



Sudan University of Science & Technology
Total Quality and Excellence Centre



Role of risk based thinking in ISO 9001: 2015 on risk reduction

Case study (SAFAT aircraft manufacturing center)

دور التفكير المبني علي المخاطر في الايزو 9001-2015
في تقليل المخاطر
دراسة حالة (مركز صافات لتصنيع الطائرات)

**A thesis submitted in partial fulfillment of the requirement of M.Sc.
degree in managing quality excellence**

Prepared by:

ABDALLAH IDRIS ABDALLAH GASMALLAH

Supervisor:

DR.ABDULMUTALLAB IBRAHIM ABDUL RASOOL

2019 April

Chapter one

Overview

Chapter one

Overview

1.1. Introduction:

The efficiency and profit maximization are the core objectives of any organization regardless of size, sector or geographical location. ISO 9001 was designed as a standard for organizations seeking to optimize their operational excellence, ISO published the first version of the ISO 9000 series of International Standards in 1987 in response to the growing internationalization of business and the need for common quality management system standards, being increasingly important as end users want increasingly more to get high quality products. Standard "ISO 9001: 2008 Quality Management Systems - Requirements" is widely used in many industries such as aerospace, telecommunications, education, health and government bodies. And for capturing the more complex organizational contexts, reflecting the needs of all potential users, enhancing an organization's ability to meet its customers. Changes made in new version touch both structure and content, ISO Corporation wants the ISO 9001:2015 to have the widest possible range of application, not just in enterprises producing goods but also in enterprises from services sector. Therefore it needed a standard that covers all aspects of production, including production services. We can say ISO 9001:2015 a major focus is placed on gaining added value to the organization and its customers. A new stage in the structure and objectives oriented towards risk management and identifying and implementing opportunities. In this conditions, continuous improvement and procedural approach will be maintained, but seen and approached from a new perspective.

For all types of organizations, there is a need to understand the risks being taken when seeking to achieve objectives and attain the desired level of reward. Organizations need to understand the overall level of risk embedded within their processes and activities. In the present research we conducted a review of the main

changes to the ISO 9001: 2015 and a critical analysis regarding risk management approach in the new version of the standard and its role and effects on organizations.

1.2. The Problem Statement:

When using the ISO 9001:2015 requirements as a basis for your Quality Management System (QMS), you will find that risk-based thinking is an important new concept that has been brought into the forefront of quality planning. It is important to be able simply to identify and address these requirements. However, there are the difficulties that face organizations to identify and implement risk based thinking in ISO 9001:2015, because there is no specific framework or structure for a formal process to monitor and control risks and opportunities within the Quality Management System. Just like risk-based thinking, although the standard 31001 is existed, the requirements for addressing risks and opportunities are spread throughout the ISO 9001:2015 standard, this does not even need to be maintained as documented information within the QMS. So you can look at these risks and opportunities in any fashion you wish. The important point of our study is that to show how risk management in ISO 9001:2015 reduce risks and changes the view for wider range of advantages with high scope of understanding what factors affecting organizations in and outside.

1.3. Questions of the study:

The main question of the study is:

What is the role of ISO 9001 – 2015 in risk reduction? And there are other sub-questions as:

- I. What are the components, tools fundamental and principles for the risk management?
- II. What are the benefits and advantages that organization get when applying risk based thinking?
- III. What are the challenges associated with the implementation of risk based thinking?

- IV. What are the level of risk based thinking awareness among employee of SAFAT aviation center.

1.4. The Objectives of the study:

Our main objective of study is:

To investigate the role of risk-based thinking in ISO 9001-2015 in risk reduction.

And other sub-objective as:

- I. To identify in simple terms the components, tools fundamental and principles for the risk management.
- II. To identify the benefits and advantages that organization get when applying risk based thinking.
- III. To identify the challenges associated with the implementation of risk based thinking.
- IV. To evaluate role of risk based thinking awareness in risk reduction.

1.5. The Study Hypotheses:

- I. There is a significant relationship between applying risk –based thinking in ISO 9001 – 2015 and risk reduction.
- II. Good awareness and understanding of risk –based thinking in ISO 9001 -2015 will lead to positive results in reducing risk.

1.6. The Significance of the Study:

In our study we aim to show the importance and benefits of define and determine the risk and take it in systematic way in mind for many organizations and this will be business as usual. On other hands we want to appear the shine image for organization after detect, clear, and preventing risk.

1.7. The Limits of the Study:

Time frame:

The study carried out during the academic year 2017-2018.

Location boundaries:

The study is limited to SAFAT aviation complex, light aircraft manufacturing center –Khartoum Sudan.

Subject: the role of ISO 9001 -2015 in risk reduction.

Key words: risk based thinking, risk management, risk assessment,

Chapter Two

Literatures Review and Previous Studies

Chapter Two

Literatures Review and Previous Studies

2.1. Introduction:

This chapter discuss risk based thinking and risk management, Concepts, principles and components of risks management, review a number of thesis and written in local and out regions, it explain different views for explicit and implicit of risk over many parts of ISO 9001-2008 to ISO 9001-2015 and the implementation of the standard and its effect on organizations, also this chapter discuss the definitions of risk, steps and stages from identifying to prevention risk, also it make review to link with process and other approaches and uses with some example from different organizations.

2.2. Risk management& risk based thinking:

Risk assessments are concerned with the identify cation of hazards and the analysis of the risks attached to them. A hazard is anything that can cause harm (working on roofs, lifting heavy objects, chemicals, electricity, etc.). A risk is the chance, large or small, of harm being actually done by the hazard. (Armstrong and Taylor, 2014) Risk represents uncertain events or situations that potentially can adversely affect a project as planned, usually in terms of cost, schedule, and/or product quality.(Aized, 2012)The risk management applications, which stem mainly from the theories of Total Quality Management and tools such as FMEA, FMECA, Fault Tree, etc., therefore focused on “operational risks” and on the management of business processes.(Borghesi and Gaudenzi, 2012)The purpose of risk assessments is to initiate preventive action. They enable control measures to be devised on the basis of an understanding of the relative importance of risks. Risk assessments must be recorded if there are five or more employees.

There are two types of risk assessment. The first is quantitative risk assessment, which produces an objective probability estimate based upon risk information that is immediately applicable to the circumstances in which the risk occurs. The second is

qualitative risk assessment, which is more subjective and is based on judgement backed by generalized data. Qualitative risk assessment is preferable if the specific data are available. Qualitative risk assessment may be acceptable if there is little or no specific data as long as the assessment is made systematically on the basis of an analysis of working conditions and hazards and informed judgement of the likelihood of harm actually being done.(Armstrong and Taylor, 2014)

Risk Based thinking: As already noted, this adds management credibility to the standard. But “risk experts” should note that this is not ISO 31000 but more a way of thinking that replaces preventive action and seeks to add some systematic evaluation of potential and actual issues with the aim of making processes more robust and capable.(Fonseca, 2015a)

An integrated risk management approach allows for the integration and coordination of strategic entrepreneurial risk management processes through the effective and efficient management of the risks that are typical of business processes, while meeting the performance expectations of the various stakeholders. The major benefits of an integrated risk management approach are:

- assessing those risks which can threaten a company’s competitive edge, protecting and enhancing organizational value (value-based theory);
- supporting the decision-making processes and focusing managers’ attention on value creation priorities;
- optimizing the cost of capital and the cost of risk;
- protecting corporate image, reputation, and relationships with stakeholders;
- Protection of the company from potential adverse impacts of regulatory issues and formal assessment systems.

Integrated risk management requires capability to move from a silo approach to a systemic approach. Note that the principles of integrated risk management are clearly stated in ISO 31000. These principles, first published in 2009, are now considered the internationally agreed standard for the definition and implementation of risk management principles.(Borghesi and Gaudenzi, 2012)

2.3. Concepts, principles and components of risks management:

Since the eighteenth century, the concept of risk is mainly linked to the concept of unfavorable event. An exception is represented by Smith, who did not comprehend risk in his studies. In the twentieth century, mainly in the U.S., we had the first instances of risk in the business sphere being dealt with for the purpose of identifying techniques and procedures for the identification, measurement, and treatment of risk in business decisions. At the beginning of the twentieth century, the first significant studies in business risk management were developed, for the first time treated risk as an independent topic of study, and described ‘risk’ as a measurable uncertainty in contrast with the concept of non-measurable uncertainty (ignorance about future events).(Borghesi and Gaudenzi, 2012)

2.3.1 Risk based thinking: had been theorized and applied in a systematic fashion since the 1950s. Since then, to date Risk Management has undergone significant evolutions, in particular with the consolidation, today, of the three main currents of thought that albeit being associated with a unitary and integrated view of risk management, remain however distinguishable: Financial Risk Management, Business Risk Management and Compliance Risk Management. Since this period in time, especially in the U.S. where recovery was rapid and significant, industrial growth led to the development of the first tools for managing the “industrial risk”, understood in particular as every unfavorable event capable of causing interruptions to production activities, quality defects and damage to production equipment.(Borghesi and Gaudenzi, 2012)

Project risk management includes the processes concerned with conducting risk management planning, identification, analysis, responses, and monitoring and control on a project; most of these processes are updated throughout the project (PMI, 2004). It involves processes, tools, and techniques that will help the project manager to maximize the likelihood and consequences of positive events and minimize the

probability and consequences of adverse events. Figure (I) shown the processes of project risk management. (Aized, 2012)



Fig(2.1) project risk management



Figure (2.2). Risk management process

A revision of several paths for the Quality journey is presented: from Quality Gurus and Total Quality Management (TQM) models to the ISO 9000 International Standards Series. Since ISO 9001:2008 is now in the revision process to the expected ISO 9001:2015 version, an analysis is made of the proposed changes and the underlying reasons and the impacts foreseen on the more than 1.3 Million certified organizations. This revision should be a step towards TQM and reflect the changes of an increasingly complex, demanding and dynamic environment, while assuring

that complying organizations are able to provide conformity products and services that satisfy their customers. Major benefits are expected such as less emphasis on documentation and new/reinforced approaches: consideration of Organizational Context and (relevant) Stakeholders, Risk Based thinking and Knowledge Management.(Fonseca, 2015a)

TQM is a vision which the firm can only achieve through long-term planning, by drawing up and implementing annual quality plans which gradually lead the firm towards the fulfilment of the vision, i.e. to the point where the following definition of TQM becomes a reality:

A corporate culture characterized by increased customer satisfaction through continuous improvements, in which all employees in the firm actively participate.

Quality is a part of this definition in that TQM can be said to be the culmination of a hierarchy of quality definitions:

1. Quality—is to continuously satisfy customers' expectations.
2. Total quality—is to achieve quality at low cost.
3. Total Quality Management—is to achieve total quality through everybody's participation.(Dahlgaard et al., 2008)

Process + Risk + PDCA Model

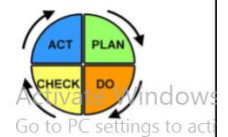
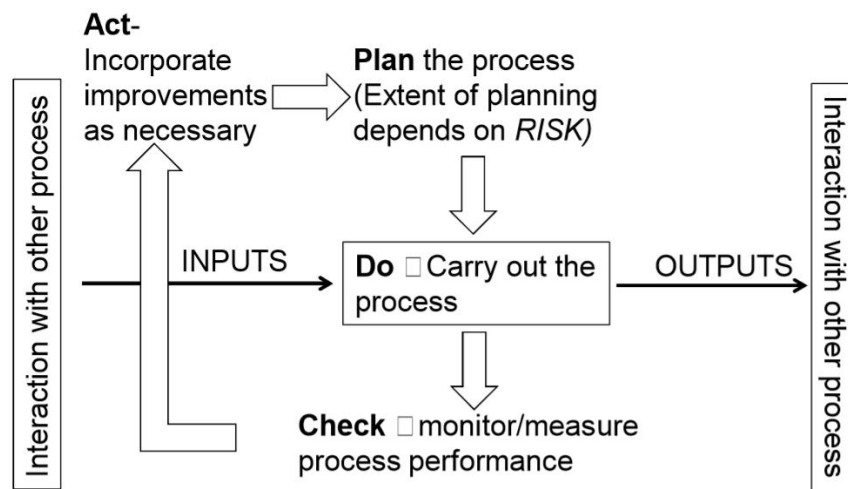


Fig (2.3) Process + Risk + PDCA Model

2.3.2 Risk analysis involves developing an understanding of risk and impacts both positive and negative. Risk analysis provides input for risk evaluation and decisions on the most appropriate risk treatment strategies and methods. Risk analysis can also provide input for making decisions where the options involve different types and levels of risk assumption, mitigation, reduction, and avoidance.

Risk is characterized by two basic features:

- The severity of the possible adverse consequences;
- The likelihood (probability) of occurrence of each consequence.

The risk level is defined by the measurement of severity and likelihood. (Borghesi and Gaudenzi, 2012)

Hazards should be ranked according to their potential severity as a basis for producing one side of the risk equation. A simple three-point scale can be used such

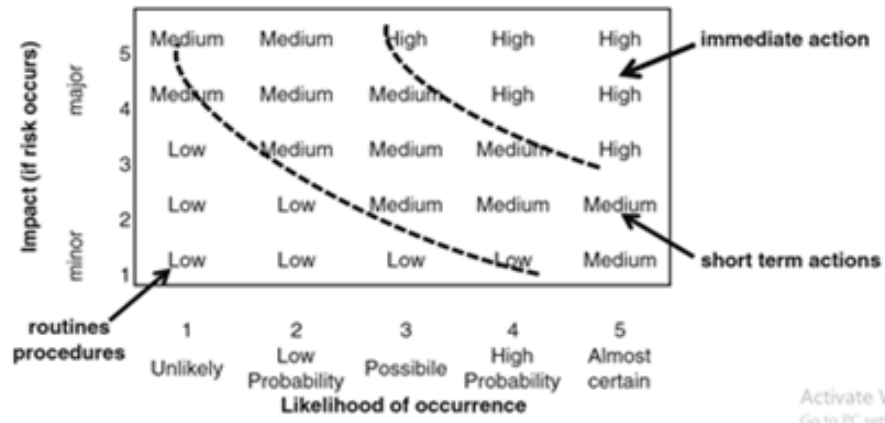
as 'low', 'moderate' and 'high'. A more complex severity rating scale has been proposed as follows: Catastrophic – imminent danger exists, hazard capable of causing death and illness on

- A wide scale. Critical – hazard can result in serious illness, severe injury, property and equipment.
- Damage. Marginal – hazard can cause illness, injury, or equipment damage, but the results would.
- Not be expected to be serious. Negligible – hazard will not result in serious injury or illness, remote possibility of
 - Damage beyond minor first-aid case.(Armstrong and Taylor, 2014)

2.3.3 Risk assessments: identify specific hazards and quantify the risks attached to them. Health and safety audits provide for a much more comprehensive review of all aspects of health and safety policies, procedures and practices programs.(Armstrong and Taylor, 2014)

Risk Evaluation: The risk appetite and risk tolerance of an organization dictate the nature and level of risks that are acceptable to that organization. Risk appetite could be defined as “the risks that an organization is in business to take, based on its corporate goals and its strategic imperatives.” While risk tolerance represents “the threshold of risk that that organization considers acceptable, based on its capabilities to manage the identified risks” ‘the process of risk evaluation allows the managers to represent risks within a matrix as shown in Fig. 6.5. In that representation, risks can be classified on the basis of their priority and nature of actions required.(Borghesi and Gaudenzi, 2012)

2.3.4 Monitoring and evaluation: Risk assessment is not completed when action has been initiated. It is essential to monitor the hazard and evaluate the effectiveness of the action in eliminating it or at least reducing it to an acceptable level.(Aized, 2012)



Fig(2.4) risk classified by priorities

Risks are prioritized according to their potential implications for meeting the project’s objectives. A risk matrix is used to combine likelihood and impact ratings values to obtain a risk score. The risk score may be used to aid decision making and help in deciding what action to take in view of the overall risk. How the risk score is derived can be seen from the sample risk matrix shown. The organization can define as many risk levels as it believe are necessary.(Aized, 2012)

		Impact				
		Very Low 1	Low 2	Medium 3	High 4	Very High 5
Probability	Very High 5	5	10	15	20	25
	High 4	4	8	12	16	20
	Medium 3	3	6	9	12	15
	Low 2	2	4	6	8	10
	Very Low 1	1	2	3	4	5

Fig (2.5) Sample risk matrix

It is important to note that there are no requirements for a formal process to monitor and control risks and opportunities within the Quality Management System, only the identification of the risks and opportunities and decisions on what action to take. This does not even need to be maintained as documented information within the QMS.

As with any new requirements for ISO 9001:2015, it is a good practice to look at what you already do within your organization to see if you address these requirements with your current business practices. For instance, many companies have business planning processes that look at the risks to the business and the opportunities that could be present, such as the use of a SWOT analysis (strengths, weaknesses, opportunities, and threats).

In ISO 9001:2015 risk is considered from the beginning and throughout the standard, making preventive action part of strategic planning as well as operation and review, Risk-based thinking has always been in ISO 9001 – 2015 this revision builds it into the whole management system.

Risk-based thinking is already part of the process approach.

Example: To cross the road I may go directly or I may use a nearby footbridge. Which process I choose will be determined by considering the risks. Risk is commonly understood to be negative. In risk-based thinking opportunity can also be found – this is sometimes seen as the positive side of risk.

Risk-based thinking is taking into account the risk to the overall management system

- Improving achievement of defined objectives
- The output will be more consistent
- Customers increasingly assured of receiving a product/service that is accepted
- Nurture a culture of proactive towards improvement
- Ensure consistency of quality of goods/services
- Increase customer confidence and satisfaction

Intuitively, successful companies already and always use a risk-based approach. It is necessary to analyze the opportunities and consider which can or should be acted on. Both the impact and the feasibility of taking an opportunity must be considered.(Bouchet, 2015)

There are several options with risk:

- 1-either by exercising risk.
2. Take risks in order to get opportunities.
3. Delete the main source of risk.
- 4 - Changing the possibilities and consequences of colored danger.
5. Sharing risk.
6. Take risks based on fact-based decisions

Identify what the risks and opportunities are in your organization – it depends on context –ISO 9001:2015 will not automatically require you to carry out a full, formal risk assessment, or to maintain a “risk register” –ISO 31000 (“Risk management — Principles and guidelines”) will be a useful reference (but not mandated)

- Analyze and prioritize the risks and opportunities in your organization – what is acceptable? – What is unacceptable?

- Plan actions to address the risks – how can I avoid or eliminate the risk? – How can I mitigate the risk?
- Implement the plan – take action.
- Check the effectiveness of the actions – does it work?
- Learn from experience – continual improvement.

Key Points to Remember:

Risk Based Thinking = Preventative Action, Risk Based Thinking is everybody's business!

– Risk Based Thinking is not just the responsibility of management.

– Risk Based Thinking must become an integral part of the organizational culture.(Deysher, 2015)

2.4. Risk based thinkingtools:

Risk management tools, techniques and system should be used to carry out the risk management process and all activities related to the planning, implementing, reviewing and reporting, and continuous improvement of the risk management framework, for example, use of risk dashboard, template, monitoring sheet, risk management information system, risk assessment matrix etc. As mentioned in MS ISO 31000:2010, organizations should apply risk identification tools and techniques that are suited to their objectives and capabilities, and to the risks faced.(ISO, 2009)

Possible methods of identifying risks are:

1. Organizational charts;
2. Flow charts;
3. Vulnerability analysis, matrix of interdependencies;
4. Checklists;
5. Event chain diagrams, decision trees. Moreover:
6. Methods based on intra- and inter-company data exchange: brainstorming, interview/focus group discussions; surveys, questionnaires;
7. Strengths, weaknesses, opportunities, and threats (SWOT) analysis. (Borghesi and Gaudenzi, 2012)

Tools used for risk assessment:

1. Brainstorming
2. Structured or semi-structured interviews
3. Delphi
4. Check-lists
5. Primary hazard analysis
6. Hazard and operability studies (HAZOP)
7. Hazard Analysis and Critical Control Points (HACCP)
8. Environmental risk assessment
9. Structure « What if? » (SWIFT)
10. Scenario analysis
11. Business impact analysis
12. Root cause analysis
13. Failure mode effect analysis
14. Fault tree analysis
15. Event tree analysis
16. Cause and consequence analysis
17. Cause-and-effect analysis
18. Layer protection analysis (LOPA)
19. Decision tree
20. Human reliability analysis
21. Bow tie analysis
22. Reliability centered maintenance
23. Sneak circuit analysis
24. Markov analysis
25. Monte Carlo simulation
26. Bayesian statistics and Bayes Nets
27. FN curves
28. Risk indices

- 29. Consequence/probability matrix
- 30. Cost/benefit analysis
- 31. Multi-criteria decision analysis.(Shuff, 2015)

RISK ASSESSMENT MATRIX				
SEVERITY PROBABILITY	Catastrophic (1)	Critical (2)	Marginal (3)	Negligible (4)
Frequent (A)	High	High	Serious	Medium
Probable (B)	High	High	Serious	Medium
Occasional (C)	High	Serious	Medium	Low
Remote (D)	Serious	Medium	Medium	Low
Improbable (E)	Medium	Medium	Medium	Low
Eliminated (F)	Eliminated			

Table (2.1). Risk assessment matrix

- Brainstorming enables gathering of opinions on all sources of risk (internal and external). Employees of various ranks should participate in brainstorming as this ensures the most complete and realistic risk assessment.
- Future scenarios / scenario analysis involves creation of various scenarios (positive scenarios/best cases and negative scenarios/worst cases), which form the basis for development of a way of acting. The method may also be used in cases when there is no past data which forecasts could be based on as well as in cases where results depend on factors that are difficult to forecast, e.g. weather.
- SWOT analysis (S-strength; W-weaknesses; O-opportunities; T-threats) belongs to the canon of strategic management methods and enables formulation of problem solutions based on gathered information.
- FMEA analysis (Failure-Mode-and-Effects Analysis) – the analysis of reasons and effects of failures, is a further development of the flow chart analysis and its adjustment to technological processes.

- Balanced Scorecard (BSC) is a management technique developed in the 1990s by scientists from Harvard - Robert Kaplan and David Norton. BSC analyses the cause-and-result relationships of a company in 4 perspectives: financial, customer, business processes as well as from the perspective of organization's ability to learn and develop.(Jodkowski, 2015)
- Monte Carlo analysis consists of a broad class of computational algorithms that rely on repeated random sampling to obtain numerical results. This method can address complex situations that would be very difficult to understand and solve by an analytical method. Whenever there is significant uncertainty in a system and you need to make an estimate, forecast or decision, a Monte Carlo simulation could be the answer.

2.5. ISO 9001 series:

ISO 9000 family of standards The International Organization for Standardization (ISO) published the ISO 9000 series of standards in 1987. This series of standards “provide guidance and tools for companies and organizations who want to ensure that their products and services consistently meet customer’s requirements, and that quality is consistently improved”. These standards have been developed to guide organizations of all types and sizes to implement and operate effective quality management systems (ISO, 2005). ISO 9001:2008 sets out the requirements for a quality management system where an organization can demonstrate its capability to deliver products and services that fulfil customer and regulatory requirements and aims to increase customer satisfaction.(Manders, 2015)

ISO 9001 Journey, Started quality for utility company in 1985, was involved with first TAG in 1987, Joined one of the first NA registrars – training, etc. Quality consultant in 7 sectors including auto, gas, electric, etc. for 15 years, Wrote 8 book on ISO and quality auditing 4 others – bestselling books in world in mid-1990’s, Moved to risk in 2002, 2005 – Critical Infrastructure Protection: Forensics, Assurance, Analytics for homeland security, Cybersecurity, asymmetric war, Developed CERM for Dep of Homeland Security. 2013 developed ISO 9001:2015 risk community, Doubling each year, Currently 32 K members, Updated ISO books for ISO 9001:2015. (Hutchins, 2018)

Novelization of the standard in 2000 was supposed to adjust the requirements of the ISO 9001 standard to real functioning of companies as well as reduce the bureaucracy of documentation forms. The process approach is based on management staff responsibility, managing of means and resources, process management, analysis, measurement and improvement, focus on customer's needs and satisfaction, self-improvement of the organization through corrective and preventive actions. The process approach includes the use of the Deming circle in the quality management process. (Jodkowski, 2015)

Eight quality management principles, Customer focus “Organizations depend on their customers and therefore should understand current and future customer needs, should meet customer requirements and strive to exceed customer expectations.” Leadership “Leaders establish unity of purpose and direction of the organization. They should create and maintain the internal environment in which people can become fully involved in achieving the organization's objectives.” Involvement of people “People at all levels are the essence of an organization and their full involvement enables their abilities to be used for the organization's benefit.”

Process approach “A desired result is achieved more efficiently when activities and related resources are managed as a process.” System approach to management “Identifying, understanding and managing interrelated processes as a system contributes to the organization's effectiveness and efficiency in achieving its objectives.” Continual improvement “Continual improvement of the organization's overall performance should be a permanent objective of the organization.” Factual approach to decision making “Effective decisions are based on the analysis of data and information.” Mutually beneficial supplier relationships “An organization and its suppliers are interdependent and a mutually beneficial relationship enhances the ability of both to create value.(Manders, 2015)

Figure 1.3. World distribution of ISO 9001 certificates in 2013 (ISO, 2013b)



Fig(2.6)world distribution of ISO9001 certification in 2013

The ISO 31000 (2009) is an international standard which provides a structured approach to risk management. ISO also produced Guide 73 “Risk management—Vocabulary—Guidelines for use in the standards”. The establishment of a common risk management language is essential to the successful sharing of information, establishment of metrics, and communicating results.

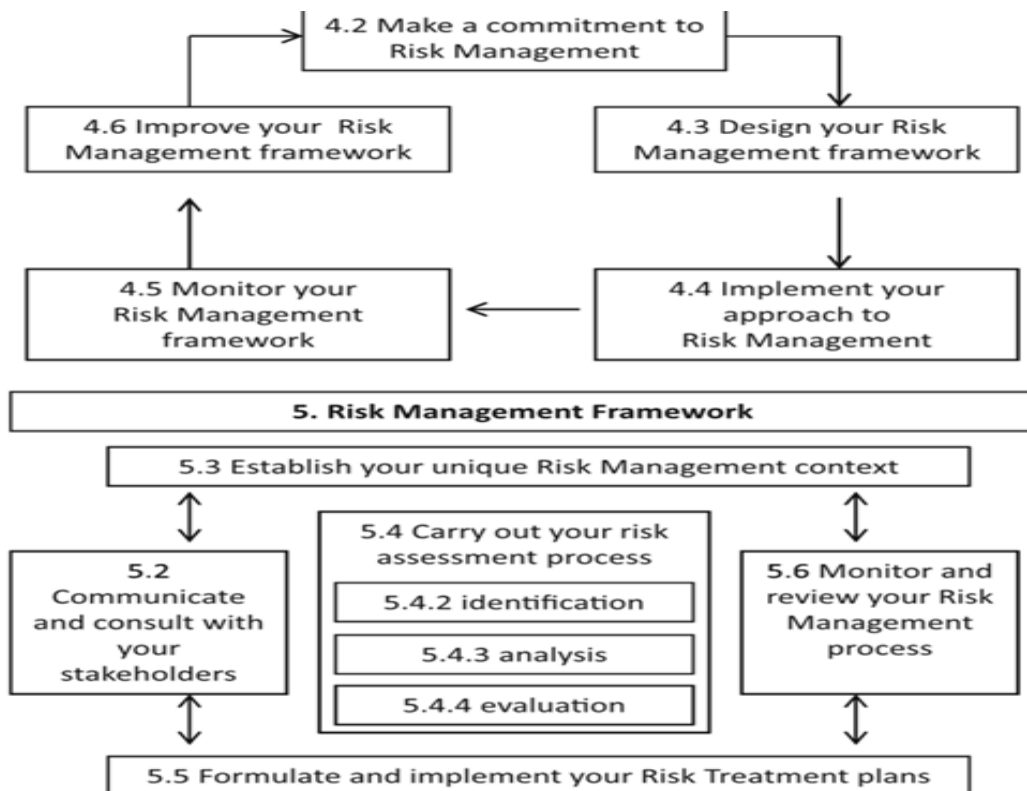


Fig (2.7) Risk management framework and process.

Number of organizations have implemented ISO 9001 Quality Management Systems, aiming to respond to external stakeholder pressures or to internal motivations and achieve increased performance. ISO 9001:2008 is based on a PDCA (Plan-Do-Check-Act) approach and on the eight quality management principles. The International Organization for Standardization (ISO) has classified the principles which guarantee a successful implementation of any quality management system into eight quality management principles: (Al-Asiri, 2004)

1- Customer focus:

Organizations depend on their customers and therefore should understand current and future customer needs, meet customer requirements, and strive to exceed customer expectations.

2- Leadership:

Leaders establish unity of purpose and the direction of the organization. They should create and maintain an internal environment in which employees can become fully involved in achieving the organization's objectives.

3- Involvement of people:

People at all levels are the essence of an organization, and their full involvement enables their abilities to be utilized for the organization's benefit.

4- Process approach:

A desired result is achieved more efficiently when activities and related resources are managed as a process.

5- Systems approach to management:

Identifying, understanding and managing interrelated processes as a system contributes to the organization's effectiveness and efficiency in achieving its objectives.

6- Continual improvement:

Continual improvement of the organization's overall performance should be a permanent objective of the organization.

7- Factual approach to decision making:

Effective decisions are based on analysis of data and information.

8- Mutually beneficial supplier relationships:

An organization and its suppliers are interdependent, and a mutually beneficial relationship enhances the ability of both to create value.(Al-Asiri, 2004)

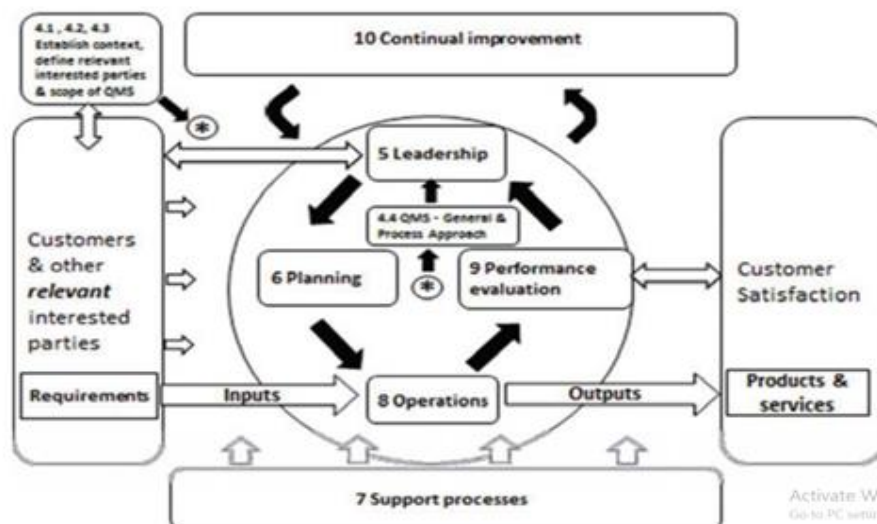


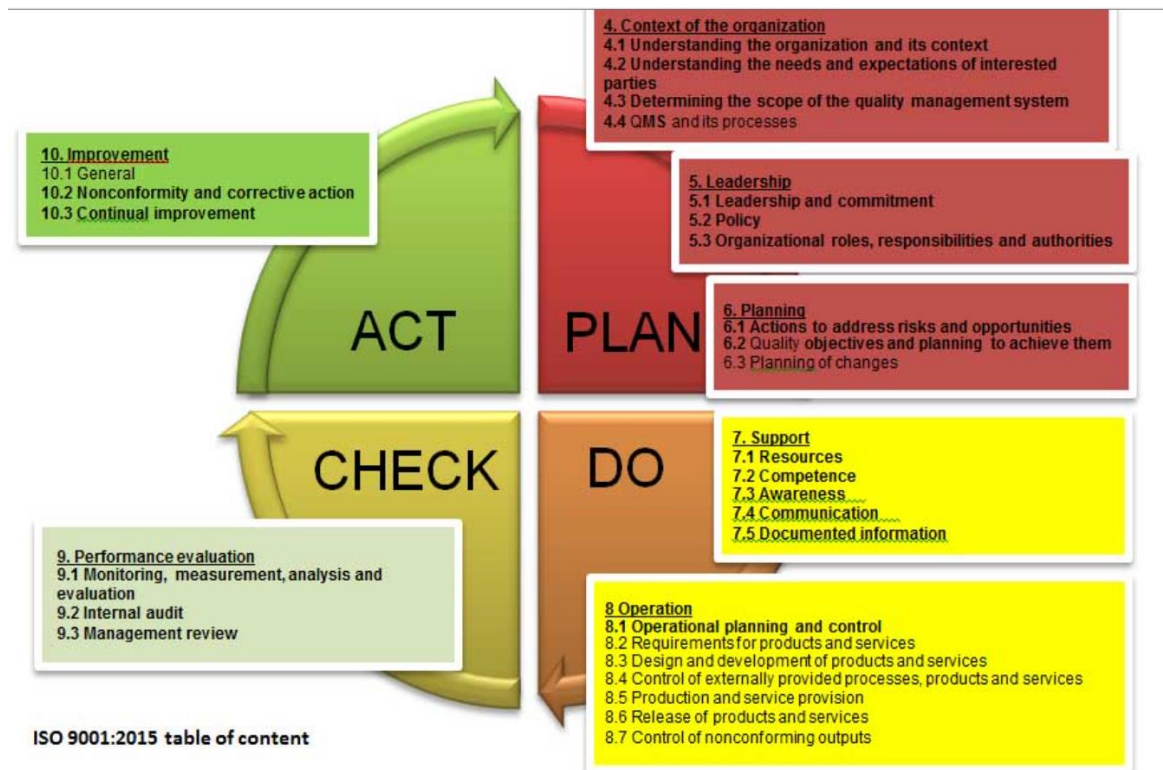
Fig (2.8) ISO 9001 and process approach

Organizations that carefully manage their relationships with suppliers and partners can nurture positive and productive involvement, support and feedback from those entities.

For ISO 9001-2015 there are some changes, the following table summarizes the new additions and removals of the requirements between the 2008 and the 2015 revision of the ISO 9001 standard:(Paul F. Koza, 2018)

	Standard section	Added	Removed
PLAN	4. Context of the organization 5. Leadership 6. Planning	Integration of the understanding of the context and interested parties Reinforcement of the requirements related to the processes. Management responsibility accentuated. Preventive actions replaced and extended to actions taken to address risks and opportunities. Reinforcement of the requirements on planning of changes.	Suppression of the requirement related to the management representative.
DO	7. Support 8. Operations	Integration of organizational knowledge. Reinforcement of requirements related to awareness and communication. Reinforcement of the requirements related to the control of operational activities (external providers, post-delivery activities, modifications...).	Reduction of the documentation (absence of requirement related to quality manual and mandatory procedures).
CHECK	9. Performance Evaluation	Reinforcement of the requirements related to monitoring, measurement, analysis and evaluation.	
ACT	10. Improvement	Improvement not limited to continuous improvement	Removal of the words « preventive actions ». Those actions are considered in the actions to face risks

Table (2.2). ISO 9001-2015 changes requirements between the 2008 and the 2015 revision



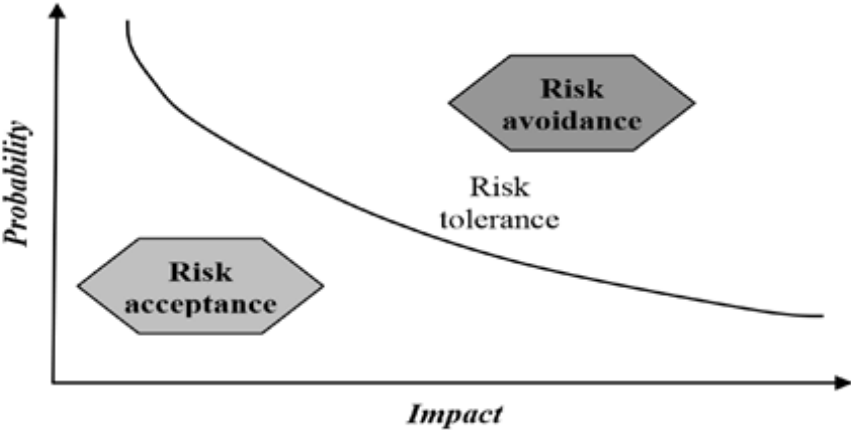
Fig(2.9) ISO 9001:2015 table of content

These principles form the conceptual foundation for the ISO portfolio of quality management standards and serve as the basis for the Good Manufacturing Practices (GMP), Good Clinical Practices (GCP), and Good Laboratory Practices (GLP) required by most government regulatory bodies. But these principles are not just the backbone of quality systems; they're also simply good business principles to put into practice across an enterprise. The standardization of management approach based on them will be driving global improvement and process excellence for at least the next 10 years.

2.6. Risk reduction:

In practical terms “risk-based thinking” is based on the concept of risk tolerance level. Risk tolerance is the ability of an organization to accept or avoid risk. Organizations that are willing to accept a high dose of risk are called speculator organizations, while that the organizations avoiding the risks are called conservative

organizations. An example of the acceptability of risk degree is illustrated in Figure 1.3 in an axis system with two variables: the probability and risk impact.(Sitnikov and Bocean, 2015)



Fig(2.10) the degree of risk acceptability

There has been a consistent growth in the number of organizations that have implemented ISO 9001:2008 International Standards has shown by the chart presented in Figure (1.4) of the trend of organizations with ISO 9001 certified Management Systems worldwide (ISO, 2014).

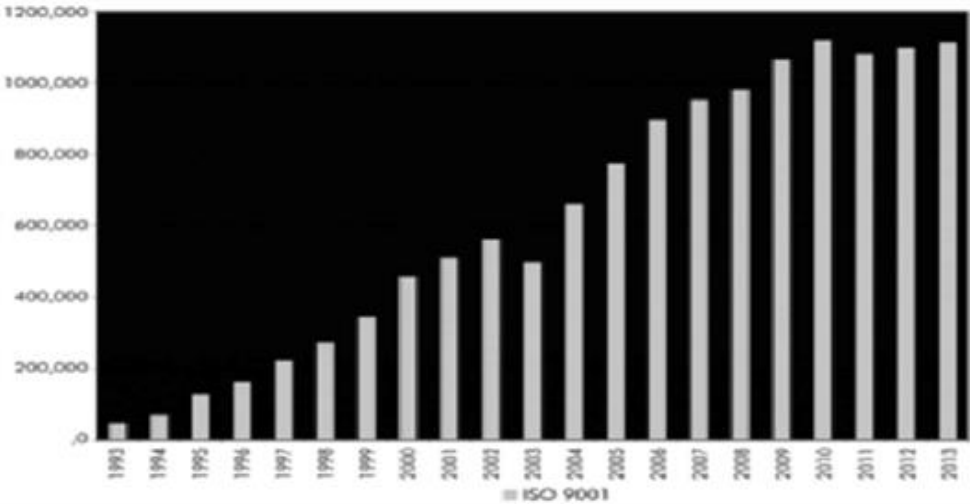


Figure (2.11) the trend of organizations with ISO 9001 certified (ISO, 2014).

There is study identified 115 empirical studies that investigate the impact of ISO 9000 standards worldwide. Another also suggest that ISO 9001 has clear benefits on organizational, operational, people and customer results. Summarized the results stating that the success in the implementation of ISO 9001 Quality Management Systems (QMS) is linked to the organization and to the way the standard is interpreted and implemented. When the main motivations to implement the standard are internal (organizational improvement) more benefits are achieved than when they are external (e.g., respond to customer requirements or expectations, achieving marketing differentiation). Also accordingly to study standardized management systems may be implemented in very different ways depending on organizations, which might explain the heterogeneous performance of these standardized systems. Fonseca (2015a), on a study of Portuguese certified organizations that also implemented the EFQM Business Excellence Model (BEM), reported there is indeed a moderate positive correlation between ISO 9001 certification maturity and EFQM BEM results, the higher the number of years of ISO 9001 certification, the higher the results of the organization EFQM model evaluation and recognition. In summary, certification is indeed a measure of QMS implementation intensity and it brings but we need to take into consideration how variations in QMS implementation may affect performance results and certification to ISO 9001 should be a result of a well implemented Quality Management System, not just “certification”. The release of the 2015 version of ISO 9001 is under way and the new standard version should be closer and more in line with the Business Models (Fonseca, 2015b): Concepts like change control, strategic direction and knowledge management will be reinforced on the ISO 9001:2015 International Standard approaching and embedding ISO 9001 and business management; Organizational context and relevant interested parties (those that have some actual or potential impact on the quality of products and services) were introduced; There will be more emphasis on process approach and less on documentation and Risk-based thinking was introduced adding a systematic

evaluation of potential and actual issues with the aim of making processes more robust and capable.(FONSECA, 2015b)

The target of a management system is achieve conformity and customer satisfaction. ISO 9001:2015 uses risk-based thinking to achieve this in the following ways:

Introduction -the concept of risk-based thinking is explained.(Standardization, 2015)

Clause 4 - (Context) organization is required to address the risks and opportunities associated with its QMS processes

Clause 5 – (Leadership) top management is required to–Promote awareness of risk-based thinking–Determine and address risks and opportunities that can affect product /service conformity

Clause 6 - (Planning) organization is required to identify risks and opportunities related to QMS performance and take appropriate actions to address them

Risk-based thinking is in:

Clause 7 – (support) organization is required to determine and provide necessary resources

Clause 8 - (Operation) organization is required to manage its operational processes

Clause 9 - (Performance evaluation) organization is required to analyze and evaluate effectiveness of actions taken to address risks and opportunities

Clause 10 - (Improvement) organization is required to correct, prevent or reduce undesired effects and improve the QMS and update risks and opportunities

Note, risk is implicit whenever suitable or appropriate is mentioned (clause 7 and 8) (Standardization, 2015)

Pervious study:

A. Local studies:

1. Mohammed Youssef Abdullah (2014)

The study of Mohammed Youssef discussed the role of total quality management in setting occupational safety and health management system, cover both quality professional OSH inspector in ministry of human resource and labor and also officer in private sector in small and medium size enterprises (SMES), discussed many topics as risk management and control in workplace, risk assessment, risk management, approaches to risk assessment, risk rating used quantitative methodology. The conclusion of the study state that: TQM has direct effect in occupational safety and health in operation improvement. Occupational safety and health and TQM are two different management approaches which support each other's and there is a lot of similarities in both systems. Integrating these two systems in SEMs depending on employee participation, continuous, continuous improvement, risk management and hazard identification which definitely decrease loss and increase the productivity and save time and cost. TQM management can support OSH activities effectively by improving work process using processes improvement. Study recommend to use quality tools to improve aircraft crash investigations and set control measurement standards. (Abdalla, 2014)

2. Mai Mohamed (2016)

The study of Mai Mohamed (2016) discuss the impact of IATA implementation on aviation safety and quality improvement, the study questionnaire distributed to employee (engineers and technicians) of ground handling department in Sudan Airways Company. It state that "the airline must insure that operation hazard are identified it is typically based on proactive, and predictive safety management, also to indicate their consequences are assessed and mitigation action must be

presenting unacceptable operation risk as an answers for some questions as what is the hazard and risk here? What control measures we can use for hazard/risk?The study conclude that there is a shortage in IATA implementation that result in poor quality and recommend that to fully implement the IATA system in all airlines.(MAHLA, 2016)

3. Om Salama Mohammed (2015)

The study of Om Salama Mohammed (2015) discussed the QMS implementation in food industry area, Sudan Airways Company,Using quantitative analysis in catering department. Mention that “the quality system in food industry is hazard analysis and critical control points (HACCP). Quality indicators are necessary because they concrete tool to measure how the QMS is improving the organization efficiency and effectiveness.The benefits result of the study of QMS as: improve customer satisfaction; improve quality of products and services; improve relation with suppliers; improve promotion of corporate image.The risk of implementation QMS; in short-time increase in production cost during the implementation of the QMS.The study conclude that the important of training in QMS and quality not less than safety in importance. The study recommend to implementing and maintaining a QMS for more safety and healthy. Also for other different enterprises the implantation of QMS increase productivities.(Shreef, 2015)

4. Samia Mohamed Ahmed Omer (2012)

The study of Samia Mohamed Ahmed (2012) concerns the development of recruitment procedures in all government organizations. The main objectives Of the Study to analyze and evaluate the Process of the recruitment & (TQM) while it is new and recently introduced in Public sector and to identify the opportunities of improving civil service procedures so as to eradicate the deterioration of the civil service also to establish strong recruitment procedures system to be used in country as whole finally to put the recent president act about civil service reform in execution. The study investigated research literature on the procedure of process, views and experience of senior managers and employees via conducting

questionnaire (case study) on major changes on recruitment of the central national selection committee. The results indicated the lack of communication, lack of competent staff, financial problems, decision complications and several other factors that led to poor management in all civil service recruitments throughout the country. It is concluded that the improvement process i.e. eliminating all non-value added activities, eliminating labor intensive procedures, faster recruitment processes with less work, automation of the recruitment process and training the staff specially in typing is a successful tool in achieving excellence and executes strategies and accordingly contribute in enhancing and developing organizations.(Omer, 2012)

B. Arabic studies:

1. MOHAMMAD M. AL-ASIRI (2004)

The study of MOHAMMAD M. AL-ASIRI (2004) argued that study is designed to investigate the implementation practices of the new ISO 9001:2000 standard in Saudi business organizations. The main objectives of this study are to identify the critical factors that lead to successful implementation of the new standard, to determine what barriers have been encountered during implementation, and to identify the most difficult parts of the standard to comply with. Furthermore, this study aims to investigate the factors that may explain the Saudi organizations' decisions to implement ISO 9001:2000 in their businesses. To accomplish these research objectives, a questionnaire was developed based on an extensive review of related literature and tested for validity and reliability. The target sample for the study was made up of all ISO 9001:2000 registered sites in Saudi Arabia up to 31 Dec. 2002, which comprised 131 organizations. The major findings are as follows: 86.5% of the total respondents had implemented ISO 9001:2000 as a transition process from previous ISO 9000 standards. 68.5% of the certified sites took less than one year to implement the standard. Most of them were previously certified in one of the ISO 9000:1994 standards. This high percentage indicates that ISO

9001:2000 can be easily implemented in a short time frame. The top five critical success factors in implementing the ISO 9001:2000 quality management system, in descending order, are as follows: commitment of management, effective internal auditing, commitment of middle management, employee motivation and involvement, resource allocation, and existence of appropriate communication routes. Based on the findings of this study, many conclusions and recommendations were drawn. In summary, for a successful implementation of ISO 9001:2000 standard, organizations must give great consideration to the people involvement factor, particularly top and middle management's involvement and commitment to quality, employees' motivation and involvement, quality awareness, and ISO 9001:2000 training.(Al-Asiri, 2004)

2. Ayman Rashed Alshehri (2016)

The study of Ayman Rashed Alshehri (2016) said that Quality management (QM) is viewed as concepts, principles, or practices within which prescriptive views and empirical facts play roles in constructing and operating the industry to improve the performance. In the Kingdom of Saudi Arabia, the cost of construction projects in Riyadh City 2014 is around SR 181 billion, and that figure does include the operation and maintenance projects that cost SR 10 billion in 2014. However, this segment of the industry faces several challenges in the Kingdom. This work draws on five Quality Management Concepts (QMCs) (Total Quality Management, Six Sigma, Lean Management, Lean Six Sigma, and ISO 9001) to underpin the research principles, methodology, and implementation. From this research, The primary aim of this research is to investigate the Quality Management System (QMS) required to improve Saudi public Building Maintenance (BM) practices through the implementation of the most suitable and effective Quality Management Concepts (QMCs). The first qualitative exercise relates to interviews conducted to collect information to examine the current BM processes in public departments, with a view to ascertaining underlying problems and assess awareness and implementation of QMCs. This was followed by a second qualitative technique, the focus group,

intended to explore the most suitable and effective QMCs for implementation in BM departments. After that, the QMS was developed and then validated by focus group method a second time. In this study, thematic analysis is used for both qualitative methods. The main results of the study emphasize that ISO 9001 is the most suitable foundation for quality management of BM and it is found to be an effective baseline on which the BM process can be improved. It was confirmed by the evaluation and validation that the developed quality management system can generate positive outcomes, lead to better management, clear responsibilities and improve communication.(Alshehri, 2016)

3. Walaa Wahid ElKelish (2014)

The study of Walaa Wahid ElKelish 2014 aim to investigate the relationship between organizational culture and corporate risk disclosure for listed companies in the United Arab Emirates (UAE). The methodology of study Set that the organizational culture is represented by four dimensions: Clan, Adhocracy, Market and Hierarchy. Data are computed from the financial reports of all listed companies on the UAE Stock Market as of the year ending 2005. The multiple regression analysis model, ordinary least square, is used to test the study hypotheses. For practical implications, listed companies in the UAE are more responsive to formal rules and regulations on reporting risk disclosure, which is quite different from the “self-regulation” practices that are more common in some Western countries. Consequently, policymakers and regulators in the UAE, and in other countries with similar conditions, are encouraged to focus on continuous development of formal rules and procedures to enable more harmony with international best practices of risk disclosure. The Results of the study show that the organizational culture of Hierarchy, which focuses on more formalized work procedures, has a significant positive effect on the companies’ risk disclosure in the UAE business environment. Several other control variables are implemented to ensure reliability of results. The originality/value of the project is that, unlike the majority of previous empirical

studies, this is the first study to incorporate a behavioral endogenous organizational culture model to explain the main determinants of risk disclosure, which opens the door for more understanding of the risk disclosure output function as a management process.(ElKelish, 2014)

4. Kasim Randeree (2012)

The study of Kasim Randeree 2012 aims to provide an examination of the extent to risk in different leadership styles impact employee job satisfaction and organizational commitment in the United Arab Emirates (UAE) through a case analysis in the construction sector. The methodology of the research is based on a survey of three companies, one client organization, one consultancy firm and one contracting company. The useable survey comprised 251 individual responses from 600 distributed, giving a response rate of 41.83 percent. The survey provides a useful instrument by which organizations across other sectors and within different cultural contexts can evaluate the significance of leadership style, job satisfaction and organizational commitment. The findings of the show that consultative and consensus leadership styles are prevalent in the construction sector in the UAE. Further, it was found that an employee's job satisfaction is strongly affected by leadership, with more than 50 percent of survey respondents stating that leadership strongly influences their job satisfaction. Leadership style was found to moderately to strongly affect organizational commitment of employees in the industry in the UAE. The Originality/value of the studythe work is unique in that it is an examination of the impact of organizational leadership style within a contemporary regional context. A number of studies have been carried out in the Arab world that suggest that leadership in Arab culture nurtures consultative and participative tendencies. These are all outdated by more than a decade and no recent study in the Arabian Gulf region exists and none which explore leadership styles' impact on employees.(Randeree and Ghaffar Chaudhry, 2012)

C. Foreign studies:

1. Mohd Shoki (2014)

The study of Mohd Shoki, Malaysia (2014) argued that Risk management is recognized as a prominent aspect of the good corporate governance of a successful institution. The study discuss the role of Framework for Risk Management Practices and Organizational Performance in Higher Education. The need for effective risk management framework is widely recognized by academic and industry to manage all type of risks encountered by an organization. In Malaysia higher education scenario, some public universities are awarded autonomous status, and therefore, a framework for effective management of risks is needed. Review of literature related to risk management indicated that Enterprise Risk Management (ERM) framework is a best practice and can be applied in higher education setting. Organizations that have implemented systematic risk management practices are enjoying high level of organizational performance. However, specific measure of performance is needed to link the risk management practices and the impact on the organizational performance. A review on organizational performance measures related to risk suggesting that the financial and non-financial performance would serve as construct of organizational performance for these universities. Hence, the study proposes a framework for risk management practices and organizational performance for managing risk in the higher education setting, particularly for Malaysia's public universities with autonomous status. The result of the study conclude that a framework of risk management practices and organizational performance in the Malaysia's public universities is not yet established. The common method for managing risk is

relatively based on criteria specified in the UGGI, which is insufficient and lack of systematic approach to managing risk.(Ariff et al., 2014)

2. Liliane (2015)

The study of Liliane,(IJMSR) (2015) state that various types of risk may occur while conducting business activity. The aim of the study is to identify selected targets and essence of planned changes in ISO 9001: 2015 with particular emphasis on the need for risk assessment in organization management. The research method adopted was a comparative analysis of ISO 9001 norm of 2008 edition and a draft of the planned edition of 2015. Occurrence of unexpected risk may make it impossible to continue the activity in its current form or put it to an end. After identification of potential risk, the possibility of its occurrence must be assessed as well as its possible influence on the conducted activity.Risk management is a process of identifying hazards which business entities are exposed to as well as selecting of proper methods and techniques used for protecting against them. The study conclude that the process of enterprise risk management includes 4 stages: risk identification, measurement, risk steering as well as monitoring and risk control. (A Framework for Risk Management Practices and Organizational Performance in Higher Education)(Jodkowski, 2015)

3. Bob Deysher (2015)

The study of Bob Deysher (2015) refer to ISO 9000 Introduction and Support Package: Guidance on the Concept and Use of the Process Approach for management systems, ISO 9001:2008, ISO 9001:2015, “Implementing the Process Approach”, Core Business Solutions and “The PDCA Continuous Improvement Cycle; Module 6.4”, the study argument that There is no standard list of components that should be included in the risk register. Some of the most widely used components are: Dates: As the register is a living document, it is important to record the date that risks are identified or modified. Optional dates to include are the target and completion dates. Description of the Risk: A phrase that describes the risk. Risk Type (business, project,

stage): Classification of the risk: Business risks relate to delivery of achieved benefit; project risks relate to the management of the project such as timeframes and resources, and stage risks are risks associated with a specific stage of the plan. Likelihood of Occurrence: Provides an assessment on how likely it is that this risk will occur. Examples are: L-Low (>30%), M-Medium (31-70%), H-High (>70%). Severity of Effect: Provides an assessment of the impact that the occurrence of this risk would have on the project. The purpose of the process approach is to enhance an organization's effectiveness and efficiency in achieving its defined objectives. This means enhancing customer satisfaction by meeting customer requirements. The study concludes that "Risk Based Thinking is an element in the Process Approach, Risk Based Thinking is an input to Management Review, Risk Based Thinking is an element in the continual improvement process that is focused on prevention, Risk Based Thinking has been demonstrated during audits; a risk register is documented information that validates an organization has done Risk Based Thinking. (Deysher, 2014)

4. Hood Atan (2015)

The study of Hood Atan (2015) stated that "the new requirements of ISO 9001: 2015 quality management system standard clause 0.3.3 required the organization to implement a risk based thinking for achieving an effective quality management system. The study discusses a review of operational risk management decision support tool. The definition of risk as stated in the standard is "the effect of uncertainty" which could be positive or negative. Thus, ISO 9001 certified organization requires to demonstrate objective evidence of the implementation of risk based thinking such risk analysis and risk mitigation plan not only to satisfy the need of ISO 9001:2015 standard, but also widely accepted that organization requires risk management activities to stay competitive. However, there many initiative, tools and approach for the operational risk management activities have been subjected to little research and are not well understood. This paper reviewed and discussed the available literatures on operational risk management decision support tools. Based on an extensive literature review, the

issues relevant to operational risk management support tools are examined, study conclude That the focus should develop an operational risk management decision support tool that include the risk assessment and management plan to imply the risk based thinking as stipulated in the latest ISO 9001 quality management system standard requirements.(Atan, 2015)

5. Chi-kuang (2015)

The study of Chi-kuang (2015) argued that, the lack of an implementation roadmap always deters enterprises from choosing Total Quality Management (TQM) as its major management approach. This study a stepwise ISO-based TQM implementation approach which is based on the notion of the new threedimensional overall business excellence framework. The proposed approach consists of nine steps comprising three categories: “TQM faith building”, “TQM tools and techniques learning”, and “system development”. The ISO 9001:2015 standard is used as a case study to demonstrate the study approach. The 2015 version emphasizes risk-based thinking, which is explicitly built into the whole management system. Risk-based thinking can help identify opportunities that can be considered as the positive side of the risk. The study result is that most surveyed ISO-certified organizations respond that the system provides no benefits once ISO 9001 certification is complete. In order to survive and prosper in a highly competitive business environment, it is not enough to implement a QMS based on the ISO 9001 standard only even if it is aimed at achieving customer satisfaction by preventing product/service nonconformities. Instead, a more proactive QMS driven by customer satisfaction and rapid response to market environments is a necessity.(Chen et al., 2016)

6. Manders, B. (2015)

The study of Manders, B. (2015) The ISO 9001 quality management standard has been implemented by more than one million organizations in 187 countries since its introduction in 1987. A newer version of ISO 9001 is planned to be introduced in 2015. Even though it is widely used by organizations to gain both operational and market benefits, the studies on the impact of ISO 9001 report mixed findings.

Therefore, the aim of this dissertation is to find out what is the impact of ISO 9001, and to better understand the differences in current literature. The findings demonstrate that ISO 9001 leads to operational and market benefits in the majority of cases. Also show that the benefits gained from ISO 9001 differs depending on the length of the period since certification, standard version, geographic location, industry sector, and company size. Further demonstrate that national differences, specifically the level of economic development and national culture, impact the performance benefits of ISO 9001. Moreover, study find that not all of the employees in a company use ISO 9001 in their daily work. Having a positive attitude towards ISO 9001 usage, being aware of ISO 9001, believing that ISO 9001 is useful and easy to use, and feeling responsible for ISO 9001 discriminated employees that did participate in ISO 9001-related practices from those that did not.(Manders, 2015)

7. Greg Hutchins (2015)

The study of Greg Hutchins (2015) state that “Risk-based thinking is automatic and often sub-conscious ” Concept of risk has always been implicit in ISO 9001 – this revision makes it more explicit and builds it into the whole management system ” Risk-based thinking is already part of the process approach ” Risk-based thinking makes preventive action part of the routine ” Risk is positive (opportunity) and negative (negative impacts). Concept of “risk” in the context of ISO 9001 relates to the uncertainty in achieving these objectives “Provide confidence in the organization’s ability to consistently provide customers with conforming goods and services “Enhance customer satisfaction. The study Solution is: Certified Enterprise Risk Manager, Enterprise Risk Management (COSO), Risk Assurance (GAGAS), Project Risk Management (ISO 31k) (Hutchins, 2018)

8. Srđan Medić, (2016)

The study of Srđan Medić, (2016) aim to show the new standard ISO 9001:2015 and its effect on organizations, Argued that “ISO 9001:2015 incorporates term “Risk-based Thinking” in its requirements for the establishment, implementation,

maintenance and continual improvement of the quality management system. This additional requirement in new version of standard is logical requirement in a way of achieve preventive management system. ISO 9000:2015 the 2015 revision are intended to ensure that ISO 9001 continues to adapt to the changing environments in which organizations operate and especially include the 'context' of the organization, restructuring some of the information, risk-based thinking. Study conclude that, ISO 9001 standard has played great and perhaps the most important role in the perception of quality and understanding of the quality assurance and quality management. The new issue of ISO 9001:2015 was released in September 2015 and changes introduced in the 2015 revision to adapt to the changing environments in which organizations operate. ISO 9001:2015 expanding the number of sections from 8 to 10 and definitely better define the specific requirements which ISO 9001:2008 left incomplete. Some requirements like Management review conduction in planed intervals or conduction of internal audits in planed intervals are still not strictly defined (Medić et al., 2016)

9. SITNIKOV1, BOCEAN2 (2015)

The study of SITNIKOV Claudiu, George BOCEAN state that Organization's quality management system will experience substantial changes when the final draft of ISO 9001: 2015 will be published and will become operational. Therefore, organizations must be informed in advance about the changes that are anticipated to be ready to implement the revised requirements of the standard. An important direction given by new version of the standard consists in a growing emphasis on managing risks faced by the organization and valorization of the opportunities that may arise. In the present study conducted a review of the main changes to the ISO 9001: 2015 and a critical analysis regarding risk management approach in the new version of the standard. Given that ISO 9001, as amended and published this year, will move to a new stage in the structure and objectives oriented towards risk management and identifying and implementing opportunities, continuous improvement, the most important component of quality management must be seen from risk perspective. The conclusion set that to cope with the changes imposed by the new version of ISO 9001 organizations must

prepare to adapt quality management system to meet the new requirements and transitional terms. The main objectives of ISO 9001 have been and still providing increased confidence in the ability of the organization to consistently provide products and services and increase customer satisfaction. Uncertainty about achieving these goals has led to the explicit introduction of the concept of "risk" and the syntagma "risk-based thinking" in vision of ISO 9001:2015.(Sitnikov and Bocean, 2015)

10. Aven, T. and Krohn (2012)

The study of Aven, T. and Krohn 2012 state that there are many ways of understanding, assessing and managing the unforeseen and (potential) surprises. The dominating one is the risk approach, based on risk conceptualization, risk assessment and riskmanagement, but there are also others, and this study focus on two; ideas from the qualitydiscourse and the use of the concept of mindfulness as interpreted in the studies of High Reliability Organization (HRO). The main aim of the study is to present a new integrated perspective, a new way ofthinking, capturing all these approaches, which provides new insights as well as practical guidelines forhow to understand, assess and manage the unforeseen and (potential) surprises in a practical operationalsetting. The risk concept—historical and recent development trends. The study reviews the definition and meaning of the concept of risk. The review has a historical and development trend perspective, also covering recent years. It is questioned if, and to what extent, it is possible to identify some underlying patterns in the way risk has been, and is being understood today. The analysis is based on a new categorization of risk definitions and an assessment of these categories in relation to a set of critical issues, including how these risk definitions match typical daily-life phrases about risk. The conclusion if the study presents a set of constructed development paths for the risk concept and concludes that over the last 15–20 years seen a shift from rather narrow perspectives based on probabilities to ways of thinking which highlight events, consequences and uncertainties. However, some of the more narrow perspectives (like expected values and probability-based

perspectives) are still strongly influencing the risk field, although arguments can be provided against their use. The implications of this situation for risk assessment and risk management are also discussed.(Aven and Krohn, 2014)

11. Michael Shuff (2015)

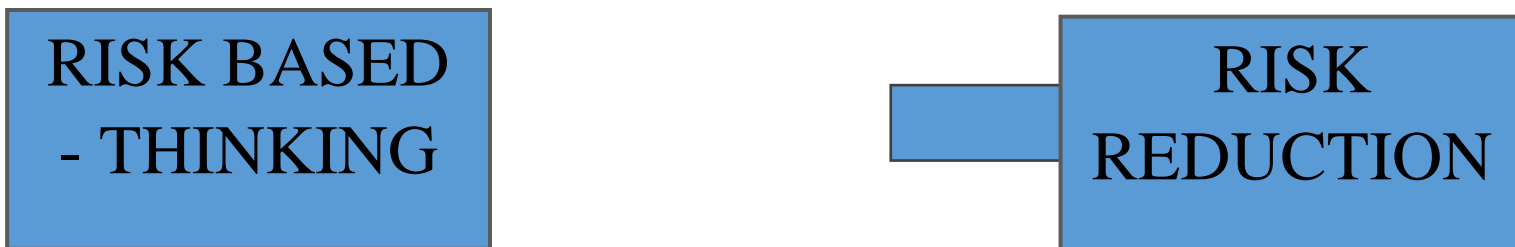
The study of Michael Shuff states that the new version of the ISO 9001:2015 standard is scheduled for final publication on September 23rd 2015. One of the new requirements is to show evidence of risk-based thinking (RBT) in the quality management system. How do you do that? How are auditors likely to respond to the new challenges that ISO 9001:2015 brings? How do you produce documented evidence of risk-based thinking? Although ISO 9001:2015 does not call for formal methods of risk management, it is likely that anyone trying to understand RBT may turn to ISO 31000 and the list of risk assessment techniques in particular. However, this is not as easy as it sounds. There are many techniques to choose from and many may not be applicable to the sectors that ISO 9001 serves. The conclusion of the study is that some believe that RBT is an ill-considered introduction in the latest revision of the standard. Others are more positively inclined towards it. Either way, the Standard revision is not at all clear on what needs to be done. One approach could be to look to the ISO 31000 family of standards for guidance. If you do, then ISO/IEC 31010:2009 – Risk management – Risk assessment techniques would be a key input. Formal risk management is not mandated by ISO 9001:2015

However, organizations can choose to develop a more extensive risk-based approach than is required by this International Standard.(Shuff, 2015)

From all above studies we notice that most of them in the period of new edition of ISO 9001-2015 starts in 2015, more than seven studies concerned with risk and risk based thinking as: Walaa Wahid Elkelish (2014), Kasim Randeree (2012), Liliane (2015), Bob Deysher (2015), Aven, T. and Krohn (2012), Greg Hutchins (2015). Two studies discussed risk in food industry one is the study of Mohammed Youssef Abdullah (2014) and another for Om Salama Mohammed (2014). Only one study of

Mai Mohamed (2016) talked about risk in airlines. Another five studies for Samia Mohamed Ahmed Omer (2012), Mohd Shoki (2014), Chi-kuang (2015), SITNIKOV1, BOCEAN2 (2015) and Ayman Rashed Alshehr discuss risk management system, five studies discuss ISO 9001 implementation: MOHAMMAD M. AL-ASIRI (2004), Hood Atan (2015), Manders, B. (2015), Srđan Medić, (2016), Michael Shuff (2015).

Conceptual research model:



Knowledge gap:

Most of above previous studies take some relation between the risk based thinking, risk management and risk reduction in ISO 9001-2015, but there **is no focus in awareness about the risk based thinking and risk managements..**

Chapter Three

Study Methodology

Chapter Three

Study Methodology

3.1. Introduction:

In this section, researcher followed the normal way of quantitative analytical descriptive studies by collecting data through questionnaire design distribution and data analysis for the study and test of its hypotheses. That, firstly we consider the tools of applied study, which contain the description of the study's population and its sample, data collection method, reliability and validity of the study, and the statistical analysis used to achieve result calculated.

3.2. SAFAT CENTER BACKGROUND:



SAFAT Aviation Complex [SAC] is located in, 20km north of the Capital, Khartoum. SAFAT has continued to play a leading role in aircraft maintenance and services in Sudan. It is Sudan's premier aircraft manufacturing and maintenance complex and one of the country's busiest organizations. From its early beginnings laying the foundation stone for the complex in 2004 was chosen as the area of the construction of the complex and began in 2005 with the participation of a number of foreign and local companies accompanied by the highest international standards and the company has been known for high quality products, service and technical innovation, began the art activity to receive the first aircraft in 2006 for overhauling and maintenance.

The company has two sections: -

1- the military Section:

for the maintenance and development of military aircraft. It divided in to two sections also:

A- Maintenance of fighters.

B- The assembly and maintenance of the training aircrafts.

SAFAT's Fighter Centre specialize in the maintenance and overhaul of Russian and Chinese fighters flown by the country's air force and by those of a number of countries in the region. Among the Chinese fighter types it overhauls are the K-8, A-5, F-6, and PT-6. It also does maintenance and overhaul work on the Su-25, Su-24, MiG-29, MiG-23, and the Mi-24. Its capability on the K-8 extends to complete overhaul of the airframe and 95 percent of components. SAFAT Aircraft Maintenance Centre has approvals to maintain and upgrade a range of Antonov aircraft. SAG also provides upgrades to the avionics and others systems on the Russian made Mi-24helicopters.

2- Civil Section:

It contains a complex manufacturing of all types of aircraft with some divisions as:

- 1.Civil Aviation Maintenance Complex.
2. Aviation Research Center.
3. Agricultural Research Center.
4. High level Aviation Science Academy.
5. Aircraft manufacturing and development center.

The group largely acts as a maintenance, repair, and overhaul contractor for the Sudanese Air Force and regional clients such as: Transportation:(AN-2 * AN-12 * AN-24 * AN-30 * AN-32 * AN-72 * AN-74 * IL-18 * IL-76).Helicopters: (Mi-8, Mi-17, Mi-24, Mi-35).Training aircraft:(PT-6, Safat-01, Safat-02, Safat-03

and Tecnam). But in recent years has begun to manufacture light aircraft and helicopters.

SAFAT group won the lawsuit and aid from:

- Russian Civil Aviation Authority.
- Civil Aviation Authority.
- Silwan Civil Aviation.
- Kenya Civil Aviation Authority.
- Civil Aviation Authority, Niger.
- Antennas design office.
- Russian Helicopters Company.

In this study we took SAFAT manufacturing and development center as a case study, the complex manufactures light aircraft as an initial stage, noting that the second stage includes the manufacture of civil aircraft, thus becoming one of the biggest complexes in the African region. The complex produce three types of small aircrafts:

- SAFAT 01:

Is the first tipper used to broken the wall of aircraft manufacturing which is small, simple, handmade 2 seated aircraft.

SAFAT 02:

A fleet of 20 helicopters with a high rate of time. Is a light multi-purpose helicopter based on the Ukrainian Aero-copter AK 1-3 and assembled in Sudan. This helicopter has a 2.5-liter Subaru EJ-25 engine that runs on automobile gasoline.

SAFAT 03:

Is a light aircraft for basic pilot training, glider tow and proficiency flight. It is completely metal aircraft with two seats, low wing aircraft with seats one along second, tricycle with fixed landing gears, with contemporary pilotage's, navigation's and communication's equipment.

SAFAT 04:

Is the coming project, a multipurpose helicopter with two military and civilian versions.

International participations:

Sudan participated in the Dubai Airshow 2013 with SAFAT 02 and participated in the 2015, 2017 Dubai Air Show with SAFAT 02 and SAFAT 03, and it was ranked 16 at the level of international companies participating in the Dubai Air Show.

3.3. The methodology:

Quantitative research using statistical methods found suitable for such a study, researcher used the tools of data collection of questionnaire that are related to measuring the effect of ISO 9001-2015 in risk reduction as a primary data in addition to the literature review data which previously collected through available, websites, books taking hypothesis in mind followed by the application of descriptive statistical methods, analysis done and some results obtained.

3.4. Population and Sample of the study:

Data collected from SAFAT aviation complex, light aircraft industry center which is concern in the assembly and operation of light aircrafts. This field need more accurate in all processes at any step in the series of the work, so workers must be well trained in their fields and especially in quality and risk aspects. Workers have different qualifications in different specializations with experiences distributed to their ages.

proposed that the appropriate sample size for most research to be greater than 30 and less than 500 (Roscoe et al., 1975). The section of the light aircraft center in the organization is not big, so the sample of the study taken **for all employee (51) except one person (50 working samples)** according to equation to calculate the sample size,

$$SS = Z^2 * (p) * (1-p) \quad SS = 1.96^2 * (.56) * (1-.56)$$

$$= \frac{\quad}{c^2} + \frac{\quad}{0.04^2}$$

Where:

Z = Z value (e.g. 1.96 for 95% confidence level).

p = percentage picking a choice, expressed as decimal.

(.5 used for sample size needed).

c = confidence interval, expressed as decimal (e.g., .04 = ±4).

equals (50) persons with most of them are engineers.

3.5. Questionnaire Design:

To get reliable result for the study questionnaire designed with four perspectives to cover all aspects related to hypotheses and research fields these are:

Part one: personal information.

Part two: (22) statements, four perspective:

- Knowledge of the ISO system
- Availability of the concept of risk management
- Knowledge of the concept of risk management
- Advantages of risk management

3.6. Procedure:

The questionnaire distributed on determined study sample (50) persons, after the step of checking questionnaire reliability and validity, and the researcher constructed the required tables for collected data. This step consists transformation of the qualitative variables (strongly agree, agree, neutral, disagree and strongly disagree) to respectively, the usable questionnaire entered in to a preset SPSS -16 software program. The analysis of the research include descriptive statistical such as calculation of frequency, percentage etc. and for determined whether there will be significant difference in the importance of statements, one-way ANOVA was applied.

3.7. Reliability and Validity

In order to check the apparent validity for the study questionnaire and validation of its statements according to the formulation and explanation, the researcher takes help from three doctors for their long and extensive experience in this field, to express their opinion in questionnaire on:

- Extent of its embodiment of the subject.
- The affiliation of the phrases to the axes.
- Suitability of alternatives to answers.

Also Cranach's alpha method used: -

Where reliability was calculated using Cranach's alpha equation shown below:

$$\text{Reliability coefficient} = \frac{n}{N-1} * \frac{1 - \text{Total variations questions}}{\text{variation college grades}}$$

$$\text{Validity} = \sqrt{\frac{n}{N-1} * \frac{1 - \text{Total variations questions}}{\text{variation college grades}}}$$

Cranach alpha coefficient = (0.89), a reliability coefficient is high and it indicates the stability of the scale and the validity of the study.

Validity coefficient is the square of the reliability coefficient so reliability coefficient is (0.94), and this shows that there is a high sincerity of the scale and that the benefit of the study.

Chapter Four

Data Analysis and Discussion

Chapter Four

Data Analysis and Discussion

4.1. Introduction:

In this chapter the researcher applies statistics and uses number, which is an iterative process whereby evidence is evaluated, the results are often presented in tables and graphs, it is conclusive. This help investigates actual effect of applying risk reduction system.

Some tools used to help in analysis:

- Statistical Package for Social Sciences (SPSS)
- Frequency distribution.
- Person correlation coefficient.
- Graphical figures.

4.2. Statistical analysis

The following table and figure shows the number of distributed questionnaire, with information and the frequency percentage.

Sex	Frequencies	Percentage
Male	49	98.0%
Female	1	2.0%
Total	50	100.0%

Table (4.1) the frequency and percentage for the sex

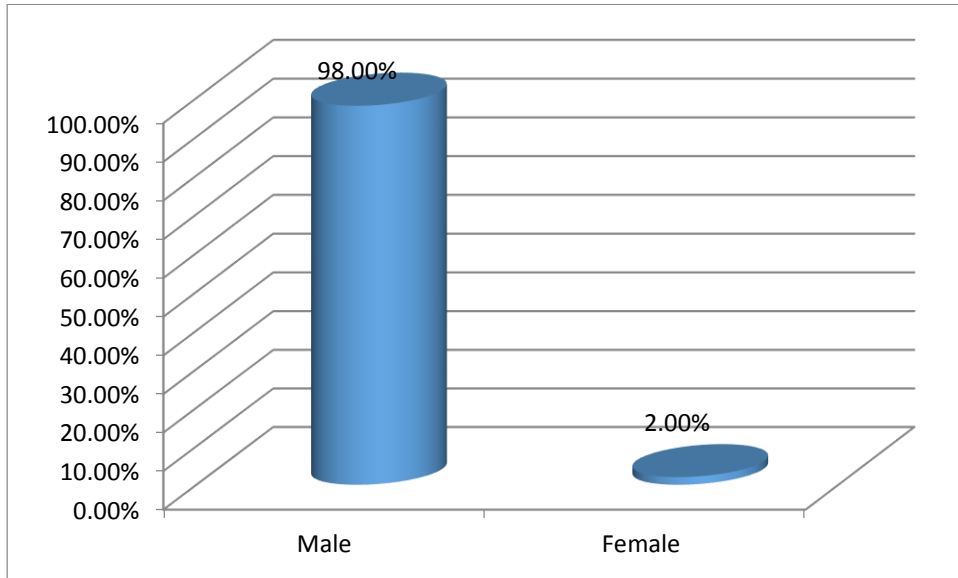


Figure (4.1) - percentage for the sex.

Table (4.1) illustrates the views of the distribution of the sex sample by male by (%98.0) and female by (%2.0).

Value	Frequencies	Percentage
Less than 30	17	34.0%
30 – 40	25	50.0%
40 – 50	7	14.0%
More than 50	1	2.0%
Total	50	100.0%

Table (4.2) the frequency and percentage for the Age

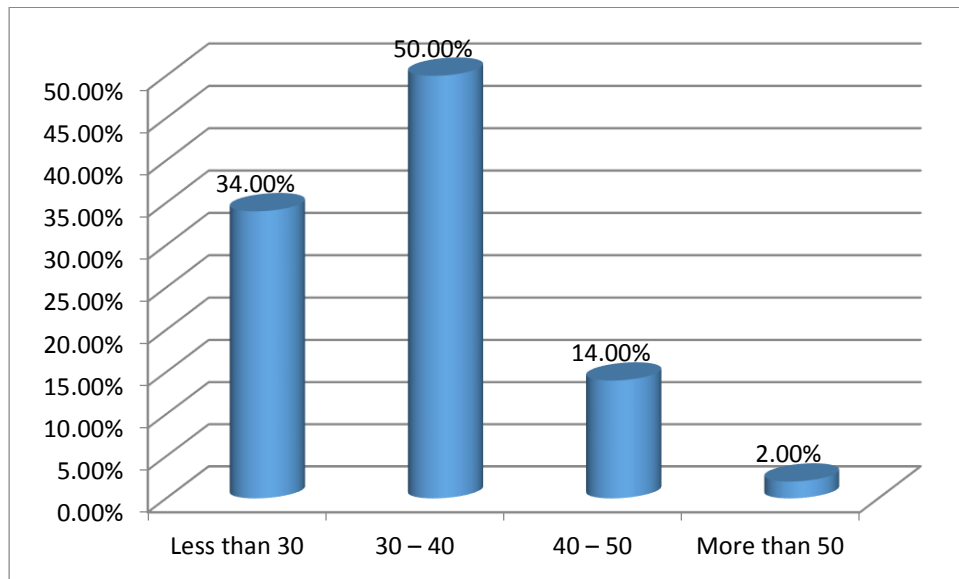


Figure (4.2) - percentage for the Age.

Table (4.2) illustrates the views of the distribution of the age sample by less than 30 years by (%34.0) and 30-40 year by (%50.0) and 40-50 year by (%14.0) and More than 50 years by (%2.0).

Value	Frequencies	Percentage
Diploma	11	22.0%
Bachelor	27	54.0%
Master	12	24.0%
PHD	0	%0.0
Other	0	%0.0
Total	50	100.0%

Table (4.3) the frequency and percentage for the Qualification

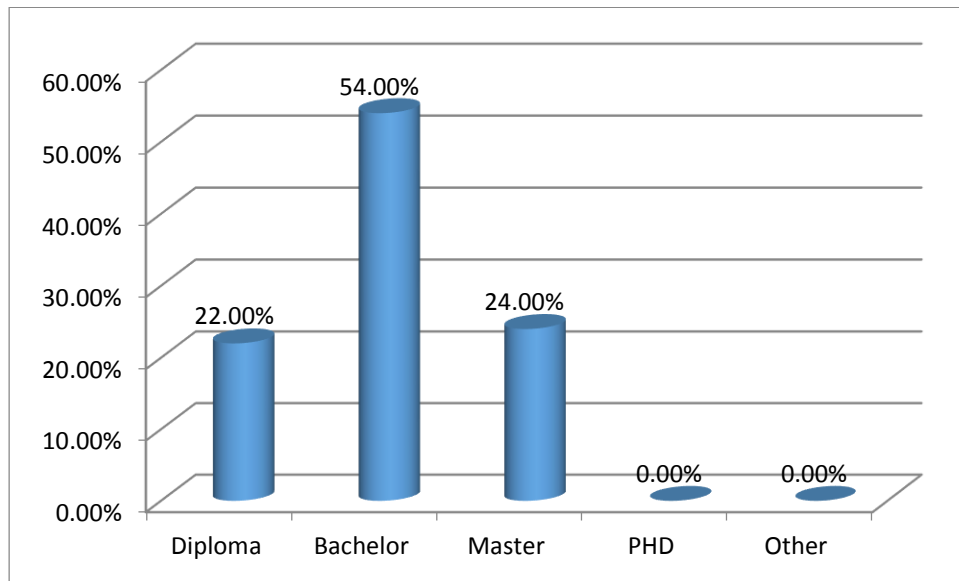


Fig (4.3) percentage for the Qualification.

Table (4.3) illustrates the views of the distribution of the Qualification sample by Diploma by (%22.0) and Bachelor by (%54.0) and Master by (%24.0) and PHD by (%0.0) and other by (%0.0).

Value	Frequencies	Percentage
Engineering	42	84.0%
Quality	1	2.0%
Economic / administration	5	10.0%
Other	2	4.0%
Total	50	100.0%

Table (4.4) the frequency and percentage for the Scientific Specialization

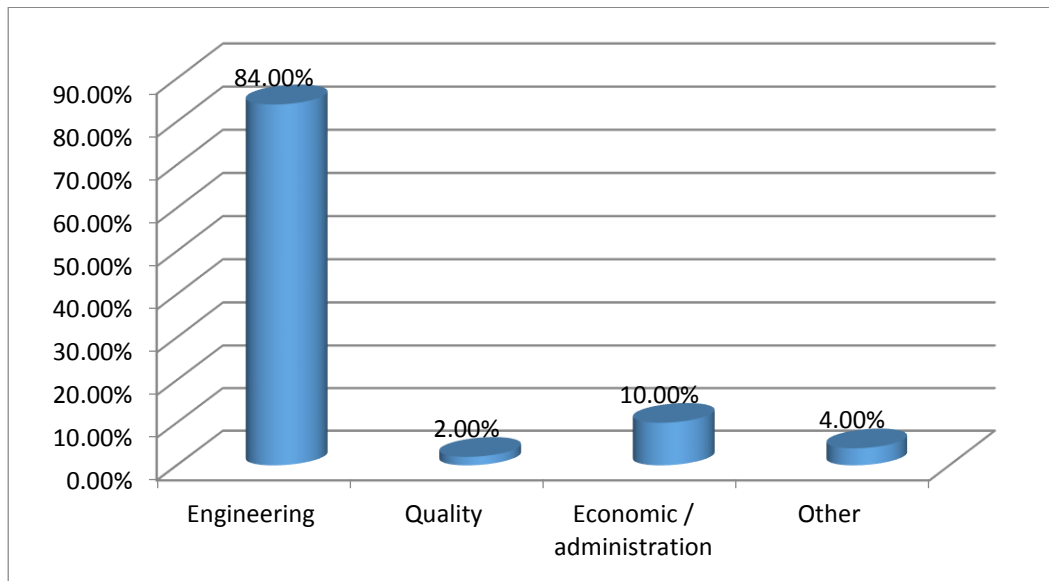


Fig (4.4) percentage for the Scientific Specialization.

Table (4.4) illustrates the views of the distribution of the Scientific Specialization Sample by Engineering by (%84.0) and Quality by (%2.0) and Economic / administration by (%10.0) and other by (%4.0).

Value	Frequencies	Percentage
Less than 5 years	10	20.0%
5 Less than 10 years	22	44.0%
10 Less than 15 years	13	26.0%
15 Less than 20 years	4	8.0%
More than 20 years	1	2.0%
Total	50	100.0%

Table (4.5) the frequency and percentage for experience

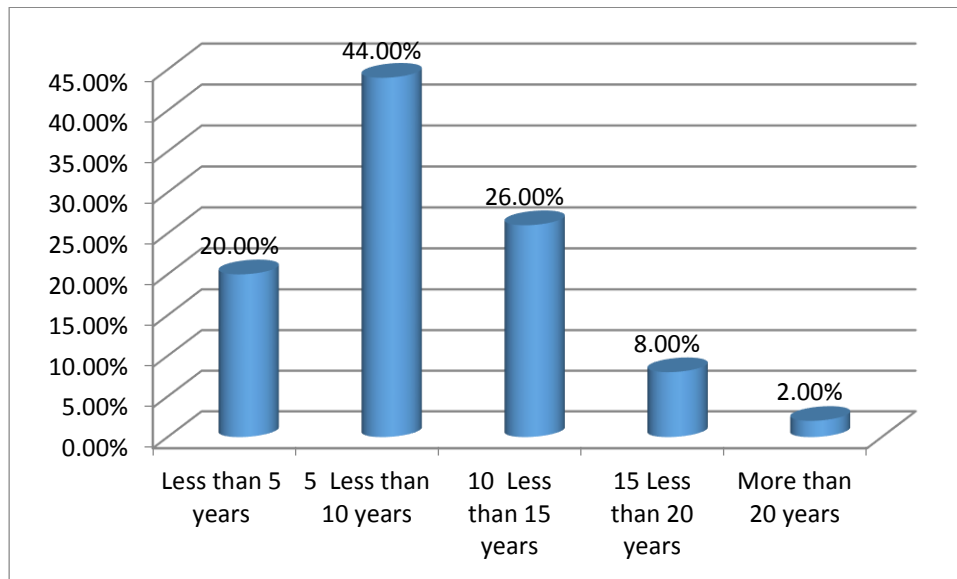


Fig (4.5) percentage for experience.

Table (4.5) illustrates the views of the distribution of the How long have you worked in this organization sample by Less than 5 years by (%20.0) and 5 Less than 10 years by (%44.0) and 10 Less than 15 years by (%26.0) and 15 Less than 20 years by (%8.0) and More than 20 by (%2.0)

No	Items	Strongly agree	Agree	Neutral	Disagree	Strongly disagree
1	The implementation of the ISO 9001 system protects against many risks	25	23	2	0	0
		50.0	46.0	4.0	0.0	0.0
2	The new version of ISO 9001 -2015 deals with the principle of risk-based thinking	22	23	5	0	0
		44.0	46.0	10.0	0.0	0.0
3	I understand the principle of risk-based thinking in 9001 -2015	14	21	10	4	1
		28.0	42.0	20.0	8.0	2.0
4	In my work I can determine exactly what is acceptable and unacceptable	25	19	5	0	1
		50.0	38.0	10.0	0.0	2.0

Table (4.6) the frequency and percentage for respondents answer about the
(Knowledge of the ISO system)

From the above table result shows:

The implementation of the ISO 9001 system protects against many risks by the strongly agree (%50.0) and agree by (%46.0) and neutral by (%4.0) and disagree by (%0.00) and strongly disagree by (%0.0).

The new version of ISO 9001 -2015 deals with the principle of risk-based thinking by the strongly agree (%44.0) and agree by (%46.0) and neutral by (%10.0) and disagree by (%0.0) and strongly disagree by (%0.0).

I understand the principle of risk-based thinking in 9001 -2015 by the strongly agree (%28.0) and agree by (%42.0) and neutral by (%20.0) and disagree by (%8.0) and strongly disagree by (%2.0).

In my work I can determine exactly what is acceptable and unacceptable by the strongly agree (%50.0) and agree by (%38.0) and neutral by (%10.0) and disagree by (%0.0) and strongly disagree by (%2.0).

No	Phrases	Chi-square value	Df	Sig.	Median	Interpretation
1	The implementation of the ISO 9001 system protects against many risks	19.480	2	0.000	4.50	strongly agree
2	The new version of ISO 9001 -2015 deals with the principle of risk-based thinking	12.280	2	0.000	4.00	agree
3	I understand the principle of risk-based thinking in 9001 -2015	25.400	4	0.000	4.00	agree
4	In my work I can determine	30.960	3	0.000	4.50	strongly agree

	exactly what is acceptable and unacceptable					
--	---	--	--	--	--	--

Table (4.7) chi-square test results for respondents answer about the (Knowledge of the ISO system)

The results of table (4.7) Interpreted as follows:

- The value of chi – square calculated to signify the differences between the numbers of individuals of the study for the statement The implementation of the ISO 9001 system protects against many risks was (19.480) with P-value (0.000) which is lower than the level of significant value (5%) These refer to the existence of differences statistically.
- The value of chi – square calculated to signify the differences between the numbers of individuals of the study for the statement The new version of ISO 9001 -2015 deals with the principle of risk-based thinking was (12.280) with P-value (0.000) which is lower than the level of significant value (5%) These refer to the existence of differences statistically.
- The value of chi – square calculated to signify the differences between the numbers of individuals of the study for the statement I understand the principle of risk-based thinking in 9001 -2015 was (25.400) with P-value (0.000) which is lower than the level of significant value (5%) These refer to the existence of differences statistically.
- The value of chi – square calculated to signify the differences between the numbers of individuals of the study for the statement In my work I can determine exactly what is acceptable and unacceptable was (30.960) with P-value (0.000) which is lower than the level of significant value (5%) These refer to the existence of differences statistically.

No	Items	Strongly	Agree	Neutral	Disagree	Strongly
----	-------	----------	-------	---------	----------	----------

		agree				disagree
1	There is risk management in my organization	18	11	10	6	5
		36.0	22.0	20.0	12.0	10.0
2	Standards and tools used to determine risk are available in my organization	7	16	15	11	1
		14.0	32.0	30.0	22.0	2.0
3	The existing level of awareness is significant in terms of risk	4	20	15	9	2
		8.0	40.0	30.0	18.0	4.0
4	There is an effective risk assessment study in my organization	3	10	22	12	3
		6.0	20.0	44.0	24.0	6.0
5	Prevention and risk management tools are available in my organization	6	19	19	5	1
		12.0	38.0	38.0	10.0	2.0
6	My organization is concerned with the main means of promoting safety and combating danger	11	25	11	2	1
		22.0	50.0	22.0	4.0	2.0

Table (4.8) the frequency and percentage for availability of the concept of risk management.

From the above table result shows:

There is risk management in my organization by the strongly agree (%36.0) and agree by (%22.0) and neutral by (%20.0) and disagree by (%12.0) and strongly disagree by (%10.0).

Standards and tools used to determine risk are available in my organization by the strongly agree (%14.0) and agree by (%32.0) and neutral by (%30.0) and disagree by (%22.0) and strongly disagree by (%2.0).

The existing level of awareness is significant in terms of risk by the strongly agree (%8.0) and agree by (%40.0) and neutral by (%30.0) and disagree by (%18.0) and strongly disagree by (%4.0).

There is an effective risk assessment study in my organization by the strongly agree (%6.0) and agree by (%20.0) and neutral by (%44.0) and disagree by (%24.0) and strongly disagree by (%6.0).

Prevention and risk management tools are available in my organization by the strongly agree (%12.0) and agree by (%38.0) and neutral by (%38.0) and disagree by (%10.0) and strongly disagree by (%2.0).

My organization is concerned with the main means of promoting safety and combating danger by the strongly agree (%22.0) and agree by (%50.0) and neutral by 0(%22.) and disagree by (%4.0) and strongly disagree by (%2.0).

No	Phrases	Chi-square value	df	Sig.	Median	Interpretation
1	There is risk	10.600	4	0.000	4.00	Agree

	management in my organization					
2	Standards and tools used to determine risk are available in my organization	15.200	4	0.000	3.00	Neutral
3	The existing level of awareness is significant in terms of risk	22.600	4	0.000	3.00	Neutral
4	There is an effective risk assessment study in my organization	24.600	4	0.000	3.00	Neutral
5	Prevention and risk management tools are available in my organization	28.400	4	0.000	3.50	Agree
6	My organization is concerned with the main means of promoting safety and combating danger.	37.200	4	0.000	4.00	Agree

Table (4.9) chi-square test results for respondents answer about the availability of the concept of risk management

The results of table (4.9) Interpreted as follows:

- The value of chi – square calculated to signify the differences between the numbers of individuals of the study for the statement There is risk management in my organization was (10.600) with P-value (0.000) which is lower than the level of significant value (5%) These refer to the existence of differences statistically.
- The value of chi – square calculated to signify the differences between the numbers of individuals of the study for the statement Standards and tools used to determine risk are available in my organization was (15.200) with P-value (0.000) which is lower than the level of significant value (5%) These refer to the existence of differences statistically.

- The value of chi – square calculated to signify the differences between the numbers of individuals of the study for the statement The existing level of awareness is significant in terms of risk was (22.600) with P-value (0.000) which is lower than the level of significant value (5%) These refer to the existence of differences statistically.
- The value of chi – square calculated to signify the differences between the numbers of individuals of the study for the statement There is an effective risk assessment study in my organization was (24.600) with P-value (0.000) which is lower than the level of significant value (5%) These refer to the existence of differences statistically.
- The value of chi – square calculated to signify the differences between the numbers of individuals of the study for the statement Prevention and risk management tools are available in my organization was (28.400) with P-value (0.000) which is lower than the level of significant value (5%) These refer to the existence of differences statistically.
- The value of chi – square calculated to signify the differences between the numbers of individuals of the study for the statement My organization is concerned with the main means of promoting safety and combating danger was (37.200) with P-value (0.000) which is lower than the level of significant value (5%) These refer to the existence of differences statistically.

No	Items	Strongly agree	Agree	Neutral	Disagree	Strongly disagree
1	I can identify the most serious aspects of my work.	13	27	3	5	2
		26.0	54.0	6.0	10.0	4.0
2	In my organization there is an object to analyze and follow up incidents	4	15	18	10	3
		8.0	30.0	36.0	20.0	6.0
3	The level of compliance with	1	21	20	7	1
		2.0	42.0	40.0	14.0	2.0

	safety procedures and laws is high in my organization					
4	Relevant tools and documents are used to avoid risk in my organization	6	17	20	7	
		12.0	34.0	40.0	14.0	
5	There is an approved contingency plan in the event of any risk	2	23	14	9	2
		4.0	46.0	28.0	18.0	4.0
6	The level of knowledge and management of risk is high in my organization compared to other institutions	5	18	20	6	1
		10.0	36.0	40.0	12.0	2.0
7	I am aware of the types of risks expected in my work	9	20	14	5	2
		18.0	40.0	28.0	10.0	4.0
8	Effective methods and procedures for reducing risk are effective in my organization	4	17	21	4	4
		8.0	34.0	42.0	8.0	8.0

Table (4.10) the frequency and percentage for Knowledge of the concept of risk management

From the above table result shows:

I can identify the most serious aspects of my work by the strongly agree (%26.0) and agree by (%54.0) and neutral by (%6.0) and disagree by (%10.0) and strongly disagree by (%4.0).

In my organization there is an object to analyze and follow up incidents by the strongly agree (%8.0) and agree by (%30.0) and neutral by (%36.0) and disagree by (%20.0) and strongly disagree by (%6.0).

The level of compliance with safety procedures and laws is high in my organization by the strongly agree (%2.0) and agree by (%42.0) and neutral by (%40.0) and disagree by (%14.0) and strongly disagree by (%2.0).

Relevant tools and documents are used to avoid risk in my organization by the strongly agree (%12.0) and agree by (%34.0) and neutral by (%40.0) and disagree by (%14.0) and strongly disagree by (%0.0).

There is an approved contingency plan in the event of any risk by the strongly agree (%4.0) and agree by (%46.0) and neutral by (%28.0) and disagree by (%18.0) and strongly disagree by (%4.0).

The level of knowledge and management of risk is high in my organization compared to other institutions by the strongly agree (%10.0) and agree by (%36.0) and neutral by (%40.0) and disagree by (%12.0) and strongly disagree by (%2.0).

I am aware of the types of risks expected in my work by the strongly agree (%18.0) and agree by (%40.0) and neutral by (%28.0) and disagree by (%10.0) and strongly disagree by (%4.0).

Effective methods and procedures for reducing risk are effective in my organization by the strongly agree (%8.0) and agree by (%34.0) and neutral by (%42.0) and disagree by (%8.0) and strongly disagree by (%8.0).

No	Phrases	Chi-square value	df	Sig.	Median	Interpretation
1	I can identify the most serious aspects of my work.	43.600	4	0.000	4.00	agree
2	In my organization there is an object to analyze and follow up incidents.	17.400	4	0.000	3.00	Neutral
3	The level of compliance with safety procedures and laws is high in my organization.	39.200	4	0.000	3.00	Neutral
4	Relevant tools and documents are used to avoid risk in my	11.920	3	0.000	3.00	Neutral

	organization					
5	There is an approved contingency plan in the event of any risk	31.400	4	0.000	3.50	agree
6	The level of knowledge and management of risk is high in my organization compared to other institutions.	28.600	4	0.000	3.00	Neutral
7	I am aware of the types of risks expected in my work	20.600	4	0.000	4.00	agree
8	Effective methods and procedures for reducing risk are effective in my organization	27.800	4	0.000	3.00	Neutral

Table (4.11) chi-square test results for respondents answer about the Knowledge of the concept of risk management

The results of table (4.11) Interpreted as follows:

- The value of chi – square calculated to signify the differences between the numbers of individuals of the study for the statement I can identify the most serious aspects of my work was (43.600) with P-value (0.000) which is lower than the level of significant value (5%) These refer to the existence of differences statistically.
- The value of chi – square calculated to signify the differences between the numbers of individuals of the study for the statement In my organization there is an object to analyze and follow up incidents was (17.400) with P-value (0.000) which is lower than the level of significant value (5%) These refer to the existence of differences statistically.
- The value of chi – square calculated to signify the differences between the numbers of individuals of the study for the statement The level of compliance with safety procedures and laws is high in my organization was (39.200) with P-value (0.000)

which is lower than the level of significant value (5%) These refer to the existence of differences statistically.

- The value of chi – square calculated to signify the differences between the numbers of individuals of the study for the statement Relevant tools and documents are used to avoid risk in my organization was (11.920) with P-value (0.000) which is lower than the level of significant value (5%) These refer to the existence of differences statistically.
- The value of chi – square calculated to signify the differences between the numbers of individuals of the study for the statement There is an approved contingency plan in the event of any risk was (31.400) with P-value (0.000) which is lower than the level of significant value (5%) These refer to the existence of differences statistically.
- The value of chi – square calculated to signify the differences between the numbers of individuals of the study for the statement The level of knowledge and management of risk is high in my organization compared to other institutions was (28.600) with P-value (0.000) which is lower than the level of significant value (5%) These refer to the existence of differences statistically.
- The value of chi – square calculated to signify the differences between the numbers of individuals of the study for the statement I am aware of the types of risks expected in my work was (20.600) with P-value (0.000) which is lower than the level of significant value (5%) These refer to the existence of differences statistically.
- The value of chi – square calculated to signify the differences between the numbers of individuals of the study for the statement Effective methods and procedures for reducing risk are effective in my organization was (27.800) with P-value (0.000) which is lower than the level of significant value (5%) These refer to the existence of differences statistically.

No	Items	Strongly agree	Agree	Neutral	Disagree	Strongly disagree
1	There are great benefits to adopting the principle of risk-based thinking	22	19	8	1	0
		44.0	38.0	16.0	2.0	0.0
2	Risk-based thinking plays an important role in mitigating risks in my organization	9	22	15	3	1
		18.0	44.0	30.0	6.0	2.0
3	There are some disadvantages when applying risk-based thinking	4	17	21	3	5
		8.0	34.0	42.0	6.0	10.0
4	I am very concerned about the risks and willing to accept lower returns in order to reduce the chances of loss	4	24	20	1	1
		8.0	48.0	40.0	2.0	2.0

Table (4.12) the frequency and percentage for advantages of risk management.

From the above table result shows:

There are great benefits to adopting the principle of risk-based thinking by the strongly agree (%44.0) and agree by (%38.0) and neutral by (%16.0) and disagree by (%2.0) and strongly disagree by (%0.0).

Risk-based thinking plays an important role in mitigating risks in my organization by the strongly agree (%18.0) and agree by (%44.0) and neutral by (%30.0) and disagree by (%6.0) and strongly disagree by (%2.0).

There are some disadvantages when applying risk-based thing by the strongly agree (%8.0) and agree by (%34.0) and neutral by (%42.0) and disagree by (%6.0) and strongly disagree by (%10.0).

I am very concerned about the risks and willing to accept lower returns in order to reduce the chances of loss by the strongly agree (%8.0) and agree by (%48.0) and neutral by (%40.0) and disagree by (%2.0) and strongly disagree by (%2.0).

No	Phrases	Chi-square value	df	Sig.	Median	Interpretation
1	There are great benefits to adopting the principle of risk-based thinking	22.800	3	0.000	4.00	Agree
2	Risk-based thinking plays an important role in mitigating risks in my organization	30.000	4	0.000	4.00	Agree
3	. There are some disadvantages when applying risk-based thinking	28.000	4	0.000	3.00	Neutral
4	I am very concerned about the risks and willing to accept lower returns in order to reduce the chances of loss	49.400	4	0.000	4.00	Agree

Table (4.13) chi-square test results for respondents answer about the advantages of risk management.

The results of table (4.13) Interpreted as follows:

- The value of chi – square calculated to signify the differences between the numbers of individuals of the study for the statement There are great benefits to adopting the principle of risk-based thinking was (22.800) with P-value (0.000) which is lower than the level of significant value (5%) These refer to the existence of differences statistically.
- The value of chi – square calculated to signify the differences between the numbers of individuals of the study for the statement Risk-based thinking plays an important role in mitigating risks in my organization was (30.000) with P-value (0.000) which is lower than the level of significant value (5%) These refer to the existence of differences statistically.
- The value of chi – square calculated to signify the differences between the numbers of individuals of the study for the statement There are some disadvantages when applying risk-based thinking was (28.000) with P-value (0.000) which is lower than the level of significant value (5%) These refer to the existence of differences statistically.
- The value of chi – square calculated to signify the differences between the numbers of individuals of the study for the statement I am very concerned about the risks and willing to accept lower returns in order to reduce the chances of loss was (49.400) with P-value (0.000) which is lower than the level of significant value (5%) These refer to the existence of differences statistically.

4.3. The Study Hypotheses:

There is a significant relationship between applying risk –based thinking in ISO 9001 – 2015 and risk reduction.

N	Pearson's R	Median	Chi-Square	Df	Sig	Scale
50	0.56	4.00	29.201	12	0.00	Significant

Table (4.14) results of hypothesis 1

The results of table (4.14) Interpreted as follows:

The value of chi – square calculated to signify the differences between the numbers of individuals of the study for the statement There is a significant relationship between applying risk –based thinking in ISO 9001 – 2015 and risk reduction was (29.201) with P-value (0.00) which is less than the level of significant value (5%) These refer to the existence of differences statistically

There is no significant reduction in risk when applying Risk –based thinking in ISO 9001 – 2015.

N	Median	Chi-Square	Df	Sig	Scale
50	4.0	35.000	4	0.000	Significant

Table (4.15) results of hypothesis 2

The results of table (4.15) Interpreted as follows:

The value of chi – square calculated to signify the differences between the numbers of individuals of the study for the statement **There is no significant reduction in risk when applying Risk –based thinking in ISO 9001 – 2015** was (35.00) with P-value (0.000) which is less than the level of significant value (5%) These refer to the existence of differences statistically

Good awareness and understanding of risk –based thinking in ISO 9001 -2015 will lead to positive results in reducing risk.

N	Median	Chi-Square	Df	Sig	Scale
50	4.0	12.280	2	0.002	Significant

Table (4.16) results of hypothesis 3

The results of table (4.16) Interpreted as follows:

The value of chi – square calculated to signify the differences between the numbers of individuals of the study for the statement **Good awareness and understanding of risk –based thinking in ISO 9001 -2015 will lead to positive results in reducing**

risk was (12.280) with P-value (0.002) which is less than the level of significant value (5%) These refer to the existence of differences statistically

4.4. Discussion:

4.4.1 Analysis of the questionnaire (Part 1):

The result of the first part of the questionnaire was as follows:

The distribution of the sex sample by male by (%98.0) and female by (%2.0) that is only one female because the nature of industry.

The views of the distribution of the age show the biggest section of employee in the age between (30-40) years which is (%50.0) and that is power full for SAFAT center.

The views of the distribution of the Qualification sample show very good qualifications and most in percentage of (%54.0) bachelor engineers then Master by (%24.0) and Diploma holder by (%22.0).

Most of the distribution of the Scientific Specialization Sample by Engineering by (%84.0) and there is only one quality specialist.

For experience the views of the distribution of the How long worked in SAFAT center Less than 10 years by (%44.0) and Less than 15 years by (%26.0).

Part one show that SAFAT center has a young male engineers with more enough experience and qualifications, but there is no enough specialist in quality and safety.

4.4.2 Analysis of the questionnaire (Part 2):

4.4.2.1. Knowledge of the ISO system:

The implementation of the ISO 9001 system protects against many risks by the strongly agree from SAFAT employees. That similar result of the study of (MOHAMMAD M. AL-ASIRI (2004) that investigate the implementation practices of the new ISO 9001:2000 standard in Saudi business organizations.

The question of new version of ISO 9001 -2015 deals with the principle of risk-based thinking and the principle of risk-based thinking in 9001 -2015 are agreed and similar result with study of (Ayman Rashed Alshehri (2016) that the developed quality management system can generate positive outcomes, lead to better management, clear responsibilities and improve communication.

In work worker show they can determine exactly what is acceptable and unacceptable by the strongly agree (%50.0) near result of (Kasim Randeree 2012)study to provide an examination of the extent to risk in different leadership styles impact employee job satisfaction and organizational commitmentgiving a response rate of 41.83 percent. For the first axis results for respondents answer of SAFAT center employee about the Knowledge of the ISO system show the median of 4.25 which is more than agree level and less than strongly agree.

1.1.2.2. Availability of the concept of risk management:

For risk management system in SAFAT about (%58.0) of employee agreed they have, but the others not sure. And for availability of standards and tools used to determine risk less than (%50.5), although the standard is available as mentioned in literature“These standards have been developed to guide organizations of all types and sizes to implement and operate effective quality management systems (ISO, 2005)”

For the existing level of awareness is significant in terms of risk less than (%50.0) of worker agree and poor result of an effective risk assessment study in organization by less than (%40.0) agree, that comply with what mentioned in the study of (Aized, 2012) “Risk assessment is not completed when action has been initiated. It is essential to monitor the hazard and evaluate the effectiveness of the action in eliminating it or at least reducing it to an acceptable level”.

Same percentage for prevention and risk management tools are available in organization by agree (%50.0) ,that means not fully applied as mentioned in MS ISO 31000:2010, organizations should apply risk identification tools and techniques that are suited to their objectives and capabilities, and to the risks faced.(ISO, 2009)

For organization is concerned with the main means of promoting safety and combating danger there is a good result by (%72.0) agree support the result of Mohammed Youssef Abdullah (2014) “TQM management can support OSH activities effectively by improving work process using processes improvement”.

For the second axis results for respondent's answer of SAFAT center employee about the availability of the concept of risk management show the median of 3.42 which is more than neutral level and less than agree.

4.4.2.3. Knowledge of the concept of risk management:

Good result of identify the most serious aspects of my work by the agree (%80.0) and opposite of the study of (Manders, B. (2015) that find not all of the employees in a company use ISO 9001 in their daily work. , and agreed result in same study that Having a positive attitude towards ISO 9001 usage, being aware of ISO 9001 believing that ISO 9001 is useful and easy to use with question of object to analyze and follow up incidents in organization and the level of compliance with safety procedures and laws is high in organization.

Result for relevant tools and documents are used to avoid risk in organization show and approved contingency plan in the event of any risk, is low same result of (Chi-kuang (2015) The lack of an implementation roadmap always deters enterprises from choosing Total Quality Management (TQM) as its major management approach.

For the level of knowledge and management of risk is high in organization compared to other institutions has a result of more than (%50.0) neutral and disagree and for aware of the types of risks expected in work result in (%58.0) agree with (Srđan Medić, (2016) study that term "uncertainty" is clarified as a lack of information or knowledge about an event that can be expressed in terms of consequences the likelihood of occurrence.

For methods and procedures for reducing risk are effective in organization less than (%50.0) agree and more than (%50.0) neutral and disagree.

For the third axis results for respondent's answer of SAFAT center employee about the Knowledge of the concept of risk management show the median of 3.31 which is more than neutral level and less than agree.

4.4.2.4 Advantages of risk management:

For great benefits to adopting the principle of risk-based thinking most worker are strongly agree by (%82.0) and for Risk-based thinking plays an important role in mitigating risks in organization agreed by (%62.0) and this comply with (Armstrong and Taylor, 2014) said that “The purpose of risk assessments is to initiate preventive action. They enable control measures to be devised on the basis of an understanding of the relative importance of risks”.

For there are some disadvantages when applying risk-based thinking, worker agreed by less than (%50.0) that show les awareness and short of knowledge and also for concerned about the risks and willing to accept lower returns in order to reduce the chances of loss agreed by (%56.0), that comply with study of (Sitnikov and Bocean, 2015) “In practical terms “risk-based thinking” is based on the concept of risk tolerance level. Risk tolerance is the ability of an organization to accept or avoid risk”.

For the third axis results for respondent’s answer of SAFAT center employee about the Advantages of risk management show the median of 3.7 which is more than neutral level and less than agree.

Chapter Five

Results, Recommendations and Suggestions

Results, Recommendations and Suggestions

5.1.Introduction:

This chapter discusses the key results and recommendations that researcher suggests to enhance and promote the strengths of the current study and over come to the areas in which the current appraisal falls short.

5.2.Results:

- There is a significant relationship between applying risk –based thinking in ISO 9001 – 2015 and risk reduction.
- There is significant reduction in risk when applying Risk –based thinking in ISO 9001 – 2015t.
- SAFAT hasa good qualified human resources, Scientific Specialization Sample by Engineering by (%84.0) but there is only one quality specialist.
- Need for good awareness and understanding of risk –based thinking in ISO 9001 -2015 will lead to positive results in reducing risk.
- From study employee clearly agreed that the implementation of the ISO 9001 system protects against many risks.
- SAFAT worker show that can easily determine exactly what is acceptable and unacceptable in their work; although they not Specialist in risk or safety.
- Study show that there is a short in standards and tools in SAFAT center used to determine risk in organization.
- The level of awareness in terms of risk is insignificantamong employees and risk assessment study in organization is insufficient also.
- The level of compliance with safety procedures and laws in SAFAT organizations is not high.
- Knowledge, Tools and documents to avoid risk in organizations are not used well.

5.3. Recommendations:

From all result achieved above the researcher set some recommendations as follows:

- ✓ All organization should take ISO 9001-2015 standard in mind -even in risk- to avoid risk and get huge benefits.
- ✓ In SAFAT continues awareness about the standard 9001-2015 must be done for all level of organization employee.
- ✓ For SAFAT center it is suitable to implement ISO 31000 that their work recommend more safety attentions.
- ✓ All time, Remember that applying tools and proceduresto bush business result forward, not to stop it.
- ✓ For SAFAT center it is suitable to establish a new department of quality and risk managements.
- ✓ Also it is important to get certified at least three persons in safety and risk managements.
- ✓ A review of the procedures used by the SAFAT for the business as a whole and in the particular area to assess risks and audit safety position.

5.4. Suggestions for future researches:

- The researcher suggest that more study will be done in risk reduction in SAFAT using the standard of ISO 9001 -2015 in term of economical view to be more clearly benefits for all business.
- Another study can be done in top management commitment in risk management and it is influence in risk reduction.
- Last suggestion to study effect of ISO 9001 certificate award in risk reduction.

References:

Sources:

القران الكريم.

References in English:

1. ARMSTRONG, M. & TAYLOR, S. 2014. *Armstrong's handbook of human resource management practice*, Kogan Page Publishers.
2. AIZED, T. 2012. Total quality management and six sigma.
3. HOYLE, D. 2017. *ISO 9000 Quality Systems Handbook-updated for the ISO 9001: 2015 standard: Increasing the Quality of an Organization's Outputs*, Routledge.
4. DAHLGAARD, J. J., KHANJI, G. K. & KRISTENSEN, K. 2008. *Fundamentals of total quality management*, Routledge.
5. Knowles, G., 2011. *Quality management*. Book boon.
6. C.R.KOTHARI, 1990. Research methodology, methods & technique.
7. BORGHESI, A. & GAUDENZI, B. 2012. *Risk management: How to assess, transfer and communicate critical risks*, Springer Science & Business Media.
8. HUTCHINS, G. 2018. *Supply Chain Risk Management: Completing In the Age of Disruption*, Greg Hutchins.
9. DAHLGAARD, J. J., KHANJI, G. K. & KRISTENSEN, K. 2008. *Fundamentals of total quality management*, Routledge.

Scientific research and studies in English language:

1. ABDALLA, M. Y. 2014. *Role of Total Quality Management in Setting Occupational Safety and Health Management System in Small and Medium Size Organizations*. Sudan University of Science and Technology.
2. MAHLA, M. M. E. 2016. *The Impact of Implementation of IATA Operational Safety Audit Program (IOSA) on Aviation Safety in Airlines*. Sudan University of Science and Technology.
3. SHREEF, O. S. M. 2015. *Total Quality Management & Excellence Center*. Sudan University of Science and Technology.
4. MANDERS, B. 2015. *Implementation and Impact of ISO 9001*.
5. AL-ASIRI, M. M. 2004. Factors Affecting The Practices Of Iso 9001:2000 Quality Management System In Saudi Business Organizations
6. ALSHEHRI, A. R. 2016 QUALITY MANAGEMENT SYSTEM FOR BUILDING MAINTENANCE *School of Energy, Geoscience, Infrastructure and Society*
7. OMER, S. M. A. 2012. *The Impact of Implementing Total Quality Management in Improving Public Sector Procedures*. thesis.
8. RANDEREE, K. & GHAFAR CHAUDHRY, A. 2012. Leadership–style, satisfaction and commitment: An exploration in the United Arab Emirates' construction sector. *Engineering, Construction and Architectural Management*, 19, 61-85.
9. ARIFF, M. S. B. M., ZAKUAN, N., TAJUDIN, M. N. M., AHMAD, A., ISHAK, N. & ISMAIL, K. 2014. A framework for risk management practices and organizational performance in higher education. *Review of Integrative Business and Economics Research*, 3, 422.
- 10.FONSECA, L. M. 2015a. FROM QUALITY GURUS AND TQM TO ISO 9001:2015: A REVIEW OF SEVERAL QUALITY PATHS *International Journal for Quality Research* 9(1) 167–180 PP 167B-180.
- 11.JODKOWSKI, L. 2015. Possibilities and Methods of Risk Assessment under ISO 9001: 2015 Volume 3, PP 14-23
12. DEYSHER, B. 2014. A “Risk Based Thinking” Model for ISO 9001: 2015.
- 13.ATAN, H. 2015. A REVIEW OF OPERATIONAL RISK MANAGEMENT DECISION SUPPORT TOOL
- 14.SHUFF, M. 2015. ISO 9001:2015 - How to apply Risk-based Thinking to Quality Processes VI-404842-TM.
- 15.FONSECA, L. M. 2015b. ISO 9001 management system through lens of organizational culture. vol. 16, PP 54-58.
- 16.CHEN, C.-K., ANCHETA, K., LEE, Y.-D. & DAHLGAARD, J. J. 2016. A stepwise ISO-based TQM implementation approach using ISO 9001: 2015. *Management and Production Engineering Review*, 7, 65-75.

17. BOUCHET, N. 2015. Introduction to Risk Risk-based Thinking based Thinking. *4th AfBSA Conference*.
18. MEDIĆ, S., KARLOVIĆ, B. & CINDRIĆ, Z. 2016. New standard ISO 9001: 2015 and its effect on organisations. *Interdisciplinary Description of Complex Systems: INDECS*, 14, 188-193.
- 19.A
VEN
, T.
&
KROHN, B. S. 2014. A new perspective on how to understand, assess and manage risk and the unforeseen. *Reliability Engineering & System Safety*, 121, 1-10.

Journals and scientific papers in English language:

1. Roscoe, A.M., Lang, D. and Sheth, J.N., 1975. Follow-up Methods, Questionnaire Length, and Market Differences in Mail Surveys: In this experimental test, a telephone reminder produced the best response rate and questionnaire length had no effect on rate of return. *Journal of Marketing*, 39(2), pp.20-27.
2. Hillson, D., 2002. Extending the risk process to manage opportunities. *International Journal of project management*, 20(3), pp.235-240.
3. International Organization for Standardization, 2009. *ISO 31000: 2009: Risk Management: Principles and Guidelines*. International Organization for Standardization.
4. International Organization for Standardization 9001:2015 Risk-based thinking - power point presentation
5. SITNIKOV, C. S. & BOCEAN, C. G. The role of risk management in ISO 9001: 2015. Proceedings of the 9th international management conference, 2015. 1009-16.
6. ELKELISH, W. W. A. H. 2014. Organizational culture and corporate risk disclosure. *International Journal of Commerce & Management*, p.279.
7. PAUL F. KOZA, P. E. 2018. ISO 9001:2015 Quality Management System *Quality Manual Version 15.0* PennDOT Engineering District 10 Construction Unit: Tab G. Boyer, P.E. – ISO Management Representative.
8. STANDARDIZATION, I. O. F. 2015. ISO 9001:2015 Risk-based thinking *CP 401*. Geneva , Switzerland: BIBC II.

Web sites:

1. <https://www.RePub>, Erasmus University Repository
<https://www.Implementation and Impact of ISO 9001.htm>
2. <https://www.intentional network for trading\risk based thinking.html>
3. https://www.ISO 9001 - 2015 _ Arabic Quality Services.html
4. <https://www. The Methodology - Organizing Your Social Sciences Research Paper - Research Guides at University of Southern California.html>