

**Development of SHEQ™ Management System for Construction
Industry in Malaysia**

by

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Dedicated to my parent

**.....my father Ikhsan Abd Raof
.....and my mother Allahyarhamah Saadiah Harun**

I declare that this project report is the result of my own research except the materials as cited by in references.



.....
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ABSTRACT

“Mishaps are like knives, that either serve us or cut us, as we grasp them by the blade or the handle”.

- *James Russel Lowell*

The construction industry remain to be one of the most dangerous industries in which to work. It accounts for over one fifth of all occupational fatalities. In addition, research estimates that a significant portion of construction contract money is wasted due to insufficient planning, project mismanagement, poor craftsmanship, and competitive “low bid” contract award process.

In reality, the management of Safety, Health, the Environment and Quality in construction field are intrinsically linked and cannot be isolated from one another without compromising the performance of the whole management system. One project must think "SHEQ" when making the decisions, otherwise it will result in conflicts and increased consumption of resources. The objectives of the study are: to review the existing management standards on health and safety (OHSAS 18001:1999), environmental (ISO 14001:1996) and quality (ISO 9001:1994); to study the correspondences data between these three management systems; to develop a guideline of SHEQ™ Integrated Management System; to analyze and study the pro and con of the proposed guidelines.

A theoretical framework is developed from a literature search and this is used by the author as the basis of an analytical model. The data were collected within this framework and analyzed it according to the precepts laid down by earlier researchers in the field. The data is used to demonstrate that our understanding can be significantly increased and this is discussed in the light of previous work. This resulted in the guidelines of an integrated SHEQ™ management system as practiced worldwide by construction companies without them realizing it. Questionnaires developed from good management practices of multinational companies. The results of sampling are discussed and compared through the existing management system documentations. The main result of this thesis discusses research that was undertaken in Malaysian construction

companies with various disciplines like civil, mechanical, electrical and oil and gas related business on the effectiveness of this system. Conclusions are drawn and it is shown that these may be useful for practitioners when practiced systematically.

ABSTRAK

“Kemalangan adalah seperti sebilah pisau, membantu atau melukakan tangan, bergantung kepada dimana kita memegangnya samada di hulu atau di bilah yang tajam”.

James Russel Lowell

Industri pembinaan masih menjadi sebuah industri yang terdedah kepada bahaya yang tinggi . Ia menyumbang kepada satu per lima daripada jumlah kematian pekerja dalam seluruh industri . Kajian menunjukkan sebahagian jumlah kewangan di bazirkan disebabkan oleh perancangan yang lemah, salah pengurusan projek, skil dan kualiti yang rendah, proses anugerah kontrak berdasar ‘harga terendah’ yang terlalu kompetitif.

Telahpun menjadi kenyataan dan tidak dinafikan bahawa bagi melancarkan keseluruhan kerja pengurusan dalam bidang kejuruteraan awam, pengurusan keselamatan (safety), kesihatan(health), alam sekitar (environmental) dan kualiti (quality) memang tidak dapat dipisahkan. Setiap projek sememangnya memikirkan “SHEQ™” terlebih dahulu sebelum membuat sebarang keputusan; jika tidak konflik dan masalah lebih pembaziran sumber-sumber projek akan berlaku. Objektif projek ini adalah untuk: mengkaji standard-standard pengurusan yang sedia ada, iaitu kesihatan dan keselamatan (OHSAS 18000:1999), alam sekitar (ISO 14000:1996) dan kualiti (ISO 9000:1994); mengkaji persamaan antara ketiga-tiga standard ini; menghasilkan satu petunjuk bagi Sistem Pengurusan SHEQ; dan akhir sekali untuk mengkaji kelebihan dan kelemahan panduan sistem yang dihasilkan.

Rangka kerja teori di bentuk dalam kajian literature dimana ini telah digunakan oleh penulis sebagai asas model analitikal. Data yang di kutip didalam rangka kerja ini di analisa menurut asas yang diperturunkan oleh pengkaji-pengkaji terdahulu. Maklumat kajian ini di gunakan untuk membuktikan pemahaman kita adalah meningkat dan ini dibincangkan berasas kerja-kerja terdahulu. Ini telah melahirkan garis panduan kepada system pengurusan SHEQ™ yang telah diamalkan diseluruh dunia tanpa disedari. Soal selidik di bina berasas tata amalan terbaik syarikat multi nasional. Keputusan-keputusannya dibincang dan dibandingkan dengan dokumen-dokumen sistem pengurusan.. Tesis

ini juga membincangkan kajian keatas syarikat-syarikat pembinaan di Malaysia dalam pelbagai disiplin seperti sivil, mekanikal, letrik dan syarikat yang berkaitan dengan minyak dan gas akan keberkesanan sistem ini. Kesimpulan telah digariskan dan ini menunjukkan sistem ini amat berguna jika diamalkan secara sistematik.

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LIST OF SHORT FORMS

US	:	United States
USD	:	US Dollar
IMS	:	Integrated Management System
SHEQ™	:	Safety Health Environment and Quality
SHEQ-MS	:	Safety Health Environment and Quality Management System
OHSAS	:	Occupational Health Safety Standard
ISO	:	International Standard Organization
JKKP	:	Jabatan Keselamatan Kesihatan Pekerjaan
CIDB	:	Construction Industry Development Board
NIOSH	:	National Institute Occupational Safety & Health
UK	:	United Kingdom
EMS	:	Environmental Management System
EHS	:	Environmental Health & Safety
OH & S	:	Occupational Health & Safety
OHSMS	:	Occupational Health & Safety Management System
PDCA	:	Plan-Do-Check-Act
TQM	:	Total Quality Management
ICT	:	Information Communication Technology
MSDS	:	Material Safety Data Sheet
HEMP	:	Hazard Effect Management Process
KPI	:	Key Performance Index
NGO	:	Non-Governmental Organization
SIRIM	:	Standard International Research Institute Malaysia
CSR	:	Corporate Social Responsibility

CHAPTER I

1.1 Introduction

The construction industry currently account for over 22% of all occupational fatalities although it employs less than 7% of the US workforce (CPWR, 2002; BLS,2003). This is an increase from 1999 , when it accounted for 19% of all occupational fatalities and employed around 5% of the US workforce (CPWR, 1998; BLS,2003). In comparison , the US manufacturing industry currently employs between 15-21% of the workforce , while accounting for only 11% of all occupational fatalities (BLS,2003). Historically , the US construction industry's injury and illness incidence rates were higher than all other industries. Only recently has the construction industry's incidence rate dipped below that of the manufacturing industry. However that trend is appears to be reversing (BLS 2003).

From the business standpoint, accident affect the bottomline or profitability of a project. Direct cost associated with an occupational injury or illness include: medical cost, premiums for workers' compensation insurance , liability and property losses (Smith and Roth, 1991). Researches have estimated that workers' compensation premiums cost contractors anywhere from 1.5% to 6.9% of total cost associated to with a construction project (Agarwall and Everett, 1997) In consideration of losses from safety accidents, a construction company operating at a 3% profit margin would have to increase sales by USD 333,000 to pay for a USD 10,000 injury, such as amputation of a finger (CPWR,1998). Injuries in construction affect project profitability in other ways as well. Indirect cost for medical-case injuries and restricted activity or lost-work day injuries were estimated at a 4.2 and 20.3 ratio , respectively, to direct cost (Hinze and Applegate ,

1991); (Agarwall and Everett, 1997). Indirect cost associated with construction accidents include the cost of lost-time for injured workers, loss of productivity, loss of supervisory time, decrease in labor morale, and cost of damage to equipment (Smith and Roth, 1991). However construction accidents and injuries are not the only cause of project profitability loss.

Dan and Bradstreet data show that construction businesses fail at a higher rate than all businesses (CPWR,1998). This increased failure rate (in comparison to manufacturing or industrial operations) could be caused by productivity and quality-related financial waste. Examples include : insufficient planning, poor craftsmanship, and the competitive “low bid” contract award process (Lahndt , 1999 Mckim and Kiani, 1995). From a quality and productivity standpoint , labor costs typically contribute around 30% of the overall project costs (Pickard, 1998,2000) Jereas et al.(2000) investigated manpower mismanagement and construction delays and determined that 40-60% of a typical construction workers’ day is non productive time. Love et al. (1999) found that cost associated with rework (having to redo a step or portion of construction due to poor craftsmanship or change in plan) was found to be as high as 12% of the total project cost and require as high as 11% of the total project working hours . The same authors commented that this costs do not take into account losses due schedule delays, litigation cost and other intangible costs of poor quality. The construction industry needs to find new and innovative ways to better control the construction process to reduce accidents and losses.

An Integrated Management System (IMS) is a management system, which integrates all components of a business into one coherent system so as to enable the achievement of its purpose and mission [1]. Anything that has an effect on business results must be part of the management system. Therefore, an IMS should integrate All currently formalized systems focusing on quality, health and safety, environment, personnel, finance, security etc. What this means is that all the processes and the documents that describe them would be integrated.

Quality, environment, and safety and health are very technical management fields. We sought to apply the discipline of continuous improvement and business know-how to the technical arena by developing a process, or way of doing work, that moves programs through a structured cycle similar to the "plan-do-check-act" cycle [2]. Refer to Figure 1.

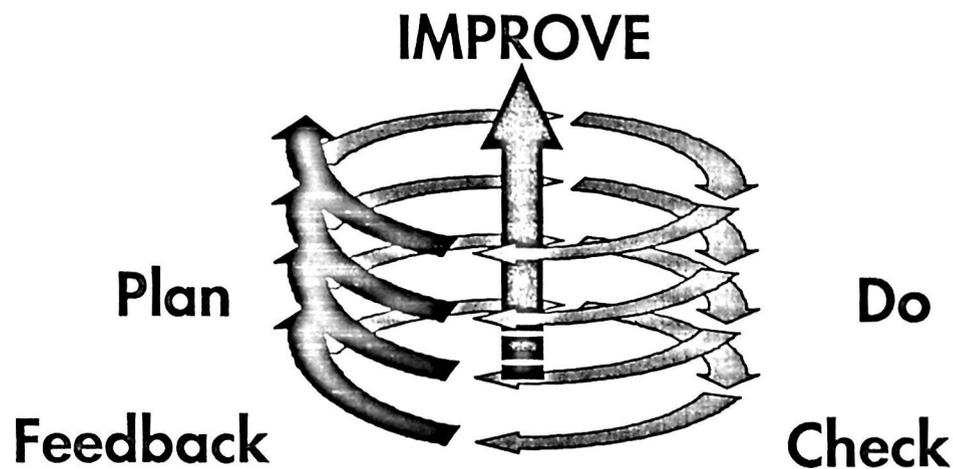


Figure 1. Deming Model of Management: Plan-Do-Check-Act Cycle

In term of resource savings and improvement in one responsibility, there is value to integrating OHSAS 18000 safety and health, ISO 14000 environmental and ISO 9000 quality standards. Success in integration will depend on cross-training of managers and skilled support and skilled support groups to maintain the systems [3]. Therefore the SHEQ™ management system is introduced as an integrated management system between safety and health, environmental and quality management system.

1.2 Problem statement

The management of Safety, Health, the Environmental and Quality (SHEQ™) are often treated as independent functions within organizations. The separate international certification norms OHSAS 18001, ISO 14001 and ISO 9001 reflect this.

"We can't continue to think about management systems in silos; we must find a way to integrate them," said Joel Charm, director of occupational and safety for AlliedSignal Corp., and chairman of the U.S. Technical Advisory Group to 207 for Subcommittee 1 [4].

On the other hands, Hans Dieter Seghezzi, president of the Swiss Committee for Testing and Certification and vice president of the Swiss Federal Commission for Accreditation, agrees that standards should be integrated. "A company needs one management system that builds on itself. Companies with a bunch of different systems that overlap will be in big trouble, " he said [4].

The local construction companies in Malaysia are short of documentation of management system and the practices are guided and governed by the gazetted acts like Act 514 of JKPP, CIDB, and the non-governmental organization like NIOSH, individual corporates etc., which can link together all the aspects of safety, health, environmental and quality and can be used locally. In reality, the management of SHEQ™ is intrinsically linked and cannot be isolated from one another without compromising the performance of the whole management system. SHEQ™ can be regarded as four dimensions of a management system. If managers and employees are focused on only one (or some) of these dimensions, then performance of the management system may suffer [5]. One project must think "SHEQ™" when making the decisions, otherwise conflicts and increased consumption of resources will be the result.

This SHEQ-MS, after some researched and compilation is tested against a sample of construction companies in Malaysia. The results are discussed and measured and a summary of performance will tell the real situation of SHEQ™ management system as practiced in this country.

1.3 Definition

1.3.1 Integration

Integrated means to make completed or combined, putting all the internal management practices into one system but not as separate components. For these systems

to be an integral part of the company's management system there have to be linkages so that the boundaries between processes are seamless [1].

1.3.2 System

A system is a group of things or parts working together in a regular relation. It is an ordered of principles where the interconnection between components supports each other to achieve a given objective. These components include the organization, resources and processes. Therefore, people, equipment and culture are part of the system as well as the documented policies and practices [1].

1.3.3 Integrated Management System

An integrated management system (IMS) is a management system, which integrates all components of a business into one coherent system so as to enable the achievement of its purpose and mission [I].

1.4 Objectives

1. To review the existing management standards on health and safety (OHSAS 18000), environmental (ISO 14000) and quality (ISO 9000).
2. To study the correspondences elements between these three management systems (ISO 9000, ISO 14000 and OHSAS 18000).
3. To develop a guideline of SHEQ™ Integrated Management System.
4. To study the advantages and disadvantages of the proposed SHEQ™ Integrated System's guidelines.
5. To study the effectiveness SHEQ™ Integrated Management System in construction industry in central region and Klang Valley.

1.5 Scope of Study

Safety, Health, Environmental and Quality are the four cornerstones of a functional management system. As in construction management field, there are several standards of managements such as ISO 9000 for Quality System, ISO 14000 for Environmental Management System, and OHSAS 18000 for Safety and Health Management System.

In this master project report, the IMS will focus on the integration of these three management systems, and will be known as SHEQ™ Management System (Safety and Health-Environmental-Quality Management System), and the scope will be more toward the literature review through the existing management system documentation.

In other word, the SHEQ™ Management System is the integration of these three management systems:

- Safety and Health Management System (OHSAS 18000)
- Environment Management System (ISO 14000)
- Quality System (ISO 9000)

The Integrated Safety and Health, Environmental and Quality (SHEQ™) Management System establishes a single, defined safety and health, environmental and quality management system that integrates requirements into the work planning and execution processes to effectively protect the clients, workers, public, and the environment.

1.6 The Importance of the Study

In spite of the good intentions demonstrated by many parties, there is a real threat that the integration of management systems will be hampered. A study carried out at the instigation of Professor Waszink, holder of the RvA/Chair at Erasmus University of Rotterdam, showed that: a wrong approach might lead to high expenses. (RvA Annual Report, 1994) [4]

The common belief among professionals in the international standards arena is that the ISO 14000 EMS, ISO 9000 QMS and OHSAS 18000 OHS-MS ultimately should be harmonized in some manner [6]. A drive toward more efficient auditing will spur efforts to eliminate multiple audits, since there is a strong desire among industry members that there should only be one audit for management system. Integrating implementation of the standards at the operational level could help cut cost by making certification (registration) efforts more economical and audits less disruptive for auditees [4].

Some of the languages and concepts in OHSAS 18001 mirrors those in ISO 9001 and ISO 14001, including a requirement for a policy statement, top management commitment, document control, training, corrective action, management review, and continual improvement. The important of this study is to embed quality, environmental, safety and health practices together in the work process, and then an outstanding management performance is achieved as an integral element of doing the work in the construction field.

1.7 The arrangement of Report

Chapter I: Introduction

This chapter will briefly discuss on the introduction of this master project; included the objectives, problem statements, scope of study and the important of the study.

Chapter II: Literature Review

This chapter will discuss the 3 foundation management systems of the integration project, which are:

ISO 9001: Quality management system

ISO 14001: Environmental management system

OHSAS 18001: Occupational health and safety management system

The discussion will make some introduction and the benefits of these systems separately. The main discussion will be focus on the elements and the different standard.

Chapter III: Methodology

This chapter shows the overall process of finishing this whole report. The method used can be compartmentalized into 6 distinct phases:

- Phase I : Awareness
- Phase II : Data collection
- Phase III : Data correspondences
- Phase IV : Integrating
- Phase V : Sampling
- Phase VI : Research Instrument
- Phase VII : Analysis
- Phase VIII : Conclusion

Chapter IV: Integration of SHEQ Management System

This chapter will cover an integrated documentation between 3 major management standards (OHSAS 18001, ISO 14001 and ISO 9001), which are discussed in Chapter II: Literature Review.

The model of documentation is known as SHEQTM management system, and the requirement are narrowed the topic in construction management. Each element and requirement will be discussed in detail in this chapter.

The 6 major elements in the SHEQTM management system guidelines are shown as below:

- Clause 4.1: General requirements
- Clause 4.2: SHEQTM policy

- Clause 4.3: Planning
- Clause 4.4: Implementation and operation
- Clause 4.5: Checking and corrective action
- Clause 4.6: Management review

Finally, some discussion of benefits will be making based on the model of guidelines.

Chapter V: Results and Analysis

Sample of questionnaires , results of questionnaires are tabulated in a table to ease the process of analysis and discussions. A comprehensive analysis from the questionnaires will be discussed which will bring to conclusion(s) to this study.

Chapter VI: Conclusion

The overall conclusion of the report will be made here, as a general comparison between the report and the objective, seeing whether the purpose of the report is achieved or not.

CHAPTER II

LITERATURE REVIEW

2.1 ISO 9001: 1994

ISO 9001:1994 is also known as *Quality management system specification standard*. This section presents the brief study of ISO 9001 include the overall scope of introduction, ISO 9000 in construction, benefits of quality management, ISO 9001 requirements and the element of ISO 9001 standard.

2.1.1 Introduction

The ISO 9000 standards are produced by an international consensus of countries with the aim of creating global standards of product and service quality. These sets of standards form a quality management system and are applicable to any organization regardless of product, service, organizational size, or whether it's a public or private company [7].

The ISO 9000 standard is a 5-part standard that was written to address the areas that are considered good business practices for every part of a company. As written, the ISO 9000 is not a product or services standard, neither an industry specific, but it is rather a general guideline to an efficient business operation. It does not contain any requirement

to comply any product or service, but the standards allow any company to evaluate each element of the standard and decide how to meet the intent of the element effectively [4]. In other word, two companies may look at an element such as design control and decide to implement programs that are radically different in content and documentation. Although the programs are different, however, both meet the intent and requirement of design control. Again, it is not a product standard, but is a process standard.

ISO 9000 is a collection of standard, ranging from ISO 9000 to ISO 9004. These standards outline the requirements of the Quality System and are published in 5 documents:

(ISO 9000:1994 is a generic name for 5 standards) [8]

1. ISO 9000:1994 Guidelines For Selection And Use Of Quality Management And Quality Assurance Standards
2. ISO 9001:1994 Specification Of Quality Assurance In Design, Development, Production, Installation, And Servicing
3. ISO 9002:1994 Specification Of Quality Assurance In Production, Installation, And Servicing
4. ISO 9003:1994 Specification Of Quality Assurance For Final Inspection And Test
5. ISO 9004:1994 Guide To Quality Management And Quality System Elements

In this standard series, ISO 9000 and ISO 9004 are the guideline. Meanwhile, ISO 9001, ISO 9002 and ISO 9003 are the categories with each, for which companies may apply for certification.

The section of the ISO 9000 series can be summarized as: [9]

- ISO 9000 Guidelines for the selection and use of 9001, 9002 or 9003
- ISO 9001 Models for programs, the applicability of which is dependent 9002 & 9003 on the activity present in the organization
- ISO 9004 Handbook for implementation of quality management and quality system elements

Use of the ISO 9000 series standards can also provide companies some assurance that a certified supplier follows sound business practices and has systems in place that will provide consistent quality of goods and services. Companies gaining certification are awarded a certificate attesting to their conformance to the requirements of the standard [9].

Whereas to enhance the good management by using ISO , Regional Sustainable Development Frameworks in Great Britain outlines the following aims:

Table 2.0: Regional Sustainable Development Framework aims

<ol style="list-style-type: none"> 1 Good quality employment opportunities available to all 2 Conditions that allow business success, economic growth and investment 3 Education and training opportunities that build the skills and capacity of the population 4 Conditions and services that engender good health 5 Safety and security for people and property 6 Vibrant communities that participate in decision-making 7 Culture, leisure and recreation opportunities available to all 8 Local needs met locally 9 A transport network that maximizes access whilst minimizing detrimental impacts 10 A quality built environment and efficient land use patterns that make good use of derelict sites, minimize travel and promote balanced development 11 Quality housing available to everyone 12 A biodiverse and attractive natural environment 13 Minimal pollution levels 14 Minimal greenhouse gas emissions and a managed response to the effects of climate change 15 Prudent and efficient use of energy and natural resources, and minimal production of waste <p>Cross-cutting themes include:</p> <ul style="list-style-type: none"> • Social inclusion and equity across all sectors • A partnership and participative approach • Geographical adaptation to the needs of rural and urban communities • Creativity, innovation and the appropriate use of technology

Figure Regional Sustainable Development Framework aims.

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2.1.2 ISO 9000 in Construction

Compare to the other fields (manufacturing fields), The adoption of ISO 9000 in construction field has been slower.

Before ISO 9000 emerged, the large construction companies in the Europe and UK already practiced quality assurance. Since UK's construction companies obtained ISO 9000 certification, then the construction companies in Europe, US and other countries picking up their interest in this standard [10].

In Asia, quality assurance in construction is just beginning to receive attention when Hong Kong Housing Authority made it a requirement in the year 1991. Then the other Asia countries start paying attention in awareness of the quality assurance in construction, follow with the ISO 9000:1994 Quality System standard [10].

2.1.3 Work with ISO 9000 Standard

To work with ISO 9000 standard, first there shall be awareness or the need to develop a quality management system that meets the requirements specified by ISO 9000 Standards. The reasons can be feeling the need to control or improve the quality services, to reduce the costs associated with poor quality, or to become more competitive to other companies.

ISO 9001 or ISO 9004 can be consulted as a guideline. However, ISO's guidelines are no need to be studied because the quality management system must meet ISO's requirements, not ISO's guidelines. If there is no requirement for the additional clarification ISO's guidelines may ignored [9].

To develop the system that meet the ISO 9001 Quality Management Standard, start with an ISO 9001 's Gap Analysis. It can identify the gaps that exist between the ISO 9001 Standard and the organization's processes. Once the precise gaps are identified, then the next step to fill the gaps will be easier. By doing so, beside comply with the new ISO 9001 Standard; the overall performance of the organization processes can be improved [11].

After the quality system has been fully developed and implemented, an Internal Audit is carried out to ensure that every single ISO 9001 requirement is fulfilled. If the quality system has met ISO's requirement, then the registrar who certified it would issue an official certificate and recorded the achievement in their registry. The certification then announce that the quality of the products and services is managed, controlled, and assured by a registered ISO 9001 Quality Management [11].

Since the ISO does not require formal registration (certification), one can be in compliance without being registered by an accredited auditor.

2.1.4 Benefits of Quality Management

The benefits of quality management make provider of products respond to the quality requirement. An efficient and effective quality system gains:

- Clients are more confident and comfortable if the evidence that their projects will be executed efficiently [9]
- Reducing reworking time and ensuring that the exposure of construction operations to liabilities or higher rectification cost are minimized [9]
- A smooth and properly run system with an efficient quality management minimize the failure and therefore saving the cost [9]
- Cost saving can be substantial if customers eliminate the need to perform audit or inspection on the materials or products they are purchasing from their supplier or subcontractor [9]
- A well-developed quality system will enable management to identify areas that need to be addressed and encourage staff to monitor and improve their own departments' performance [10]

ISO 9000 is important because of its international orientation. Currently, national standard bodies from more than 120 countries support ISO 9000. This makes it the

logical choice for any organization that does business internationally or that serves customers who demand an international standard of quality [12].

Leading the experts to determine the benefits of achieving compliance to the ISO 9000 standards has performed many studies on ISO 9000 registered organizations.

The following list summarizes some of the conclusions, from companies or organization [10]:

- Increased operational efficiency
- Increased productivity
- Reduced overtime
- Reduced administrative costs
- Increased profitability
- Eliminated unnecessary procedures

2.1.5 ISO 9001 Requirements

There are twenty requirements in ISO 9001, and they are shown from clause 4.1 to clause 4.20. The basic requirements of ISO 9001 Guidelines for the selection in Table 2.1 [10]:

Table 2.1: ISO 9001:1994 - Guidelines for the Selection

Content	
0	Introduction
1	Scope
2	Normative References
3	Definition
4	Quality System Requirements
4.1	Management Responsibility
	4.1.1 Quality policy
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4.2	Quality System

	4.2.1 General
	4.2.2 Quality system procedures
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Annex A (informative) Bibliography	

2.1.6 Element of ISO 9001: 1994 standard

There are twenty elements of the ISO 9000:1994, which addressed all in the ISO 9001:1994 too. Table 2.2 identifies key activities that need to be performed and procedures that need to be in place to comply with the requirements.

Table 2.2: Elements of ISO 9001: 1994 standard [9,10,11,13]

Clause	Element	Key Activities/ Procedures Required
4.1	<i>Management Responsibility</i>	<p>Quality policy</p> <ul style="list-style-type: none"> ○ Define, document and communicate the company's quality policy to all personnel. The quality policy should include the quality objectives, management's commitment to the policy and their objectives, the goals of the organization, and the customer's needs and expectations. <p>Responsibility and authority</p> <ul style="list-style-type: none"> ○ Define and document the responsibilities and authorities for all personnel whose work activities affect quality. In addition, define their interrelationships.

		<p>Management representative</p> <ul style="list-style-type: none"> ○ Assign a manager representative with the responsibility of implementing and maintaining a quality system, and for ensuring that all appropriate requirements of the quality system have been met. ○ The manager representative reviews the performance of the Quality System with senior management <p>Management review</p> <ul style="list-style-type: none"> ○ Periodically, review the Quality System, and the quality policy and objectives for effectiveness ○ Maintain records of the reviews
4.2	<i>Quality System</i>	<p>Document the Quality System, by:</p> <ul style="list-style-type: none"> ○ Establishing a Quality Manual and/or defining and implementing quality plans ○ Defining and documenting the documentation structure of the Quality System ○ Documenting processes and procedures consistent with the quality policy <p>Ensure an effective implementation of the Quality System</p>
4.3	<i>Contract Review</i>	<p>Establish procedures to review contracts, considering the following:</p> <ul style="list-style-type: none"> ○ Are requirements defined in the contract? ○ Have differences been resolved? ○ Ensure that you can meet the requirements in the contract ○ Allow the verbal contracts ○ Describe the method for handling amendments to contracts <p>Maintain records resulting from contract reviews</p>
4.4	<i>Design Control</i>	<p>Maintain a documented process to control and verify the design of the product</p> <p>Design and develop plans</p> <ul style="list-style-type: none"> ○ Prepare plans that define how the design process will be carried out, and identify the tasks/ activities that need to be performed. ○ Assign the appropriate personnel to the tasks

		<ul style="list-style-type: none"> ○ Document interfaces between groups <p>Document and review design input requirements, including regulatory requirements, resolving any differences</p> <p>Conduct and document design reviews at various stages of the design process</p> <p>Document design output</p> <ul style="list-style-type: none"> ○ Establish the acceptance criteria to verify that the design output meets the design input requirements ○ Ensure conformance to the appropriate regulatory requirement ○ Identify any critical design characteristics <p>Validate the design to ensure that the product meets the customers needs</p> <p>Verify the design output meets the design input requirements, by:</p> <ul style="list-style-type: none"> ○ Performing design reviews ○ Performing verification and validation tests ○ Reviewing alternatives ○ Performing comparisons against some proven designs <p>Design changes</p> <ul style="list-style-type: none"> ○ Identify, document, review, and approve any design changes
4.5	<i>Document and Data Control</i>	<p>Establish and implement a process for controlling all relevant documents and data, including external documents, if they are part of the Quality System</p> <p>Review and approve documents, prior to issuing and using them</p> <ul style="list-style-type: none"> ○ Establish a master list of all Quality System documents, reflecting their current revision status ○ Documents must be available or accessible to those who are required to use them ○ Promptly remove obsolete documents from use ○ Obsolete documents that are retained, must be identified

4.6	<i>Purchasing</i>	<p>Conformance to requirements is the supplier's responsibility</p> <p>Evaluation of subcontractors is based on:</p> <ul style="list-style-type: none"> ○ Their ability in meeting quality requirements <p>Supplier maintains records of acceptable subcontractors</p> <p>Provide purchasing documents that clearly describe the product, service, or materials being ordered, including any applicable specifications or requirements</p> <p>Supplier reviews and approves purchasing documents, before releasing them</p> <p>Verifying products</p> <ul style="list-style-type: none"> ○ Purchasing documents must specify details for products to be verified at the subcontractor's site ○ The customer has the right to verify the quality of the product that was purchased ○ Supplier has the responsibility of delivering acceptable product
4.7	<i>Customer-Supplied Products</i>	<p>Establish and document procedures for maintaining the quality of products supplied</p> <p>Record and report to the customer any products that are lost, damaged, or deteriorated</p>
4.8	<i>Product Identification and Traceably</i>	<p>Establish and document procedures for identifying the product throughout production. Delivery, and installation</p> <p>Assign a unique identifier to the product or production batch, and record the identifier</p>
4.9	<i>Process Control</i>	<p>Identify production, installation, and servicing processes under controlled conditions, including:</p> <ul style="list-style-type: none"> ○ Document procedures ○ Provide a suitable work environment ○ Comply with standards and procedures ○ Establish and control process parameters ○ Control product characteristics ○ Approve and maintain processes and equipment

<p>4.10</p>	<p><i>Inspection and Test</i></p>	<p>Inspection or verify all incoming product against requirements and documented procedures</p> <p>Inspect and test in-process product, as required. Determine product conformance, and hold product until inspections and tests are completed</p> <p>Perform all final inspection and tests to ensure that the product meets specified requirements</p> <ul style="list-style-type: none"> ○ Product is not to be released until all specified activities are complete and all data are available <p>Establish records for evidence of conformance, identifying the individual having the authority to release the product</p>
<p>4.11</p>	<p><i>Control of Inspection, Measuring, and Test Equipment</i></p>	<p>Equipment must be controlled, calibrated, and maintained</p> <p>Identify what needs to be calibrated</p> <ul style="list-style-type: none"> ○ Determine the measurements that need to be made ○ Identify the accuracy/ tolerance of measurements that are required for each type of equipment ○ Ensure capability of the equipment ○ Ensure a suitable environment <p>Establish a calibration program, including:</p> <ul style="list-style-type: none"> ○ Calibrating equipment against nationally recognized standards ○ Establishing the frequency that each type of equipment is to be calibrated, and maintaining a calibration schedule ○ Defining and maintaining calibration procedures ○ Determining the status of equipment that is calibrated ○ Maintaining calibration records <p>Assess and record results of equipment found out of calibration</p> <p>Check test hardware and software to verify their validity for determining the acceptability of products</p> <p>Maintain records as evidence that test equipment is calibrated</p>

4.12	<i>Inspection and Test Status</i>	<p>Specify the conformance or nonconformance of a product, on completing a product inspection and identifying its test status</p> <p>Maintain the identification of the inspection and test status throughout production, installation, and servicing to ensure that only conforming product is used</p>
4.13	<i>Control of Nonconforming Product</i>	<p>Control nonconforming product to prevent its usage. A system or procedure to control nonconformance should include:</p> <ul style="list-style-type: none"> ○ Identification of the nonconforming product ○ Documentation, explaining the nonconformance of the product ○ Evaluation ○ Segregating the nonconforming product ○ Notification to the appropriate individual of the nonconforming product <p>Review and disposition the nonconforming product, according to documented procedures, according to documented procedures. The nonconforming product may be disposition as follows:</p> <ul style="list-style-type: none"> ○ Repaired or reworked, and reinspected per documented procedures ○ Accepted by the purchaser, without any changes ○ Regarded to a new specification ○ Scrapped
4.14	<i>Corrective and Preventive Action</i>	<p>Establish and document a process that addresses corrective and preventive actions. The procedure should address the handling of customer complaints</p> <p>Investigate causes of the problem that were identified to prevent a recurrence</p> <p>Ensure corrective and preventive action plans are defined, implemented, and effective</p> <p>Apply and record changes to procedures, where appropriate</p> <p>Address corrective and preventive actions in management reviews</p>

4.15	<i>Handling, Storage, Packaging, Preservation, and Delivery</i>	<p>Establish and document procedures that address handling, storage, packaging, preservation and delivery</p> <p>Prevent damage or deterioration when handling materials or finished product</p> <p>Provide storage that prevents damage or deterioration of product by:</p> <ul style="list-style-type: none"> ○ Providing a secure storage area ○ Establishing a procedure for approving the receipt of materials into the storage area and release of materials from the storage area ○ Periodically checking the condition of the stored product <p>Control packaging to ensure quality and conformance to requirements</p> <p>Preserve and segregate product</p> <p>Protect product quality until the product is delivered to its final destination</p>
4.16	<i>Control and Quality Records</i>	<p>Establish and document procedures for handling quality records. The records must be:</p> <ul style="list-style-type: none"> ○ Legible ○ Stored and maintained in an environment that prevents deterioration or damage ○ Readily accessible and retrievable <p>Establish and record retention times of records</p> <p>Records may be in hard copy or electronic form</p>
4.17	<i>Internal Quality Audits</i>	<p>Schedule and conduct internal quality audits to:</p> <ul style="list-style-type: none"> ○ Verify conformance to the Quality System and to ensure that requirements are met ○ Determine effectiveness of the Quality System <p>Internal audits must be:</p> <ul style="list-style-type: none"> ○ Scheduled regularly ○ Conducted per documented procedures <p>Audit results must be:</p> <ul style="list-style-type: none"> ○ Documented and reviewed with the preventive actions

4.18	<i>Training</i>	<p>Establish and document procedures to:</p> <ul style="list-style-type: none"> ○ Identify training needs ○ Provide training <p>Verify qualifications of personnel assigned to specific tasks</p> <p>Maintain training records</p>
4.19	<i>Servicing</i>	<p>When specified in a contract, establish and maintain procedures for:</p> <ul style="list-style-type: none"> ○ Performing services ○ Verifying and recording the results, and ensuring that the services that were provided met the requirements in the contract
4.20	<i>Statistical Technique</i>	<p>Establish procedures for identifying and controlling statistical techniques</p>

2.2 ISO 14001:1996

ISO 14001:1996 is also known as Environmental management systems specification standard. This section presents the brief study of ISO 14001 include the overall scope of Environmental Management System, ISO 14000, ISO 14001, ISO 14001 aim , benefits of ISO 14001, ISO 14001 structure, ISO 14001 model, ISO 14001 requirements, and the elements of ISO 14001 standard.

2.2.1 Environmental Management System (EMS)

Environmental management system, or the EMS is the backbone for the set of ISO 14001 standards. It is a set of management tools, principles, and procedures that an organization can use to help protect human health and the environment from the potential impacts of the organization's activities, products and services. As such, an EMS will also assist in maintaining and improving the quality of the environment [2].

2.2.2 ISO 14001:1996

In response to the growing concern about the environment, an international team of environmental experts was convened in 1993 under the auspices of the International Organization for Standardization (ISO) to develop a series of environmental management system standards known as the ISO 14000 series.

The ISO 14000 environmental management system specification standard was published in September 1996 organizations worldwide have been preparing to implement an EMS that conforms to the requirements of ISO 14001 since mid-1994.

Similar in structure to ISO 9000, ISO 14000 is based on the popular Deming model of management, with the key ingredients being plan-do-check-act. The ISO 14000 series are not a technical guideline. It defines requirements for a management system rather than providing a series of prescriptive requirements [14].

Below are the ISO 14000 environmental management standards:

(ISO 14000:1996 environmental management system specification standard) [8,15]

- ISO 14001 Environmental management system - Specification with Guidance for use
- ISO 14004 Environmental management system - General guidelines on principles, systems and supporting technique
- ISO 14010 Guidelines for environmental auditing - General principles
- ISO 14011 Guidelines for environmental auditing - Audit procedures – Auditing for environmental management system
- ISO 14012 Guidelines for environmental auditing - Qualification criteria for environmental auditors
- ISO 14020 General principles for all environmental labels and declarations
- ISO 14021 Environmental labels and declarations - Self-declaration environmental claims - Terms and definitions
- ISO 14022 Environmental labels and declarations - Self-declaration