be an impediment to achieving the conformity of products and services and customer satisfaction.
- Clause 6.1.1 and 6.1.2 requires the determination of risks and opportunities and planning of actions that address these risks and opportunities in order to provide assurance for the ability of the quality management system to achieve its intended result, increase the desirable effects, reduce or eliminate the undesired effects, and enable continual improvement.
- Clause 6.1.2 also requires planning for integrating and implementing actions that address risks and opportunities into the quality management system processes and also plan for the evaluation the effectiveness of these actions.

International Standard ISO 31000 for Risk Management

ISO 31000 recommends addressing risk through a structured and systemic management process. Some of the most important characterization of risk that ISO 31000 is concerned with is the determination of the nature and context of risk, probability of occurrence, the estimation of the length of potential impacts, the level of acceptable risk and level at which response is required, the complexity and increased risk that arises from the compounding of risks. The two frameworks, ISO 9001 and ISO 31000, work in high synchrony as management frameworks for addressing both quality and risk.

CHAPTER 4. PROPOSED FRAMEWORK

Applied Systems Thinking Decision-Making

ISO 9001:2015 is a self-contained system. Decisions made by the organization, at any organization level, should be made while referencing relevant information in the QMS. ISO 9001 advocates systems thinking in implementing the QMS. For an ISO 9001 certified organization, quality management processes operate within a well-defined system with the quality policy and quality objectives of the organization serving as the primary goal and purpose of the QMS. Systems thinking requires the identification of key mechanisms or structures that optimize the performance of the QMS. The decision made would operate within the QMS and will utilize various aspects of its processes, as well as abide by the restrictions and objectives specified by the QMS. Furthermore, the sixth principle of quality management calls for "Evidence-based decision-making". A standardized decision-making process will enable the organization to provide evidence for its decisions. More research should be done to identify scenarios which require complex decision-making and develop decision-making processes for them that are native to ISO 9001. In this study, the product selection problem is explored, and a decision-making process is developed for it that adopts hard systems thinking, in accordance with ISO 9001 guidelines. The proposed methodology utilizes systems analysis through utilizing Analytical Hierarchical Process (AHP) to structure the selection problem in the context of the wider organizational and quality management systems. AHP organizes and structures the factors relevant to a decision problem and determines the importance weight of these factors through pairwise comparison. The methodology also discusses extensively information and data collection through identifying sources of information that are utilized in the decision-making process. The proposed methodology assumes a deterministic steady state system with regards to

the decision performance criteria, while the uncertainty with regards to achieving the expected performance is addressed through formulating decision risk criteria within an integrated risk assessment framework. The risk assessment assumes a non-deterministic steady state system and addresses factors and scenarios that could impact the expected performance for each decision alternative. The methodology applies system design through formulating an optimized decision based on the decision maker's preferences and the forecasted performance of the various decision alternatives with regards to the various criteria and attributes that characterize the decision problem. The approach involves first studying the problem carefully through clearly defining it, conducting literature review and discussions with subject matter experts. Next, ISO 9001 guidelines are interpreted and understood in relation to the decision problem being explored. ISO 9001 guidelines are contextualized by relating them to the various aspects of the decision problem. Then a decision framework is structured as a proxy to the ISO 9001 guidelines to resolve the decision problem being considered. The proposed framework is then implemented in a product selection problem case study for a small E-commerce business.

Product Selection Problem Background Information

Product selection problem is a multiple criteria decision-making problem. A number of multi criteria decision-making methodologies can be utilized to solve it. AHP, ANP, MAUT, TOPSIS are among the most prominent methodologies that are suited for this decision problem. LIAO et al. (2015) identify five main criteria for evaluating new products launching strategies; market characteristic, social capital, technological capability, new product development organization, and marketing mix. The selection problem considered in this study does not consider various designs of the same product, as that is an extensive problem that is better addressed in a separate study.

Risk-Based Decision-Making Process

The decision process starts with a problem that needs to be addressed, where multiple routes could be taken towards the decision maker's objectives and there is no clearly preferable route that could be taken. Hence, a decision-making process is initiated due to the existence of threats or opportunities. The Analytic Hierarchy Process (AHP) is one of the most popular choices for modeling problems. It was developed by Thomas Saaty at Wharton School of Business in 1992 and have widely utilized for structuring problems for decision-making. Both QMS and RMS are oriented towards achieving organizational objectives in a systemic way. Hence, one of the important aspects of problem modeling is identifying and analyzing the link between the problem at hand and the organizational objectives. ISO 31000 recommends designing a risk management framework that enables the integration of the process of risk management with the decision-making process (ISO 31000, clause 5.2.2). And according to ISO 9001: 2015, risk analysis can provide an input into making decisions for selecting among multiple alternatives with consideration to the different types and levels of risk involved in the decision. The ISO standard emphasizes the seamless integration between risk considerations and strategic and operational considerations when making decisions. A list of important terminologies is provided in the following table.

Table 1. Important Terminologies in the Proposed Decision-Making Methodology

Term	Description
Decision Alternatives	Options which the decision-maker can select from, with the aim of resolving the decision problem.
Performance Criteria	Important characteristics and factors for resolving the decision problem.
Performance Attribute	Characteristics at the lowest level of the performance evaluation tree that acts as a performance indicator for the criteria or sub criteria it belongs to.
Performance Attribute value	The value resulting from a value function for an attribute based on some scale.
Value Function	A function that measures the utility of an alternative based on some scale with regards to an attribute.
Importance Weight	Expresses the preference of importance that the decision maker places on each of the attributes or criteria over the others within the same level. It is determined through Pairwise Comparison.
Risk Criteria and Sub-Criteria	Important categories of risk modes through which a hazard could occur.
Risk Scenario	Sequence of events that lead to consequences and are controlled or prevented by a risk treatment plan.
Event Likelihood	The probability that an event within a risk scenario would occur based on the expected number of occurrences within a given time frame.
Risk Initiating Event	The event that initiates the risk scenario.
Risk Event	The intermediate event within a risk scenario that makes risk consequences possible.
Risk Consequence Event	Negative impact on a tangible or intangible resource or capital that is valued by the decision maker.
Risk Treatment Plan	Actions taken to reduce the likelihood of the occurrence of risk consequences or the reduction of their magnitude.
Recovery Ratio	The percentage of the risk consequences magnitude that was mitigated through the risk treatment.

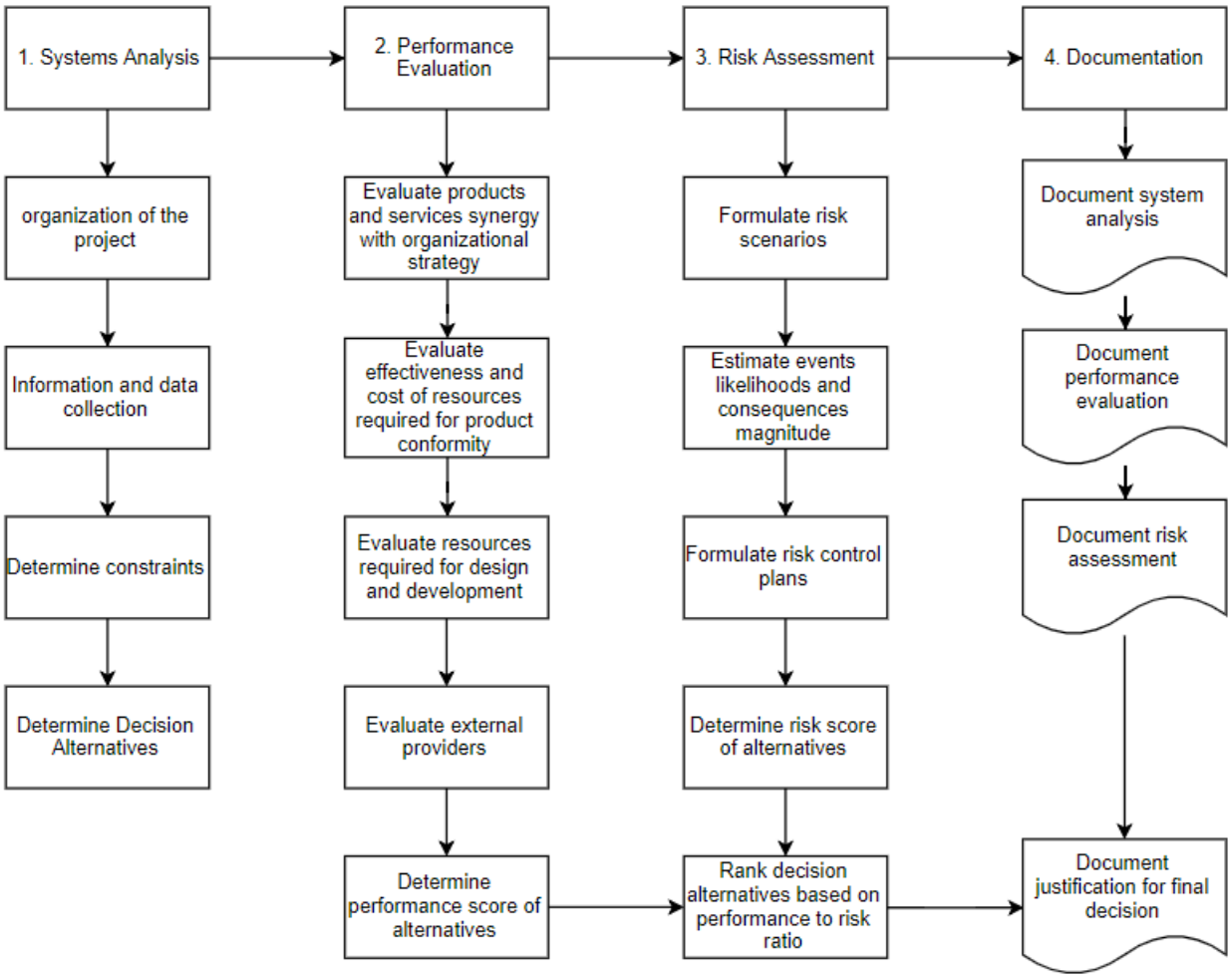


Figure 3. Proposed Decision-Making Process

The steps involved in the proposed risk-based decision-making process are listed below. It consists of four main steps; system analysis, performance evaluation, risk assessment, and documentation.

System Analysis

Project Organization

Project organization is the mechanism that brings together people and resources for the purpose of achieving the project objectives. The decision-making process occurs within the new product launching project. The various participants and stakeholders of the project participate in

the product selection decision-making. A typical new product launching project includes representatives from the quality department, marketing department, customer retention department, manufacturing department, risk engineers, external consultants and top leadership. The launching strategy evaluation factors identified by LIAO et al. (2015) describe the organizational and market attributes that are relevant to the product selection problem; market characteristics, social capital, technological capability, new product development organization, and marketing mix. The project team should select the strategy that is well suited for the overall organization's strategy.

Information and Data Collection

Information and data will need to be collected for the various aspects of the decision analysis. First, the constraints of the decision solution will need to be determined in order to qualify the decision alternatives. Second, information is gathered regarding the performance of each of the alternatives and the information needed to evaluate the performance of decision alternatives. Finally, Risk information is gathered during the risk assessment step. Information on constraints are dictated by the formulated strategy for new product launching, budget and duration. The constraints are applied in an absolute sense; no decision alternatives are allowed to violate any of the constraints. After a short list of decision alternatives is formulated, information regarding the values of each of the performance attributes for each of the alternatives. A table that details the list of information and data required for alternatives performance evaluation is presented below.

Table 2. Information and Data Required for Performance Evaluation Criteria "Synergy with Organizational Strategy".

Performance sub criteria	Attributes	Examples of Information and data required
Market characteristics	Market growth, market competitiveness, firm performance	Market growth data, forecast of future growth, number of competitors, benchmarking of competitors performance in the market, customer feedback, customer databases
Social capital	External strategic relationships	Strategic supply chain, external sources of financing, partnership research institutes
Technological capability	Internal and external Innovation resources	Technicians count, R&D count, Expertise of R&D team, firm internal capital, patents count, closeness with foundries
New product development organization	Project team	expertise of project team and its availability, its performance in previous projects
Marketing mix	Marketing prowess, distribution capabilities	Branding strategies, number of channels, distribution of expenditures, penetration, skimming, promotion expenditures, sales force intensity.

Table 3. Information and Data Required for Performance Evaluation Criterion "Effectiveness and Cost of Resources for Post Development Product Quality Management".

Performance sub criteria	Attributes	Examples of Information and data required
Resources for monitoring and measuring	Cost and effectiveness of resources	Quality policy and quality objectives, scope of implementation, expected level of risk impact, required external provider controls
Required human capital and competencies	Human capital	Existence of expertise, potential for hiring new expertise, long term value
Infrastructure	Cost of infrastructure	Cost of purchasing and cost of utilization of required infrastructure such as buildings, equipment, transportation and technological infrastructure.
Environment	Characteristics of the environment	Required social, psychological and physical environment.

Table 4. Information and Data Required for Performance Evaluation Criterion "Resources Required for Design and Development".

Performance sub criteria	Attributes	Examples of Information and data required
Effectiveness of Resources for design and development activities	Cost and effectiveness of resources	Design requirements, appropriateness of these resources for the requirements.
Cost of Resources for design and development activities	Required duration	Required activities, validation, verification, prototyping, Cost of purchasing, leasing or utilizing required resources,
	Human capital	Required expertise and competencies, Cost of purchasing, leasing or utilizing required resources,
	infrastructure	Required space, buildings, equipment, transportation and technological infrastructure, Cost of purchasing, leasing or utilizing required resources,
	environment	Required social, psychological and physical environment, Cost of purchasing, leasing or utilizing required resources.

Table 5. Information and Data Required for Performance Evaluation Criterion "Quality of External Providers".

Performance sub criteria	Attributes	Examples of Information and data required
Cost	Cost of products and services	Cost and quantity of required materials, products, or services.
Compliance	Compliance with all requirements	Historic compliance data, cost of assurance mechanisms for compliance
Financial Stability	Financial performance	Total debt to equity, earnings to interest and principal expenses, net foreign exchange exposure to equity, corporate defaults (from Irvin Fisher Committee on Central Bank Statistics Publications)
Quality	Defects rate, timeliness of delivery	Historic data on late deliveries, defect rates, process capability
Mutually beneficial relationships	Shared and integrated knowledge, prospect for long-term cooperation	Level of knowledge sharing, synergy between long term organizational strategies, demonstrated understanding of the requirements.

Performance Evaluation Tree

Performance evaluation can be done through a number of multi-attribute decision-making techniques. This methodology utilizes a combination of Analytical Hierarchical Process (AHP) and Multi Attribute Utility Theory (MAUT). AHP is a multi-attribute decision technique that assists decision makers in selecting a decision alternate given a set of competing criteria. AHP is suitable for both single and multiple decision makers. It's has a simple structure an requires that

the performance criteria are not in large numbers. AHP is utilized in conjunction with value functions, which are borrowed from the MAUT framework. MAUT allows for better quantification of performance than AHP and is dependent on data availability, which according to our methodology's application within QMS, should be the case. To construct an AHP tree, the decision maker develops a decision hierarchy that consists of decision alternatives and performance criteria, performance attributes, and value functions.

Performance evaluation is carried out through a methodology that combines AHP and MAUT techniques. In attempting to decide among multiple alternatives, the decision-maker structures the problem as a set of criteria and attributes which enables the comparison between the alternatives. The performance evaluation structure links the high-level objectives of the organization to the attributes that measure the performance of the decision. At the high levels of this hierarchy, the decision maker places the high-level objectives, high-level performance measures that are affected by the decision problem. At the mid-levels of the hierarchy (sub criteria and sub-sub criteria), the decision maker places the intermediate criteria that behave as a link that extends and explains the effects of the lower levels of the hierarchy to the high levels of the hierarchy.

The lowest level of the hierarchy contains attributes, value functions and decision alternatives. Attributes act as the fundamental decision performance measures within each performance criteria. Elements in each hierarchy level should be mutually independent in order to utilize AHP. If assuming mutual independence is not feasible, then ANP (Analytical Network Process) should be utilized and the hierarchical levels are expressed instead as clusters. Developing the performance evaluation tree can be done with the aid of a variety of techniques that analyze and link organizational objectives with decision performance metrics. For example,

influence diagrams, QFD, strategy maps, Balanced Scorecard. Other techniques include simulation techniques and systems analysis. In conjunction, the information in Category A should provide a reference and a guide for determining the important issues that need to be addressed when constructing the performance evaluation tree. The lowest level of the tree contains the attributes that, when aggregated and transformed through pairwise comparison weights, measure the value of an alternative. A representative performance evaluation tree that accurately reflect the important aspects of the problem according to which decision should be judged is very critical to the quality and value-adding of the selection of the appropriate decision alternative. The decision-maker also provides "importance weighting" to give more importance and impact to the criteria that hold high strategic value, based on the organizational strategy and relevant stakeholders. ISO 9001 and ISO 31000 require "addressing risks and opportunities" to ensure the conformity of the quality of products and services. Through the proposed framework, a decision can be formulated to seek opportunities or avoid risks by selecting a decision alternative that achieves either goals. The performance evaluation tree would enable the decision maker to describe those opportunities or risks through the metrics that can be used to comparatively measure the ability of the alternatives to achieve them as well as their link to and impact on the organization's objectives and strategy.

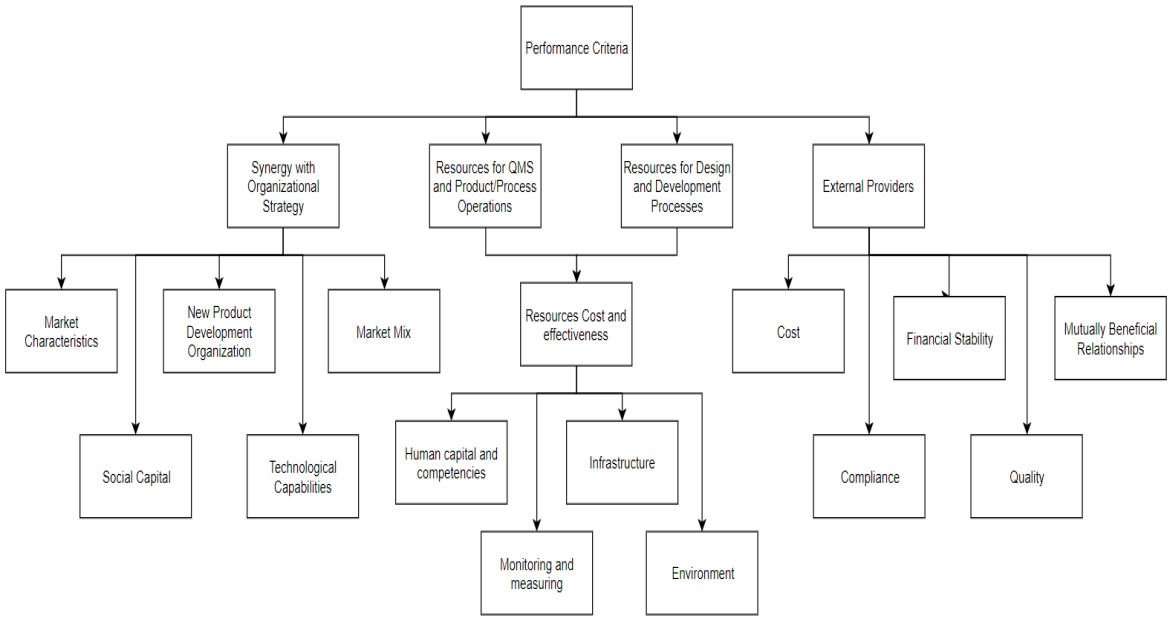


Figure 4. Performance Evaluation Criteria and Sub-Criteria

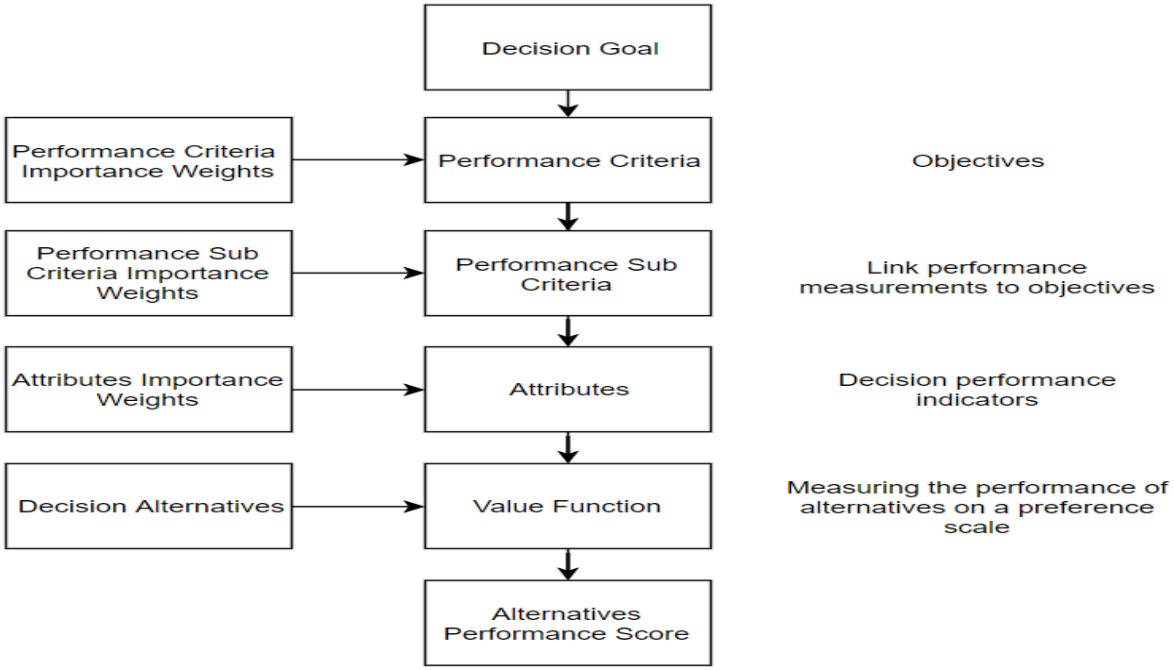


Figure 5. Function of the Performance Evaluation Tree levels

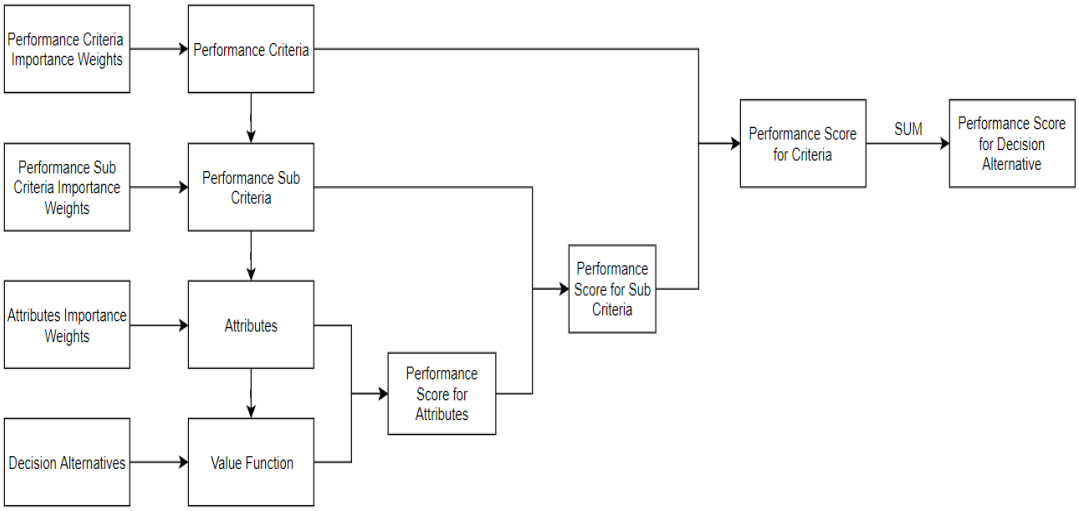


Figure 6. Determining Performance Scores Based on the Performance Evaluation Tree

Performance Criteria Score

The decision-maker determines the importance of each of the performance criteria based on its relative impact compared to established performance goals set by the organization and the decision-maker. A value function is constructed for each performance criterion to enable the representation of preferences; greater values are preferred to smaller values. The performance value can be determined through a simple value function based on a pairwise comparison, or a context-based formulated value function for each performance criterion. Given that there are K decision alternatives and *J* performance criteria (or sub-criteria) containing *I* attributes. Each performance criteria *j* has a specific number of attributes *ij* that serve to measure and express this particular performance criteria. The formula for obtaining performance score for criteria *j* is shown below;

$$Performance\ Score\ for\ criteria_j = \sum_{i=1}^{I} w_{ij}\ .v(x)_{ij} \qquad \text{(Equation 1)}$$

Where *w* is the importance weight for the i^{th} attribute x_i for criteria j, and *v*(*x*) is the resultant of the value function of attribute x_i in criteria *j*. The aggregation of performance score for alternate *k* is the summation of performance score of *J* performance criteria.

$$Performance\ Score\ (Alternate_k) =$$

$$\sum_{j=1}^{J} w_j\ X\ Performance\ Score\ for\ Criteria_j \qquad \text{(Equation 2)}$$

Where there are *K* performance criteria, and *I* decision alternatives. The product of each criteria's performance score and importance weight results in the overall performance score for decision alternate *i*.

Formulate Performance Criteria and Sub-Criteria

Four performance criteria were identified according to ISO 9001 for the product selection problem. This list was based on the analysis of ISO 9001 guidelines and selecting the clauses critical to a product selection decision;

- Synergy with Organizational Strategy (sub clause 4.1)
- Effectiveness and Cost of Resources for Product Conformity Assurance (Post Development) (sub clause 8.1)
- Resources Required for Design and Development Activities (sub clause 8.3.2)
- Quality of external providers (sub clause 8.4)

Performance Criteria 1: Synergy with Organizational Strategy

The organizational strategy is formulated by the organization and derived from its context. According to clause 4.1, understanding the organizational context is paramount to making strategic decisions. The launching strategy evaluation factors identified by LIAO et al. (2015) describe the organizational and market attributes that are relevant to the product selection problem; market characteristics, social capital, technological capability, new product development organization, and marketing mix. The organizational strategy documented in sub clause 4.2 was shown to have a strong link to the success of a new product launch strategy (Hultink et al., 1997) in that the new product launch strategy is dependent on the organizational

strategy. The launch strategy could be centered around one of the five identified factors, or a combination of them. Hence, the organizational strategy dictates the importance given to the five sub criteria.

From within the reviewed literature, Liao et al. (2016) provided the most comprehensive and recent listing of criteria and attributes for new product launching evaluation. Though the authors intended to use these criteria and attributes for selecting a new product launch strategy, they are being used in this study to select new products to be launched based on the existing organizational strategy and context, which are defined based on these sub criteria and attributes in order to consider the specific aspects of the organizational context that is relevant to new product launch, according to Liao et al. (2016), who based their listing of these criteria and attributes on a comprehensive review of the literature on new product launching. The products being considered for launching are evaluated based on each of these attributes in terms of how adequately each of the attributes support the product being evaluated. High synergy of the product with the organizational strategy is considered a proxy for profitability. Given that the organization positions its resources and configures its operations in a specific way, it will have a competitive edge for products that have high synergy with its strategic allocation of its resources.

Performance Criteria 2: Effectiveness and Cost of Resources for Product Conformity Assurance (Post Development)

According to sub clause 8.1, the organization should plan, implement and control processes that are needed for quality and conformity assurance of the products and services offered, post development. This provides an important performance criterion for product selection that is not particularly discussed in the product selection literature. Song et al. (2011) pointed out the importance of product quality and performance compared to being the first to

launch a particularly innovative product. Hence, it is suggested that directing the organizational resources to ensure the highest achievable product quality takes a high priority. The required resources should be documented according to sub clauses 7.1.5, which documents the resources needed for monitoring and measuring conformance, 7.1.2, which documents the required human capital, 7.2, which documents the required competencies of the human capital, sub-clause 7.1.3, which documents the required infrastructure, and 7.1.4, which documents the required environment for the design and production processes. These effectiveness of these resources should be evaluated, according to clause 6, based on the ability of the organization to utilize them to address risks and opportunities, enhance desirable effects, prevent, or reduce, undesired effects, and achieve improvement, and ensure the effectiveness of the quality management processes that are used to assure product conformity. These resources are to be utilized by configuring them into quality management processes according to sub-clause 4.4.

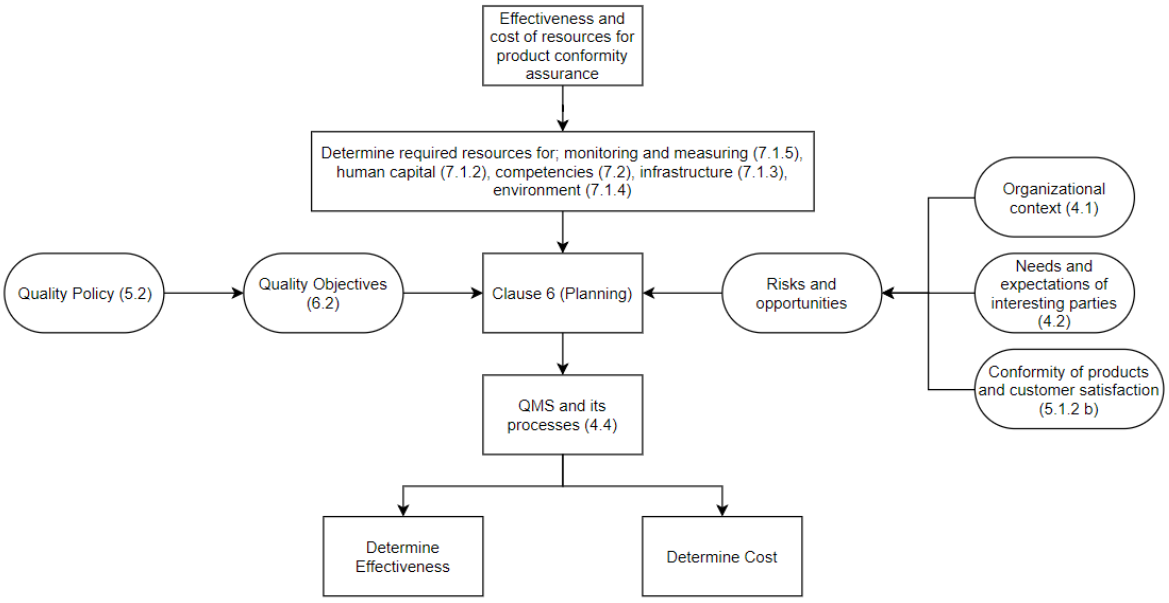


Figure 7. Performance Criteria "Resources for Product Conformity Assurance (Post Development)"

Effectiveness is determined qualitatively based on the attributes listed in sub-clause 6.1.1; assurance that the QMS can achieve its intended results, enhance desirable effects, prevention of undesired effects, achieve improvement. Cost is determined based on purchase and utilization of the required resources. Various conventions for cost calculations can be utilized, depending on each organization's methods of accounting. For example, resources that are not particularly purchased for the post-development quality assurance of the new product might not be considered to have a purchasing cost.

Performance Criteria 3: Resources Required for Design and Development Activities

Unlike the previous performance criterion, which was concerned with the quality management processes that govern the new product's quality assurance post its development, here we are concerned with the resources needed for the actual design and development activities. The planning of the design and development activities should occur according to sub clause 8.3.2, and in particular sub clause 8.3.2 (e), which requires the determination of the internal and external resources needed for the design and development activities. These resources could be competencies, expertise, technologies, etc. There are a number of methodologies that can be used to estimate the cost of a new product's development process. Chwastyk and Koloswski (2014) proposed a method for estimating the cost of the planning, development and operational activities for a new product development. Levtushenki and Hodge (2012) reviewed a number of cost estimation methodologies for product development. All of these methods are appropriate as long as they're well suited for the context of the organization and as long as they're applied consistently across the decision alternatives.

Performance Criteria 4: Quality of External Providers

According to sub clause 8.4, the organization must ensure that the externally provided processes, products and services conform to requirements. These requirements should be determined in full according to sub clauses 8.2 and 8.3. Sub clause 8.2 requires the determination of all requirements of the products and services through communicating with the customer, applicable statutory, regulatory, and organization requirements, and meeting the claims of the organization regarding the products and services it offers. Sub clause 8.3 incorporate all the required design and development activities. The two sub clauses 8.2 and 8.3 provide a comprehensive listing of requirements that, if any of them are outsourced to external providers, should be adhered to for the successful development of the product. External provides should be evaluated based on the quality and importance of the services they provide. Also, External providers could be involved in the post development quality management activities and hence must be evaluated based on their ability to meet the requirements of these activities.

Formulate Value Functions

A value scale is constructed for each attribute. A scale can be considered to be a function that describe an empirical system of relationships through a numerical system (LAI, 1995). This scale can be a natural quantitative scale or a qualitative scale that is based on verbal descriptions. The scale should be monotonic so as to be consistent throughout the methodology, especially in the score evaluation phase. A monotonic scale indicates that a value increases or decreases monotonically along the scale. If there is a region in the scale where the value starts to behave differently, then it should be considered a constraint and alternatives with attributes that have such value are excluded from the analysis. A value function maps the value of an attribute to the value scale. The value function should also be linear or near linear. This provides simplicity and

allows for the assumption that we can compare alternatives based on the ratio between their scores. The ratio between the scores is the difference between the attribute levels assigned for the various alternatives. Value functions should be scaled to range from 0 to 1. Value functions can be an expression of a mathematical description of preferences, or it can be based on analysis of preferences. Hence, value functions are the primary performance comparison mechanism. Value functions can be uni-attribute or multi-attribute. Meaning, a value function can be formulated for each attribute, or it can incorporate a number of attributes. The performance score resultant from the performance evaluation tree is a relative measure and not an absolute. The value function incorporates the relative value of the performance of an alternative for one or more of the attributes and the importance weights of these attributes. When constructing the value function scale that is assumed to be linear or near linear, the decision maker needs to determine the highest and lowest possible values on the scale, then assign "1" to the highest value and use equation 3 to determine the score of the lowest value;

$$\text{(Lowest Value on Scale 0 to 1)} = \frac{1}{Highest\ value / Lowest\ value} \qquad \text{(Equation 3)}$$

Equation 3 serves as a scaling mechanism that scales the levels of an attribute to a 0-1 scale. All attribute levels values are determined based on their ratio to the highest value. There are three cases considered for determining the value of the attribute(s); a)value function transforms the attribute(s) value to reflect the DM's preference structure, b) attribute's natural scale (as defined by Von Winterfeldt and Edwards (1986, p.220) reflects the DM's preferences naturally, and c) attribute values are assigned scores subjectively. In the first case, the scale of the attribute value is constructed through a value function that reflects the DM's preferences with regards to the values of the attribute. This preference structure could include more than one attribute and thus the value function becomes a multi-attribute function. Though normally

pairwise comparison would be utilized in AHP instead of value functions, this author recommends utilizing value functions where data and empirical analysis is available. Zahedi (1987) shows that value functions and AHP are compatible for uni-attribute functions unconditionally. Uni-attribute functions or uni-variable functions are any functions that contain only one variable such that they exist in a single dimension. He also shows the same compatibility exists for multi-attribute functions on the assumption that the pairwise comparison is utilized consistently for deducing the importance weights of attributes utilized in the value functions calculations. Multi-attribute functions are functions that depend on more than one attribute or variable. For example, a vehicle's fuel efficiency can be measured using a value function that incorporates a particular distance covered by the vehicle using a specific number, particular to each vehicle, of fuel gallons. This ideal measuring state does not consider things such as tire material, tire pressure, surface roughness, aerodynamic mechanics of each vehicle that would allow us to determine the impact of the wind's speed on the vehicle's fuel consumption.

The critical discipline in using value functions is to formulate them in a way that provides a consistent measurement of value across the various performance criteria (or sub-criteria) that we are aiming to measure. The end goal is to have a consistent linear (or close to linear) scale that reflects the difference in performance of each of the decision alternates with regards to a particular performance criterion. In the example we discussed, a vehicle's fuel consumption efficiency is a performance criterion that is measured through attributes mentioned above. After studying the specific context within which the fuel efficiency is measured, a value function would be devised. The value function must reflect the context of the value measurement sufficiently enough for the purpose of comparing the performance of the various alternatives. In

both the uni-attribute and multi-attribute cases, the interpretation of weights of the attributes, which is obtained through pairwise comparison, should be compatible with the interpretation of these attributes preference structure, measured by the value function. The second case is a special case of utilizing data where the natural values of the attributes reflect the DM's preference and thus need no transformation. In such cases, it's important to verify that the context in which the data was collected is sufficiently representative of our decision problem context. For example, the fuel efficiency value function that we mentioned earlier might not be needed at all if we already have data regarding the fuel efficiency of the various vehicles on average and having those averages is sufficient for our purposes as we are expecting significant influences from the external environment as our vehicles will be running in a predictable environment in which the vehicle efficiency measurements would be represented sufficiently by the data of the average of measurements collected by some third party entity. have a performance criterion "suitable climate" inside Finally, the third case is when there is no empirical data or analysis to base the performance comparison on and in this case the default utilization of pairwise comparison is applied. Regardless of which case is at play, the value obtained will still be normalized according to equation 3.

Determine Importance Weights Using Pairwise Comparison

In addition to determining the structure and elements of the performance evaluation tree, the importance of each element, relative to the other elements on its level, need to be determined with respect to the hierarchy parent of that level. AHP uses Pairwise comparison in order to systematically compare the importance of each two performance criteria or attributes to provide an importance weight for each element in each hierarchy level of the performance evaluation tree. This provides local priorities of each element in the hierarchy level. The comparison can be

based on a) statistical analysis such as MANOVA or Pareto analysis, b) organizational strategy and current/future internal and external issues, or, c) experts' opinion. Hence, the importance weights constitute a transformation vector that transforms the comparative performance value vector for each alternative to reflect the priorities of the DM. This transformation increases the impact of the difference in performance for attributes and criteria that are deemed more important and reduces the impact of the ones deemed less important. The performance value vector for an alternative is the comparison between an alternative and all other alternatives with regards to each attribute, while the importance weights vector either amplifies or diminishes the impact of this performance comparison based on the importance weights of the performance criteria and attributes. Using importance weights to transform the performance value vector ensures that the performance comparison between alternatives, with respect to each attribute, is scaled in a way that reflects the DM's preference with regards to how important a particular attribute or criteria is. As mentioned in the previous section, where empirical data regarding the performance of an attribute is not available, pairwise comparison is used as a substitute to the natural quantification of attributes.

Pairwise comparison was first introduced scientifically by L.L. Thurstone in 1927 as a psychometric tool. Its application was further expanded by pioneers such as Thomas L. Saaty who integrated pairwise comparison into the Analytical Hierarchy Process (Saaty,1999). A pairwise comparison matrix is a simple matrix that gives a score for comparing the importance of each criterion with all other criteria that are on the same level in the AHP. The pairwise comparison is set as an eigen value problem. The results of the eigen value problem are arranged in a matrix. The weighting is obtained from the dominant normalized right Eigen vector. The inconsistency ratio, determined from the eigen value, should conventionally not exceed 10%.

There are a number of ready-made calculators that can be utilized to conduct a pairwise comparison. This study uses an online Pairwise Comparison calculator constructed by Klaud D. Goepel (2018).

Table 6. Pairwise Comparison Scale

Relative Importance	Definition
1	Equally Important
2	Weak or slight
3	Moderate importance
4	Higher moderate importance
5	Strong importance
6	Higher strong importance
7	Very strong/Demonstrated importance
8	Very, very strong importance
9	Extreme importance

To utilize the online AHP calculator, the decision maker starts with specifying the names of the criteria that will be compared.

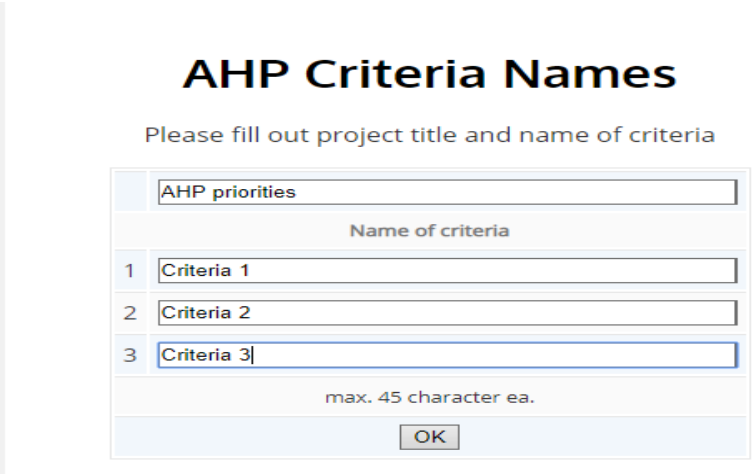


Figure 8. AHP Calculator Criteria Set-Up.

We assume that criteria 1 is equal in importance as criteria 2, that criteria 1 is strongly more important than criteria 3, and that criteria 2 is extremely more important than criteria 3. The results of the pairwise comparison show 4% consistency ratio, which is acceptable because it is below the recommended 10% consistency ratio maximum.

	A - Importance - or B?			Equal	How much more?
1	◉ Criteria 1	or	○ Criteria 2	◉ 1	○ 2 ○ 3 ○ 4 ○ 5 ○ 6 ○ 7 ○ 8 ○ 9
2	◉ Criteria 1	or	○ Criteria 3	○ 1	○ 2 ○ 3 ○ 4 ◉ 5 ○ 6 ○ 7 ○ 8 ○ 9
3	◉ Criteria 2	or	○ Criteria 3	○ 1	○ 2 ○ 3 ○ 4 ○ 5 ○ 6 ○ 7 ○ 8 ◉ 9

CR = 4% OK

Figure 9. Example Pairwise Comparison Preferences for 3 Criteria

The results show Criteria 2 as the most important criteria, followed closely by Criteria 1, and finally Criteria 3 with a significantly much less importance than the other 2 criteria. This result was expected and indeed reflect the way that the decision maker had specified the relative importance between the 3 criteria. The priorities or importance of the 3 criteria were 42%, 51.1%, and 6.9% respectively.

Priorities

These are the resulting weights for the criteria based on your pairwise comparisons

	Category	Priority	Rank	(+)	(-)
1	Criteria 1	42.0%	2	8.2%	8.2%
2	Criteria 2	51.1%	1	10.0%	10.0%
3	Criteria 3	6.9%	3	1.3%	1.3%

Number of comparisons = 3
Consistency Ratio CR = 4.0%

Decision Matrix

The resulting weights are based on the principal eigenvector of the decision matrix

	1	2	3
1	1	1.00	5.00
2	1.00	1	9.00
3	0.20	0.11	1

Principal eigen value = 3.039
Eigenvector solution: 4 iterations, delta = 2.3E-9

Figure 10. Example of Pairwise Comparison Results

Define Alternatives Set

The alternatives set is defined based on the problem goal that the decision-maker is attempting to achieve as well as category B information, and to a lesser extent category A information from the problem definition step. Through brainstorming sessions with stakeholders

and subject-matter experts, unrealistic and invalid alternatives are eliminated. Hence, each of the formulated alternatives should be;

- feasible and can be considered a viable solution, in its own right, to achieving the goal. Feasibility is judged based not violating the constraints listed in category B information in the problem definition step.
- limited in number to abide by and adhere to the limitation on the decision process available time.

In the context of the new product selection problem, a number of constraints were derived from the ISO 9001 guidelines. Sub clause 4.1 and 4.2 provide a general set of constraints related to the organizational context and the interested parties. Furthermore, statutory, regulatory, and organizational requirements are all considered to be constraints that all decision alternatives must satisfy. Finally, all requirements that are necessary to deliver products and services while satisfying the claims that the organizations makes about them are considered constraints. Hence, the ability to acquire expertise, knowledge, technology, or any other resources that are necessary for the design, development and production efforts need to exist for all decision alternatives. Each of alternatives can be considered a point in an attribute space, which has a dimensionality that is composed of the attributes that describe the alternatives (LAI, 1995). Hence, if the alternatives are described by 10 attributes, then the alternatives exist in a 10-dimensional attributes space.

Risk Assessment

Risk assessment is performed in four primary steps; risk identification, risk analysis, risk evaluation, and risk control. Risk identification results in the formulation of various risk scenarios, while risk analysis enables the assignment of likelihoods of events in the risk

scenarios and the estimation of the consequences magnitude level. Risk evaluation involves the calculation of the risk score for each risk criteria. Finally, risk control is the formulation of a plan to mitigate negative consequences associated with each risk scenario.

Risk Criteria

Risk criteria were formulated based on ISO 9001 guidelines;

- Requirements for products and services (8.2.2 a)
- Meeting claims regarding the products or services offered (8.2.2 b)
- Delivery and post-delivery Requirements (8.2.3.1 a)

Defining risk criteria is called for in ISO 31000 sub-clause 6.3.4. Risk will be judged based on two primary dimensions (in line with ISO 31000); likelihood and consequences. The likelihood is determined through the probability of the occurrence of a chain of leading events that cause the consequences with a certain magnitude. ISO 31000 Standard advocates an integrated risk management that is intertwined with all organizational activities, including decision-making. Determining the scoring of each alternative with respect to risk criteria will incorporate risk analysis and evaluation. Below, each of the risk criteria and the suggested sub criteria are discussed.

Risk Criteria 1: Products and Services Requirements

Determining the requirements comprehensively and accurately is the strong basis on which a successful product launching can occur. This risk criterion is concerned with not considering, not being aware, or not accurately and comprehensively formulating the requirements associated with the product. This risk exists when;

- formulating the design and development requirements
- formulating relevant regulatory and statutory requirements.

- Determining and meeting the processes, products or services are provided by an external provider (8.4.2 c)
- during the post-delivery activities (8.5.5 a).

Risk Criteria 2: Meeting Claims Regarding Products and Services

The risk of the inability to meet the claims regarding the products and services offered by the organization rises from;

- lack of tangible or intangible required resources due to inadequate determination and availability of resources needed for QMS processes (4.4.1 d) during the planning of;
    - the organization's quality objectives (6.2.2 b)
    - the products and services design and development (8.1 c)
    - the control of design and development processes.
- Lack of adequate QMS processes planning
    - Inadequate inputs or outputs of the QMS processes (4.4.1 a)
    - Inadequate sequencing or interaction between QMS processes (4.4.1 b)
    - Inadequate criteria, monitoring and measuring methods, or performance indicators (4.4.1 c)
    - Inadequate assignment of responsibilities or authorities (4.4.1 e)
    - Inadequate leadership commitment to QMS (5.1.1)
- Inadequate operational planning and control
    - Inadequate criteria for processes and the acceptance of products and services (8.1 b).
    - Inadequate implementation of processes controls. (8.1 d) in accordance with controls required by sub-clause 8.5.1.

Risk Criteria 3: Delivery and Post-Delivery Requirements

This risk criterion is concerned with the delivery of products and services to the customer. This risk could result from;

- Inadequate delivery process
    - Timeliness of delivery
    - Meeting all parameters of a successful delivery
    - Unintended consequences of delivery
- Inadequate post-delivery activities
    - Violating statutory, regulatory, or customer requirements (8.5.5 a)
    - Hazards due to the nature of products and services (8.5.5 b)

Risk Identification

Let the risk scenario S be initiated by a risk initiating event IE, which could trigger a risk event E, that could result in consequence C. Hence, a risk scenario S (IE, E, C), can be viewed as a pathway of the build-up from initiating event IE to consequence C. Each risk scenario S has a treatment plan T that is designed to mitigate the risk consequences. Risk scenarios are developed within each risk criterion. The relationship between risk scenarios within a risk criterion is either "AND" or "OR". A relationship "AND" means that the risk scenarios can occur simultaneously. A relationship OR means that the risk scenarios cannot occur fully simultaneously because either the leading events in the scenarios cannot occur simultaneously or the consequences of the scenarios cannot occur simultaneously. For example, if a risk scenario has more than one possible level for the magnitude of its consequence, then it will be broken down to multiple scenario, each representing one of those levels, and the relationship between these scenarios will be "OR". For "OR" relationship, the sum of the likelihood of occurrence of the various risk

scenarios cannot exceed 100%, while an "AND" relationship allows for a sum of likelihood of occurrence that exceeds 100%. In other words, "AND" relationship between scenarios represent a parallel or simultaneous relationship while "OR" relationship represents a mutually exclusive relationship within the same time frame. The formulation of a risk scenario occurs through consultation with subject matter experts in brainstorming sessions. Furthermore, system analysis techniques, such as simulation or event tree analysis, are very instrumental in risk identification and risk scenario-building. Risk identification is performed with respect to performance criteria. Each risk scenario describes a pathway to a negative impact on at least one performance criterion.

Risk scenarios are the main building block of the proposed risk assessment methodology. The occurrence of multiple risk scenarios simultaneously could result in catastrophic impact on one or more of the performance criteria. Thus, for risk scenarios S_1 and S_2, the combination of risk scenarios and the probability (P (S_1), P (S_2)) of their simultaneous occurrence should be studied if there is a potential for catastrophic events, even if the probability of this simultaneous occurrence is highly unlikely. This serves as an exploration of the domino effect of scenarios, which enables further identification of high impact risk that is unlikely to occur but constitute a vulnerability that the decision maker should be aware of. The probability of the domino effect of simultaneous occurrence of scenarios should be quantified but the magnitude of the impact of the domino effect should be descriptive as it is usually difficult, and often pointless, to quantify the impact of a catastrophe. The way to control a domino effect is both through controlling the likelihoods P (S_1) and P (S_2), and the probability of simultaneous occurrence $P(S_1) \cap P\ (S_2)$. This probability of simultaneous occurrence is context dependent, meaning it should only be applicable where it makes sense to consider it within the context of the decision problem.

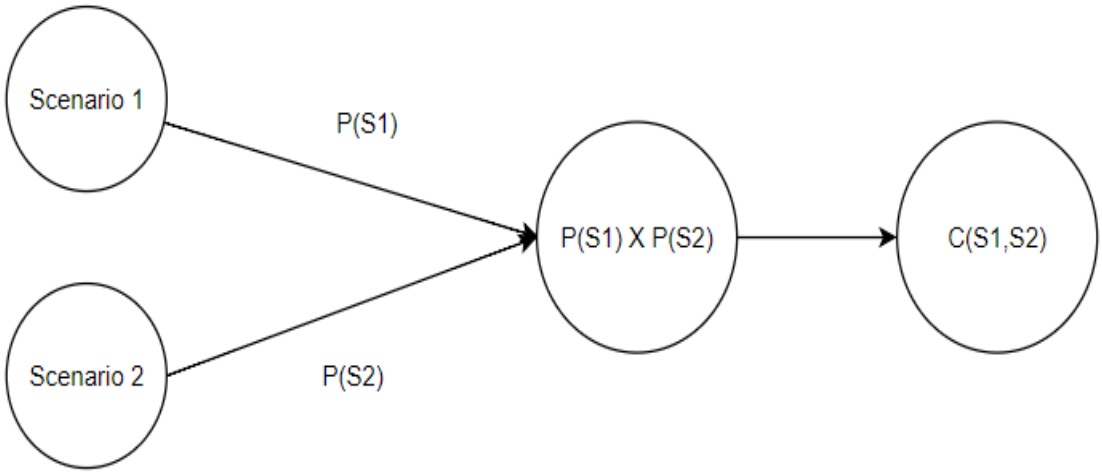


Figure 11. Domino Effect of Scenarios Simultaneous Occurrence

Risk Analysis

Risk analysis is the determination of the risk likelihood and magnitude of its consequences. The framework for risk analysis sets the groundwork for the method of measuring the likelihood of events and the measuring of the magnitude of consequences. The method of measurement of likelihood of events need to be compatible across all risk criteria with regards to timeframe of events; the frequency of occurrence of an event should be determined for equal timeframes across all risk criteria. The levels of the magnitude of consequences for each risk criteria are determined in the context of the specific consequences that are assigned to each risk scenario. For example, if the risk criterion is “Failure of On Time Delivery to Customer”, then we need to look at the minimum and maximum time for late delivery based on historic data and experts’ opinion, while considering the decision problem context. In other words, if we are later developing a decision-making process that includes the same risk criterion, the minimum and maximum will be based on what’s possible, given the context of this specific decision-making

problem. Hence, the minimum and maximum levels of consequences magnitude are local to the decision problem and not global.

Risk analysis enables the assignment of likelihoods $P\ (IE_S, E_S, C_S)$ to events in the risk scenarios. Likelihoods can be deduced through experts, historical data, simulation, among other methods. For a risk scenario *S*, the likelihood of risk initiating event and, given that the risk initiating event occurred, the likelihood of a risk event is needed to calculate the likelihood of risk event *E*.

$$P(E_S) = P(IE_S)\ X\ P(E_S|IE_S) \qquad \text{(Equation 4)}$$

Where, IE_s is the initiating event for scenario *S*, and $E_s$is the risk event that makes a risk consequence possible. Just like a risk event makes a risk consequence possible, a risk initiating event makes a risk event possible. The likelihood of a scenario risk event is equal to the product of the likelihood of a scenario initiating event and the likelihood of a scenario risk event given that the initiating event already occurred.

Similarly, the likelihood of risk event and, given that the risk event occurred, the likelihood of a risk consequence is needed to calculate the likelihood of risk event E.

$$P(C_S) = P(E_S)\ X\ P(C_S|E_S) \qquad \text{(Equation 5)}$$

The likelihood of a scenario risk consequence is equal to the product of the likelihood of a scenario risk event and the likelihood of a scenario risk consequence given that the risk event already occurred.

Risk Evaluation

Risk evaluation involves the assessment of the consequence's magnitude on some scale. The high end of the scale should represent the maximum possible negative impact, for all the decision alternates in consideration, on the performance criterion that the risk scenario belongs

to. The magnitude of the risk consequence is estimated in a similar way by which the performance value was estimated for the attributes of the performance criteria. Hence, a value function can be formulated to evaluate the magnitude of risk consequences for scenarios within a given risk criterion, or the decision maker's assessment, based on expert's opinion, can be solicited directly. Risk evaluation put the organization's context into perspective when estimating the risk consequences and magnitude.

Risk Criteria Score

Scoring of the risk criteria is possible after conducting risk assessment. Since risk criteria are assumed to be mutually independent, to calculate risk criteria score, scenario risk scores are summed up to obtain a total risk score for each risk criteria. Each scenario is assumed to be independent of other risk scenarios, nevertheless, they are common in the nature of the impact of their consequences on the performance criteria.

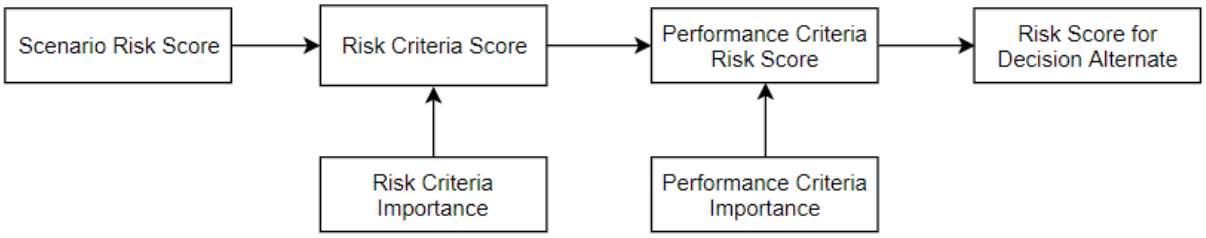


Figure 12. Risk Score of Decision Alternate

$$Scenario\ Risk\ Score_S = P(C_s)X\ (C - (RR\ X\ C\ X\ P(T)) \qquad \text{(Equation 6)}$$

Where, C is the magnitude of risk consequences, RR is the recovery ratio, P(T) is the likelihood of success of the risk treatment plan. The likelihood of the scenario's risk consequence is multiplied by risk consequences magnitude after it had been reduced due to the impact of the risk treatment plan. The reduced magnitude of consequence is calculated by subtracting the expected recovery from the initial consequence magnitude. The expected recovery is calculated

through multiplying the likelihood of successfully carrying out the treatment plan and the recovery ratio. The recovery ratio measures the percentage of the negative consequences that has been mitigated due to utilizing the risk treatment plan. The scenario risk score is aggregated to give the risk criteria score, as shown in equation 7.

$$Risk\ Criteria_h\ Score\ = \sum_{S=1}^{N} Scenario\ Risk\ Score_s \qquad \text{(Equation 7)}$$

The risk scores for each risk scenario s belonging to risk criteria *h* are summed up to calculate the risk score for risk criteria *h*. Given a Risk Criteria *h* has *S* risk scenarios, the risk criteria score is the summation of risk scores of scenarios 1 to N. Once the risk score of the risk criteria is determined, the risk score of the performance criteria is determined through a weighted average of the risk score of each risk criteria. Weighted risk score is summed for all performance criteria for each alternative, thus obtaining the overall risk score for each alternative.

$$Alternate_k\ Risk\ Score = \prod_{RC=1,PC=1}^{I,K} RC_h\ Weight\ X\ RC_h\ Score \qquad \text{(Equation 8)}$$

Where *RC* is the risk criteria h. All alternates have the same set of risk criteria. The calculation of the risk criteria score is obtained by the summation of the scenario risk scores. Risk criteria are formulated for each performance criterion based on the nature of the consequences that could impact the performance criterion. Hence, each performance criterion could have a varying number of risk criteria, and in turn, each risk criteria could have a varying number of risk scenarios. A performance criterion that has a large number of risk scenarios and a large number of risk criteria could end up with a large risk score compared to other performance criteria that, though have significant risk, has small number of risk criteria and risk scenarios. However, this is not an issue because ultimately, the risk score is used in combination with the performance score in order to obtain a performance-to-risk ratio for each decision alternate.

Hence, a high-risk value due to an exaggerated breakdown of risk scenarios or risk criteria does not impact the final result of the analysis.

Risk Treatment

Risk treatment consists of formulating a risk treatment plan for each risk scenario. Risk objectives are achieved through various techniques; safety barriers, contingency plans, specification limits that consider natural variation in performance, control mechanisms that consider potential special-cause variation in the outcome of the activity or unintended consequences of the activity, or risk monitoring mechanisms such as leading safety indicators. A risk treatment plan has a likelihood of success and a recovery ratio. A 100% recovery ratio implies that the successful implementation of the treatment plan will eliminate the negative effects of the consequences of the risk scenario in full; as if the consequences of the risk scenario had never occurred. The risk scenario plan could either mitigate the risk or enable the reduction of, or recovery from, its consequences. ISO 9001 guidelines mention guidance directly related to risk control. The table below lays out risk criteria, sub criteria and their corresponding controls.

Table 7. Proposed Risk Management Framework According to ISO 9001 Guidelines

Risk Criteria	Risk Sub Criteria	Risk Control
Requirements	Design and development Requirements	Verify that the design and development outputs meet the input requirements (8.3.4 c), validation activities to ensure that the resulting products and services meet the requirements for the specified application or intended use (8.3.4 d)
	Regulatory and Statutory Requirements	Verify that none of the requirements violate regulatory or statutory requirements.
	Processes, products or services are provided by an external provider	Plan for determining and applying criteria for evaluation, selection, monitoring of performance, and re-evaluation of external providers (8.4.1). Apply controls to the external provider, continuously monitor and evaluate the effectiveness of these controls, and continuously verify that processes, products, and services meet requirements (8.4.2).
	Post-delivery activities	Design and implement post-delivery activities according to sub-clause 8.5.5. Review delivery and post-delivery requirements to ensure the ability to meet them (8.2.3.1 a)
	Requirements specified by the organization	Review organizational requirements to ensure the ability to meet them (8.2.3.1 c)
Meeting claims regarding the products or services offered (8.2 a)	Inadequate determination or availability of resources for processes	Ensure the availability and use of suitable monitoring and measuring resources (8.5.1 b) and control the implementation of these activities at the appropriate stages (8.5.1 c)
	Inadequate implementation of processes	Ensure the use of suitable infrastructure and environment for the operation of processes (8.5.1 d) Implement actions to prevent human error (8.5.1 g)
Nature of Products and Services	Hazards to consumer, environment, or society	Control nonconforming outputs to keep it from causing any potential harm (8.7)

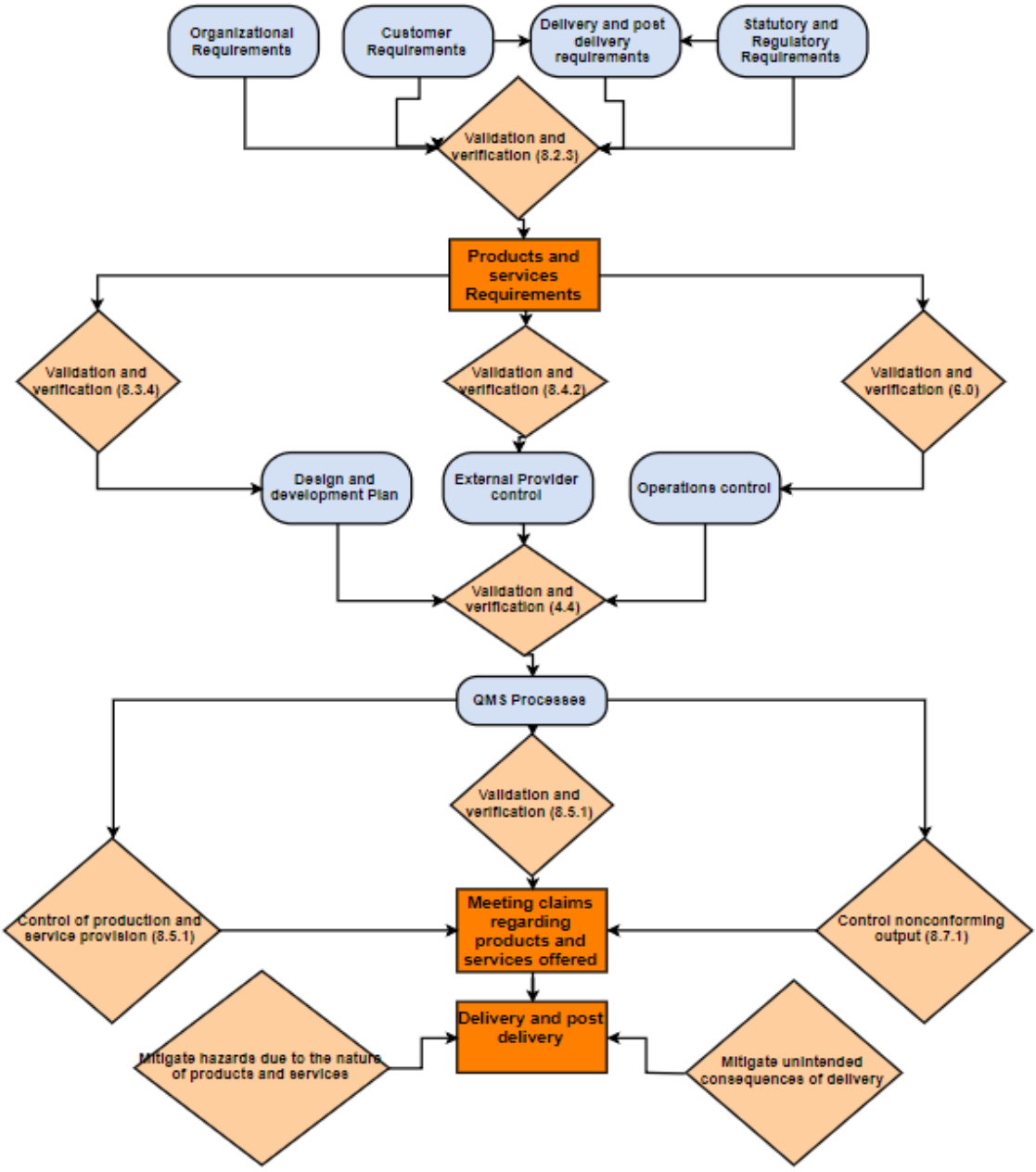


Figure 13. Proposed Mapping of Risk Management for New Product According to ISO 9001 Guidelines

The presented figure provides a top view of the risk management of the new product processes. The orange boxes represent the proposed three main risk criteria. These risk criteria represent the three main choke points at which the quality of the product or service is at risk. The pink diamonds represent the risk control mechanisms that are prescribed by ISO 9001 guidelines.

The decision alternatives risk evaluation will be dependent on both the cost and effectiveness of these risk controls. The ideal decision alternative will have the highest performance with regards to its performance evaluation and can be achieved with the lowest cost and most effective risk controls. Such ideal alternative might not exist. Hence, AHP and MAUT are used in order to quantify the tradeoff between these various attributes in order to find the most optimal decision alternative.

Alternatives Evaluation

Each alternative has two resulting scores; performance score, which represents the benefits gained from selecting the alternative, and the risk score, which represents the risks associated with selecting the alternative. The performance/risk score ratio is calculated for each alternate. And finally, the alternatives are ranked from the highest to the lowest ratio. The alternate with the highest ratio yields the most benefits given the risks associated with it.

Best Alternative Selection

Decision alternate selection and implementation should carefully consider the organization's context in a wholesome manner. All stakeholders should participate in the final decision and reach an agreement based on the analysis conducted during the decision process. The expected decision impact, decision analysis and decision process should all be documented. This documentation will be communicated as we as transferred as organizational knowledge to the QMS documented information and the decision-making support information database.

Decision Documentation

Decision implementation plans are documented, including the required resources in terms of competence, infrastructure, environment, action plan, and quality control plan. Furthermore, documentation is critical to benefit from the knowledge gained during the experience of the

decision-making process. Documentation is continuous throughout the decision-making process. Once the decision is made, the decision impact, decision analysis, and decision process are documented. Documentation and communication of the decision-making process is the final step in the development phase. Through documentation, the organization can trace back the justification for the decision made as well as make traceable and justified changes to the decision-making process based on; the availability of new information, changes to the organizational context, or any other changes in the problem definition. Furthermore, the decision process is communicated to the relevant stakeholders, and knowledge transfer and retainment occurs through storing the documentation in the QMS documented information database as well as the decision-making support information database.

CHAPTER 5. CASE STUDY: PRODUCT SELECTION FOR E-COMMERECE BUSINESS

Product selection is perhaps the most important decision that an e-commerce business faces regularly. Market research can narrow down the candidate products, but it cannot account for more than the market and selling aspect of the product selection problem such as the shipping cost, the required inventory space and the supplier's quality. Chenu and Wilemon (1973) developed a list of product evaluation criteria under; market characteristics, product characteristics, corporate capabilities and characteristics. Any form of a multi criteria decision-making technique can help in solving this problem. However, the advantage of our proposed methodology is expected to surpass any of these other criteria due to its explicit inclusion of risk assessment in the product selection, the ability to align the product selection decision with the organization's strategy, the ability to align the product selection with the ISO 9001 guidelines, and the ability to utilize this methodology as a generic decision-making tool that can work for decisions for new product selection.

Background Information

This case study is conducted for an e-commerce business that sells its products on Amazon and Etsy primarily, as well as other websites such as Ebay and Shopify. The company has a number of lines of products that are being designed and developed in the US and then manufactured in China. Currently, the company relies on market data querying to select the products they're interested in selling. However, querying the market data returns too many viable products. Querying the market data also does not consider other aspects that the company is interested in, such as inventory requirements and the manufacturer's expertise with the product. Currently, the manager responsible for this decision just uses common sense, discussions with

the various stake holders, his own intuition, and the lessons learnt through experience. He sees the need for a systemic methodology for the product selection decision-making. He believes that the product selection decision needs to be justified, mistakes should be documented to prevent repetition, and good selection decisions need to be repeated and learnt from. He also is interested in the methodology's ability to capitalize on the organization's QMS ISO 9001. The organization has maintained QMS documented information in an information database. The scope of ISO 9001 implementation is the supply chain operations and sales operation. Though the newly imposed tariffs due to the trade war between the United States and China are expected to reduce the profit margin, the organization has distribution channels in Europe that can help compensate for that loss. Among the prospective new products that the organization is interested in, there are no special requirements with regards to shipping, handling, or other regulatory requirements related to international trade or shipping.

Applying the Proposed Decision-Making Process to the Case Study

The proposed risk-based decision-making process is applied to the product selection problem of the e-commerce business that was chosen for the case study. The needed data was already stored as ISO 9001 QMS documented information.

Organization of The Project

The project team is comprised of the company owner, a representative of the external supplier, manufacturing engineer, and marketing consultant. The project team was informed about the proposed decision-making methodology and a detailed presentation was made to them regarding how the information should be structured, what are the high-level performance criteria and risk criteria, and what kind of information and analysis will be required. The strategy for launching new projects determined by the project team is a combination of "Market

Characteristics", which entails market growth, number of competitors, and firm performance, and "Marketing Mix", which entails marketing prowess and distribution capabilities. The team determined that these two strategies fully represent the issues that matter to the organizations with regards to new product selection and that the organization have positioned itself to excel at. The organization have extensive market data on various product segments, which include information on the competition's position in the market, and the feedback of customers. There is high awareness of market needs due to the massive resources that the organization spent to gain that intelligence. Furthermore, the organization has a strong distribution capability due to its strategic partnerships with 3rd party logistics company and distribution representatives in North America, Europe and Asia and a number of high-profile e-commerce platforms. In addition, the organization has an exceptional marketing team that excels at marketing, branding and social media. The targeted market must have a growth rate averaging at least 5% of the last 5 years. The number of competitors cannot exceed 3 top level competitors. The material from which the product would be made must be from among the selection of materials made available by the external suppliers. The organization is open to forging new partnerships with external suppliers, but they must have good financial stability, excellent communication and competitive cost and be ISO 9001 certified. The product also must not be too bulky. This is due to limitations on storage capacity and the strategy of the organization to reduce operational cost by maintaining a limited storage capacity, and also due to extra cost that might be incurred when shipping bulky items. Also, the product design must not violate copy rights. Finally, the organization must be able to achieve at least 30% profit for selling the product.

Information and Data Collection

The decision goal is product selection for a new product launching project. In this step we will gather all the required information for the decision-making process. First, the constraints of the decision solution were determined based on the new product strategy, budget, and duration. Given the limited technological capabilities of the organization, the product development must be within the current technological capabilities of the organization and its suppliers. The organization maintains a list of potential products that it considers launching. After ensuring that none of the potential products violate the constraints, a short list of 3 products where selected to be the decision alternatives. Product 1 is a drinking cup that has a unique modern design. Product 2 is a modern neckless jewelry. And Product 3 is an outdoor game that consists of an assembly of a limited number of parts. Information and data were then gathered for the requirements of each of the products. The following table summarizes the differences in the requirements for the quality management of the operations for the new product.

Table 8. QMS Processes Requirements for Alternative Products

Requirement	Product 1	Product 2	Product 3
Monitoring and measuring resources	Geometric and material features measuring devices	Third party testing	Geometric and material features measuring devices
Human capital	Quality Engineer	Quality Engineer	Quality Engineer
Infrastructure	A number of measuring devices	N/A	A number of measuring devices
Environment	N/A	N/A	Simulation of external environment such as extreme rain, heat, etc.

With regards to the design and development processes, all three products have similar requirements, though there are some differences in considerations of the design requirements. Product 1 is required to be durable and have low limit geometric tolerance. Furthermore, it's required to have a specific level of brittleness, specific volume for holding liquid, and to be safe

for automatic dishwashing. Product 2 must follow the design requirements of Amazon's "Jewelry Quality Assurance Standards". Product 3 is made out of a number of parts. It will require complex designing and tolerancing compared to the other two parts. Furthermore, the design should consider that the product will be left outdoors for prolonged periods of time. Hence, the material and the paint must be well suited for harsh weather conditions. As for external providers requirements, while product 1 and 3 don't have special requirements, product 2 is different in that the external provider should be fully responsible for quality checking the product as the organization does not want to invest in quality management infrastructure. Market information was gathered for the three products (appendix A). Information regarding the external providers was also obtained.

Performance Evaluation

The three products were evaluated based on each of the performance criteria and sub criteria. The performance score was carried up the performance tree while being multiplied by the importance weight along the way. The performance score of the sub criteria is calculated according to equation 1. An Example is provided below for the sub criteria "market characteristics".

Table 9. Performance Score of Sub-Criteria "Market Characteristics"

Attribute	Importance	Product 1	Product 2	Product 3
Market growth	0.35	0.2	0.8	1
Market competitiveness	0.65	0.7	0.4	1
Performance Score		0.525	0.54	1

As discussed previously, the value of the performance attributes is normalized, with score '1' given to the highest value, and the values of the rest of the attributes is calculated using equation 7. The values of the attributes can be qualitatively or quantitatively deduced using value

functions or pairwise comparison. Market growth values were obtained from a market research data set then normalized. Market competitiveness was evaluated using pairwise comparison. Product 3 was deemed to be the most competitive due to a number of factors. First, there are not many competitors in the market compared to its size. Also, the marketing team has a well-developed strategy for the marketing and branding of product 3. Product 2 has the least score in competitiveness due to the massive number of competitors.

The sub-criteria 'Marketing Mix' is dependent on the branding, capacity for distribution and experience of the sales team. Product 3 has the highest score in 'Marketing Mix' due to its branding potential and the experience of sales team. Product 2 has the lowest score in the sub criteria due to the lack of strong experience in branding it and massive and strong competition. Product A summary of the performance scores of the performance sub criteria 'synergy with Organization's strategy is presented in the following table.

Table 10. Performance Score of the Performance Criteria "'Synergy with Organizational Strategy"

Sub Criteria	Importance	Product 1	Product 2	Product 3
Market Characteristics	0.68	0.525	0.62	1
Marketing Mix	0.32	0.55	0.71	0.8
Criteria Performance Score		0.533	0.648	0.936

Resources Required for QMS Processes

For this E-Commerce business, the organization's primary operations that contribute to providing the product to the customer is conducting the QMS processes, as the product's manufacturing is outsourced to external providers in China. Product 1 has the highest monitoring and measuring resources performance due to both the low cost and high effectiveness of these resources. The resources required for product 2 are highly effective but require high cost due to the outsourcing of the monitoring and measuring processes. Product 3 is highly effective and has

a medium cost. Monitoring and measuring processes for product 3 are done in-house but is relatively costly due to the complex nature of the product. The required human capital required for all three products is the same. The costliest infrastructure required is for product 2, as it is not available for the organization, hence it is outsourced to the external provider. Product 1 is the least costly in infrastructure compared to the other two products due to the relative simplicity of the design and hence the simplicity of its quality management. The sub criteria "environment" is not applicable as there are no special requirements for the QMS environment for any of the products.

Table 11. Performance Score of the Performance Criteria "QMS Processes Required Resources"

Criteria: QMS processes Resources Required	Importance	Product 1	Product 2	Product 3
Monitoring and measuring	0.72	0.8	0.62	0.71
Human capital and competencies	0.1	0.95	0.92	0.9
Infrastructure	0.08	0.68	0.64	0.61
Environment	0	0	0	0
Criteria Performance Score		**0.725**	**0.589**	**0.65**

Resources Required for Design and Development

The effectiveness of the resources required for the design and development process is the same for all products. The organization is highly experienced in the design and development of all products in question. However, the relative cost is different; Product 3 will incur the most cost due to the complexity of the product design. This complexity causes the duration of the design and development process to be prolonged and require more validation and verification. Product 2 and product 1 require similar cost for design and development.

Table 12. Performance Score of the Performance Criteria "Resources Required for Design and Development"

Criteria: Resources Required for Design and Development	Importance	Product 1	Product 2	Product 3
Effectiveness of Resources for design and development activities	0.3	1	1	1
Cost of Resources for design and development activities	0.7	0.8	0.77	0.71
Criteria Performance Score		0.86	0.839	0.797

The organization places more importance on cost of the resources rather than the effectiveness of the resources required for the design and development process. Being a small organization and currently aspiring to expand, the organization aims at keeping its costs low with regards to design and development. This means that the designs are usually relatively simple. Product 1 and product 2 have similar performance with regards to this criterion. Product 3 has an inferior rating in this criterion due to the increased cost of the design and development of a more complex product.

External Providers

The last performance criteria to be evaluated is the evaluation of the external provider. The sub criteria evaluated are cost, compliance, financial stability, quality, and mutually beneficial relationships. The most cost is associated with product 2 as the quality management associated with the product is outsourced. Product 1 and product 3 have similar costs for the external provider. Cost is measured in proportion to the selling price of the product. Product 3 costs more with regards to the external provider than product 1 but its selling price is also higher than product 1. With regards to compliance and financial stability, all external providers for all product alternatives are ISO 9001 certified and have an excellent track record of compliance. Compliance and financial stability are all set to be equivalent for all three products because the

organization cannot differentiate between their qualitative performance. Next, we look at the "Quality" sub-criteria. In that regard, the quality is not measured based on defects per output because the performance of the three external provider is similar in that regard. Hence, the quality is measured based on the value that the quality provides. For product 2, the value of the quality provided is relatively higher due to the ability of the external provider to not only fulfill the required products but also provide an independent quality check on the product, which is required by Amazon, which is the biggest platform that the organization operates through. Finally, the mutually beneficial relationships exist for all three products. The mutually beneficial relationship with the external providers is based on long term cooperation, shared data, strong communication.

Table 13. Performance Score of the Performance Criteria "External Provider"

Criteria: External provider	Importance	Product 1	Product 2	Product 3
Cost	0.43	0.84	0.2	0.76
Compliance	0.15	0.79	0.8	0.82
Financial Stability	0.15	0.72	0.69	0.74
Quality	0.20	0.71	0.75	0.7
Mutually beneficial relationships	0.07	0.52	0.82	0.6
Criteria Performance Score		0.76	0.52	0.74

Performance Evaluation

Table 14. Overall Performance Score for Product Alternatives

Performance Criteria	Performance Criteria Importance	Product 1 Performance Criteria Score	Product 2 Performance Criteria Score	Product 3 Performance Criteria Score
Synergy with Organizational Strategy	0.4	0.533	0.648	0.936
QMS Processes Required Resources	0.11	0.86	0.839	0.797
Resources Required for Design and Development	0.11	0.748	0.694	0.745
External Provider	0.38	0.76	0.52	0.74
Overall Performance Score		0.679	0.625	0.825

The performance criteria calculations result in product 3 getting the highest performance score, followed by product 1 and then product 2. This is primarily due to its high score in the performance criteria in its synergy with the organizational strategy, which is the most important criteria for the organization. Product 3 has the lowest score in the QMS processes required resources, but it's not much lower compared the other product alternatives. Product 3 has a comparable performance to product 1 for resources required for design and development and for external providers.

Risk Assessment

Each of the risk criteria and sub criteria were reviewed with respect to each of the decision alternatives. The information regarding the likelihood and impact was obtained from the organization's historical data. We take a look at the design and development inputs requirements risk sub criteria as an example.

Risk Identification

First risk scenarios are identified through defining the risk initiating event, risk event, consequences, and treatment. The risk scenarios are identified for each of the product alternatives. The nature of each of the products is considered when considering the possible risk scenarios.

Risk of Inadequate Requirements

The consequence of an inadequate design and development input requirements is that the design would need to be revised, which would increase the cost and time of the design and development process. Various risk treatment plans were devised. Mostly the risk treatment plans are constituted of verification activities, prototyping, and avoiding incorporating complex features in the design.

Table 15. Product 1 Risk Identification for Sub Criteria "Design and Development Inputs Requirements"

Scenario Index	Risk Initiating Event	Risk Event	Risk Consequence	Risk Treatment
1	Inadequate geometric tolerance	Inadequate product design	Design needs revision, increasing cost and time of the design phase	Verify geometric tolerance and its impact on the product's quality.
2	Inadequate ergonomic design			Develop prototypes to test the ergonomics of the product
3	Inadequate material for the product design	Inadequate product durability or visible defects		Develop prototypes to test the material under various conditions for the purpose of the product usage, give recommendations for the adjustments needed to the material.
5	Features that are difficult to manufacture	The features are not manufactured, and the structure of the product is compromised	Design needs revision, increasing cost and time of the design phase	Do not design complex features or features that are relatively small.

Table 16. Product 2 Risk Identification for Sub Criteria "Design and Development Inputs Requirements"

Scenario Index	Risk Initiating Event	Risk Event	Risk Consequence	Risk Treatment
1	Inadequate sizing	Inadequate product design	Design needs revision,	Verify scale specifications
2	Inadequate material specifications	Inadequate product finish	increasing cost and time of the design phase	Develop prototypes to test the material under various conditions for the purpose of the product aesthetics
3	Design could result in an injury	Inadequate product design		Avoid designs that involve sharp edges

Table 17. Product 3 Risk Identification for Sub Criteria "Design and Development Inputs Requirements"

Scenario Index	Risk Initiating Event	Risk Event	Risk Consequence	Risk Treatment
1	Inadequate geometric tolerance	Inadequate product design	Design needs revision, increasing cost and time of the design phase	Verify geometric tolerance and its impact on the product's quality.
2	Inadequate color specifications	Inadequate product design		Verify the specifications of the coloring of the product
3	Inadequate material specification for the purpose of the product usage or storage conditions			Test the material in the external environment where the product will be used and internal environment where the product would be stored.
4	Inadequate product ergonomics			Utilize focus groups.
5	Features that are difficult to manufacture	The features are not manufactured, and the structure of the product is compromised		Do not design complex features or features that are relatively small.

Formulating these scenarios was based on brainstorming sessions with subject matter experts and historical data. The tools used for risk identification were brainstorming sessions. The risk scenarios identified for product 1 and product 3 were similar compared to product 2. This is due to the nature of products 1 and product 3 as they are utilized by the consumer in a more active fashion compared to product 2.

Risk scenarios were explored for regulatory and statutory requirements. There were no significant regulatory or statutory requirements that were identified. Organizational requirements were abided by during the early phase of selecting the decision alternatives. As far as the organization is concerned, there was no risk of these organizational requirements being violated by the products now or in the future. There are also no known concerns regarding regulatory or statutory requirements that are critical but unknown to the organization. The organization has enough experience in launching similar types of products to be able to determine that this is the case. The External providers requirements, in this case study, are the designs of the product, and delivery and quality objectives. Miscommunications regarding these requirements could occur. This risk is controlled with strong and constant collaboration in a virtual setting on a daily basis. Risk in capturing delivery requirements are non-existent as well as there are no special requirements in that regard that the organization might not be aware of.

Risk of Inability to Meet Claims Regarding the Product

The organization verified that it possesses all the required resources for carrying out the required QMS processes for all product alternatives being considered. The exception is product 2 which is outsourced in full for a high cost, which the organization can afford. The organization is aware of risks resulting from inadequate planning and control. However, it does not seem that this risk is different for any of the three product alternatives.

Risk from Delivery and Post-Delivery Requirements

Potential risk is late delivery by the third-party logistics companies that the organization utilizes. Another issue is potential for improper packaging, which could cause the products to be damaged during or on delivery. There were no other risks that could be identified in this risk criterion.

Risk Analysis

Next, risk analysis is conducted in order to determine the events likelihoods. The likelihoods were determined based on prior experience, historical data and experts' opinions. This includes the risk initiating event likelihood, risk event likelihood, and risk consequences likelihood, and risk treatment success likelihood.

For the likelihood of inadequate product requirements, the organization estimated 10% chance of inadequate requirements specifications for product 1 and product 2. Product 3, due to its relative complexity, has a likelihood of 15% of inadequate requirements specifications. The organization's quality testing historically gives 95% confidence in the quality of each batch of product 1 and product 3. Product 2 has its QMS process outsourced. The external provider supplies product 2 with at least 95% confidence in quality. The organization does not invest in QMS processes for product 2. The organization uses third party logistics companies such as FedEx and UPS. The organization has observed an on-time delivery rate averaging at 96%. This rate is not expected to change with different products. The organization is also concerned with packaging risk; all packages must be able to withstand a drop of 10 feet. Due to this measure, there have been no complaints regarding receiving damaged items. The risk of improper packaging is estimated at 0.5%, and it is the same for all three product alternatives.

Risk Evaluation and Treatment

To enable risk evaluation, the nature of the risk in terms of its consequences and the measures that can be taken to mitigate these consequences. The consequences were identified based on the risk criteria and sub criteria they belong to. For the sub criteria "design and development input requirements", the consequences' nature is in the context of faulty planning, which is mostly easily detectable. Hence, the consequences are limited to "increasing the cost

and duration of the design and development process". The consequences thus are comparatively measured based on the magnitude of the increase in cost and duration. The organization feels confident in the effectiveness and discipline it has in the implementation of the risk treatment plan for this sub criteria. From experience, the organization considers that improper material specification has much more negative impact on cost and duration of the design and development process compared to improper scaling, as an example.

The risk sub-criteria "Meeting claims regarding products" has the consequence of a finished product that does not meet the organization's claims about it. This can occur in various degrees, depending on the particular failure that occurred. If the claim that was not met can be quickly discovered by the customer and is of high importance, then it gets maximum consequence rating. An example of such maximum consequence in this risk sub-criteria is if product 1 holds volume of liquid less than that it claims to be able to hold. For the last risk sub-criteria "inadequate delivery and post-delivery" has a maximum consequence in the case that the product never arrives to the customer or if the product arrives damaged to the customer. Pairwise comparison is used to determine how consequences of the various scenarios compare to the maximum consequence, so that the consequences for the various scenarios can be rated. Furthermore, pairwise comparison is also used to compare the importance of the three risk sub-criteria. The organization deemed the risk of inadequate requirements as the most important as it is the most demanding task in the project and where most of the failures occur. The risk sub-criteria of not meeting claims made about the product comes very close in terms of importance to the risk sub-criteria "Inadequate Requirements". The risk sub-criteria "inadequate delivery or post-delivery" comes last in importance as it has a much less impact on the organization's business compared to the other two risk sub-criteria.

Table 18. Risk Sub-Criteria Relative Importance

Risk Sub-Criteria	Importance
Inadequate Requirements	0.52
Not Meeting Claims about the product	0.4
Inadequate Delivery or Post-Delivery	0.08

Here, we will provide an example of calculating a scenario risk score. There is a 5% chance of increased cost and duration of the design process, and a consequence magnitude of 1, which is the maximum possible from the organization's experience. The risk treatment effectiveness, or recovery ratio, is equal to 0.6, which indicates that only 40% of the expected increase in cost and duration would actually be realized, if the risk treatment plan is implemented. The risk treatment plan has a chance 95% of being successful. This indicates that there is a 5% chance that after reviewing and attempting to adjust the materials specifications, the defects in the prototype are not eliminated and the organization is forced to change the design entirely, effectively abandoning the process and restarting with a whole new design. The risk score for this scenario is calculated using equation 6;

$$Scenario\ Risk\ Score_S = P(C_s)X\ (C - (RR\ X\ C\ X\ P(T))$$= 0.05 X (1 – (0.6 X 1 X 0.95)) = 0.0215.

Scores of risk scenarios belonging to the same risk criterion are summed up to obtain a risk criterion score. An overall risk score is obtained by calculating the product of importance weight and risk score for each risk criterion. These calculations are represented by equation 6, 7 and 8. A summary of the overall risk score for each alternative is presented below.

Table 19. Alternatives Risk Score

Risk Criteria	Risk Criteria Importance	P1 Risk Criteria Score	P2 Risk Criteria Score	P3 Risk Criteria Score
Inadequate Requirements	0.52	0.1	0.068	0.11
Claims about the product are not met	0.4	0.08	0.07	0.098
Inadequate delivery or post delivery	0.08	0.01	0.01	0.01
Overall Risk Score		0.085	0.064	0.097

Product 3 has the worst score, which corresponds to the highest risk, followed by product, then followed by product 2. Product 3 has the highest risk associated with it because of its complexity, the number of sub-assemblies involved, and the conditions where it would be utilized and stored, and the manner in which it would be utilized. Product 1 and product 2 are simple enough that the risk associated with them are very limited. In the following table, we combine the risk score with the previously calculated performance score. The overall score is calculated by dividing performance score by risk score.

Table 20. Overall Scores for Decision Alternatives

Score	Product 1	Product 2	Product 3
Performance Score	0.679	0.625	0.825
Risk Score	0.085	0.04	0.128
Overall Score	8	6.67	5.4

Product 1 provides the most efficient solution among the three alternatives. The efficiency is measured by the increase in risk score compared to the increase in performance score; the bigger the better. The Product 1 provides the best value of performance, given the associated risk. Alternatives that are not on the efficiency line are less efficient. Alternatives positioned above the line at the left top corner (Quadrant 1) are increasingly inefficient, as there are associated with lower performance and higher risk, they should never be considered. Alternatives positioned above the line at the right op corner (Quadrant 2) are inefficient but yield higher performance and

is suitable for high risk appetite. Alternatives positioned in the left lower corner (Quadrant 3) below the line are for decision makers with low risk appetite as they're associated with low risk and low performance. Finally, alternatives in the lower right corner (Quadrant 4) below cannot occur as they would definitely be more efficient than the efficiency benchmark product 1. Alternatives positioned in quadrant 4 should become the benchmark.

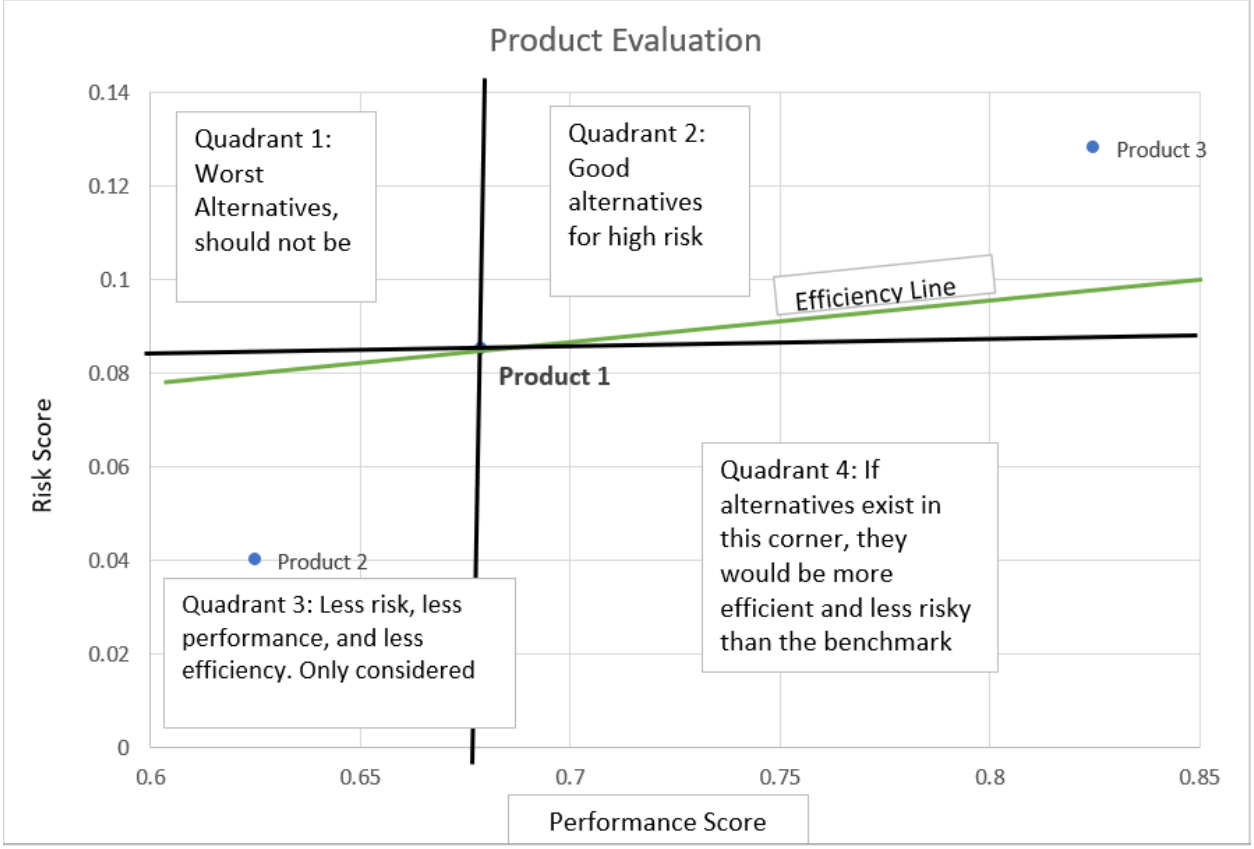


Figure 14. Alternatives Evaluation

Analysis Results

Product 1 had the highest score of 8. It has the best performance and an average risk score. Though Product 3 scored much higher on a key performance sub-criterion "synergy with organizational strategy", product 1 still caught up by performing better in the other performance criteria. Product 2 scores better in terms of resources utilization for design and development as

well as for the resources required for the QMS processes. On the other hand, the risk associated with product 3 was higher than that of product 1 because of the complexity element, which comes from the number of parts the product is made out of, the conditions that it must withstand in operation and in storage, and the extensive ergonomics designing required. The 2nd highest score was 6.67, which belonged to product 2. Product 2 had lower risk compared to the other two products because the service that the supplier provides in terms of quality assurance that, though costs more, ensures the quality of the product, compared to the other two products, where the organization had historically seen many problems with the quality of products similar to it. Product 2 provides a safe solution that has low risk and relatively decent performance. Product 1 provides an average risk but the highest performance. Product 3 would have performed best if it wasn't for the risks associated with it. Reducing the complexity of product 3 sufficiently enough would make it a more viable alternative compared to the other two products. Based on the current analysis and the discussions that ensued, the organization decided to move forward with product 1.

Decision Documentation

Information gathered and analysis made for all three products are documented. The project team formulated an action plan for launching product 1. The team already had all the high-level information it needs and with it, the detailed action plan was constructed. The team went through the high-level information gathered during the decision analysis and used it to help guide them to determine the needed details for carrying out the project. The team was aware of the various levels of resources required and made sure that the numbers were matching the assumptions they made during the decision-making process. The risk analysis that was

conducted also helped guide the team in implementing the controls effectively as the priority of allocating resources for risk control was based on the risk score of each risk scenario.

Discussion of the Case Study

The utilization of the proposed decision-making methodology proved to have multiple benefits. First, going through the process allowed the decision-maker to be continuously aware of ISO 9001 QMS and its requirements. The process at its core required the utilization of the QMS while simultaneously comparing the decision alternatives. Usually, at best, the selected decision alternative would be chosen independently from the QMS and then the QMS would be adhered to in the design, development and other related processes. But using our proposed methodology allowed the decision-maker to have the foresight to understand how each of the decision alternatives would be handled within the QMS before actually making the decision. Second, the decisions alternatives were compared based on aspects that are highlighted by the QMS and are central to its function; product requirements, external provider, resources required, QMS processes required, risks regarding requirements, external provider, and the nature of the product. Third, explicitly conducting risk assessment was something that the organization lacked in its decision-making, as it was something that was implicitly incorporated in the performance evaluation of the decision alternatives. Fourth, exploring risk scenarios proved to be very beneficial for expressing the lessons learnt from previous mistakes. Fifth, the scenario risk scores helped guide the allocation of resources to control risk consequences associated with the risk scenarios. Sixth, utilizing the proposed decision-making process allowed for the simultaneous adherence to the ISO 9001 requirements. Seventh, by the end of the utilization of the decision-making process, almost all of the work required for adhering to ISO 9001 requirements and its documentation had been already completed. Without the proposed methodology, the organization

would not be considering the requirements of the QMS until after the decision has been implemented. Finally, the decision alternatives were analyzed through a multi-attribute decision-making framework, which allowed for a multi-layered perspective, examining resources, strategic value, and risk through a number of criteria and sub criteria. These criteria and sub-criteria are nested within ISO 9001 guidelines, which allows for drawing connections between the various perspectives as they relate to the organization and to the ISO 9001 guidelines, resulting in a seamless integration between the decision-making process and the ISO 9001 guidelines.

The decision-making process was deliberate and did take a significant amount of time. However, the organization was satisfied with the tradeoff. Deliberation allowed for systematic thinking regarding their selection process which added value, given how important the decision is. Also, the organization was happy with utilizing the QMS's perspective on the processes associated with the new product, which ensures excellent documentation for the purpose of the utilization of and compliance with ISO 9001 QMS.

CHAPTER 6. CONCLUSION

The methodology presented in this paper can be utilized in decision-making for a new product selection problem. The complexity of the context associated with real life problems and decision-making is structured through AHP. AHP uses pairwise comparison or MAUT to determine the comparative values of attributes for each decision alternative. Comparisons allow the construction of context in a meaningful way. A risk-based decision-making process framework was developed in the context of ISO 9001 Quality Management System. This was expected to add value in terms of more frequent referencing and utilization of the QMS when making decisions and encouraging the involvement of the top leadership in the QMS through a decision-making process that is based on the QMS. AHP and MAUT were used to structure a decision-making process that ties strategic, quality, and risk objectives and criteria together as important aspects of the decision. A new product is thus selected not only based on its strategic value to the organization, but also the evaluation of the resources utilizing for both its quality management and risk management. This study went beyond what others have done in that it bases the decision-making process within ISO 9001 QMS. This allows for anchoring the decision-making process within the QMS, effectively forcing the utilization of the QMS when decisions are made and ensuring an alignment between the decisions made and the QMS in terms of the expected consequences of the decision with regards to both strategy and resources. Utilizing the QMS actively and the active involvement of top management are critical success factors for ISO 9001, both of which would be promoted by the utilization of the proposed methodology. To ensure that the reader as well as practitioners in the field are up to date with the new ISO 9001 edition, the new changes present in the latest version of the QMS were reviewed, and the methodology reflected the emphasis on these important changes. One of the most

important changes is risk-based thinking, which is integrated into the proposed decision-making methodology. Risk assessment was viewed from the point of view of ISO 9001 guidelines and the risk criteria and sub criteria were based on these guidelines. A top view of the new product operations was provided from a risk management point of view. The integration of the product selection decision-making based on performance and risk evaluation was presented based the performance of the product, and the resources required for the required operations for the design, development and operations of the product, as well as the resources required for the quality assurance of the product through risk mitigation and control.

REFERENCES

Ali, A., Krapfel, R., & Labahn, D. (1995). Product innovativeness and entry strategy: Impact on cycle time and break-even time. The Journal of Product Innovation Management, 12(1), 54–69. https://doi.org/10.1016/0737-6782(94)00027-D

Ananda, J., & Herath, G. (2005). Evaluating public risk preferences in forest land-use choices using multi-attribute utility theory. Ecological Economics, 55(3), 408–419. https://doi.org/10.1016/j.ecolecon.2004.12.015

Andre Naime & Jean Andrey (2013) Improving risk-based regulatory processes: identifying measure to pursue risk-informed regulation, Journal of Risk Research, 16:9, 1141-1161, DOI: 10.1080/13669877.2012.761265

Aniyan, S. (2002). Quality Management System Implementation at KELTEC-A Case Study. Defence Science Journal, 52(4), 393–402. https://doi.org/10.14429/dsj.52.2196

Barad, M., & Dror, S. (2008). Strategy maps as improvement paths of enterprises. International Journal of Production Research, 46(23), 6627–6647. https://doi.org/10.1080/00207540802230405

Barczak, G. (1995). New product strategy, structure, process, and performance in the telecommunications industry. The Journal of Product Innovation Management, 12(3), 224–234. https://doi.org/10.1016/0737-6782(95)00022-LChiu et al. 2006 (Marketing Mix)

Borgonovo, E., Cappelli, V., Maccheroni, F., & Marinacci, M. (2018). Risk analysis and decision theory: A bridge. European Journal of Operational Research, 264(1), 280–293. https://doi.org/10.1016/j.ejor.2017.06.059

Canbolat, Y., Chelst, K., & Garg, N. (2007). Combining decision tree and MAUT for selecting a country for a global manufacturing facility. Omega, 35(3), 312–325. https://doi.org/10.1016/j.omega.2005.07.002

Chwastyk, Piotr, Kolosowski, Mariusz. (2014). Estimating the Cost of the New Product in Development Process. Procedia Engineering, 69(1), 351-360. https://doi.org/10.1016/j.proeng.2014.02.243

Easingwood, C., & Harrington, S. (2002). Launching and re-launching high technology products. Technovation, 22(11), 657–666. https://doi.org/10.1016/S0166-4972(02)00097-4

Forman, Ernest H., Gass, Saul. (2001). The Analytic Hierarchy Process—An Exposition. Operations Research, 49(4), 469–486. https://doi.org/10.1287/opre.49.4.469.11231

Garza-Reyes, J., Rocha-Lona, L., & Kumar, V. (2014). A conceptual framework for the implementation of quality management systems. Total Quality Management & Business Excellence, 26(11-12), 1–13. https://doi.org/10.1080/14783363.2014.929254

Gensch, Dennis.(2001). A Marketing-Decision-Support Model for Evaluating and Selecting Concepts for New Products. Interfaces, 31(3_supplement), S166–S183. https://doi.org/10.1287/inte.31.3s.166.9684

Goodwin, P., Meeran, S., & Dyussekeneva, K. (2014). The challenges of pre-launch forecasting of adoption time series for new durable products. International Journal of Forecasting, 30(4), 1082–1097. https://doi.org/10.1016/j.ijforecast.2014.08.009

Goepel, K.D. (2018). Implementation of an Online Software Tool for the Analytic Hierarchy Process (AHP-OS).International Journal of the Analytic Hierarchy Process, Vol. 10 Issue 3 2018, pp 469-487, https://doi.org/10.13033/ijahp.v10i3.590

Gómez-Limón, J., Arriaza, M., & Riesgo, L. (2003). An MCDM analysis of agricultural risk aversion. European Journal of Operational Research, 151(3), 569–585. https://doi.org/10.1016/S0377-2217(02)00625-2

Gorny, Adam. (2017). Choice and assessment of improvement measures critical for process operation (in reference to the requirements of ISO 9001:2015). DOI: 10.1051/matecconf/20179404006

Hampton, D. M. H. (2014). A step forward. Quality Progress, 47(3), 38-43. Retrieved from https://ezproxy.lib.ndsu.nodak.edu/login?url=https://search-proquest-com.ezproxy.lib.ndsu.nodak.edu/docview/1510291776?accountid=6766

Hrbackova, L. (2016). Risk-based thinking in the production process using the methods of quality assurance matrix and the FMEA process. Journal of Systems Integration, 7(1), 21-28. Retrieved from https://ezproxy.lib.ndsu.nodak.edu/login?url=https://search-proquest-com.ezproxy.lib.ndsu.nodak.edu/docview/1764822120?accountid=6766

Hsieh, M., & Tsai, K. (2007). Technological capability, social capital and the launch strategy for innovative products. Industrial Marketing Management, 36(4), 493–502. https://doi.org/10.1016/j.indmarman.2006.01.002Chwastyk, Kolosowski 2014

Hultink, E., Griffin, A., Hart, S., & Robben, H. (1997). Industrial new product launch strategies and product development performance. The Journal of Product Innovation Management, 14(4), 243–257. https://doi.org/10.1016/S0737-6782(97)00009-X Gao, J., Yao, Y., Zhu, V., Sun, L., & Lin, L. (2011). Service-oriented manufacturing: a new product pattern and manufacturing paradigm. Journal of Intelligent Manufacturing, 22(3), 435–446. https://doi.org/10.1007/s10845-009-0301-y

Hunt, L. (2017). Management commitment starts with you. Quality, 56(5), 41-43. Retrieved from https://ezproxy.lib.ndsu.nodak.edu/login?url=https://search-proquest-com.ezproxy.lib.ndsu.nodak.edu/docview/1892116136?accountid=6766

Ievtushenko, O., & Hodge, G. (2012). Review of Cost Estimation Techniques and Their Strategic Importance in the New Product Development Process of Textile Products. Research Journal of Textile and Apparel, 16(1), 103–124. https://doi.org/10.1108/RJTA-16-01-2012-B012

ISO 9001:2015 And The Advantages. (2017). Quality, 56(5), 17. Retrieved from https://ezproxy.lib.ndsu.nodak.edu/login?url=https://search-proquest-com.ezproxy.lib.ndsu.nodak.edu/docview/1892115967?accountid=6766

"Jack" West, J.,E., & Cianfrani, C. A. (2016). ISO 9001:2015-what's vital. Quality Progress, 49(9), 53-54. Retrieved from https://ezproxy.lib.ndsu.nodak.edu/login?url=https://search-proquest-com.ezproxy.lib.ndsu.nodak.edu/docview/1821753918?accountid=6766

"Jack" West, J.,E., & Cianfrani, C. A. (2014). Managing the system. Quality Progress, 47(8), 53-56. Retrieved from https://ezproxy.lib.ndsu.nodak.edu/login?url=https://search-proquest-com.ezproxy.lib.ndsu.nodak.edu/docview/1566416490?accountid=6766

"Jack" West, J.,E., & Cianfrani, C. A. (2016). Where is preventive action? Quality Progress, 49(3), 56-57. Retrieved from https://ezproxy.lib.ndsu.nodak.edu/login?url=https://search-proquest-com.ezproxy.lib.ndsu.nodak.edu/docview/1774763783?accountid=6766

Kang, C., & Feng, C. (2009). Risk measurement and risk identification for BOT projects: A multi-attribute utility approach. Mathematical and Computer Modelling, 49(9), 1802–1815. https://doi.org/10.1016/j.mcm.2008.10.015

Kiker, G., Bridges, T., Varghese, A., Seager, P., Linkov, I., & Kiker, G. (2005). Application of multicriteria decision analysis in environmental decision making. *Integrated Environmental Assessment and Management*, *1*(2), 95–108. https://doi.org/10.1897/IEAM_2004a-015.1

Konidari, P., & Mavrakis, D. (2007). A multi-criteria evaluation method for climate change mitigation policy instruments. Energy Policy, 35(12), 6235–6257. https://doi.org/10.1016/j.enpol.2007.07.007

Lai, S. (1995). A preference-based interpretation of AHP. Omega, 23(4), 453–462. https://doi.org/10.1016/0305-0483(95)00025-J

Lee, Y., & Lam, K. (1997). Managing quality at an engineering maintenance centre: from QCC to ISO 9001 and beyond. The International Journal of Quality & Reliability Management, 14(2), 118–137. https://doi.org/10.1108/02656719710165392

Liebesman, S. (2014). Brought into Focus. Quality Progress, 47(9), 22-29. Retrieved from https://ezproxy.lib.ndsu.nodak.edu/login?url=https://search-proquest-com.ezproxy.lib.ndsu.nodak.edu/docview/1567557698?accountid=6766

Linkov, I., Satterstrom, F., Kiker, G., Batchelor, C., Bridges, T., & Ferguson, E. (2006). From comparative risk assessment to multi-criteria decision analysis and adaptive management: Recent developments and applications. Environment International, 32(8), 1072–1093. https://doi.org/10.1016/j.envint.2006.06.013

Maria, Popescu, Adina, Dascălu. (2011). Considerations on Integrating Risk and Quality Management. Annals of Dunarea de Jos University. Fascicle I : Economics and Applied Informatics, 1(1), 49–54. Retrieved from https://doaj.org/article/d0cbcb2511a64a46b9f1e26f9f51479b

Mu, Enrique, Pereyra-Rojas, Milagros (2017). Practical Decision Making. An Introduction to the Analytic Hierarchy Process (AHP) Using Super Decisions V2. Springer International Publishing.

Murray, W. (2016). Risk And ISO 9001: 2015. Quality, 55(2), 17-18. Retrieved from https://ezproxy.lib.ndsu.nodak.edu/login?url=https://search-proquest-com.ezproxy.lib.ndsu.nodak.edu/docview/1769716914?accountid=6766

Palmes, P. (2016). Small change, big impact. Quality Progress, 49(2), 62-63. Retrieved from https://ezproxy.lib.ndsu.nodak.edu/login?url=https://search-proquest-com.ezproxy.lib.ndsu.nodak.edu/docview/1769410692?accountid=6766

Pergher, I., & de Almeida, A. (2017). A multi-attribute decision model for setting production planning parameters. Journal of Manufacturing Systems, 42, 224–232. https://doi.org/10.1016/j.jmsy.2016.12.012

Porter, M. (1980). Competitive strategy : techniques for analyzing industries and competitors . New York: Free Press.

R. A. Harpster, "How FMEAs can be the cornerstone of ISO 2001:2015 compliant risk based quality management system," 2016 Annual Reliability and Maintainability Symposium (RAMS), Tucson, AZ, 2016, pp. 1-5. doi: 10.1109/RAMS.2016.7448088 URL: http://ieeexplore.ieee.org.ezproxy.lib.ndsu.nodak.edu/stamp/stamp.jsp?tp=&arnumber=7448088&isnumber=7447953

Reid, R. D. (2015). Putting things in context. Quality Progress, 48(12), 67-70. Retrieved from https://ezproxy.lib.ndsu.nodak.edu/login?url=https://search-proquest-com.ezproxy.lib.ndsu.nodak.edu/docview/1761612021?accountid=6766

Risk And The ISO 9001 Revision. (2015). Quality, 54(10), 25. Retrieved from https://ezproxy.lib.ndsu.nodak.edu/login?url=https://search-proquest-com.ezproxy.lib.ndsu.nodak.edu/docview/1722362519?accountid=6766

Salo, A., & Hämäläinen, R. (1997). On the measurement of preferences in the analytic hierarchy process. Journal of Multi-Criteria Decision Analysis, 6(6), 309–319. https://doi.org/10.1002/(SICI)1099-1360(199711)6:63.0.CO;2-2

Samani, M., Ismail, N., Leman, Z., & Zulkifli, N. (2014). Quality Management System and Risk Management System: Similarities and Possibilities for Integration. Applied Mechanics and Materials, 564(Advances in Mechanical and Manufacturing Engineering), 700–705. https://doi.org/10.4028/www.scientific.net/AMM.564.700

Scholz, M., Franz, M., & Hinz, O. (2017). Effects of decision space information on MAUT-based systems that support purchase decision processes. Decision Support Systems, 97. Retrieved from http://search.proquest.com/docview/1914203095/

Song, L., Song, M., & Benedetto, C. (2011). Resources, supplier investment, product launch advantages, and first product performance. Journal of Operations Management, 29(1), 86–104. https://doi.org/10.1016/j.jom.2010.07.003

Srđan Medić. Biljana Karlović. Zrinko Cindrić. (2016). NEW STANDARD ISO 9001:2015 AND ITS EFFECT ON ORGANISATIONS. Interdisciplinary Description of Complex Systems. http://indecs.eu/2016/indecs2016-pp188-193.pdf

Shulyar, R. V., Reverenda, N. Y. (2017). International Standard ISO 9001:2015 - Adaptation for Flexibility Of Quality Management. Natsional'Nyi Hirnychyi Universytet.Naukovyi Visnyk; National Mining University.Scientific Bulletin, (1), 128. Retrieved from https://ezproxy.lib.ndsu.nodak.edu/login?url=https://search-proquest-com.ezproxy.lib.ndsu.nodak.edu/docview/1893891282?accountid=6766

Su, M., & Rao, V. (2011). Timing decisions of new product preannouncement and launch with competition. International Journal of Production Economics, 129(1), 51–64. https://doi.org/10.1016/j.ijpe.2010.09.001

Sylvia J. T. Jansen, Henny C. C. H. Coolen and Roland W. Goetgeluk (eds): The measurement and analysis of housing preference and choice. Chapter 5 “the multi-attribute utility method”. *Journal of Housing and the Built Environment*, *27*(4), 543–544. https://doi.org/10.1007/s10901-012-9287-4

Terje Aven, Bodil S. Krohn. (2013). A new perspective on how to understand, assess and manage risk and the unforeseen. Reliability Engineering and System Safety.

Wilson, J. P., & Campbell, L. (2016). Developing a knowledge management policy for ISO 9001: 2015. Journal of Knowledge Management, 20(4), 829-844. Retrieved from https://ezproxy.lib.ndsu.nodak.edu/login?url=https://search-proquest-com.ezproxy.lib.ndsu.nodak.edu/docview/1841764615?accountid=6766

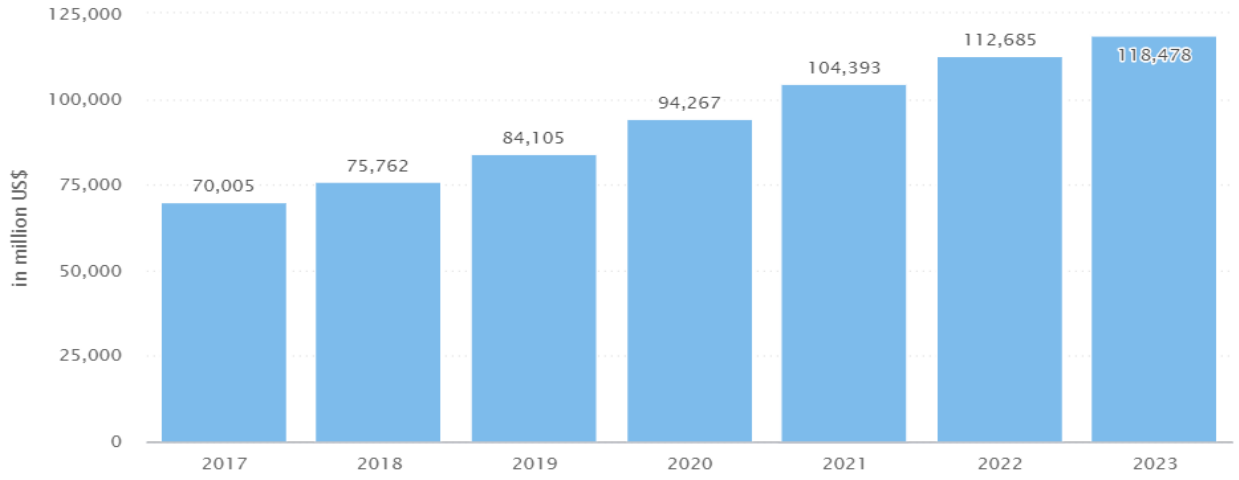
Yasenchak, L. (2016, 12). ISO 9001:2015 certification takeaways. MoldMaking Technology, 19, 32-33. Retrieved from https://ezproxy.lib.ndsu.nodak.edu/login?url=https://search-proquest-com.ezproxy.lib.ndsu.nodak.edu/docview/1845769913?accountid=6766

Yang Zou, Arto Kiviniemi, Stephen W. Jones. (2016). A review of risk management through BIM and BIM-related technologies. Journal of Safety Science.

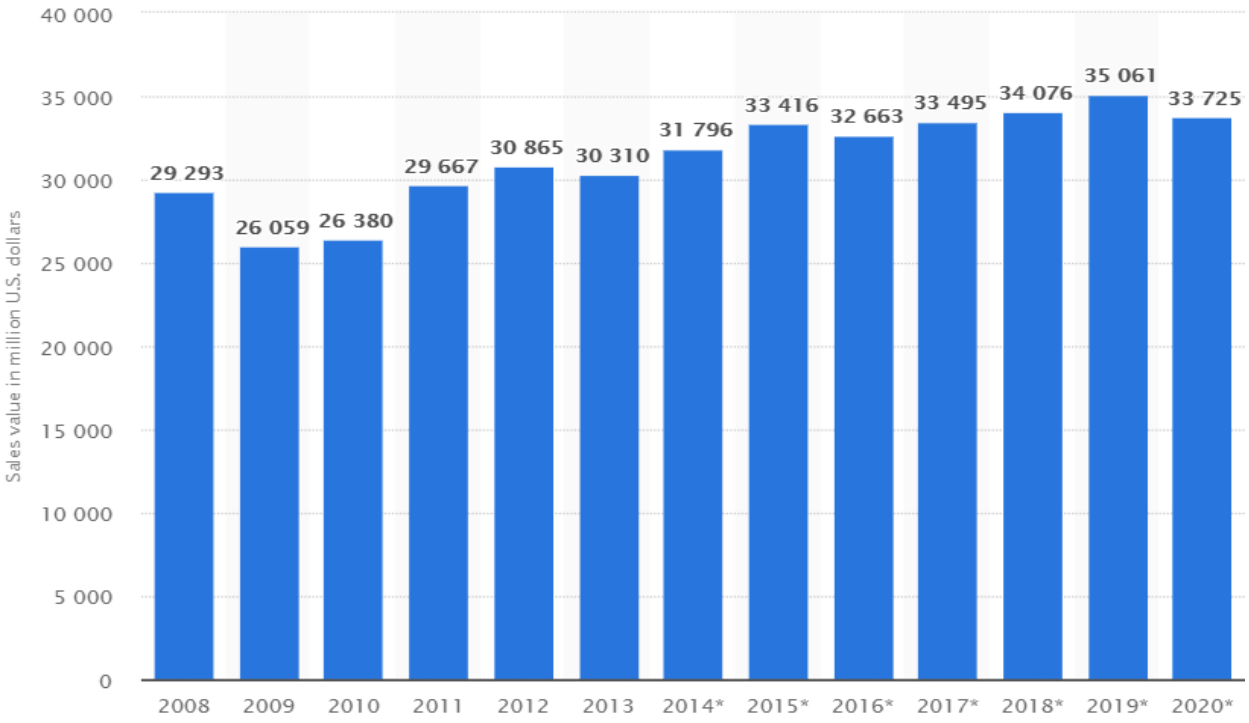
Yasenchak, L. (2016). Moving to ISO 9001:2015 requires a top-down approach. MoldMaking Technology, 19(1), 30. Retrieved from https://ezproxy.lib.ndsu.nodak.edu/login?url=https://search-proquest-com.ezproxy.lib.ndsu.nodak.edu/docview/1786210307?accountid=6766

Zahedi, F. (1987). A utility approach to the analytic hierarchy process. Mathematical Modelling, ISSN: 0270-0255, Vol: 9, Issue: 3, Page: 387-395

APPENDIX A. SPORTS AND OUTDOOR MARKET REVENUE BY YEAR (STATISTA, 2019)



APPENDIX B. JEWELRY REVENUE BY YEAR (STATISTA, 2019)



APPENDIX C. DRINKING GLASSES AMAZON SEARCH (JUNGLESCOUT, 2019)

Keyword	Exact Match Search Volume
drinking glasses	34,761
glassware drinking set	1,659
drinking glasses glass	90
glassware set	1,937
glass sets for drinking	1,581
glass drinking	146
drinking glasses set	390
drinking glasses sets	1,693
drinking glass set	587
kitchen glassware	120
everyday glasses	86
glasses drinking	1,050
glassware sets of 12	99
glasswear drinking sets	291
glass wear sets	484
glassware sets	420
glass wear	296
everyday drinking glasses	171
vasos de vidrio	1,251
kitchen glasses	1,817
glass ware	570
clear drinking glasses	767
glassware glasses set	171
glass drinkware	129
glassware	9,446
drinking glass	1,213
libbey drinking glasses	1,864
glasses set of 12	176
glass tumbler set	334
glass cups set	107
water glasses	7,149
drinking set	141
glasswear	313
drink glasses set	270
everyday glassware	116
everyday glasses drinkware	167
water drinking glasses	94
libby glasses drinking	951
glass drinking cups	249
heavy drinking glasses	124
drinkware set	334

Keyword	Exact Match Search Volume
thick drinking glasses	159
glass set	3,034
glass cups sets	1,813
drinkware	1,221
libby glasses	553
unbreakable glassware	291
galaxy glassware	107
libbey glassware	810
basos	244
glassware sets of 16	261
glass tumblers	947
large drinking glass	386
tall drinking glasses	339
16oz glasses	103
vasos	1,389
16 oz glasses	441
tom collins glasses	274
modern drinking glasses	133
highball drinking glasses	111
water glasses set	86
glass base	180
tall glasses for drinks	313
small glasses drinking	201
12 oz drinking glasses	189
heavy duty drinking glasses	116
tall glass cups	99
libbey glasses	506
acrylic glasses drinkware	296
highball glass set	90
tumbler glasses	879
acrylic glasses drinkware set	853
libby glassware	141
stackable drinking glasses	133
luminarc glassware	99
vintage drinking glasses	437
ikea drinking glasses	133
glass	22,406
juice glasses	2,923
drinking cups	1,967
highball glasses	3,587
unbreakable drinking glasses	600
acrylic drinking glasses	514
tall cocktail glasses	99

Keyword	Exact Match Search Volume
highball glass	429
blue glasses drinking	261
hiball glasses	163
acrylic glassware	390
small drinking glasses	369
anchor glassware	339
break resistant drinking glasses	300
12 oz glasses	244
blue drinking glasses sets	120
amazon basics glasses	103
corelle drinking glasses	99
collins glass	814
crate and barrel glasses	437
novica glassware	317
glass tumbler	2,876
anchor hocking glasses	1,024
blue drinking glasses	651
plastic glassware	489
colored drinking glasses	377
colored glassware	330
shatterproof glasses	313
8 oz drinking glasses	236
anchor glasses	137
anchor hocking glassware	137
libbey impressions glasses	133
palaks glassware	111
colored glass drinking glasses	99
colored drinking glasses sets	99
picardie glassware	90
crisa glassware	90
party drinking glasses	86
glass cup	2,777
acrylic cups	1,127
mexican glassware	669
unbreakable glasses	424
vintage glassware	321
crystal drinking glasses	304
stackable glasses	159
blue rimmed mexican glasses	111
crisa glasses	103

Keyword	Exact Match Search Volume
mojito glasses	326
plastic glasses drinking	150
anchor hocking drinking glasses	146
unique glasses drinking	111
picardie glasses	107
libbey cobalt blue glassware	90
christmas glasses drinkware	909
duralex glasses	669
mexican glasses	424
non breakable drinking glasses	219
unbreakable glasses drinking	197
mexican glass	184
mexican drinking glasses	120
blue drinking glass	120
smoke glassware	107
plastic drinking glass	103
duraflex glasses	99
mixed drink glasses	296
unique drinking glasses	291
drinking glasses plastic	227
glass water cup	154
brown drinking glasses	124
cocktail glassware	116
ikea glasses drinking	99
cup set	2,859
acrylic tumblers	1,427
tumbler set	793
acrylic glasses	561
plastic tumblers dishwasher safe	527
duralex picardie	446
circleware glasses	356
ice tea glasses	193
bar glassware	184
rocks glasses set	167
picardie	111
clear plastic drinking glasses	111
drinking glasses blue	103
hand blown glasses	94
glass tumblr	90
blue glassware	321

Keyword	Exact Match Search Volume
glasses anchor hocking	244
outdoor glassware	107
bubble glassware	94
novica	2,511
christmas drinking glasses	716
iced tea glasses	591
drinking cup	471
plastic drinkware	351
cocktail glasses set	334
plastic rocks glass	189
clear glass cups	163
water drinking	124
drinking tumblers	124
short drinking glasses	111
shatterproof cups	111
duraclear glasses	107
borosil glasses	107
fancy drinking glasses	103
amici glassware	103
plastic glass set	99
french drinking glasses	90
duralex tumbler	90
mexican blown glass	90
rustic glassware	90
hand blown glass	831
christmas glassware	313
juice glasses 8 oz	266
cobalt blue glassware	231
duralex glassware	223
french glassware	214
16 oz glass	159
8 oz glasses drinking	150
plastic water goblets	129
libby water goblets	120
planetary glass set	120
rainbow glassware	116
tritan glass	111
14 oz glasses	90
french glasses	90
colored wine glasses	476
duralex glass	411
crystal water glasses	356
plastic water glasses	309

Keyword	Exact Match Search Volume
tumbler glass	291
plastic drink glasses	249
unbreakable cups	223
blue water glasses	214
drink glass	189
cocktail glass set	184
melamine glasses	116
vintage juice glasses	116
antique drinking glasses	111
glasses set of 4	103
acrylic tumbler set	99
drink ware	99
bistro glasses	94
big drinking cup	94
anchor hocking	4,993
crystal glasses set	780
libbey glass	266
bubble glass	261
plastic stemware	240
amber drinking glasses	240
20 oz glasses	227
bormioli glasses	197
holiday glassware	180
red drinking glasses sets	154
pint glass set	146
us acrylic tumblers	141
duralex picardie glasses	129
vasos de cristal	120
plastic tumbler set	120
colorful drinking glasses	107
drinking glasses 8 oz	103
waterford highball glasses	94
duralex	2,790
bormioli rocco glasses	1,753
bar glass set	381
square drinking glasses	309
crystal highball glasses	189
glass dinner table	176
tumbler sets	150

APPENDIX D. OUTDOOR GAMES AMAZON SEARCH DATA (JUNGLESCOUT, 2019)

Keyword	Exact Match Search Volume
cornhole boards regulation size	193
cornhole game	30,651
corn hole	7,050
corn hole games	304
corn hole game	1,333
corn hole sets	133
wood cornhole game	124
corn hole boards	484
wood cornhole	86
cornhole wood	47
wood corn hole	51
corn hole outdoor game	1,423
cornhole game set	313
corn hole board	120
corn hole game set	197
regulation cornhole game	99
regulation cornhole game set	403
cornhole sets	223
corn hole wood	56
cornhole boards	3,964
regulation size corn hole	77
cornhole set	969
cornhole bean bags game	476
regulation corn hole boards	64
regulation cornhole	124
corn hole toss game	184
unfinished cornhole boards	176
blank cornhole boards	94
cornhole kit	351
cornhole board sets	167
regulation size cornhole boards	159
cornhole bean bag game	60
cornhole games	206
corn toss game	56
regulation size cornhole game	90
cornhole game portable	56
corn hole set	356
bag toss	184

Keyword	Exact Match Search Volume
corn hole toss	86
bean toss game	184
corn toss	107
bean toss	56
outdoor cornhole game	86
bean bag game	660
travel cornhole game	107
bag toss game	103
bag toss game outdoor	77
outdoor games cornhole	56
wooden cornhole set	167
cornhole toss game set	90
bean bag toss	3,960
bean bag toss game	1,731
beanbag toss game outdoor	47
cornhole boards regulation	69
beanbag toss game	150
backyard cornhole game	73
cornhole board bags	56
travel cornhole	47
bean bag games	167
cornhole boards unfinished	129
board games bag	77
beanbag game	73
bing bag toss game	47
bean bag toss games	116
american cornhole association	51
tailgate cornhole game	47
cornhole official size	133
go sports cornhole	60
bean bag toss board	51
cornhole game official size	69
gosports cornhole game	266
bags for cornhole game	90
cornhole game bags	81
board game bag	411
coinhole game	133
bean bag boards	51
corn hole game bags	90
backyard toss games	69
baggo bag toss game	133
cornhole beans bags	47

Keyword	Exact Match Search Volume
corn toss bags	77
game bags	3,420
hole games	189
game bean bags	51
all cornhole bags	47
corn hole bean bag	133
board game bags	94
cornhole bags american flag	73
harley davidson cornhole game	94
cornhole bean bag	86
cornhole bean bags	16,436
tournament cornhole bags	51
corn hole bags	1,646
bean bags corn hole	111
cornhole beanbags	107
bean bags for cornhole	90
outdoor board games	60
indoor cornhole	141
portable board games	111
board game sets	99
cornhole waterproof	47
corn hole bean bags	686
custom cornhole boards	154
bag toss bean bags	124
cornhole bags regulation	77
bag toss bags	60
corn hole light	47
coinhole	750
victory tailgate cornhole boards	231
professional cornhole bags	146
cornhole bags	6,000
all weather cornhole bags	94
bean bag toss bags	51
wedding cornhole game set	47
tailgate cornhole boards	47
gosports	330
cornhole bean bags regulation	90
corn hole beanbags	60
slide rite cornhole bags	154
cornhole light	116

Keyword	Exact Match Search Volume
cornhole lights for hole	77
play corn	69
regulation corn hole bags	64
flag game	51
kids cornhole game set	493
cornhole board carrying case	154
patriots cornhole game	120
beanbags for cornhole toss	111
outdoor lawn games	94
kids cornhole game	86
coin toss game	60
wooden game sets	51
cornhole board lights	279
slick woodys cornhole boards	150
corn hole decals	137
cornhole bag tote	73
bean bags for games	47
lawn games	2,293
horseshoes game	2,289
cornhole lights	1,890
outdoor games for adults	1,067
back yard games	223
cornhole game for kids	176
lights for cornhole boards	107
toss bean bags	69
horse shoes game	64
bags for corn hole	60
game board set	47
yard games	11,730
cornhole decals	784
slick woodys	60
coin hole game quarters	60
led cornhole	56
coinhole quarters game tabletop	776
coin hole game	506
halloween bean bag toss	227
coinhole table game	214
corn bags	184
red flag game	154
cornhole game kids	73
wooden board game set	56

Keyword	Exact Match Search Volume
nfl cornhole bags	56
double sided cornhole bags	51
backyard games	3,056
cornhole board decals	300
sports board games	240
yard games for adults	227
adult lawn games	206
lawn game	201
outdoor game set	77
cornhole decal	283
wood board games	210
board games set	171
cornhole for kids	163
outdoor bean bag	159
corn hole bag	150
cornhole score keeper	107
pro cornhole bags	103
american games	86
led cornhole lights	81
outdoor beanbag	81
light up bean bags	77
triumph sports	69
cornhole score	69
cornhole game led	56
giant beanbags	56
desktop bag toss	51
kids cornhole	249
cornhole bag	176
nfl board game	163
wild sports	141
last will board game	103
toss games for adults	77
waterproof bean bag	64
cornhole scoreboard	896
washers game	879
giant bean bags	459
board game set	424
board game carrying bag	107
table cornhole	81
cornhole lights white	56
bean bags for tossing	3,634
outdoor games for family	2,417
ladder toss	870

Keyword	Exact Match Search Volume
pool bean bag toss	129
christmas bean bag toss	94
patriots cornhole boards	86
nfl cornhole game set	77
coinhole quarters game	51
beans for bean bag	823
cornhole wraps and decals	364
victory tailgate	360
flag bag	214
cornhole skins	210
ball toss game	210
bean bag small	201
board bag	189
alabama cornhole game	171
cornhole board wrap	154
cornhole led lights	124
beans bulk	107
bean products	107
board games for 2	107
bag of beans	103
american flag bag	90
snowball toss game	81
corn hole board wrap	69
college cornhole boards	69
corn sack	60
2x4 board wood	60
bean bags small	60
corn hole bag filler	56
barbecue party game	51
outside games	1,221
yard game	433
golf cornhole chipping game	334
kids bean bag toss	244
go board game set	193
large board games	154
himal	133
coin hole tabletop game	111
bean bag toss kids	99
toss game for adults	94
games for outside	90
jiant jenga	69
game portable	69
pumpkin bean bag toss	60

Keyword	Exact Match Search Volume
desktop cornhole game	60
carnival bean bag toss	51