STUDIES ON DEVELOPMENT OF LEAN AND SUSTAINABILITY INTEGRATED QUALITY MANAGEMENT SYSTEM AND ITS TEST IMPLEMENTATION IN INDIAN SMES

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By

MANMOHAN C M

Department of Mechanical Engineering

Government Engineering College, Thrissur-9

University of Calicut

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DEPARTMENT OF MECHANICAL ENGINEERING
GOVERNMENT ENGINEERING COLLEGE, THRISSUR
Engineering College P.O, Ramavarmapuram
Thrissur, Kerala, India, PINCODE - 680009
Phone No. 0487-2334144 Fax : 0487-2336124
Website : www.gectcr.ac.in

CERTIFICATE

This is to certify that the thesis entitled "**Studies on Development of Lean and Sustainability Integrated Quality Management system and its Test Implementation in Indian SMEs**" is the record of bonafide research work done by **Mr. Manmohan C M** under my supervision and guidance at Department of Mechanical Engineering, Govt. Engineering College, Thrissur in fulfilment of the requirements for the Degree of Doctor of Philosophy under the Faculty of Engineering, University of Calicut.

Thrissur-9
01.12.2020

Dr. Shalij P R
(Supervising Guide)
Professor
Production Engineering
Government Engineering College Thrissur

Certified that all corrections and suggestions by the examiners in their report of evaluation as communicated in the letter no a Letter No. 211279/RESEARCH-E-ASST-3/2021/Admn. Dated 25/08/2021, from the Director of. Research, University of Calicut are incorporated in the thesis.

Thrissur-9
18.~~10~~.2021
18.9.2021

Dr. Shalij P R
(Supervising Guide)
Professor
Production Engineering
Government Engineering College Thrissur

PROFESSOR AND HEAD
DEPT.OF MECHANICAL ENGINEERING
GOVT.ENGINEERING COLLEGE
THRISSUR-9

GOVT.ENGINEERING COLLEGE ★ THRISSUR-9 ★
Department of Mechanical Engineering

DECLARATION

I **Manmohan C M,** hereby declare that the thesis entitled "**Studies on Development of Lean and Sustainability Integrated Quality Management system and its Test Implementation in Indian SMEs**" is based on the original work done by me under the guidance of **Dr. Shalij P. R**, Professor, Department of Production Engineering, Govt. Engineering College, Thrissur for the award of Ph.D. under the University of Calicut. I further declare that this work has not been included in any other theses submitted previously for the award of any Degree, Diploma, Associate ship, Fellowship or other title for recognition.

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Manmohan C M

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ABSTRACT

A Quality Management System (QMS) is a set of policies, processes and procedures for planning, production, design, development, inspection, quality assurance of the products, optimum wastage during production and to maintain harmonious environment within and between organisations of similar type. It is envisaged that a quality system with Lean and Sustainable integrated management concepts as per ISO 9001:2015 can provide “responsible growth” to small and medium scale industries in our country.

An evaluation of the development of “Lean and Sustainability Integrated Quality Management System (LSIQMS)” and its implementation in Small and Medium Enterprises (SMEs) has been carried out in this study. The important findings from the study are the following.

i) It is possible to develop LSIQMS in all SMEs for positive growth of industries.

ii) Requirements for the implementation of the system identified ten constructs for all ISO 9001 certified SMEs.

iii) The case study conducted in two SMEs and the results obtained show that scope for implementation of LSIQMS in SMEs to achieve overall productivity exist.

iv) It is also noted here that one of the main limitations experienced in the case study was to generate favourable attitudes towards the implementation of the new system without disturbing the current production programme.

v) The case study also helped to develop more flexible strategies for quick implementation of LSIQMS not only in SMEs (ISO 9001) but even in the large industries of our country.

vi) The quantitative benefits due to the proposed system can be evaluated in important functional management areas of both the SMEs, taken for the case study.

Keywords: Integration, Lean, Sustainability, SMEs, LSIQMS, ISO 9001:2015

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CHAPTER 1

INTRODUCTION

1.1 INTRODUCTION

The globalized and competitive markets have necessitated more sophisticated strategies in order to survive in the field and satisfy the fast-changing needs of customers. The capability of industries to sustain long-term competitiveness relies on their performance. Improving the performance of manufacturing industries amid global challenges like speedy globalization, resource utilization, advanced technologies, increased competition, and protection of innovations is an important issue. The major global market challenges are improving the efficiency and competitiveness of the organisation. This led several organisations to follow new manufacturing methods and philosophies [1].

One of the strategies that improve competitiveness is quality. The quality of products and services refers to the degree to which they meet customer expectations. Customers demand products and services at lesser prices with better quality. Therefore, quality is referred to as a set of predetermined, well-organised actions that are to be applied by any organisation, irrespective of their size.

The quality management systems (QMS) equip organizations to meet the current quality and customer requirements, to communicate with the employees and to keep up with the latest technology. An effective quality management system not only creates value for an organisation and its stakeholders but also manages its exposure to risk. The ISO 9001 QMS standard helps the organization regularly upgrade its overall performance, meet the requirements of customer and other stakeholders, and to meet their future needs and expectations. According to definitions of ISO 9001, QMS can be understood as what the organization does to manage its processes so that its products or services meet the organization's objectives, thus satisfying the customer's quality requirements, or meeting environmental objectives. ISO 9001 quality management system can generate quality products at lesser costs thus satisfying more customers and providing better operational and performance [2].

Another manufacturing policy that emerged in recent years is Lean Manufacturing. The concept of lean manufacturing ensures the attainment of continuous improvement through the elimination of waste [3]. Even though lean manufacturing was known in the beginning of the twentieth century itself, only during the current millennium is it being deliberated and accepted widely by manufacturing units. The concept of lean manufacturing is preferred due to the achievement in cost reduction, quality improvement, flexibility, and quick results [4]. Lean manufacturing aims to create a new environment that expends in less human effort, reduced inventory and creation quality products at competitive rates [5-8].

Sustainable Manufacturing has become another major concept in manufacturing sectors. The definition of sustainability proposed in 1987 by the 'Brundtland Commission', was to meet the needs of the present requirements without compromising the future [9]. Also, sustainability is a new aspect of lean manufacturing [10]. Sustainable manufacturing processes lead to green practices and technologies in manufacturing by consuming least quantity of energy and non-renewable or harmful materials with minimum wastages and lesser emissions [11]. Through this concept, the organizations can continue to use existing practices and improve the general "triple-bottom-line performance" which includes social, environmental, and economical factors.

1.2 RESEARCH GAPS AND RELEVANCE OF THE PRESENT STUDY

More than ninety-five percent of the world's organisations are either small or medium-sized enterprises. Several countries around the globe look to small and medium enterprises (SMEs) to generate employment and economic development. SMEs are directly involved in quality development, through the execution of the ISO 9000 standards. This helps the SMEs to maintain global level standards.

Recently ISO 9001 has made a new revision to the standard ISO 9001: 2015 which was published in 2015. Based on this SMEs can easily adopt the new version. It is noted that the ISO 9001:2015 system describes its purpose as to establish, implement, operate, monitor, and to improve a Documented Management System, with quality performance. The requirements set by ISO 9001:2015 are also flexible, to all types of organizations.

ISO 9001:2015 QMS can be integrated with similar management systems such as Lean and Sustainability. The new ISO 9001:2015 QMS requirements encourage an organization to improve products and services to meet customer requirements and also to predict the future needs and expectations of the customers. Several research works are being conducted on the implementation of ISO 9001:2015 QMS and the evaluation of the effects of this QMS on the performance of the organisations.

The interaction of Lean and sustainability are addressed in the specialized research literature that highlights the advantages of the integrated application of the two concepts [10 – 14].

Manufacturing units across the country are having the benefits of implementing the lean manufacturing principles [15]. Lean principles bring both quality and productivity improvement, enhance organizational performance and its need to implement effective techniques like sustainable practices [16]. One of the major benefits of 'lean' is that it helps to improve the process as envisaged by the ISO 9001:2015 QMS. It is observed that the increased demand for Green Products and Services lead to the development of better environmental practices in SMEs [17 – 21].

The literature and practical endeavours do not provide sufficient guidelines to transform Sustainability concept into manufacturing strategies [22]. Hence many organisations of ISO 9001 quality standards, are reluctant to implement the Lean and Sustainability practices in the Quality system in their existing one.

1.3 SIGNIFICANCE OF THE STUDY

The present study is expected to devise programmes for improvement in organizational performance as well as in quality performance by meeting standards specified by the designer and the expectations of the customer. The study also brings momentum to the development of organisations by eliminating bottlenecks.

Improving performance is a never-ending process. The implementation of both lean and sustainability is intended to improve the operational and quality performance of the industry with a competitive priority. This study will provide methods for decision making in resource allocation and customer satisfaction.

The research questions posed for the study are

(i) What is the status of the adoption of Quality Management Systems and its advantages and disadvantages in improving productivity?

(ii) What are benefits of implementing lean and sustainability philosophies in ISO certified SMEs for overall improvement?

(iii) Does there exist a necessity of adopting an appropriate model for SMEs similar to ISO standards?

1.4 RESEARCH PROBLEM

The implementation of the ISO 9001:2015, with Lean Principles and Sustainable Manufacturing Methodologies is expected to produce positive results mainly in quality aspects. Most of the SMEs preferred the implementation of QMS for standardising their processes. However, SMEs may face difficulties in implementing 'Lean and Sustainability' in the absence of a proper system to be followed by the organisations.

Integration of Lean and Sustainable principles to Quality Management Systems may help organisations in reaping the benefits of Lean and Sustainable integrated manufacturing practices in friendly environments to optimise the use of resources efficiently by reducing unnecessary practices prevailing at present. It also aims to reduce the manufacturing cost and lead time resulting in increased Market Response and Customer Satisfaction.

Under this scenario, it is advisable to propose to implement Lean and Sustainability through ISO 9001:2015 standard-based QMS in ISO certified SMEs. Thus the problem for study is to ascertain the benefits of implementation of Lean and Sustainable Integrated Quality Management System in the ISO approved Small and Medium Enterprises.

1.5 OBJECTIVES OF THE STUDY

(i) To assess the adoption level of ISO 9001: 2015 quality management system standards in Small and Medium Enterprises (SMEs).

(ii) To identify the requirements of Lean and Sustainability principles, the level of practical use of Lean and Sustainable manufacturing practices in industries.

(iii) To develop a Lean and Sustainable integrated QMS model in SMEs.

(iv) To verify the feasibility of adoption of Lean and Sustainability integrated QMS model in the working of SMEs.

1.6 RESEARCH METHODOLOGY

The methodology adopted to pursue the research being reported in this thesis is illustrated in Figure 1.1. As shown, this research was commenced by identifying literature in the areas of Lean, Sustainability, SMEs and ISO 9001 certification. The constructs of Lean and Sustainability as identified by researchers are collected from literature. A questionnaire survey was also conducted to identify the level of implementation of the ISO 9001:2015 among the SMEs. The integration of Lean and Sustainability constructs into the ISO 9001:2015 QMS were carried out. The lean and Sustainability integrated Quality Management System was test implemented in two SMEs where questionnaire survey was conducted earlier. The suitability of the developed Lean and Sustainability Integrated Quality Management System and the possible benefits were collected from after test implementation. The responses were analysed using simulation and conclusions drawn from it.

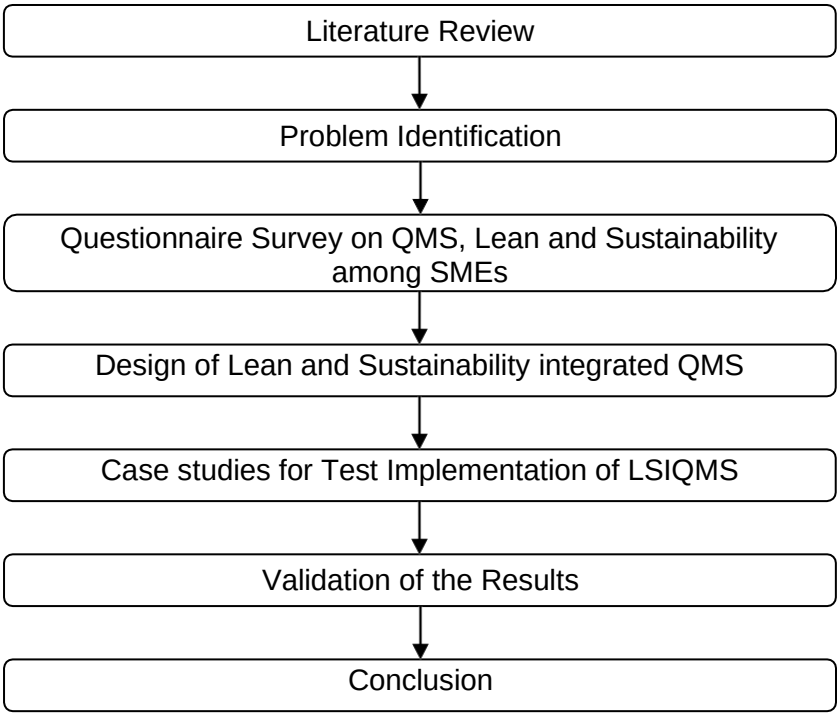

Figure 1.1. The research methodology adopted for conducting the study

1.7 SOURCE OF DATA AND METHOD OF COLLECTION OF DATA

The Data collection on the level of adoption of QMS and Lean and sustainability was made based on the implementation of a questionnaire based on constructs related to operational performance. This data was collected from the SMEs of the state of Kerala. The data collection on validation of the results was also carried out by questionnaire survey among the selected people.

1.8 TOOLS FOR ANALYSIS

(i) ISO guidelines were studied for evaluation plans in the study (observation method).

(ii) For case study data, a Likert scale was used as the basis for measuring the responses. Both Nominal and Ordinal scales were used.

(iii) Data was analysed using a paired “t” test (parametric test) and the method is validated by Mann-Whitney ‘U’ test. (Non-parametric test for attributes).

(iv) Analysis was done at $p < 0.01$ and also at $p < 0.05$ and inferences made accordingly in both levels.

(v) Monte-carlo simulation method was used for generating values of responses in a “stationary state” for analysis.

(vi) Frequency curves, Percentage Pie charts, Percentage bar charts, Schematic diagrams were used for presentation of quantitative/qualitative data of the case study.

1.9 CHAPTERISATION OF THE THESIS

This thesis comprises six chapters. Figure 1.2 provides the general idea of the structure of the thesis. The contents of each of these chapters are précised as follows.

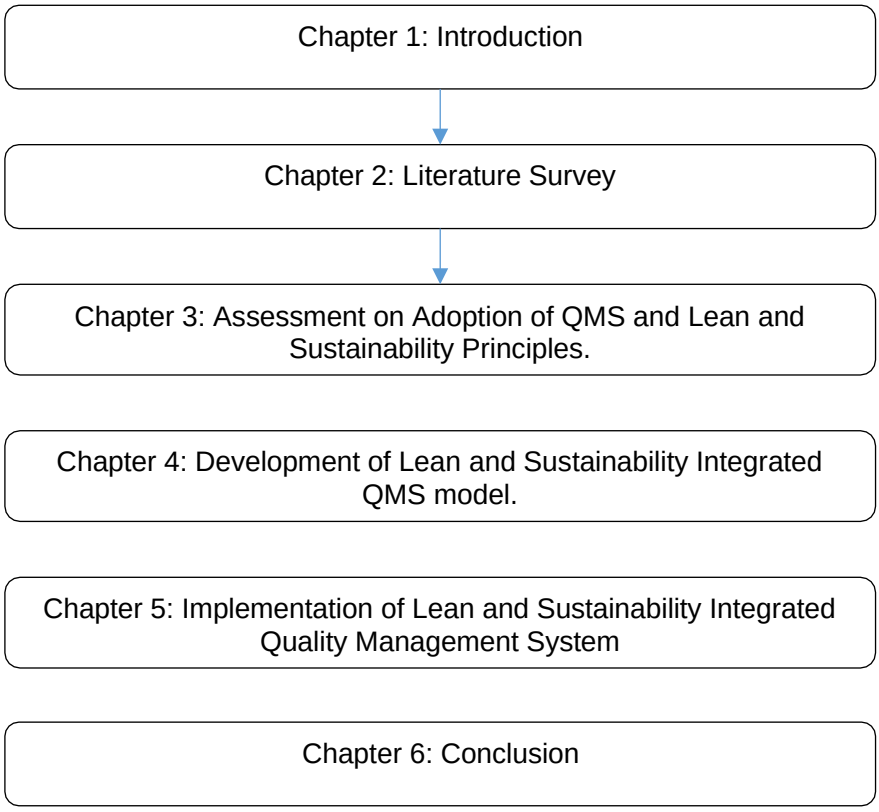

Figure 1.2 Structure of this thesis

Chapter 1 describes the introduction for conducting initial studies, which provides the guidelines for identifying the research problem, interpreting the research questions, establishing the research objectives and confirming the specific research

topic to study [23]. By doing an initial study, the problem area can be reduced and the problem statement can be easily defined [24]. A brief outline of the research methodology that was adopted and a description of the research design are discussed.

In the second chapter, an ample literature review is carried out, in the area identified as the research topic. Based on the literature review, the benefits of ISO 9001 certification are understood and the practical use of lean and sustainable manufacturing practices are identified. Then, the major constructs of Lean and Sustainability are found from the literature. The information from the literature review is then used to design an integrated quality management system supported by Lean and Sustainability for ISO 9001:2015 certified SMEs.

Questionnaire design, sample size, and data collection methods, tools and techniques and types of analysis are discussed in Chapter 3. The details of the survey conducted to study the benefits of Lean and Sustainability expected on implementation on various SMEs is mentioned. The results from the findings of the questionnaire survey are also discussed.

In chapter 4, the Lean and Sustainability Integrated Quality Management System (LSIQMS)model developed for this work is described in detail.

Chapter 5 presents the findings of the case study implementation in two ISO 9001:2015 certified SMEs are discussed. The analysis and inferences drawn from the findings are also discussed in this chapter.

Chapter 6 summarises the main conclusions of the research study. This chapter acknowledges some of its limitations and gives recommendations for further research.

1.10 CONCLUSION

This chapter presents the topic of research and the methodology adopted for research. The research problem and the objectives, as well as the orientation of the thesis are presented in this chapter.

CHAPTER 2

LITERATURE REVIEW

2.1 INTRODUCTION

The purpose of this chapter is to acquire knowledge on topics related to the one being researched. This chapter explains the literature relevant in finding research issues in the area of the Small and Medium Enterprises, Quality Management Systems, ISO Standards, Lean and Sustainability and its integration and organisational culture. The earlier literature related to these research topics has been gathered in this chapter. Further, this also continues with the theories, techniques and tools, and the research gap involved. The key finding of this systematic literature review has been utilised to evolve a roadmap for implementing Lean and Sustainability through ISO 9001:2015 standard-based QMS in SMEs.

2.2 LITERATURE SURVEY METHODOLOGY

Conducting a literature review involves collecting, evaluating and analyzing publications such as books, dissertations, conference papers and journal articles. The literature review reported in this chapter was carried out in five phases. The first phase is started by identifying scholarly writings such as peer-reviewed journals. The keywords "Lean manufacturing", "Lean manufacturing practices", “Lean constructs", “Sustainability", “Sustainability performances", “Sustainability constructs", Quality Management Systems", "ISO 9001", "ISO 9001:2015", “SMEs" and words in the title and, study have been used for the search. In this study, the following journal sites have been referred: Taylor & Francis, Emerald Insight; Elsevier; Science Direct, Springer and other academic journals. Hundreds of likely papers were collected whose abstracts and conclusions were initially examined.

In the first search, around 600 research papers were collected having the topic of Lean, Sustainability, ISO 9001:2015 and SMEs. This list was then reduced by searching using keywords that were related only to the exact research topic. Through this, around 520 papers for ‘Lean manufacturing’, about 340 papers on Sustainable manufacturing, 170 papers on ‘SMEs’, 250 papers for ‘Lean and Sustainability’, 200 for

'ISO 9001:2015' and 150 papers for 'Lean and ISO' were discerned. Papers collected from various conferences and journals were those published after the year 2000 and have been read thoroughly.

The methodology adopted for carrying out the review of the literature review is shown in Figure 2.1.

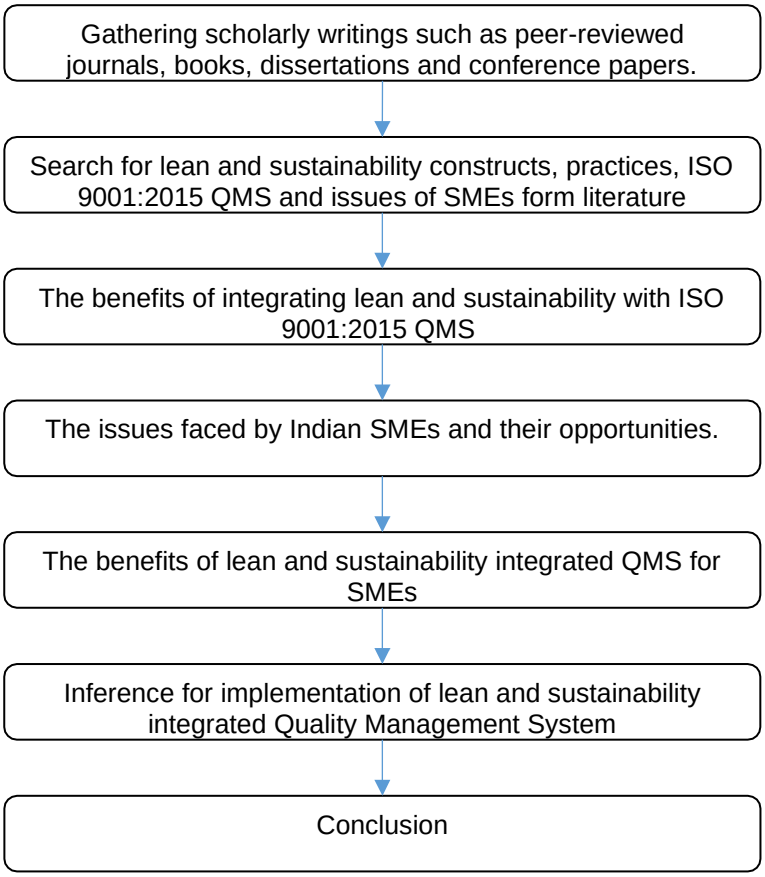

Figure 2.1. The methodology adopted for carrying out the literature review

From the review of literature, various constructs connected to lean and sustainability could be identified from the material and have been defined and suitably arranged for convenience. The applicability and relevance of these constructs were identified and evaluated through a screening process. The information gathered was then used to design the Lean and Sustainable integrated QMS for SMEs. During the last phase, the data is presented in a meaningful way to prepare the documented information for the implementation in two ISO 9001:2015 certified SMEs as case studies. The significant performance improvements with the implementation of Lean and Sustainability were reviewed.

2.3 SMALL MEDIUM ENTERPRISES

Today business has to satisfy the varying, multiple and conflicting requirements of the customer. In meeting Quality, Cost, Delivery and Services the large scale industries have kept pace with technological changes. Because of lack of capital, men, knowledge and other input resources small and medium scale sectors are facing major issues. The definition of SMEs are different in different countries. The definition of SMEs as applied in India is shown in Table 2.1.

*Table 2.1 - SME Definition in India**

TYPE	INVESTMENT	TURNOVER
Small Enterprises	Up to10 crore rupees	Up to50 crore rupees
Medium Enterprises	Up to50 crore rupees	Up to250 crore rupees

**The recent changes in the definition of SMEs.(26th June 2020).*

According Ministry of Micro, Small and Medium Enterprises, Government of India, there are 3,30,000 Small and 50,000 Medium Enterprises in India. The percentage distribution is shown in Figure 2.2.

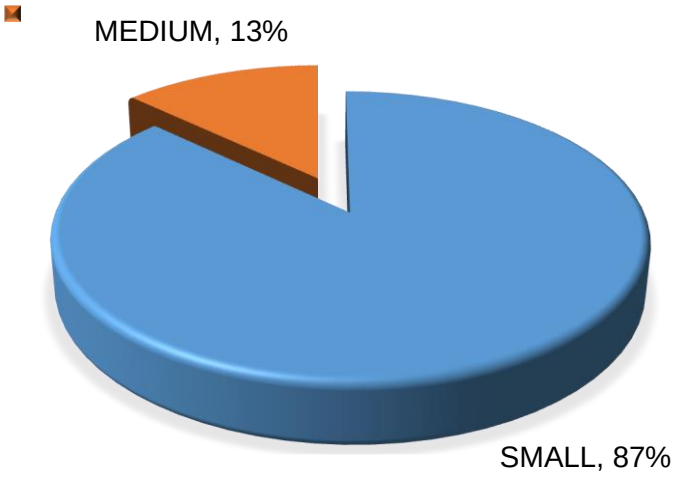

Figure 2.2. SME in India

The Small and Medium Enterprises (SME) sector has emerged as a highly vibrant and dynamic sector of the Indian economy over the last five decades. It contributes significantly in the economic and social development of the country by fostering entrepreneurship and generating the largest employment opportunities at comparatively lower capital cost, next only to agriculture. The SME sector has a lot of potential for growth.

The Importance of SMEs in the contributions to various indicators are summarised in Table 2.2.

*Table 2.2 - Importance of SMEs in India**

Category	Details
Number of SMEs in India	The number is estimated to be at 42.50 million, registered & unregistered together. A staggering 95% of the total industrial units in the country.
SME & Employment opportunity	Employs about 106 million, 40% of India's workforce. Next only to the agricultural sector.
Products	Produces more than 6000 products.
GDP Contribution	Currently around 6.11% of the manufacturing GDP and 24.63% of Service sector GDP.
SME Output	45% of the total Indian manufacturing output.
SME Exports	40% of the total exports.
SME Growth Rate	An average growth rate of over 10%.

Sources: msme.gov.in/KPMG/CRISIL/CII

According to Venkatesh and Muthiah [25], the role of SMEs in the industrial sector is rapidly growing and they may lead the industrial sector in the future. SMEs are a major contributing factor for creating job vacancy [26]. Even though SMEs are considered the backbone of the economy in any country, they are less cared for [27].

SMEs in India have achieved a good amount of steady growth over the last few years. The Indian industries in various sectors like manufacturing, food processing, textile and garments, chemicals, pharmaceuticals, agriculture and service sectors contribute to the socio economic growth of India. SMEs are faced with both opportunities and challenges. In India SMEs face a number of challenges. Due to these challenges

the growth of SMEs is very slow and is affecting the Indian Economy on a very large scale.

Even though various kinds of support are being given by the governments, the problems of SMEs have not been studied well or resolved. In order to utilize their full potential, this sector the entrepreneurs and the government must take necessary steps. For the economic well-being of our nation, the development of this sector is quite essential. Harvie et. al., mentioned that SMEs need to improve their competitiveness by focusing on international markets, better quality systems, and skills. They are forced to make new products with reduced price and improved quality and compelled to follow advanced technologies to survive in the market [28].

2.4 ISSUES AND CHALLENGES IN SMEs

The major challenges faced by the Indian SMEs include high cost of credit, inadequate marketing, lack of skilled labourers, lack of procurement of raw materials at a competitive price, inadequate infrastructure facilities, inadequate amounts of required technology and infrastructure. This is and are described furher below:

a. *The high cost of credit:*

Basu et al., having conducted an analysis of recent studies in this area by researchers [29 -32] indicated the difficulties of Indian SMEs being due to poor credit facilities. SMEs have usually depended on bank finance for their functioning. Timely access to banks, adequate availability of funds and high transaction costs are major issues faced by the SMEs.

b. *Inadequate Marketing and Branding:*

Inadequate market environment is another reason for SME failures [33].

c. *Lack of skilled labour:*

The SME sector faces a shortage of skilled labour formanufacturing, servicing, etc., even though India has very high human resources [34 - 36].

d. *Availability of raw materials at a competitive cost:*

Appropriate and timely availability of resources is an important aspect for the development of industries [37]. SMEs usually procure the raw materials locally at smaller quantities and at higher prices due to their financial constraints compared to larger industries.

e. *Inadequate infrastructure facilities:*

SMEs are usually located in industrial estates which were set up many years ago and most of them are functioning in rural areas in an unorganized manner. Lack of power/electricity infrastructures are major issues that affect the performance of manufacturing SMEs [38 - 40].

f. *Lack of availability of adequate and appropriate technology:*

SMEs still follow outdated technologies in production processes and marketing strategies.

Although these challenges are significant, SMEs still have opportunities to improve their performance. Industry associations in India have to a lot to contribute to help upgrade their technology, skills of the workers, and making these harmonious with the new requirements. The National Policy on Skill Development has already set a target for training 500 million employees by the year 2022.

SMEs have enough capability and possibilities to accelerate the industrial growth in our developing economy. National programmes like 'Make in India' plays a key role in encouraging SMEs to develop modern and efficient infrastructure, skill enhancement and to thus increase the manufacturing sector’s growth. SMEs in India have an important role in large manufacturing supply chain networks. As of late, the SME segment has reliably enlisted a higher development rate contrasted with manufacturing sectors [41].

2.5 QUALITY

The internationally accepted definition of quality as consensually agreed by 2005 (ISO 9000) is that: “Quality is the degree to which a set of inherent characteristics fulfils the requirements”. It is a set of well-organised actions that can be used in any organisation whether they are small, medium or large, regardless of manufacturers,

suppliers or customers. A perfect quality system will ensure that all of these organisations get standard products and services that satisfy their individual or collective needs. Customers expect more from the manufacturers and not just the level of quality 'intended' by them. They also expect this quality level to remain the same throughout their period of usage of the product. Customers are looking for those manufacturers who are capable of supplying quality products. So each manufacturing firm is focused on improving their quality standard on their product, which attains certain strategy of production management [42].

2.6 QUALITY MANAGEMENT SYSTEMS

Organisations have to develop and follow proper Quality Management Systems (QMS) to control and monitor the various stages of the manufacturing process. A Quality Management System develops a systematic approach for eliminating waste, selecting more effective and efficient processes, focusing on continuous improvement, and meeting the customer requirements more effectively. QMS consists of standards, guidelines and procedures that form a base for all procedures.

The implementation of the QMS is an important process for the organization because it can help the organization improve their performance. The organizations can achieve higher benefits by implementing the quality management system thus improving their organizational consistency in providing products and services [43]. QMS will improve the product quality, reduce the manufacturing cost, make the customers more delighted and achieve better financial position [44].

2.6.1 ISO 9001 STANDARD

ISO is the International Organisation for Standardisation and was first initiated in 1947 as a United Nations Agency and is a worldwide federation of the national standards organisations. It is a non-governmental organisation and the members of ISO can act as a link between the organisations and the customers. ISO 9000 is a common name given to a group of standards developed to provide a frame work around which a QMS can effectively be implemented. This makes it a standout amongst the most conspicuous declarations on the planet and is embraced in for all intents and purposes all enterprises from extensive, multi-site, multi-national federations to small, single district organizations.

ISO 9001 is a compilation of good business practices that have evolved over many years. Organizations following ISO 9001 based QMS have the ability to control the organisations operations, can consistently provide products and services that meet customer requirements. [45 - 47].

Figure 2.3 History of ISO 9001 (Bureau veritas 2015)

ISO9001, is among ISO's most well-known standard and is entrenched far and wide as a valuable Quality Management System standard. Many benefits can be achieved on implementing the ISO standard. ISO ensures continuous improvement for the organization. The systematic process approach of ISO system provides consistency. It allows the development better relationships between companies. For small and medium enterprises, the ISO certification helps to improve their communications, relationships, customer satisfaction and opens venues for more business opportunities across worldwide and increases revenue [48].

Following the rules of ISO, all ISO standards are required to undergo review and revision every five years, if needed. This helps ensure they remain useful tools for the marketplace and ISO 9001:2015 is the current version of the ISO 9001 standard. ISO 9001:2015 is the only quality management standard that can be applied to all organisations, irrespective of their size and nature, providing products and services.

ISO 9001 certification is appropriate for all sizes and sorts of organisations. It sets out the fundamental prerequisites for a useful and successful QMS which is, generally, a framework for limiting the danger and boosting opportunity. It can be utilized to concentrate on enhancing performance in a specific facility, plant or site. In any case, it is best when actualized all through a corporation at each level. [49].

ISO quality standard is followed by many manufacturing firms around the world. But the influence attains massive responses and has confusion in the enlargement of ISO certification in the business sector. The quality standard of product, short delivery, and service enhance the manufacturing firm's performance. The manufacturer produces products with ISO standards to improve the demand from customers and to enhance market strategy. The quality standard frameworks are developed in the manufacturing firms for enhancing the performance of larger firms rather than small manufacturing firms [50].

The organizations achieve excellence and improved customer satisfaction through the ISO 9001:2015 system certification. This standard is also intended to help the organisation to develop a stronger customer satisfaction and their support. The new version ISO 9001:2015 standard helps the organizations to upgrade their present Quality Management System by training employees, and developing the leadership team in Quality Management System.

The ten elements of the ISO 9001 standard are summarised in Table 2.3. and are based on the seven quality management principles.

Table 2.3 - Summary of the Ten Elements of ISO 9001 Standard

No	Elements	Description
E1	Improve Customer Focus	The primary objective of an organization's quality management system is to meet customer requirements. Organizations would understand both the current and future needs of the organization and adjust their programs and processes to deliver to these goals. It is also essential to implement programs and processes to measure customer satisfaction and act on the results.
E2	Enhance Leadership Involvement	Leaders are to inspire, encourage, and recognize people’s contributions, and also provide the required resources and training to improve quality management.
E3	Improve Engagement of People	Organizations are expected to improve employee communication, provide better clarity on job expectations, find ways to motivate employees to contribute to organizational success, capture regular feedback, and facilitate interaction with supervisors to help employees achieve their growth plan.

No	Elements	Description
E4	Adopt a Process-Based Approach	The new standard requires organizations to adopt a process-based approach to quality management that involves documenting and implementing processes, resources, methods, and controls to demonstrate compliance with ISO 9001:2015.
E5	Enable People and Process Improvement	Organizations should also focus on the improvement of products, processes, and management systems, to enable the growth of every individual in the organization.
E6	Facilitate Evidence-Based Decision-Making	Organizations are expected to revamp their quality management systems to support effective evidence gathering through observations, measurements, and tests, or by using any other suitable method like audits and inspections.
E7	Ensure Relationship Management	Identify and select the right suppliers, establish joint development plans, and determine improvement activities, including training. Scorecards and metrics are also important to measure supplier performance, recognize improvements, and benchmark achievements.
E8	Establish a Systematic Approach to Risk Management	Organizations need to support the creation and implementation of corrective actions as well as preventive actions.
E9	External Provision – Manage Third-Party Risks	They need to define processes and controls for suppliers, and then constantly monitor and compare supplier scores, to benchmark supplier performance.
E10	Enable Knowledge Management	Organizations need to identify whether they have the knowledge to carry out the activities necessary for compliance with ISO 9001:2015.

2.6.2 Benefits of ISO 9001 certification

The major benefits that can be achieved by implementing ISO 9001 certification are:

a. *Improved Customer Fulfilment:*

ISO 9001 technically tracks failures and solves them thus decreasing the number of client complaints.

b. *Global Gratitude:*

ISO 9001 is a globally accepted quality standard that can open new markets through attaining a continuous improvement in customer satisfaction.

c. *Employee Commitment:*

ISO 9001 QMS supports correspondence and expands assurance among the agents.

d. *Competitive Benefit:*

Standardization gives favourable position over competitors or the chance to contend on an indistinguishable premise from bigger organisations.

e. *Focus on Intentions and Customer Prospects:*

More noteworthy on meeting client necessities and inferred needs through constant incremental change.

2.6.3 ISO QMS as a Standardized Factor in SMEs

This new revision, ISO 9001: 2015 published in 2015, has been updated to support SMEs specifically. This means, ISO 9001:2015 QMS has been considered as a major component for driving the SMEs towards success in the global competition. SMEs should be able to achieve the benefits offered by ISO 9001 system standards. ISO hopes that it will enable SMEs to gain the maximum benefits through ISO 9001 certification, because SMEs are considered an essential tool of the world economy.

The quality system standards in SMEs are practised to improve the global competencies and market strategy of the manufacturing firms. SMEs assume a basic part in economies around globally [51]. The purpose of organisations implementing the ISO Quality Management System (ISO QMS) is to improve their operational and financial performance, and thus gaining an advantage in global competition. The ISO

9001 QMS can ensure improved products at reduced price, and can make sure that customers are more satisfied.

2.7 LEAN MANUFACTURING

Lean manufacturing (LM) is one of the advanced manufacturing approaches that play a major role in organizations' focus towards global market [52]. The term Lean was used for the first time in 1988, aimed at differentiating productivity between Japanese and Western industries. According to Shah and Ward, Lean production is "an system with the main objective of elimination of waste by concurrently reducing or minimizing various resources" [53 - 56]. The academic and the industrial communityies have mentioned Lean manufacturing as a golden standard for manufacturing enterprises. Lean is not restricted to manufacturing alone, its success has been so stunning that it can be adopted to the non-manufacturing area as well [57].

Nowadays, the implementation of Lean manufacturing, especially in manufacturing organizations has become very popular [58]. The process improvements that are required by the ISO 9001 QMS can be ensured the implementation of lean manufacturing. Today customers are looking for better quality products and competition is very high. So, to survive with other competitors and to satisfy the customers; implementation of concepts like Lean manufacturing has become a must. Even many of the major and large organisations have started using Lean manufacturing tools and techniques. The concept of Lean manufacturing focuses on optimized utilization of available resources to minimize the wastages [59] and creation of best-quality goods and services at the lowest price ensuring maximum customer delight [60], [61]. Lean has been considered to be empowering employees and it has been well-known for the well-being of employees [62]. Lean manufacturing enhances manufacturing processes by boosting up the employee's through job satisfaction [63].

The concept of Lean manufacturing has been widely accepted by many manufacturing enterprises. Holweg, M et al defined lean concept as an outcome of a dynamic learning process [64]. The attainment of a lean organization is a critical requirement. Liker and Wu et al. defined it as a manufacturing philosophy that focuses on delivering the highest quality product on time and at a lowest price to the customer [65]. S.S. Mahapatra et al. described lean manufacturing as a manufacturing strategy

for the organizational effectiveness by focusing on reduction of waste and productivity improvement through the application of various lean tools [66].

Present technological requirements and customer needs force the manufacturing enterprises to adopt philosophies like Lean manufacturing [67]. According to Eswaramoorthi et al., usage of lean practices in the manufacturing sector is still in the infant stage. Indian organizations have still not considered it as a quality performance improvement methodology [68]. So, more research is required in the area of implementation of Lean manufacturing philosophy in manufacturing industries [69]. Pius Achanga et al., identified several critical factors that determine the successful implementation of lean manufacturing within manufacturing SMEs. These critical factors are are classified as the most important for the successful adoption of lean manufacturing within SMEs [70].

Stamm et al found that Small and Medium Enterprises can also achieve most of the benefits of lean aspects that are enjoyed by larger enterprises. Benefits like reduced inventories, reduced wastage, reduced cost of manufacturing, enhanced quality and shorter lead times [71]. Small and Medium enterprises are considered to be more flexible, management and employees are usually very close and have open interactions, have more number of general-purpose machineries, have multi talented and multifunctional workers [72]. The literature also reports that the concept of lean manufacturing in many countries across the world, is not yet to be known. Many organizations in India have started implementing it recently.

2.7.1 LEAN WASTES

Anything that does not add value to the product can be defined as waste. The implementation of Lean manufacturing techniques requires that all the wastes are identified and eliminated from the System [73]. According to Micklewright, the Lean and Quality Managers should work together to understand and eliminate the waste involved in the systems. So merging of Lean practices with QMS will make both systems more effective than thinking separately [74].

Lean wastes are classified mainly into seven types namely excessive motion, defects, inventory, over-processing, overproduction, transportation, and waiting time. Reducing these wastes is the primary goal of a lean production process.

a. Defects

Defects are generally defined as errors on materials, products during the process of manufacturing or during transportation or handling inside the shop floor resulting in scrap or rework, as well as poor delivery performance [75]. It is ideal to attempt to anticipate absconds instead of identifying them. Executing Poka-yoke frameworks can offer assistance [76].

b. Inventory

Inventory is defined as storage of excess materials, parts or products under process and products that are waiting for customers [77].

c. Overproduction

Overproduction is nothing but producing parts that are no longer in demand.

d. Transportation

Transportation is defined as the excessive movement of people, information or rawmaterials and in process items resulting in wastage of time and cost [75].

e. Waiting Period

Waiting Period or waiting time is the time during which the machine and people are waiting for tools, information, facility and that may affect to long lead-times [75], [77].

f. Over-processing

Over-processing refers to using precision machine tool or highly skilled labour for machining low accuracy jobs. This consumes more cost unnecessarily.

g. Excessive motion

Motion costs money. All unnecessary motion results in non-value added time and increased cost. This not only includes raw materials but also employees and equipment [75].

2.7.2 LEAN TOOLS AND TECHNIQUES

The hard Lean practices, also called tools and techniques, are generally implemented to enhance the shop floor performance of an organization. A set of Lean tools and techniques can be used to control or minimize the waste. Lean manufacturing helps the organisation achieve waste at zero level. The commonly used Lean techniques are: just-in-time (JIT), kaizen, poka-yoke, kanban, 5S, single minute exchange of dies (SMED), Total Quality Management (TQM), Total Productive Maintenance (TPM), Value Stream Mapping (VSM),etc.

Just-In-Time: Just In Time (JIT) is said to be a set of principles, tools and techniques that allows the organisation to manufacture and deliver products in smaller quantities with lesser time, to meet the specific customer needs [65]. JIT is mainly used to meet the sudden changes in demands by modifying the internal manufacturing processes and to deliver right quantity and right material at right time.

Continuous Improvement: Continuous improvement helps the organisation to identify opportunities for improving the production processes. Continuous improvement is also known as Kaizen [75], [78], [79].

Poka-yoke: Poka-yoke is a Japanese quality assurance technique. It implies inadvertent errors (poka) may be avoided (yokeru) [80], [81]. It is also known as a mistake-proofing tool.

Kanban: Hobbs states kanban methodology is a material presentation method by providing simplification of material handling and inventory management. Materials are replenished with kanban or signal instead of placed in kits into manufacturing based on the production schedule [82].

5S Strategy: 5S is a primary tool of continuous improvement for waste reduction attempts. It is coined using five Japanese words Seiri, Seiton, Seiso, Seiketsu

and Shitsuke which mean sort, set-in-order, shine, standardize and sustain correspondingly. The primary objective of 5S is to eliminate wastes. Some forms of wastes are surplus raw materials, inventory, defects, scrap, defective tools and outdated holding and guiding equipment. Inside the worldview of Lean Manufacturing, 5S is a basic, yet intense, Japanese apparatus that is utilized with the end goal of sorting out a work environment in an exceptionally deliberate, clean, and safe way [83].

SMED: Setup time reduction is another technique to improve the production process by reducing the setup times of machines. The tool named SMED was first used at Toyota to reduce the setup time. The idea is to develop a method for speedy exchange of dies during a production of a variety of products or processes. As a result, they developed a system to reduce the die exchanging time from a few days to a few minutes.

Value Stream Mapping (VSM): A Value Stream Mapping (VSM) includes main processes starting from receiving order(s), coordinating with the required supplier(s), passing through production and inspection processes, and terminating by shipping to customer. The main goal of a VSM is to highlight various sources of all types of waste and to develop solutions to eliminate or reduce them [84], [845].

Total quality management (TQM): Total quality management (TQM) is system for continuous improvement that mainly focuses on requirements of customers. TQM make use of key components like; problem-solving, employee training and involvement, statistical methods and analysis, understanding the system inefficiencies and long-term goals. It is expected as a rule to the business by and large and to the small and medium enterprises (SMEs) specifically [86].

Total Productive Maintenance (TPM): Total Productive Maintenance (TPM) program consists of three main elements. The first one is preventive maintenance and it deals with planned periodical and regular maintenance of all the equipment. It avoids random check-ups. Whenever a variance or irregularity occurs in any equipment, it can be easily detected by following regular maintenance. This helps avoid major accidents/breakdowns of machines and components during production and improves the throughput of each equipment and machine. The second is corrective maintenance and it deals with the decisions to repair or buy new equipment. It is better to replace an

old part with a newer one if it breaks down all the time and incurs heavier maintenance cost. The new substitute part would increase the uptime and reliability of the machine. The third, maintenance prevention, involves the buying of a new machine. Machines with less maintenance are used to avoid the investment of a huge amount of money. Machines that are hard to maintain, like those which require very frequent lubrication and hard to tight up are to be avoided. This also creates fatigue on labour which would reduce labour productivity [87].

2.7.3 STEPS OF LEAN MANUFACTURING IMPLEMENTATION

Organizations need to recognize the types of waste and their causes. Lean manufacturing helps in identifying the causes of these wastes and various tools and techniques are used to reduce or eliminate these types of waste thus curing the problems permanently. Basic lean concepts are followed to identify the root causes. The next step is to identify the effects of the solution on the entire system. The final step is to find the solutions and test the solutions. Once these solutions are tested then they are implemented [88]. Lean manufacturing is a helpful tool for Indian industries to improve their quality, reduce cost and improve performance.

2.7.4 DRIVING FORCES FOR ADOPTION OF LEAN

The lean manufacturing implementation tries to make value for customer demand and eliminates waste in processes. Researchers have reported various benefits of the adoption of lean principles [85, 89, 91]. Proper implementation of lean manufacturing can lead to many improvements for the organization. Besides these improvements, lean manufacturing also has many hidden benefits.

The various improvements identified were, reduced, scrap, manufacturing cost, inventory and labour requirement customersatisfaction and product delivery werealso improved. Improvements inworker efficiency, productivity, profit, product quality, waste reduction and throughput were experienced [91].

Lean manufacturing has improved innovation, employee involvement, morale and participation, supplier reliability. Lead time and delivery were also improved and delays were restricted during production. Inventory of raw material wasreduced along with lead time. Work progress was reduced and the capital was increased. Overall

financial growth of enterprises was improved along with improved equipment availability, plant utilization and competitive position [72].

Lean thinking helps the managers to identify the inefficient components within the processes. Apart than these, many potential benefits to the organizations include reduced operating cost, a better understanding of customer requirements, improved quality processes, empowered multi-skilled people and team and increased level of understanding of all the processes within the value stream.

2.7.5 BARRIERS IN LEAN IMPLEMENTATION

Lean manufacturing offers so many benefits to the organisation. However, there are some barriers that oppose its implementation [92]. The major barriers are; lack of responsibility, financial constraints, lack of education and training, and fluctuating demand. The attitudes of the employees in the industry require a change in their culture to survive. To remain in the field of business has become a necessity for all industries, they should change their attitudes and reform their working practices with lean tools.

2.8 SUSTAINABLE MANUFACTURING

Manufacturing industries are focused on implementing the product with least resources [93]. One of the most recent definitions of sustainable manufacturing has been adopted here: "the ability to smartly use natural resources for manufacturing, by creating products and solutions that, thanks to new technology, regulatory measures and coherent social behaviours, can satisfy economic, environmental and social objectives, thus preserving the environment, while continuing to improve the quality of human life" [94]. One of the key points in the definition of the Sustainable Manufacturing introduced lies in the word “smartly” and the way researchers implement “smart” or “intelligent” mechanisms to achieve sustainable manufacturing [95], [96].

The Quality Management System is one of the feasible approaches to sustainability performance. Several studies examined how sustainability challenges would be addressed by Quality Management principles and practices [97]. Kuei and Lu proposed a conceptual framework of quality-driven sustainability management systems by integrating quality management principles into Ssustainability management. The study also found implementation steps for cross-enterprise and functional units

operations. Lean production practice is also positively related to environmental management [98].

2.9 CONSTRUCTS OF LEAN MANUFACTURING

Theory has a central role in research. Although theory should ideally guide research, theory and research are interrelated and are dependent on the other to make sense of a phenomenon. The primary issue of concern in the definition of research is that it must be used to collect and analyze new information or data that will enhance the body of knowledge [99]. The theory is a statement of a hypothesized relationship between and among variables involving a series of interrelated constructs, abstractions, concepts, variables, definition, and propositions that have been hypothesized or assumed with a systematic view of phenomena, to explain and predict the phenomena.*Constructs* are the building blocks of *theories*, helping to explain *how* and *why* certain phenomena behave the way that they do. In this chapter, we *(a)* identify the constructs; *(b)* define the theoretically and the meaning of constructs, and *(c)* validate the constructs.The studies from whose work these constructs of lean were collected are listed in Table 2.4.

During the conduct of the literature survey, it was found that numerous empirical researches have resulted in identifying the validated constructs of lean and sustainability. A construct is an abstract idea, underlying theme, or subject matter [100]. Understandably, many of the constructs were being repeated. After removing the repeating titles, a total of 81different constructs were identified.

Table 2.4 - Lean constructs reported in the literature

Sl.No.	***Lean Constructs***	***Author***
1	Employee engagement	A. Chamara De Alwis, (2017)
2	Resource utilization	A.Chandrasekar et al., (2014)
3	Waste Reduction	Al-Khafaji SKH, Al-Rufaifi HMR (2012)
4	Training employees	Amanda Sterling et al., (2012)
5	Customer involvement	Amelia Natasya et al., (2013)
6	Manufacturing Planning and Scheduling	Amelia Natasya Abdul Wahaba et al., (2013)
7	Supplier Relationship	Amelia Natasya Abdul Wahaba et al., (2013)

Sl.No.	*Lean Constructs*	*Author*
8	Product Development	Amelia Natasya Abdul Wahaba et al., 2013
9	Continuous Improvement	Arnaud Stimec et al., (2014)
10	Workforce Management	Avinash Panwar. et al., (2015)
11	Lead time reduction	Bharath R et al., (2014)
12	Employee Satisfaction	Chen et al., (2012)
13	Employee Involvement	Cottini et al., (2011)
14	Top management leadership	Cua et al., (2011)
15	Inventory reduction	Denish B.Modi et al., (2014)
16	Increase productivity	Dhruv Shah et al., (2018)
17	Problem-solving	Dr Eric Olsen et al., (2014)
18	Quick decision-making process	Effendi Bin Mohamad et al., (2017)
19	Customer satisfaction	Etna Moraira et al ., (2014)
20	Supplier Management	Foerstl et al., (2010)
21	New process/ technologies	G T Padmane et al, (2013)
22	Just in time	Gurinder Singh et al. (2014)
23	Customer Focus	Habidin and Yusof, (2012)
24	Quality Assurance	Habidin et al.,(2012)
25	Technology improvement	Hasan Hosseini-Nasab (2013)
26	Product development	Hilda Cecilia Martinez Leon et al., (2011)
27	Manufacturing Planning & Scheduling	Jalel Ben Hmida et al., (2014)
28	Setup time reduction	Janez Kušar et al ., (2010)
29	Performance measures	Jiri Tupa (2013)
30	Workplace Organization	Jordi Olivella et al., (2018)
31	Cellular manufacturing	Jostein Pettersen. et al., (2013)
32	Failure prevention	Jostein Pettersen. et al., (2013)
33	Layout adjustments	Jostein Pettersen. et al., (2013)
34	Workforce reduction	Jostein Pettersen. et al., (2013)
35	Employee involvement	Juan A. Marin-Garcia et al., (2015)
36	Design standardization	Julio Cesar Fin et al., (2017)
37	Workforce reduction	Kazi Mohammed Saidul Huq, et al., (2018)
38	Customer involvement	Kumar Naveen et al., (2013)
39	Performance measures	Leonardo Rivera et al., (2014)

Sl.No.	*Lean Constructs*	*Author*
40	Supplier Selection	Manoj Kshirsagar, 2014
41	Quality management	Martin Pech et al., (2018)
42	Just in time	Mohamed Baymont (2013)
43	Effective communication	Mohammed AlManei et al., (2017)
44	Management commitment	Mohammed AlManei et al., (2017)
45	Organisational culture	Mohammed AlManei et al., (2017)
46	Organisational readiness	Mohammed AlManei et al., (2017)
47	Adequate resources	Mohammed AlManei et al., (2017)
48	Delivery Dependability	Nigel Slack et al., (2015)
49	Organizational culture	Pedro Ernesto Pereira Paro et al ., (2017)
50	Cycle time reduction	Rahman, et al., (2010)
51	Resource reduction	Rakesh Kumar et al., (2012)
52	Time-based manufacturing	Reinaldo Guerreiro et al., (2013)
53	Supplier reliability	Riza Sulaimanb, 2013
54	Competitive skills	Roberto Giro Moore et al., (2013)
55	Creativity and innovation	Roger W. Hoerl et al., (2010)
56	Work standardization	Sahebagowda Malhar et al., (2017)
57	Manufacturing planning and control	Seyed Mojib Zahraee, (2016)
58	Customer relationship	Seyed Mojib Zahraee, (2016)
59	Human resources	Seyed Mojib Zahraee, (2016)
60	Supplier relationship	Seyed Mojib Zahraee, (2016)
61	Automation	Shafras Nafais, (2017)
62	Inventory reduction	Shahzad Nasim et al., (2016)
63	Efficient variety handling	Sharifi and Zhang (2001)
64	Standardisation	Sourabh Sharma (2014)
65	Production flow management	Teerasa et al., (2014)
66	Cost savings	Teerasa et al., (2014)
67	Customer Focus	Teerasa et al., (2014)
68	Processes development	Teerasa et al., (2014)
69	Product quality	Teerasa et al., (2014)
70	Supplier Management	Teerasa et al., (2014)
71	Workforce management	Teerasa et al., (2014)
72	Process management	Teerasa et al., (2014)
73	Customer Relationship	Tun-Chih Kou. et al., (2015)

Sl.No.	*Lean Constructs*	*Author*
74	Continuous improvement	U. Dombrowski and T. Mielke, (2014)
75	Setup time reduction	Urs K. Buehlmann et al., (2016)
76	Waste Reduction	Vikas Dave, (2015)
77	Defects control	Virender Chahal et al., (2017)
78	Processes satisfying customer needs	Womack, J., & Jones, D. (2003).
79	Effective communication	Worley and Doolen, (2016)
80	Standardise processes	Yang et al., (2010)
81	Organizational Support	Youngkeun Choi et al. (2019)

2.10 CONSTRUCTS OF SUSTAINABLE MANUFACTURING

Similarly,constructs of sustainability were also collected for the study. Many of the constructs were being repeated. After removing the repeating titles, a total of 61 different constructs were identified. The study from whose work these constructs of sustainability were collected are listed in Table 2.5. On further analysis, it was found that many of the constructs indicate similar requirements. This prompted a further grouping of the similar constructs and finally, 32 clusters were identified and are given in Table 4.2. These constructs were used during this research while designing the clauses of lean and are discussed in Chapter 4.

Table 2.5 - Sustainable constructs reported in the literature

Sl.No.	**Sustainability Constructs**	**Authors**
1	Competitive strategies	Abbas Nadim et al., (2010)
2	Communication	Anastasiia Moldavska et al., (2016)
3	Appraisal of sustainability	Andrew Stirling, (2007)
4	Working with local communities	Anne Behan et al., (2002)
5	Identify economic value	Arne Fagerström, (2016)
6	Strategic Financing	Arseculeratne, D. et al., (2014).
7	Energy Efficiency	Banjo Roxas et al., 2012
8	Partnership working	Barbara Gray et al., (2013)
9	Society Health and Safety Concerns	Boubaker Elleuch, (2018)
10	Design for Environment	Cassandra Telenko et al., 2016
11	Respect for staff	Daniel Maughan et al., (2016)

Sl.No.	Sustainability Constructs	Authors
12	Delineate actions to social well-being	Efrat Eizenberg et al., (2017)
13	Adaptability	Eva Wieners et al., (2015)
14	Profitability	Fernando G. Alberti et al.,(2017)
15	Natural environment	Figge, F. (2005)
16	Environment management	Figge, F. (2005),
17	Sustainability Plan	G. Seliger et al., (2008)
18	Promote behaviour change of customers	Gerrit Antonides, (2017)
19	Workers Health	Gerry Eijkemans, (2018)
20	Clear Vision	Hans van Weenen (2000)
21	Organizational Capacity	Hartmann, P., & Ibanez, V.A. (2006)
22	Performance	Heather Eilers et al., (20160
23	Top management beliefs	Hélène Cherrier et al., (2012)
24	Reconfiguration	Hongjia Ma et al., (2019)
25	Human rights	Inga T. Winkler et al., (2017)
26	Design for Environment	Jack Jeswiet et al., (2008)
27	Globalization	Jeffrey D. Sachs et al., (2005)
28	Identify the economic value	John C. V. Pezzey, (2002)
29	Environmental impacts	John Reap et al., (2008)
30	Social challenge	Jose Antonio Puppim de Oliveira, (2019)
31	Occupational safety and health	KassuJilcha et al., (2017)
32	Business issues	Ki-Hoon Lee (2009)
33	Political Support	Ki-Hoon Lee (2009)
34	Ecological challenge	Koo, C., (2014)
35	Leadership	Kwasi Dartey-Baah (2014)
36	Design for Environment	M. DeMendonça and T.E. Baxter, (2001)
37	Performance of the organization	Matjaz Maletic et al., (2015)
38	Protecting and Enhancing Biodiversity	Md. Mahmudul Alam, (2008)
39	Corporate social responsibility	Michael Fontaine (2013)
40	Societal commitment	Michael Fontaine (2013)
41	Innovation on different levels	Mike Dieterich, (2018)

Sl.No.	Sustainability Constructs	Authors
42	Pollution	Muhammad Imran Quresh et al., (2015)
43	Pollution	Naveen Kumar Arora, (2018)
44	Use of Resources	Naveen Kumar Arora, (2018)
45	Information sharing	Nina Shin et al., (2018)
46	Social well-being	Paul Dolan et al., (2007)
47	Measurement and reporting	Pitt, M., et al., (2009)
48	Education and training	Pitt, M., et al., 2009
49	Program Evaluation	Rajeshkumar, M. L. (2012).
50	Customer delight	Rashad Yazdanifard et al., (2011)
51	Customers	Rashad Yazdanifard et al., (2011)
52	Innovation	Richard Adams et al., (2015)
53	Economic Sustainability	Robert Nstavins et al., (2002)
54	Process Redesign	Sainio, L.M. et al., (2012)
55	Productivity	Sanjay Kumar et al., (2015)
56	Environmental Sustainability	Schalk Petrus Raath, (2008)
57	Social Sustainability	Suzanne Vallance et al., (2011)
58	Leadership	Timothy Galpin et al., (2012)
59	Promote the behaviour change of customers.	Tracy Bhamra et al, (2011)
60	Improved Project Delivery	V.K. Chawla, (2018)
61	Sustainable Consumption and Production	Wagner, M. et al., (2002)

2.11 LEAN APPROACH IN SUSTAINABLE MANUFACTURING

Industries familiar with lean, upgrade towards sustainability. Sustainable lean considers both worth and resource protection through initial pilots and salvos. It focuses on the long-term and concentrates on profitability, people and the planet. Waste reduction is a common advantage in lean and sustainable manufacturing. And other aspects of the environment, economy, and society is achieved through lean and sustainable manufacturing. Sustainability and lean works on the same principles, the only difference being the decision making criteria. Tools of lean and sustainable manufacturing are same as operator involvement, single minute exchange of die, kanban, kaizens, VSM, cellular manufacturing, Total Quality Management, total

productive maintenance and continual improvement through quality circles that monitoring the effect of environment's impact [101]. The lean-green manufacturing is still a relatively new practice, lacking a clear and structured research definition, and of significant evidence of successful cases in the practice [102], [103].

2.12 LEAN AND ISO 9001

ISO 9001 is nothing more than the compilation of good business practices that have evolved over many years. Lean is nothing more than getting rid of the waste in those practices, making them more effective and efficient, to reduce lead time. The hardest thing about Lean is sustaining improvement, while an ISO 9001 is all about controlling organisations operations. When used properly, an ISO 9001 based QMS should help to ensure discipline and adherence to Lean practices and improved processes.

Considering the similarities and differences between Lean and ISO we can find that both ISO QMS and Lean are complementary and mutually benefitting. Micklewright, [74] mentioned the importance of applying Lean management into ISO 9001 QMS. He wrote that ISO QMS and lean are both intended to improve the production processes of the organisations whereas, in real picture, they are two different systems and controlled by two different departments, resulting in wasted resources.

It should be noted that there is a positive and significant relationship between the implementation of Lean manufacturing tools and the effectiveness of QMS ISO 90001. This observation should be the basis for their integration [104], [105]. ISO must provide the umbrella, directing towards broader goals and paving the way for gross waste elimination through LM and hence improving the value stream.

2.13 INTEGRATION OF LEAN AND SUSTAINABILITY IN SMEs

Most of the Small and Medium Enterprises do not understood what Lean management is. They often do not adopt some of the major components of Lean management systems. There are several reasons for the lack of SMEs adoption of Lean practices. Major factors include the lack of top management commitment, limited financial resources and lack of perception. The present manufacturing organizations identified the importance of Lean manufacturing as a tool to eliminate wastes and to

improve the processes. They also concentrated on developing eco-friendly products and processes. So we can mention that Lean manufacturing concepts provide a pathway for attaining sustainable benefits [106 - 109].

Lean manufacturing, Quality Management System and Sustainable management system are clear initiatives to improve the effectiveness and efficiency of organizations. Martines-Jurado et al. indicated that the success of Lean transformation depends on the application of the tools and techniques and to ensure the sustainable benefit by focusing on the human resources and culture that sustains lean transformation [110]. SMEs need to adopt integrated lean and green manufacturing as this can address economic and environmental concerns together.Today the customer tastes are changing very fast and global competition is increasing day by day, so the Small Medium-size Enterprises need to understand and respond accordingly to meet the customer demands and global competition [109].

The relevance of SMEs in society is increasing because of their contribution to the national economy and social development. Considering the sustainable aspects, SMEs have stated implementing many new methodologies for their performance improvement [111].

2.14 LEAN AND SUSTAINABILITY INTEGRATION WITH QMS IN SMEs

Performance improvement is a continuous process and organizations are striving to achieve this along with improved customer satisfaction and goodwill, reduced price and to attain potential future business. Researchers, dealing with the effects of ISO 9001 and, Lean and Sustainability in organisations mentioned the lack of research studies in the field of SMEs and suggested the same. The SMEs constitute an important segment of the economy in terms of their contribution to the country's industrial production, exports, employment and creation of an entrepreneurial base. The small manufacturers are very sensitive in terms of production due to the cost, time and income of the firms. So the research will help these organisations deal with domestic customers and serve the local market to find a place in the international market by adopting integration standards.

SMEs have a golden opportunity to downsize their manufacturing cost and lead-time through the application of Lean Manufacturing technologies [112]. To

safeguard the interest of these manufacturers in the long run in the Indian economy, the manufacturers need to be competitive, simultaneously maintaining quality standards which would be possible by implementing lean techniques in their system. It is important to minimize and eliminate the wastes for better performance. The size of the SME is, however, an influential factor in Lean implementation [99]. Achanga et al. have identified the critical factors that will support the integration of lean manufacturing within SMEs Indeed, SMEs have distinctive characteristics when compared to big companies, and their pass criteria is specific.

Lean implementation has been accomplished through the implementation of a revised method, viz., Plan-Do-Check-Act (PDCA) cycles [109]. The proper implementation of lean in SMEs can lead to immense advantages like improved quality, reduced lead time and reduced cost. It is insisted that SMEs focus on parts that require less investment in lean implementation like a quality circle, 5S, preventive maintenance and worker involvement. Quality circle is taken into account and is favourable to SMEs thanks to its simplicity and traightforwardness, making it easily adoptable by all industries. Applying this conjointly may also help enhance worker participation and involvement within the organization. Researchers pointed out that the SMEs ought, to begin with, lean practices. The review of lean for sustainable integration framework provides a building framework for promoting companies to offer an integrated framework for embedding sustainable operational practices.

2.15 BENEFITS OF CHOOSING ISO 9001 QUALITY MANAGEMENT SYSTEM CERTIFIED SME FOR THE STUDY

The major benefits in choosing an ISO 9001 Quality Management System certified SME for the integration are the following. The organisation attaches great importance to quality and that has been checked regularly. This commitment increases the organisation’s confidence. Organisations that consider Quality Management to be an integral part of their business operations usually achieve higher operating efficiency than those that do not.

A certified ISO 9001 Quality Management System increases the quality of services and raises the staff’s awareness. A certified ISO 9001 Quality Management System ensures clear processes and (communication) structures, tasks, and responsibilities throughout the entire organisation. This increases the involvement of the

staff, which improves the working atmosphere and reduces the pressure of work. We can detect and identify problems in good time and quickly take steps to avoid the same mistakes in the future. An ISO 9001 certified Quality Management System gives a good image to the SME, increasing the level of competition and customer satisfaction.

2.16 RESEARCH GAP

The literature review shows that before 2012, most of the research presented that Lean and Sustainability benefits were particularly limited to environmental responsibility. Only post-2012 research has picked up momentum in the area of Lean and Sustainability. But most of the studies are focused on large enterprises. For a country like India, the SME sector is a big contributor to the GDP and hence research in the application of the concept of Lean and Sustainability in the context of SMEs is expected to be of significant value.

2.17 SUMMARY OF LITERATURE REVIEW

Implementing Lean and Sustainable practices is a revolution in manufacturing firms. This revolution will ensure economical, cultural and organizational benefits throughout its operations. This paper provides a detailed review of existing literature related to lean and sustainable management practices in manufacturing firms. This study is conducted to evaluate basic concepts and definition of Lean and Sustainability, quality management and quality management principles. Various research methodologies are proposed on Lean and Sustainable manufacturing. How ever the combinational implementation of Lean and Sustainable manufacturing is a novel concept and it has to be implemented to improve the manufacturing and quality performance of the production firms. This review illustrates the result of the analysis of objectives achieved through the elimination of waste and increased productivity. The sustainable practices also carry out operations that consequently result in improving the productivity and well-being of its employees. A predominant thing found from the review is that strong commitment from top management is vital.

Current literature suggests that the SMEs may differ from the larger companies in a number key characteristics, lead to greater strains. The resource limitations associated with SMEs highlights the importance of productivity. The lack of money may cause liquidity risk in the SMEs.

The reliance on a small number of customers necessitates that the SMEs have to ensure a high level of customer satisfaction and flexibility to respond quickly to changes in the market. The flatter structure of SMEs means that the employees have several job roles and more responsibility. Multi-skilled employees are therefore a necessity to these enterprises.

2.18 CONCLUSION

From the literature, it has been found that both Lean and Sustainable manufacturing systems aim for the improvement of performance in the enterprises. Based on the studies, it has also been found that a Lean and Sustainable integrated Quality Management System can create value for the customers by eliminating wastes throughout the process and by adopting eco-friendly and economically viable processes that are also safe for the employees in the organisation and to produce sustainable products that enhance social significance.

Researchers have suggested the integration of Lean and Sustainable practices into a single management system. The Lean and Sustainability integrated quality management and manufacturing concept is still a new idea, lacking evidence of practical implementation.

This chapter mainly highlights the review of the literature related to Lean manufacturing, Sustainability and ISO 9001. In this review, the development stages, the basic principles, relevance, and possibilities of integration of these concepts in the manufacturing locale are examined. The characteristics of SMEs are also explained. The importance of SMEs in the various economies in the world with their limitations is substantiated by this review. The review on performance studies of Lean and Sustainability implementation in manufacturing firms indicates that Lean – Green Approach is an effective method for the betterment of manufacturing firms.

CHAPTER 3

ASSESSMENT ON THE ADOPTION OF QMS AND LEAN AND SUSTAINABLITY PRINCIPLES

3.1 INTRODUCTION

Prior to designing a Quality Management System containing Lean and Sustainability constructs, a questionnaire survey on the adoption of ISO 9001:2015 Quality Management system and the principles of Lean and Sustainability was carried out. This chapter presents an overview of the methodological perspective and the analysis of the results of this survey.

3.2 QUESTIONNAIRE SURVEY

A questionnaire was used in this research work for obtaining information from a wide range of Small and Medium manufacturing Enterprises about lean and sustainability implementation benefits using the constructs identified from the literature. This data was then used to check how the implementation of lean and sustainability improve the manufacturing performance of these firms.

3.2.1 Questionnaire development

The questionnaire was developed based on the constructs identified from literature. Questions on the benefits of the ISO 9001:2015 Quality Management Systems and the perception of the Lean and Sustainability principles are included in the questionnaire. The questionnaire has two sections. The first section of the questionnaire consists of general information about the SME and that of the respondents. This section includes questions related to the name of the firm, size, level of investment and other relevant details of the firm.

The second section consists of questions aimed at examining how the industries benefited with their QMSs and their perception on the Lean and Sustainable

principles. A total of 26 questions were included in the questionnaire. The first seven questions are related to the benefits of the QMS. Questions 8 to 18 are on the Lean principles and the remaining questions were on the Sustainable principles.

Respondents were requested to rate their level of agreement to the questions which were identified as the measures of variables. The responses were collected on a five-point 'Likert scale' in which respondents were asked to identify their level of agreement to each question in five points namely (1) “Strongly disagree”; (2) “Disagree”; (3) “Neither agree nor disagree” (4) “Agree”; (5) “Strongly agree”. The advantage of the Likert Scale is that they do not anticipate a simple yes or no answer from the respondent, but prefer a degree of opinion, and even no opinion at all. With five choices to answer, Likert scale questions are used to collect information as well as a neutral answer option for respondents to select in case they don’t desire to answer from the ultimate choices.

In this work, a 'five-point Likert scale' was used due to the following reasons: Likert scales are perfect for encouraging the respondents to answer detailed questions about their firm. The respondents can understand the questionnaire and an easy answer to the questions. The results are easy to interpret. The literature suggests that the five-point scale appears to be less confusing and to increase the response rate. It decreases the respondents' bitterness level in contrast to the other types of the Likert scales [108]. The literature shows that the five-point Likert scale has been most recommended by the researchers that it would even reduce the frustration level of respondents and increase response rate and response quality and was commonly accepted and used by different previous researchers [113 - 115].

The Constructs used for preparing the questions are described here. The questionnaire finally used for this research work is shown in Appendix I.

3.2.2 PILOT STUDY

Preliminary studies were conducted prior to the actual data collection. Interviews were conducted with various experts from the field of academics and industries as a part of the preliminary studies. A sample questionnaire was developed for knowing the importance of the topic being researched, and also for initiating an operational communication support during the actual data collection.

Pre-testing of the survey questionnaire is very important before using it to collect data. Pretesting as well as the pilot survey can aid to spot the questions that don't make sence to participants, and those that might lead to biased answers. Pretesting was conducted by a panel of experts with academicians from reputed institutes, and experts from industries, possessing solid proficiency in the area of ISO, lean manufacturing and sustainability. After obtaining their feedback the revised questionnaire was developed. This revised questionnaire was then administered on respondents selected randomly.

The pilot study was carried out among 30 people, selected randomly from the targeted population as suggested by Perneger et al. [116]. Based on the pilot survey results, suggestions were incorporated and a revised questionnaire was prepared.

3.2.3 SOURCES OF DATA

In this research, both primary and secondary data were used. The primary data was collected by the researcher by conducting an organised, extensive questionnaire survey in the appropriate area. Secondary data sources were taken from published/ unpublished research works, research articles in the form of journals and data from websites.

3.2.4 SAMPLE DESIGN

For the present study, only the performances of SMEs were considered and, the sample design population includes firms under the classification of SMEs in India. Currently, there are around 42.5 million SMEs in India (*Source: msme.gov.in/KPMG/CRISIL/CII).* The database for sampling included the SMEs located in the industrial estates, various industrial clusters established by the Government as well as other industries situated outside this specified industrial sector.

3.2.5 Sampling technique

For choosing the sample from the selected population, sampling techniques are used. Feasible sample size is taken using appropriate sampling techniques [112], [117]. Random Sampling was used in this study for selecting the sample SMEs. However, Judgmental Sampling was applied for selecting the respondents from the above SMEs. Maximum care has been taken to choose the firms from different areas.

3.2.6 Sample Size

SMEs' population in India was estimated (2018) to be a large one (3.35 lakhs, Ministry of Micro, Small and Medium Enterprises, Government of India) in which case, as per standard sizes, the sample is around 384 (Krejcie and Morgan, 1970). The sample was split into two groups - ISO 9001:2015 certified SMEs and non-ISO 9001:2015 certified SMEs. Based on Random Sampling, 400 were identified and out of each SMEs, respondents were selected based on Judgmental Sampling. Out of these 400 respondents, 248 questionnaires were returned, which is a rate of response of 62.00 per cent. Through a rigorous follow-up, a total of 302 responses were obtained at a response rate of 75.05 per cent, which is considered to be more than the acceptable limit.

3.2.7 SCALE AND MEASUREMENT

The questionnaire is an instrument which consists of a series of questions to gather information from respondents. The development of the questionnaire was done very carefully since they are very essential to the survey. The length of the questionnaire has to kept short to get better responses. Hague et al. suggested some methods for preparing a questionnaire such as: prepare questions without prejudice, the questions should be simple to understand, questions should be very specific, unfamiliar words should be avoided, etc. Generally, multiple-choice close-ended questions are used, since they are easy and flexible, and helps the researcher obtain data that is clean and easy to analyse [118]. The close-ended questions are easy to understand compared to open ended questions. The respondents don't have to spend much time on reading the questions [119]. Therefore, the questionnaire of this study contains only simple and close-ended questions and respondents are instructed to choose from multiple answers.

3.2.8 THE RELIABILITY AND VALIDITY OF THE SCALE

Reliability and validity jointly called the "psychometric properties" of measurement scales, are the criterion for measuring the adequacy and accuracy of the questionnaire in scientific research for getting meaningful results. So these are considered as the instruments to assess the features of good measurement [120]. The facts of the variables being measured will be reflected through this, so performing validity and reliability is an important concern [121].

Reliability means dependability; by which we may obtain the same answer when we use a tool to measure something repeatedly. It is the degree to which the chosen research method produces consistent and steady results. It is a statistical measure to check the accuracy of the survey instrument [122].

Internal consistency is just to compare the answers to see if they all agree with each other. This is important because a good internal consistency means respondents will answer the same for each question. Internal consistency is measured by Cronbach's alpha, *α* (or coefficient alpha), which was developed by Lee Cronbach in 1951. Cronbach's alpha tests are used to check whether the multiple-question Likert scale surveys are reliable. Cronbach's alpha will help test whether the test will accurately measure the variable of interest. In other words, it is a statistic that reviews the uniformity of the measuring scale. Usually, reliability coefficients of 0.70 or more are considered to be good. When the measurements are taken repeatedly, the test must regularly give the same results under the same conditions [123]. To be specific, reliability shows how consistent the findings are done based on the method of data collection and analysis [112]. Moreover, reliability is considered to be more important when the questionnaire is a Likert-scale because many variables are used to test the theory.

Calculation of Cronbach's alpha is done by correlating the score for each scale item with the total score for each observation and then comparing that to the variance for all individual item scores with the help of a statistical package. Using the correlations between these items, the estimate can be done. The value of Cronbach's alpha coefficient usually varies from 0 to 1. In certain other studies it is mentioned that this value should be minimum of 0.6 and any value more than 0.7 represents a internal reliability of high level [123] and Nunnally [124] based on studies suggested that 0.7 as alpha value is acceptable. So many other studies have used to test reliability suggest the value from 0.6 to 0.96 [125], [126]. In this research, the value of Cronbach's alpha coefficient is set as 0.6 being the minimum acceptable level. The internal consistency analysis was performed using SPSS version 21.0, to evaluate the reliability feature of the instrument [127].

Validity means the accuracy of an instrument that measures what it is intended to measure. It is an indication of how sound the research is. In this study, content validity and then the construct validity were conducted for evaluating the

measurement instruments. Content validity implies the degree to which the content of the survey matches the content domain connected with the construct. At the same time, construct validity is used to determine how well a test measures what it is supposed to measure. A relevant and valid information which is free from systematic errors will be produced by this test. In other words, validity is concerned with the test being competent to testing what it was designed for [123]. Zikmund and Babin stated that, validity means the measurement accuracy that truly represents a concept [124].

The data set was also tested for normality of distribution. It was found that in some cases, the coefficient of skewness was as tilted as 1.33. To avoid the risk of dealing with asymmetrical data, before the data analysis, the questionnaire was tested for reliability by calculating the Cronbach's Alpha as shown in Table 3.1.

Table 3.1- Reliability of the questionnaire (Cronbach's Alpha)

Sl. No.	***Category***	***Number of questions***	***Cronbach's Alpha***
1	Entire questionnaire	26	0.964
2	Quality system	7	0.958
3	Lean benefits	11	0.941
4	Sustainability benefits	8	0.896

The internal consistency will be high when the Cronbach's alpha is nearer to 1. The alpha value above 0.80 is deliberated to be good when it is between 0.70 and 0.80 it is considered as acceptable, while it is below 0.70 is considered to be poor (Sekaran and Bougie 2009). In this study the Cronbach's alpha for factor 1 was 0.964, for factor 2 it was 0.958, for factor 3 it was 0.941, and for factor 4 it was 0.896; all were greater than 0.80 and the internal consistency calculation used for this particular study, and is hence, observed to be good for the measurement of the system. Also, the Cronbach's Alpha was well above the standard of 0.80, the questionnaire was considered as reliable. This was within the recommended range by Hair et al [123].

3.2.9 TOOLS AND TECHNIQUES

The statistical software package of the IBM Statistical Package for Social Science version 21.0 (SPSS 21.0) was used for the data analysis. Initially, the collected

data was carefully entered into the data view of SPSS. The preliminary statistical requirements such as normality and linearity were tested using this package. The descriptive analysis, Mann - Whitney test, paired t-test etc., are the major statistical analysis performed in this work. Further, the case study method is used to validate the results. Two case studies were conducted in selected organisations representing different types of industries across the state of Kerala.

3.2.10 DESIGN OF DOCUMENTED INFORMATION

One of the results of the literature review discussed in chapter two revealed that the synergy of designing the essential documented information can be realised through the integration of lean and sustainability constructs with different clauses of ISO 9001:2015 QMS. By this result, lean and sustainability integrated QMS model was designed by appending the respective constructs of lean and sustainability with the clauses of ISO 9001:2015 standard. The details of this exercise are described in chapter 5. The steps to be followed to test implementation studies of the model are enumerated in this chapter.

3.3 DATA ANALYSIS, INTERPRETATION AND DISCUSSION

The data collected using the questionnaire is analysed for arriving at the outcomes. The details of the outcomes and the method adopted for analysis are presented in the following sections.

3.3.1 Descriptive analysis

Descriptive characteristics of the entire set of 302 sample SMEs that have an ISO 9001:2015 certification is shown in Table 3.2. A pie chart is also used to represent the statistics.A total of six items were tested. Number of participants per group was shown. The breakdown of each ia as follows:

Table 3.2 - Descriptive characteristics of the entire sample

Gender	*Male*	*Female*	*Total*	
	269	33	302	
	89%	*11%*	*100%*	
ISO 9001:2015	*Yes*	*No*	*Total*	
	170	132	302	
	56%	*44%*	*100%*	
SME Existence	*<5 years*	*5-10 years*	*>10 years*	*Total*
	15	154	133	302
	5%	*51%*	*44%*	*100%*
Turnover	*5-50 crores*	*50-150 crores*	*150-250 crores*	*Total*
	97	97	108	302
	32%	*32%*	*36%*	*100%*
Workforce	*<25*	*25-50*	*>50*	*Total*
	145	48	109	302
	48%	*17%*	*36%*	*100%*

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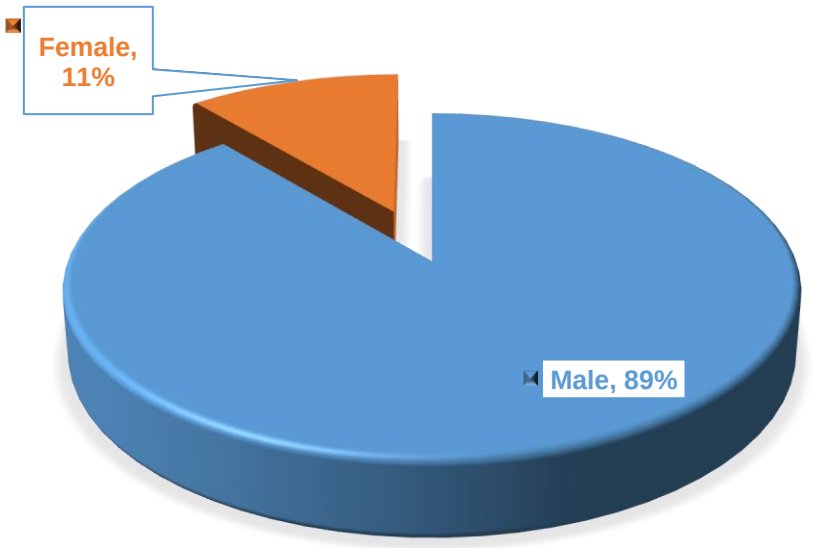

Figure 3.1 A pie chart showing the genders of all respondents.

Eighty-nine percentage of the total were male, and this could be because they are manufacturing firms.

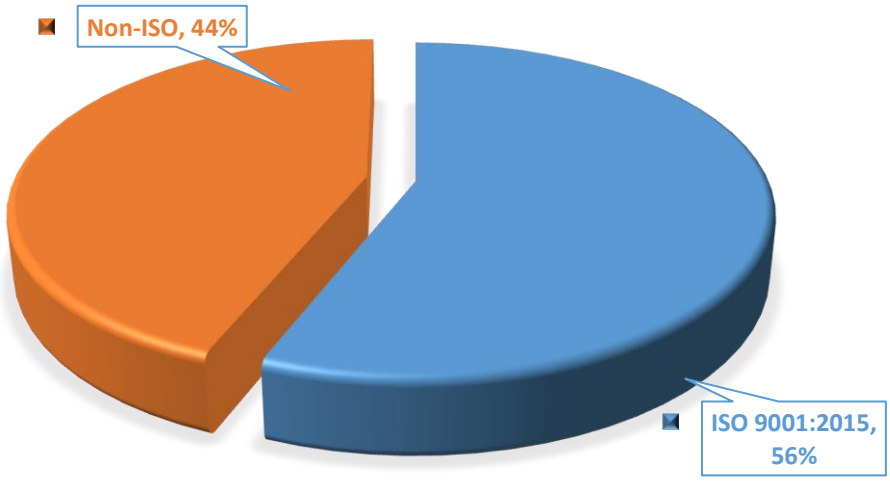

Figure 3.2. Pie chart showing the availability of ISO certification.

Out of these 302 SMEs, 170 SMEs were ISO 9001:2015 certified and the remaining were non-ISO certified firms.

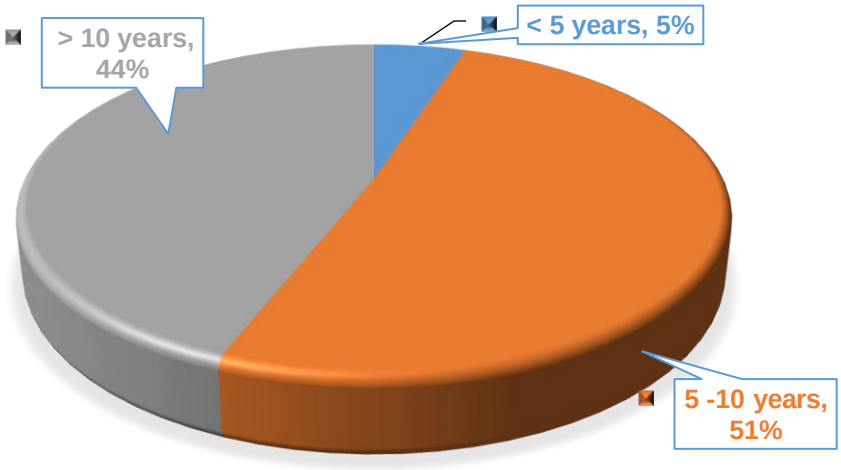

Figure 3.3. A pie chart showing the existence of SME.

While considering the existance of the SMEs, 44% were in business for more than 10 years, 51% of the SMEs were in business for a period between 5-10 years, and the remaining less than 5 years. So most of the firms were in business for more than 5 years.

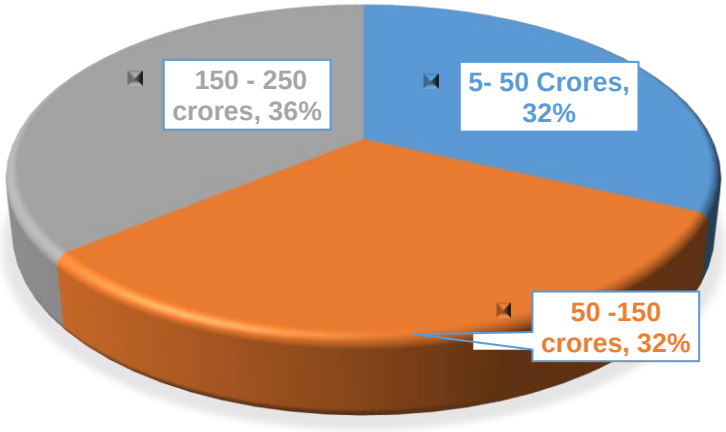

Figure 3.4. A pie chart showing the turnover of SMEs.

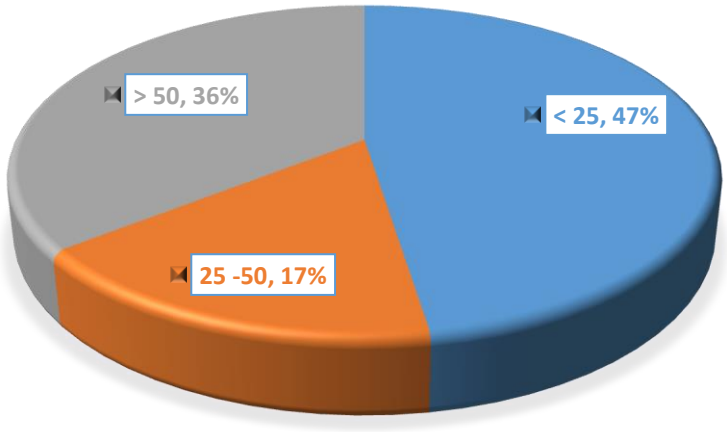

Figure 3.5. A pie chart showing the strength of workforce.

32% of them had turnovers from Rs. 5 to Rs.50 crores, another 32% have it in the range of Rs.50-150 crores and another 36% have their turnover between Rs.150 and 250crores. 48% of the SMEs employ a workforce <25, 17% in the range of 25-50 and 36% > 50.

3.3.2 Implementation level of principles of ISO 9001:2015 standard

Table 3.3 summarises the responses on the implementation level of each principle of ISO 9001:2015 standard in the respective organisations. The analysis was

established based on the grading of the respondents for each item mentioned in the questionnaire.

Table 3.3 - SME Implementation Levels of ISO 9001 Principles (N=302)

No.	QMS- ISO 9001 Principles	Mean	SD	LoI
1	Customer focus	4.27	0.62	4
2	Continuous improvement	4.15	0.67	4
3	Engagement of People	4.09	0.73	4
4	Evidence-based Decision Making	4.02	0.74	4
5	Process approach	3.96	0.81	4
6	Leadership	3.85	0.74	4
7	Relationship Management	3.74	0.80	4
Average		4.01	0.72	

Notes: Level of Implementation (LoI): 5 = fully implemented (mean = 4.51 - 5.00), 4 = three fourth implemented (3.51 - 4.50), 3 = half-implemented (2.51 - 3.50), 2 = one fourth implemented (1.51 - 2.50), 1 = yet to be implemented (< 1.50).

From Table 3.3, it is visible that all the seven major principles of ISO 9001:2015 were at a level of implementation value of “4”, which means a state of being “only three fourth implemented”. The mean scores for the level of implementation were observed as being between 3.74 to 4.27. The standard deviations (SDs) calculated were found to be very small, indicating that the data points were very close to the means. These results also show that the mean is an appropriate statistical metric to sum up the current implementation level of ISO 9001:2015 principles.

3.3.3 Perceived benefits of implementation of Lean Principles

Table 3.4 shows the responses related to the knowledge of the benefits of lean practices on the performance levels in various SMEs. The findings of the survey indicate that all the 11 variables were expected to improve the performance of their own companies. The standard deviations calculated were very small, showing that the mean is also an appropriate summary statistic.

Table 3.4 - Performance benefits on implementation of lean practices (N=302)

No	Lean benefits	Mean	SD	Std. error
1	A better understanding of customer needs	4.67	0.71	0.0409
2	Reduction of wastages	4.55	0.67	0.0386
3	Increased product quality	4.24	0.62	0.0357
4	Manufacturing lead time reduction	4.02	0.81	0.0466
5	Increase in productivity and profit	3.98	0.65	0.0374
6	Inventory reduction	3.74	0.72	0.0414
7	Usage of new process technologies	3.71	0.79	0.0455
8	Employees get motivated	3.68	0.65	0.0374
9	Increased process knowledge	3.57	0.74	0.0426
10	Improvement in organisation culture	3.54	0.66	0.0380
11	Growth for the industry	3.56	0.61	0.0351

3.3. 4 Perceived benefits of implementation of Sustainability Principles

Table 3.5 represents the responses concerning the knowledge of the benefits of Sustainable practices on the performance levels in various SMEs. The findings of the survey indicate that all 8 variables were expected to improve the performance of a large percentage of companies.

Table 3.5 - Performance benefits on implementation of sustainable practices (N=302)

No.	**Sustainability benefits**	**Mean**	**SD**	**Std. error**
1	More delighted customer	4.51	0.71	0.0409
2	Environment friendly	4.35	0.74	0.0426
3	Increase in profit	4.02	0.58	0.0334
4	Employee safety	3.95	0.69	0.0397
5	Energy efficient	3.88	0.77	0.0443
6	Respect for staff	3.56	0.82	0.0472
7	More competitive	3.41	0.94	0.0541
8	Increase in organisational capacity	3.21	0.61	0.0351

From Table 3.4 and 3.5, it can be observed that Lean and Sustainability parameters have a significant impact on both manufacturing performance and quality improvement.

3.4 CONCLUSION

This study revealed that ISO 9001 certified organisations perform well in the documentation and maintaining procedures. They are well aware of the benefits of ISO 9001 QMS and are enjoying the benefits of ISO certification.

The findings from the study indicated that the SMEs are well aware of the benefits of Lean implementation. Benefits like improved customer satisfaction increased profit reduced wastage and lead-time are key factors that make them ready for lean implementation.

The benefits on implementing sustainable practices are also understood by the SMEs. The major benefits as perceived by SMEs that are driving them to go for sustainability implementation are delighted customer, reduced energy utilisation, environment-friendly design and manufacturing, improved employee safety, reduced cost of manufacturing and technological development

The results indicated that non-ISO certified SMEs can go in for the ISO 9001:2015 certification since the difference in their processes and outcomes are very small. Moreover, the certified SMEs proved to be better on lean-sustainability as well. Thus the study emphasised the need to give priority for implementing the ISO system certification in all SMEs for better growth.The analysis justifies the need for development of the Lean and Sustainability Integrated QMS for implementation for Indian SMEs.

CHAPTER 4

DEVELOPMENT OF LEAN AND SUSTAINABLE INTEGRATED QMS MODEL

4.1. INTRODUCTION

This chapter describes the development of a Lean and Sustainable integrated QMS model for ISO 9001:2015 certified manufacturing enterprises. The model was developed after studying various literature and discussion with experts. The lessons learned by conducting the questionnaire survey in various SMEs in India were also used to develop this model. The model has been designed in such a way that it can be viewed as a separate document. The steps adopted for the conceptualization and design of a QMS and the various constructs identified from the literature are described in this chapter.

4.2. INTEGRATED QUALITY MANAGEMENT SYSTEM

Lean and Sustainable Integrated QMS (LSIQMS) comprises instructions and approaches that shape a base for all documented information. A well organized Lean and Sustainability integrated QMS was developed to improve the organization's performance, meet the customer requirements, and for many other long-term achievements.

4.3. METHODOLOGY ADOPTED FOR THE DEVELOPMENT OF QMS

The methodology adopted for designing the Lean and Sustainability integrated QMS is shown in figure 4.1. As indicated, the constructs of Lean and Sustainability as proposed and verified through exploratory research conducted by various studies are collected from literature. These constructs are grouped into clusters according to their similarity and application. The clusters are then analyzed, by identifying proper definitions for improving clarity.

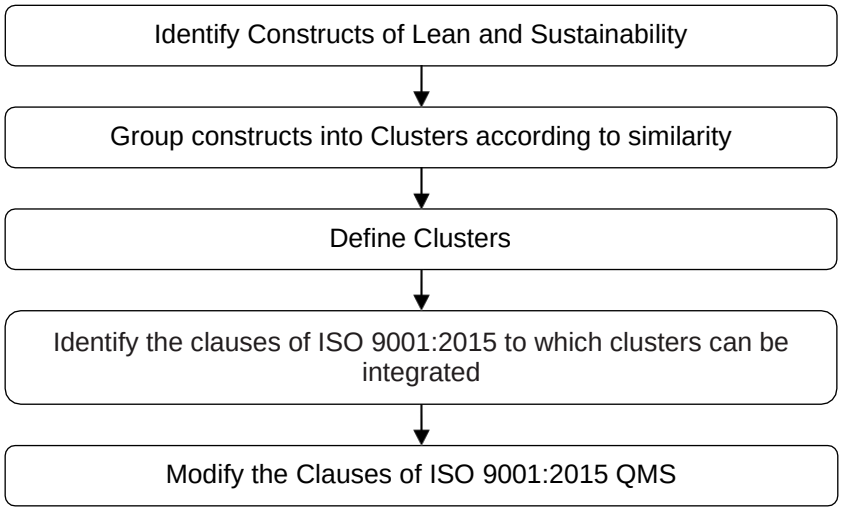

Figure 4.1 : Procedrure Adopted for Developing the QMS

These clauses of ISO 9001:2015, into which these clusters can be incorporated, is identified by carefully examining the same. The clauses are then modified to incorporate the clusters, as requirements of the Lean and Sustainability Integrated QMS. The process details are explained in the subsequent sections.

4.3.1. Grouping of constructs into Clusters

The constructs of Lean manufacturing, identified during the literature survey are grouped into clusters. A total of 33 clusters have been identified, by grouping. The clusters and the constructs included in the groups are shown in Table 4.1.

Table 4.1 - Lean clusters and constructs

Serial No.	Title of the cluster	Constructs *(Numbers shown in the brackets indicate the serial numbers of the construct listed in Table 2.4)*
1	Automation	Automation (61)
2	Continuous improvement	Continuous improvement (9), (74)
3	Cost savings	Cost savings (66)
4	Creativity and innovation	Creativity and innovation (55)
5	Customer Focus	Customer Focus(23), (68), Customer involvement (5), (38), Customer Relationship (58), (73).
6	Customer satisfaction	Customer satisfaction (19).
7	Delivery Dependability	Delivery Dependability (48)
8	Effective communication	Effective communication (43), (79)
9	Efficient variety handling	Efficient variety handling (63)

Serial No.	Title of the cluster	Constructs *(Numbers shown in the brackets indicate the serial numbers of the construct listed in Table 2.4)*
10	Employee engagement	Employee engagement (1)
11	Employee involvement	Employee involvement (13), (35),
12	Human resources	Human resources (59)
13	Inventory reduction	Inventory reduction (15), (62)
14	Just in time	Just in time (22), (42), Cellular manufacturing (31)
15	Reduction in lead time	Lead time reduction (11), Cycle time reduction (50), Increase productivity (16), Setup time reduction (28), (75)
16	Manufacturing planning and control	Manufacturing planning and control (57)
17	Manufacturing planning and scheduling	Manufacturing Planning & Scheduling (6), (27)
18	Organizational culture	Organisational culture (45), (49), Management commitment (44), Top management leadership (14), Organizational Support (81), Organisational readiness (46)
19	Performance measures	Performance measures (29), (39)
20	Problem-solving	Problem-solving (17), Quick decision-making process (18)
21	Processes development	Processes development (68), Process Management (72), Processes satisfying customer needs (78), New process/ technologies (21)
22	Product Development	Product Development (8), (26),
23	Quality Assurance	Quality Assurance (24)
24	Quality management	Quality management (41)
25	Resources utilization	Resources utilization (2), Resource reduction (51)
26	Standardisation	Standardisation (64), Standardise processes (80), Design standardization (36), Work standardization (56)
27	Supplier Management	Supplier Management (20), (70), Supplier relationship (7), (60), Supplier Selection (40), Supplier reliability (53)
28	Technology improvement	Hasan Hosseini-Nasab (25)
29	Time-based manufacturing	Time-based manufacturing (52)
30	Training of employees	Training employees (4) Competitive skills (54)
31	Waste Reduction	Waste Reduction (3), (76), Defects control(77), Failure prevention (32)
32	Workforce Management	Workforce Management (10), (71), Workforce reduction (34), (37), Adequate resources (47)
33	Workplace Organization	Workplace Organization (30), Layout adjustments (33)

The constructs of sustainability are also grouped into clusters. A total of 30 clusters are identified through this process. The details of the clusters and the constructs included in the group are shown in Table 4.2.

Table 4.2 - Sustainability clusters and constructs

Serial No.	Title of the cluster	Constructs (Numbers shown in the brackets indicate the serial numbers of the studies listed in Table 2.2)
1	Adaptability	Adaptability (13)
2	Appraisal of sustainability	Appraisal of sustainability (3)
3	Clear Vision	Clear Vision (20), Business issues (30), Partnership working (8), Top management beliefs (23).
4	Communication	Communication (2)
5	Competitive strategies	Competitive strategies(1), Improved Project Delivery (60), Innovation on different levels (41)
6	Corporate social responsibility	Corporate social responsibility (39)
7	Customer delight	Customer delight (50), Customers (51), Promote behaviour change of customers (18), (59)
8	Design for Environment	Design for Environment (10, 26, 36)
9	Economic Sustainability	Economic Sustainability (53), Ecological challenge (34), Identify the economic value (5), Strategic Financing (6)
10	Education and training	Education and Training (48)
11	Energy Efficiency	Energy Efficiency (7)
12	Environment management	Environment management (16), Natural environment (15)
13	Environmental impacts	Environmental impacts (29), Pollution (42, 43), Protecting and Enhancing Biodiversity (38).
14	Environmental Sustainability	Environmental Sustainability (56)
15	Globalization	Globalization (67)
16	Human rights	Human rights (25)
17	Information sharing	Information sharing (45)
18	Innovation	Innovation (52)
19	Leadership	Leadership (58), Measurement, and reporting (47), Organizational Capacity (21).
20	Measurement and reporting	Measurement and reporting (47)
21	Organizational Capacity	Organizational Capacity (21)
22	Performance	Performance (22)
23	Process Redesign	Process Redesign (54)
24	Productivity	Productivity (55)

Serial No.	Title of the cluster	Constructs (Numbers shown in the brackets indicate the serial numbers of the studies listed in Table 2.2)
25	Profitability	Profitability (14)
26	Program Evaluation	Program Evaluation (49)
27	Reconfiguration	Reconfiguration (24)
28	Respect for staff	Respect for staff (11)
29	Social Sustainability	Social Sustainability (57), Delineate actions to social well-being (12), Political Support (33), Social challenge (30), Societal commitment (39), Society Health and Safety Concerns (9), Workers Health (19), Working with local communities (4), Occupational safety and health (31), Social well-being (46).
30	Sustainability Plan	Sustainability Plan (17), Sustainable Consumption and Production (61).
31	Use of Resources	Use of Resources (43)

Descriptions are proposed for these clusters. These descriptions are formulated in such a way that the adoption and implementation of the same in the Quality Management Systems would be easy and understandable. The definitions of the lean and sustainability clusters are written down in Table 4.3 and 4.4 respectively.

Table 4.3 - Descriptions of Lean Clusters

Sl.No.	Lean Constructs	Description
1	Automation	Automation is an important technique to remove the waste. It is the use of self-controlled machinery, equipment, etc. to make a manufacturing system or process to operate with little or no human involvement. This eliminates scrap and reworks — one of the important aspects of lean manufacturing.
2	Continuous improvement	Continuous improvement is a process for identifying chances for improvement that can help an organization to meet its goals for increasing profits, reducing costs, improving the quality, to improve human safety and overall performance.
3	Cost-saving	Cost saving is the process of maintaining costs at competitive figures, to ensure sustainable growth.
4	Creativity and innovation	Creativity is a function of knowledge, curiosity, imagination, and evaluation. Innovation is focused on increasing efficiency and minimizing wastages in the product development stage onwards. Both increase productivity, profitability, and customer retention.

Sl.No.	Lean Constructs	Description
5	Customer focus	Customer Focus is understanding the needs of a customer. A proper Customer focus in an organization results in increased customer satisfaction by identifying as well as anticipating their requirements, adding value, and avoiding manufacturing defects and wastes.
6	Customer satisfaction	Customer satisfaction is defined as the feeling of pleasure which results from comparing a product's perceived performance or outcome against his/her expectations.
7	Delivery dependability	Delivery dependability is the confidence that delivery promises will be met.
8	Effective Communication	Communication is an important process that helps successful implementation of lean manufacturing practices. The communication process should be clear and concise. It is required to make sure the recipient understands the intention of the communication as well as the content.
9	Efficient variety handling	Efficient variety handling relies on increasing interest for high-variety, low-volume production environments.
10	Employee engagement	Employee engagement is to perform well and keep motivated. Two major factors for employee engagement are the job satisfaction and job contribution. Engaged employees are less likely to quit the job and tend to express a higher state of happiness.
11	Employee involvement	Employee involvement is the degree to which employees in an organisation are involved in various activities. By personally participating in activities, employees attain new knowledge and obtain a sense of accomplishment by solving various problems.
12	Human resources	Human resources are the personnel with necessary skills. Proper human resources management is very important in a lean manufacturing system.
13	Inventory reduction	Inventory reduction is a system practiced by manufacturers looking to reduce as much waste as they possibly can from their manufacturing processes.
14	Just in time	Just in time (JIT) manufacturing system focused on minimising material process time in production systems, as well as the response times from external providers and to end-users. JIT manufacturing helps organizations to increase their productivity and reducing manufacturing costs.
15	Lead time reduction	The manufacturing lead time is the total time taken by a job to finish. Shortest manufacturing lead time is always preferred.

Sl.No.	Lean Constructs	Description
16	Manufacturing planning and control	Manufacturing planning and control environments are the interaction of the customer demand, manufacturing process and product produced. Although they are not dependent on each other, these three elements are closely related.
17	Manufacturing planning and scheduling	Manufacturing planning is the process of arranging, controlling, and developing work in the manufacturing process. Scheduling is the process of allocating the machinery and equipment, manpower, process plan, and materials.
18	Organisation Culture	Organisation culture is a major aspect of the integration of lean because the culture determines whether a process can be accepted or rejected. Organizational culture affects each activity of lean process.
19	Performance measures	Performance measurement is defined as the process of measuring the efficiency, effectiveness, and capacity of a process or a system. Performance measurement tools and techniques are essential for an enterprise for its continuous improvement.
20	Problem-solving	Lean problem solving is a method of addressing the organizational issues that are identified by continuous improvement and the use of proven, problem-solving methodologies.
21	Process development	Process development is used to establish, implement, or improve an existing manufacturing process by eliminating wasteful practices.
22	Product development	Lean product development is a method used for developing products that focus on waste reduction, delivery speeding up, and thus focusing on increased profit and customer value.
23	Quality Assurance	Quality Assurance provides the best possible process and product. Lean manufacturing ensures customer satisfaction and cost reduction.
24	Quality management	Quality management and lean are a potent combination; neither can be very effective without the other. Quality management helps the organization design and manufacture a product the customer wants.
25	Resource utilisation	Resource utilization is the process of efficient and effective use of an organization's resources. The resources can include human resources, financial resources, material, machinery, manufacturing methods.
26	Standardisation	Standardisation is the process of executing and developing technical standards. Standardized work is one of the most powerful tools of lean.

Sl.No.	Lean Constructs	Description
27	Supplier management	Supplier management is the process of effective management of the suppliers. This includes the business strategy, supplier categorization, supplier improvement, and supplier evaluation.
28	Technology improvement	Technology is defined as the usage of tools, techniques, systems, or methods of organization, to solve a problem. Technology improvement is considered to be one of the important aspects of lean manufacturing.
29	Time-based manufacturing	Time-based manufacturing is a manufacturing system that focuses on fast response to changing customer needs. The SME can design, produce, and deliver products at a faster rate to meet specific customer requirements.
30	Training of employees	Training is the process of improving the skills, capabilities, and knowledge of employees for carrying out the works. The training process develops the thinking ability of employees and leads to quality improvement of the products.
31	Waste Reduction	Lean focus on the elimination of waste and thus increasing the value of products manufactured thus to provide value to customers.
32	Workforce Management	It is a process that optimizes the productivity of its employees. A motivated workforce is the major component of a successful lean process.
33	Workplace organisation	An efficiently organized workplace is the most fundamental step to guaranteeing organizational productivity. In lean manufacturing, workplace organisation is a method to organize the working environment into a safe, efficient, ergonomic with clear visual management.

Table 4.4- Descriptions of Sustainability Clusters

Sl.No.	Sustainability Constructs	Description
1	Adaptability	Adaptability is defined as the extension of the utility (service) of products.
2	Appraisal of sustainability	Sustainability appraisal is an assessment of the economic, environmental, and social effects of a product from the beginning from the preparation of the process to allow decisions to be made that accord with sustainable development.
3	Clear Vision on sustainability	A clear vision of sustainability means how the industry works within the larger social and natural world. Its emphasis on environmental, social, and economic prosperity in every decision made by the organization and to think about how it takes hold at the operating level.

Sl.No.	Sustainability Constructs	Description
4	Communication	In any organisation, to plan and develop sustainability, organisations must develop better communication both internally and externally.
5	Competitive strategies	It is difficult for a manufacturing enterprise to survive without competitive strategies. It is a long-term action plan of an organisation which is directed to gain a competitive advantage over its competitors after evaluating their strengths, weaknesses. A sustainable competitive strategy is an element of business that provides a meaningful advantage over both existing and future competitors.
6	Corporate social responsibility	Corporate social responsibility (CSR) is, how an organisation connects their values and behaviour with the expectations and needs of customers, employees, investors, suppliers, special interest groups, and society as a whole.
7	Customer delight	Customer delight is providing above or beyond meeting customer expectations and providing a positive experience with the brand, products, or services. It's about building authentic relationships between the customer and the organisation that stand the test of time.
8	Design for Environment	Design for Environment is a method to minimize or eliminate environmental impacts when the product is manufactured. This design process is meant for conserving and reusing the earth's scare resources; where energy and material consumption are optimized, minimal waste is generated and waste resulted from any process was used as the raw materials.
9	Economic Sustainability	Economic sustainability refers to the practices that support long-term economic growth without negatively impacting the various aspects of the community.
10	Education and training	Education and training improve the knowledge and sensitivity of environmental problems; and motivate for active participation in environmental protection and improvement; acquisition and development of skills to identify and solve environmental problems; make them participate in all social groups and business players.
11	Energy Efficiency	Energy efficiency means bringing down energy usage along with a decreasing amount of carbon emissions. It is a cost-effective method that addresses challenges on sustainable economic growth.
12	Environment management	The environment management system consists of organisational structure, planning, activities, responsibilities, practices, procedures, processes, and resources for developing, implementing, attaining, reviewing, and maintaining environmental policy.

Sl.No.	Sustainability Constructs	Description
13	Environmental impacts	An environmental impact is defined as thedamagethat is caused to the environment, resulting from the process followed, the products made, or services provided by the firm. For manufacturing industries, sustainable manufacturing is the only way to decrease the environmental impact of their products.
14	Environmental Sustainability	Environmental sustainability means whether environmental resources will be protected and maintained for future generations. The creation of manufactured products is being carried out through economically-sound processes that minimize negative environmental impacts while conserving energy and nature.
15	Globalization	Globalisation is the process by which an organization develops international influence or start operating on an international scale.
16	Human rights	It is stated that everyone is 'entitled to participate in, contribute to, and enjoy economic, social, cultural, and political development, in which all human rights and fundamental freedoms can be fully realized.'
17	Information sharing	Information sharing is an activity through which ideas, opinions, facts and documents are transferred from an individual (or group) to other people.
18	Innovation	Innovation is a key driver for sustainability. Technological innovation is a "must" for sustainable development. The successful introduction of new technology is always a matter of socio-technical change.
19	Leadership	Leadership is a process by which an executive can direct, control and influence the behaviour and work of others towards the achievement of specific goals of the organisation.
20	Measurement and reporting	Measuring sustainability can help the organisation with assessing progress, encouraging participation, assessing trade-offs, meeting or anticipating new requirements, rewarding excellence, and conferring benefits.
21	Occupational safety and health	Occupational health and safety integrate the efforts of management, administration, employees, and health care professionals in an active, evolving program that promotes a culture of safety in the workplace. This can improve the employability of workers, through redesigning the workplace, creating a healthy and safe work environment, training, work assessments, medical diagnosis, health screening, and assessment of all functional capacities.

Sl.No.	Sustainability Constructs	Description
22	Organizational Capacity	Organizational capacity is the ability of organizations to perform functions effectively, efficiently, and sustainably.
23	Performance	Sustainable performance can be achieved through the harmonisation of financial, environmental, and social objectives while manufacturing a product.
24	Process Redesign	Process Redesign is an approach to ensure that a particular set of interconnected activities are *performed correctly most efficiently and effective*ly. Process Redesign improves customer satisfaction, reduce manufacturing costs, improve performance and quality.
25	Productivity	Productivity is the measure of the combined efficiency of employees, machines, and other devices and equipment, the nature of raw material inputs, the performance of the management, efficiency of the whole production system.
26	Profitability	Sustainable profitability for a business means that an organisation provides a service or product that is both profitable and environmentally friendly.
27	Program Evaluation	Program evaluations are systematic studies conducted periodically to assess program performance. Program evaluation improves delivery mechanisms by increasing efficiency and decreasing costs. It serves to identify program strengths and weaknesses to improve the program.
28	Reconfiguration	The reconfigurable manufacturing system is a philosophy or strategy to achieve agility in manufacturing systems.
29	Respect for staff	Employees who feel respected are more grateful for and loyal to their firms.
30	Social Sustainability	Social sustainability can be defined as specifying and managing both positive and negative impacts of systems, processes, organisations and activities on people and social life. The objective of social sustainability is to secure people's socio-cultural and spiritual needs equitably.
31	Sustainability Plan	The sustainability plan is a document, that describes how your project will be sustained in the long term. This document focuses on community sustainability, financial sustainability, and organizational sustainability.
32	Use of Resources	Sustainable resource use occurs when our rate of consumption can continue forever without damaging the environment. Resources determine the economy of an area. With the judicious utilization of these resources, a country can sustain the resources for future generations.

4.4. LEAN AND SUSTAINABLE INTEGRATED Q M S

The clauses of ISO 9001:2015 which specifies the requirements of QMS are clause numbers 5 to 10 with Clause 4 providing an overview of the considerations regarding the context of the organisation and how to apply the process approach. These considerations are addressed in detail in Clauses 5 to 10. Clauses 1 to 3 set the stage for the requirements.

Clauses of ISO 9001:2015 into which these clusters can be appended are identified by assessing its suitability. Individual clusters are added into all sub-clauses to which the same is relevant and applicable. The clusters of constructs appended to sub-clauses and the resulting contents in a sub-clause of clauses 4 to 10 are described in the subsequent sections.

4.4.1. Modification of Clause 4: Context of the Organization

There are 4 sub-clauses in clause 4 of the ISO 9001:2015 based QMS. As stated before, these sub-clauses provide an overview of considerations regarding the context of the organisation and how to apply the process approach.

The constructs of Lean and Sustainability that were identified as suitable for incorporating the sub-clauses of clause 4 are shown in Table 4.5. These constructs were appended with suitable sentences in the sub-clauses 4.1 to 4.4. As a sample, the original and amended sub-clause 4.2, understanding the needs and expectations of interested parties is shown in Table 4.6. Corporate social responsibility, a sustainable construct is added to this clause. .

Table 4.5: Sub-Clauses Clause 4 of ISO 9001:2015 QMS and the Lean and Sustainability Constructs added

Clause	Description	Lean Constructs	Sustainable Constructs
4.1	Understanding the organization and its circumstances		Environmental impacts
4.2	Understanding the needs and expectations of interested parties		Corporate social responsibility
4.4	Quality management system	Quality Assurance, Quality Management	

As seen from the modifications shown in Table 4.6, the requirement for establishing a process for identifying and fulfilling responsibilities towards society is added in this sections. Such a requirement was not mandatory in the ISO 9001:2015 Quality Management System.

Table 4.6 - Descriptions of ISO and LSIQMS for clause 4.3

Clause	ISO 9001:2015 Clauses	Description in the ISO 9001: 2015 QMS	Descriptions in the corresponding clause of Lean and Sustainable Integrated QMS
4.2	**Understanding the needs and expectations of interested parties**	Due to their effect or potential effect on the organization's ability to consistently provide products and services and services that meet customer and applicable statutory and regulatory **customer requirements**, the organization shall determine: a) the interested parties that are relevant to the quality management system; b) the requirements of these interested parties that are relevant to the quality management system. The organization shall monitor and review information about these interested parties and their relevant requirements.	Due to their effect or potential effect on the organization's ability to consistently provide products and services and services that meet customer and applicable statutory and regulatory **customer requirements**, the organization shall determine: a) the interested parties that are relevant to the ***lean and sustainable integrated*** quality management system; b) the requirements of these interested parties that are relevant to the ***lean and sustainable integrated*** quality management system. The organization shall monitor and review information about these interested parties and their relevant requirements. ***The organization shall establish processes for identifying and fulfilling its responsibilities towards the society.***

4.4.2. Modification of Clause 5: Leadership

There are 3 sub-clauses in clause 5 of the ISO 9001:2015 based QMS. These clauses establish the requirement of Top management commitment and Leadership towards the organisation.

The constructs of Lean and Sustainability that were identified as suitable for incorporating the sub-clauses of clause 5 are shown in Table 4.7. These constructs were appended with suitable sentences in the sub-clauses 5.1 to 5.3.

Table 4.7 - Sub-Clauses Clause 5 of ISO 9001:2015 QMS and the Lean and Sustainability Constructs added

Clause	***Description***	***Lean Constructs***	***Sustainable Constructs***
5.1.1	Leadership and commitment	Employee Engagement	Respect for staff
5.1.2	Customer focus	Customer focus	Customer delight
5.2.1	Establishing quality policy		Clear Vision
5.3	Organizational roles, Responsibilities and duties	Effective Communication	Communication

As a sample, the original and amended sub-clause 5.1.2, "Customer Focus" is shown in Table 4.8. The scope for the lean and sustainable integrated QMS is established based on this clause.

Table 4.8 - Descriptions of ISO and LSIEQMS for the clause 5.1.2

Clause ISO 9001:2015 Clauses	Description in the ISO 9001: 2015 QMS	Descriptions in the corresponding clause of Lean and Sustainable Integrated QMS
5.1.2 Customer Focus	Top management shall demonstrate leadership and commitment to customer focus by ensuring that: a) customer and applicable statutory and regulatory requirements are determined, understood and consistently met; b) the risks and opportunities that can affect the conformity of products and services and the ability to enhance customer satisfaction are determined and addressed; c) focus on enhancing customer satisfaction is maintained. Every message from a customer is considered as an opportunity to improve customer satisfaction.	Top management shall demonstrate leadership and commitment to customer focus by ensuring that: a) customer and applicable statutory and regulatory requirements are determined, understood and consistently met; b) the risks and opportunities that can affect the conformity of products and services and the ability to enhance customer satisfaction are determined and addressed; c) focus on enhancing customer satisfaction and ***customer delight are*** maintained.

The two key aspects included in this clause were customer focus and customer delight. The quality policy of an organisation is a strong and highly evident statement on quality by the top management. While establishing a quality policy, the organisation's top management should keep in mind its purpose and strategic direction (mission, vision, guiding principles, and core values). Good regulatory practices and quality management principles can also be used for establishing commitment of the Organisation top management towards quality services.

Two requirements added in this clause are the need for a sustainability plan and commitment to attending to customer requirements. This necessitated the quality policy to address the commitment to satisfy customer's and stakeholders' needs and Commitment to establish a lean and sustainable integrated QMS.

4.4.3. Modification of Clause 6: Planning

There are 3 sub-clauses in clause 6 of the ISO 9001:2015 based QMS. These clauses establish the requirement of identifying the risks, establishing objectives, and devising plans to achieve them and methods of adopting changes in plans.

Table 4.9 - Sub-Clauses Clause 6 of ISO 9001:2015 QMS and the Lean and Sustainability Constructs added

Clause	***Description***	***Lean Constructs***	***Sustainable Constructs***
6.1	Actions to address risks and opportunities	Automation	Sustainability Plan

The constructs of Lean and Sustainability that were identified as suitable for incorporating the sub-clauses of clause 6 are shown in Table 4.9. Only two constructs, namely Automation and Sustainability Plan were identified to be added to the subclauses of clause 6. These constructs were appended with suitable sentences in the sub-clause 6.1. The original and amended sub-clause 6.1,'Actions to address risks and opportunities', are shown in Table 4.10. This clause intends to make sure that the quality objectives are set up by the organisation, and later the plan of action to attain them will be finalised. The respective quality objectives should be established for each function, process, and levels as suitable, to make sure the effective arrangement of the organisation's approach and its quality policy.

Table 4.10 - Descriptions of ISO and LSIQMS for the clause 6.1

Clause	ISO 9001:2015 Clauses	Description in the ISO 9001: 2015 QMS	Descriptions in the corresponding clause of Lean and Sustainable Integrated QMS
6.1	Actions to address risks and opportunities	**6.1.1** When planning for the quality management system, the organization shall consider the issues referred to in 4.1 and the requirements referred to in 4.2 and determine the risks and opportunities that need to be addressed to: a) give assurance that the quality management system can achieve its intended result(s); b) enhance desirable effects; c) prevent, or reduce, undesired effects; d) provide problem-solving methods; e) achieve improvement;	**6.1.1** When planning for the quality management system, the organization shall consider the issues referred to in 4.1 and the requirements referred to in 4.2 and determine the risks and opportunities that need to be addressed to: a) give assurance that the quality management system can achieve its intended result(s); b) enhance desirable effects; c) prevent, or reduce, undesired effects; d) provide problem-solving methods; d) achieve improvement; *f) Achieve sustainable plan that can help to reduce undesirable business issues;* *g) Including automated technology concerned with the use of electronic, mechanical and computer-based systems to operate and control manufacturing.*

4.4.4. Modification of Clause 7: Support

This clause intends to ensure that the resources, organisational knowledge, competence, awareness, and documented information required for the initiation and execution of lean and sustainable integrated QMS are available to the organisation for its effective operation.

Table 4.11 - Sub-Clauses Clause 7 of ISO 9001:2015 QMS and the Lean and Sustainability Constructs added

Clause	Description	Lean Constructs	Sustainable Constructs
7.1.1	Resources	Resource utilisation	Education and training
7.1.2	People	Employee involvement, Workforce Management	Social Sustainability
7.1.4	Environment for the operation of processes	Workplace organisation	Environment management
7.1.5	Monitoring and measuring resources		Measurement and reporting
7.1.6	Organizational knowledge	Organisation Culture	Globalization
7.2	Competence	Technology improvement, Training of employees	Competitive strategies

7.4	Communication	Effective Communication

There are 5 sub-clauses in clause 7 of the ISO 9001:2015 based QMS. The constructs of Lean and Sustainability that were identified as suitable for incorporating the sub-clauses of clause 7 are shown in Table 4.11. These constructs were appended with suitable sentences in the sub-clauses 7.1 to 7.5.

Table 4.12 - Descriptions of ISO and LSIQMS for clause 7.1.2

Clause	ISO 9001:2015 Clauses	Description in the ISO 9001: 2015 QMS	Descriptions in the corresponding clause of Lean and Sustainable Integrated QMS
7.1.2	People	The organization shall determine and provide the persons necessary for the effective implementation of quality management system and the operation and control of its processes.	The organization shall determine and provide the persons necessary for the effective implementation of *lean and sustainable integrated* quality management system and the operation and control of its processes. The organization shall ensure *a) Employee involvement in aspects related to internal and external systems* *b) workforce management to improve productivity* *b) Social sustainability*

The original and amended sub-clause 7.1.2, 'People' is shown in Table 4.12. This clause intends to establish the requirements of people for effective implementation of the quality management system. The organisation needs to ensure employee involvements in the internal and externals systems, improve productivity through workforce managing and maintain social sustainability

Since the requirements of lean and sustainability attributed to this clause are addressed with the existing requirements implicitly, much of the additions were not required. However, explanations of the requirements about lean and sustainable QMS is added in this clause.

4.4.5. Modification of Clause 8: Operation

The sub-clauses of the clause 8, Operation clause intend to ensure that the organisation plan, execution, monitoring, and control of the operational processes that are needed, including any externally provided (outsourced) processes. There are 5 sub-clauses in clause 8 of the ISO 9001:2015 based QMS. The constructs of Lean and Sustainability that were identified as suitable for incorporating the sub-clauses of clause 8 are shown in Table 4.13. These constructs were appended with suitable sentences in the sub-clauses 8.2 to 8.5.

Table 4.13 - Sub-Clauses Clause 8 of ISO 9001:2015 QMS and the Lean and Sustainability Constructs added

Clause	Description	Lean Constructs	Sustainable Constructs
8.2	Requirements for products and services	Delivery dependability	
8.3	Design and development of products and services	Creativity and innovation, Efficient variety handling, Cost-saving	Adaptability
8.5.1	Control of production and service provision	Reduction in Lead time	
8.5.4	Preservation		Environmental Sustainability

The original and amended sub-clause 8.3.4, which is the sub-clause of Clause 8.3, is shown in Table 4.14. The controls required in the design and development of products and service are established in this clause.

Creativity and innovation in the products and processes, offering varieties in the product line, incorporating cost saving measures in the products and processes and the extension of life and utility of products are added in this clause as additional requirements.

Table 4.14: Descriptions of ISO and LSIQMS for clause 8.3.4

Clause	ISO 9001:2015 Clauses	Description in the ISO 9001: 2015 QMS	Descriptions in the corresponding clause of Lean and Sustainable Integrated QMS
8.3.4	**Design and development controls**	The organization shall apply controls to the design and development process to ensure that: a) the results to be achieved are defined; b) reviews are conducted to evaluate the ability of the results of design and development to meet requirements; c) verification activities are conducted to ensure that the design and development outputs meet the input requirements; d) validation activities are conducted to ensure that the resulting products and services meet the requirements for the specified application or intended use e) any necessary actions are taken on problems determined during the reviews, or verification and validation activities; f) documented information of these activities is retained;	The organization shall apply controls to the design and development process to ensure that: a) the results to be achieved are defined; b) reviews are conducted to evaluate the ability of the results of design and development to meet requirements; c) verification activities are conducted to ensure that the design and development outputs meet the input requirements; d) validation activities are conducted to ensure that the resulting products and services meet the requirements for the specified application or intended use e) any necessary actions are taken on problems determined during the reviews, or verification and validation activities; f) documented information of these activities is retained; *g) creativity and innovation are promoted;* *h) maximum possible varieties of products are offered to customers;* *i) cost saving measures are incorporated in products and processes;* *j) the extension of utility of products are ensured.*

4.4.6. Modification of Clause 9: Performance Evaluations

The sub-clauses of clause 9, Performance Evaluations clause, intend to ensure organisations conduct assessment and analysis to determine if the intended results are being achieved. There are 3 sub-clauses in clause 9 of the ISO 9001:2015 based QMS. The constructs of Lean and Sustainability that were identified as suitable for incorporating the sub-clauses of clause 8 are shown in Table 4.15. These constructs were appended with suitable sentences in the sub-clauses 9.1 to 9.3.

The constructs performance measure and performance are inherent in the ISO9001:2015 QMS in the clause 9.1.1. Similarly,construct customer satisfaction is already included in the clause 9.1.2. No modification is carried out in these clauses. The construct appraisal of sustainability is added in clause 9.3.3. The original and amended sub-clause 9.3.3, 'Management Review inputs'are shown in Table 4.16. This clause stipulates that the appraisal of sustainability forms an input to the management review.

Table 4.15 - Sub-Clauses Clause 9 of ISO 9001:2015 QMS and the Lean and Sustainability Constructs added

Clause	Description	Lean Constructs	Sustainable Constructs
9.1.1	Performance evaluation	Performance measures	Performance
9.1.2	Customer satisfaction	Customer satisfaction	
9.3.3	Management review		Appraisal of sustainability

Table 4.16 - Descriptions of ISO and LSIQMS for clause 9.3

Clause	ISO 9001:2015 Clauses	Description in the ISO 9001: 2015 QMS	Descriptions in the corresponding clause of Lean and Sustainable Integrated QMS
9.3.2	**9.3.2 Management review inputs**	The management review shall be planned and carried out taking into consideration: a) the status of actions from previous management reviews; b) changes in external and internal issues that are relevant to the lean and sustainable integrated quality management system; c) information on the performance and effectiveness of the quality management system, including trends in: i) customer satisfaction and feedback from relevant interested parties;	The management review shall be planned and carried out taking into consideration: a) the status of actions from previous management reviews; b) changes in external and internal issues that are relevant to the lean and sustainable integrated quality management system; c) information on the performance and effectiveness of the *lean and sustainable integrated* quality management system, including trends in: i) customer satisfaction and feedback from relevant interested parties;

ii) the extent to which quality objectives have been met; iii) process performance and conformity of products and services; iv) nonconformities and corrective actions; v) monitoring and measurement results; vi) audit results; vii) the performance of external providers; d) the adequacy of resources; e) the effectiveness of actions taken to address risks and opportunities (see 6.1); f) opportunities for improvement.	ii) the extent to which quality objectives have been met; iii) process performance and conformity of products and services; iv) nonconformities and corrective actions; v) monitoring and measurement results; vi) audit results; vii) the performance of external providers; *viii) Appraisal of sustainability* d) the adequacy of resources; e) the effectiveness of actions taken to address risks and opportunities (see 6.1); f) opportunities for improvement.

4.4.7. Modification of Clause 10: Improvement

The sub-clauses of clause 10, Improvement clause, intends to make sure whether the SMEgives opportunities for improvement, prepares improvement plans, and takes action for implementation to attain the desired results and to improve the satisfaction of customer. Improvements can aid the organisation in mainlining the customer requirements and expectations by providing better goods and services, through a better process to achieve the performance and effectiveness of lean.

Table 4.17 - Sub-Clauses Clause 10 of ISO 9001:2015 QMS and the Lean and Sustainability Constructs added

Clause	Description	Lean Constructs	Sustainable Constructs
10.1	Improvement		Innovation
10.2.1	Nonconformity and corrective action	Problem-solving	
10.3	Continual improvement	Continuous improvement	

There are 3 sub-clauses in clause 10 of the ISO 9001:2015 based QMS. The constructs of Lean and Sustainability that were identified as suitable for incorporating the sub-clauses of clause 10 are shown in Table 4.17. These constructs were appended with suitable sentences in the sub-clauses 10.1 to 10.3.

Table 4.18 - Descriptions of ISO and LSIQMS for clause 10.2

Clause	ISO 9001:2015 Clauses	Description in the ISO 9001: 2015 QMS	Descriptions in the corresponding clause of Lean and Sustainable Integrated QMS
10.2	Nonconformity and corrective action	**10.2.1** When a nonconformity occurs, including any arising from complaints, the organization shall: a) react to the nonconformity and, as applicable: i) take action to control and correct it; ii) deal with the consequences; b) evaluate the need for action to eliminate the cause(s) of the nonconformity, so that it does not recur or occur elsewhere, by: i) reviewing and analysing the nonconformity; ii) establishing the causes of the nonconformity; iii) establishing if similar nonconformities exist, or could potentially occur; c) implement any action needed; d) review the effectiveness of any corrective action taken; e) update risks and opportunities determined during planning, if necessary; f) make changes to the quality management system, if necessary. Corrective actions shall be appropriate to the effects of the nonconformities encountered.	**10.2.1** When a nonconformity occurs, including any arising from complaints, the organization shall: a) react to the nonconformity and, as applicable: i) take action to control and correct it; ii) deal with the consequences; *iii) problem solving;* b) evaluate the need for action to eliminate the cause(s) of the nonconformity, so that it does not recur or occur elsewhere, by: i) reviewing and analysing the nonconformity; ii) establishing the causes of the nonconformity; iii) establishing if similar nonconformities exist, or could potentially occur; c) implement any action needed; d) review the effectiveness of any corrective action taken; e) update risks and opportunities determined during planning, if necessary; f) make changes to the quality management system, if necessary. Corrective actions shall be appropriate to the effects of the nonconformities encountered.

The construct ‘innovation’ were added into clause 10.1. The construct ‘problem solving’ were added into the clause 10.2.1. Since the construct ‘continual improvement’ was already present in clause 10.3 of ISO 9001:2015 QMS no changes were made in that clause.

4.5 CONCLUSION

The constructs of Lean and Sustainability were successfully appended to the different clauses of ISO 9001:2015 QMS. Some of the constructs of Lean and Sustainability were already present in the ISO 9001:2015 QMS. The remaining constructs were added to the existing sub-clauses of the clauses 4 to 10. New sub-clauses were not introduced in the LSIQMS developed by adding the constructs of lean and sustainability. The organisations can use this model by modifying their ISO 9001 QMS documentations.

CHAPTER 5

TEST IMPLEMENTATION OF THE LEAN AND SUSTAINABILITY INTEGRATED QUALITY MANAGEMENT SYSTEM

5.1 INTRODUCTION

The documentation of the QMS for the LSIQMS is carried out in two organisations to understand the difficulties and feasibility of developing the documents based on LSIQMS. This chapter presents the processes adopted for the modification of documentation, and the envisaged QMS of the organisations where the test implementations were carried out. The LSIQMS was developed by appending the constructs of lean and sustainability to the existing ISO 9001:2015 QMS. Due to this reason, there is no need to prepare separate documents for the Lean and Sustainability practices as the required modifications can be made in the existing QMS documentation. Accordingly, the elements of lean and sustainability were included where ever applicable in the modified documented information.

The 2015 revision of the ISO 9001 standard has four mandatory-documented information. The same standards are followed for the design of the LSIQMS. The mandatory documented information are Scope of the Quality Management System (clause 4.3), Quality policy (clause 5.2), Quality objectives (clause 6.2) and Criteria for evaluation and selection of external providers (clause 8.4.1).

5.2 CASE STUDY

The implementation of Lean and Sustainable Integrated Quality management systems, was carried out in two Small and Medium Enterprises A and B. Details of these industries are summarised in Table 5.1. Data on the response from the workforce were randomly collected for the cluster of constructs. The details of responses are described in subsections.

Table 5.1 SME demographic details

SME	Manufacturing activity	SME type	Annual sales turnover (Rs)	Location	Number of employees
A	Rubber moulds	Partnership	4 crore	India	25
B	Machinery manufacturing	Individual	5 crore	India	24

5.2.1 SME A

This SME was established in 1994 and is located in Thrissur district. The SME manufactures and distributes the finest quality rubber moulds for floor tiles, wall tiles, and pavers. They are specialized in the manufacturing of customized designs. They have had a good market in India and in 26 countries across the globe. There are 25 employees in the firm and the SME has been ISO 9001:2015 certified since 2017.

5.2.2 DEVELOPMENT OF LSIQMS FOR SME - A

The LSIQMS document of SME A was prepared by integrating the Lean and Sustainability with the existing QMS. The first and foremost requirement to integrate lean and sustainability was the commitment from the top management. Organizations should formulate their vision and strategy. The priority of lean and sustainability implementation was fixed considering these strategies.The Top Management expressed their willingness to implement the LSIQMS model in their SME. The SME-A had more employee retention and they were placed in a better position in comparison to the similar industries in the field.The documentation of the system based on LSIQMS is shown in Appendix III.

SME A had gone through the process of ISO 9001:2015 certifications to retain its position in the global market. SME A had initially once attempted the implementation of Lean principles but failed due to internal communication issues and poor commitment from different levels. They learned from their faults and this forced the SME to attempt once again. This could help to access the SME easily, thereby proposing to integrate Sustainability practices along with lean.

During management reviews, they discussed their vision, which was focused on waste optimization and an environment for Sustainable practices in the firm's performance. Sustainable manufacturing is very cost-effective. By improving the

processes and using modern equipment, reducing energy consumption, minimizing the manufacturing time, eliminating waste, and effective utilization of material, the SME can significantly save on cost. Automated and efficient equipment can even provide better safety for workers.

It was also mentioned that many customers were looking for manufacturers with eco-friendly manufacturing practices and products. Customers usually feel good about the products they are purchasing. Sustainable manufacturing, especially the adoption of eco-friendly practices encourages customers to purchase from that SME. However, certain barriers existed, especially those that did not allow SMEs to achieve economic sustainability owing to shortage of skills. Usually, manufacturing companies follow lean manufacturing practices to achieve economic sustainability through emphasizing waste reduction. So linking Lean management practices with Environmental Sustainability could help the SME to achieve a better position.

To achieve an improvement in the Sustainability performance of products, it was suggested that thet adopt new concepts like eco-design, and more innovation, to improve the process and production methods of cleaner production. Thus, overall Sustainability can be achieved through a lean approach and that will enable the SME to achieve a competitive position. It was suggested that studies on Lean and Sustainability, process improvements and organization innovation were available but to find a study on both lean and sustainability-related to SMEs' performance was difficult. This effort will therefore be very useful for the SME community in the future, and the employees of SME - A have been requested to work for that.

The implementation results could be measured through the performance of the SME. For example, effective energy management can reduce energy consumption, and thus lead to cost reduction. Increasing recycling, reusing, and remanufacturing may enhance sustainability performance. The importance of the 3R (Reduce-Reuse-Recycle) concept in manufacturing has to be pointed out here.. This means the waste should be reduced from the beginning. Only when the creation of waste can no longer be avoided, should it be reused, thus reducing the usage of fresh resources. When materials can no longer be reused, the waste is recycled, and formed into a new product with slightly lesser quality.

The importance of Sustainability-oriented innovation was emphasised, which is to be promoted, as it achieved superior environmental and social performance. Training for the same has resulted in a positive change among the people.The awareness about the benefits of implementing Lean were discussed among the employees, like increase in productivity, return on investment, good customer support, improved quality, reduction in lead times etc. Sustainable products were manufactured through economically-viable processes to minimize the cost of manufacturing and environmentally safe manufacturing practices Sustainable manufacturing practices ensure employee, society, and product safety. The importance of Sustainability in today's environment was made clear to the employees.

5.2.3 SME - B

The second industry identified for the case study was SME- B. It was established in 2003, and is located near Palakkad. The industry was famous for manufacturing eco-friendly, disposable paper products manufacturing machinery. A total of 24 people are employed at this SME and the annual turnover is 5 Crores. The SME has been ISO 9001:2015 certified since 2019. SME B had developed high value and cost-efficient machinery, being high performing, energy saving, user-friendly, and maintenance-free. Moreover, they offered fully automated machinery, specially designed for women empowerment, as it can be installed at domestic production centres to leverage high performing output.

5.2.4 DEVELOPMENT OF LSIQMS FOR SME-B

Based on discussions with the top executives, it was decided to go with the design of Lean and Sustainable integrated QMS documentation. It was agreed to hold an in-house programmme to address all the details of the implementation of Lean and Sustainability within the existing system.

All the employees of SME - B underwent half a day’s training on the concepts of Lean and Sustainability and, its impact on firm performance. It was made clear that the standardization of the existing principles through Lean and Sustainability integration would provide solutions to the issues faced by the manufacturing unit. Through this the employees of the manufacturing unit became well aware of Lean and Sustainability and its benefits. The employees also understood the benefits on

implementing Lean and Sustainability, since they are manufacturing mainly eco-friendly and disposable paper product manufacturing machinery and focusing on continuous improvement.

It was observed that the organizational culture of SME- B was transparent. The manager used to meet their employees before/after each shift to discuss the production schedule and issues related to that. This transparent communication helped to build a healthy work environment. During the daily review meeting, the managers were also able to discuss standardized work processes. The daily targets were displayed by the management. They encouraged the employees to communicate their observations and opinions during these interactions. The management continuously monitored production activities to identify major issues. The study repeatedly witnessed the management team inspiring employees during their interactions. Furthermore, the management asked the study team to meet their employees to collect their feedback during the design of the model. The management considered their opinions and observations to be as a critical element for designing the modified QMS documents.

Employees of SME-B were highly motivated to work efficiently and effectively. Employees understood that their knowledge in the work was a major aspect of their long-term stability with the SME.

It was noticed that the auditors were trained to audit for compliance with the standards of interest and the SME's procedures. Most audit programs did little in the way of auditing for effectiveness. Therefore, certain employees viewed the audit process very negatively. It was also found that the internal auditors are trained only if, their performance feedback was taken in to consideration.

It was also suggested that a root cause analysis be carried out, as the Lean solution may not fix the problem if the root cause is not known. Therefore, it was suggested to include the root cause analysis first, before randomly applying Lean tools. The documentation of the system based on the LSIQMS is shown in Appendix IV.

5.3 REASONS FOR ADOPTION OF LSIQMS

Following the initial survey which was conducted initially to identify the constructs of Lean and Sustainability practices, both these SMEs participated and were

ready to undergo Lean and Sustainability implementation.The reasons identified by SMEs A and B for undergoing lean and sustainability integration are presented in Table 5.2. This information was collected through interview with the top management of both SMEs.

Table 5.2 - Reasons to undergo lean and sustainability integration

System	SME A	SME B
ISO 9001:2015	Pressure from the global market Continuous improvement	Improving market performance Focus on customer requirements and expectations.
Lean	Wastage reduction A better understanding of customer needs Use new process technologies Increase product quality	Increase process knowledge Inventory reduction Use new process technologies Increase productivity and profit
Sustainability	Become environment friendly Become energy efficient. Increase the organisational capacity	Focus on eco-friendly products. More delighted customer Focus on Energy efficient

5.4 ANALYSIS OF THE IMPLEMENTED LSIQMS IN TWO SMES

The analysis carried out was to determine the effectiveness of the LSIQMS documents (part A) and its implementation response (part B) in both the SMEs A and B. A questionnaire survey was conducted among the people of both the SMEs. Details of the survey and its analysis are presented in this section.

Since the sample size was 6 respondents and 5 respondents respectively from SMEs A and B, a simulated model of “Stationary behaviour of pattern” of respondents using Monte Carlo Method was used. This helps to get ‘stationary response data’ for analysis with a larger sample size for getting reliable results.A paired ‘t’-test, was used for the test implementation studies of the LSIQMS model. Samples were taken from two groups using this paired 't'- test. The validation of the paired t-test was done by Mann-Whitney 'U' test.

Monte Carlo Methods are a broad class of computational algorithms that rely on repeated random sampling to get numerical results. The underlying concept is to use randomness to solve problems that might be deterministic. They were used in physical and mathematical problems. These methods are useful for simulating systems and in

modelling programs where the empirical sample size is very small. It is based on the Law of Large numbers with expected values of some "random variables". When the probability distribution of the variable is parameterized, Markov chain model based stationary probability distribution is used , which gives the same behaviour of the empirical series, but more precise estimation can be done using the series developed by Monte Carlo method. Many research studies are done by generating stationary data with the same behaviour that is present in the original data [125 -128].

In this study the response collected for SMEs A and B were small in number, and hence the Monte Carlo method was used to generate stationary response data. The procedure adopted is given in detail. It is also noted Monte Carlo Method, probability principles are used and is considered as a precise method.

The steps adopted for of simulation using Monte Carlo method were the following.

(i) Data generation - This stage involves the sample observations of the variables and determining the probability distribution for each variable with corresponding probability.

(ii) Determine the cumulative probabilities distribution corresponding to (i)

(iii) Assign random intervals for the variables as per (ii)

(iv) Allot random numbers against each variable in (iii) in the random intervals (iii)

(v) Generate simulated observations using random numbers and allot values of the variable corresponding to the random interval and the original values in column (i).

5.5 LSIQMS PERFORMANCE

An analysis was performed to determine the effect of lean and sustainability integration on the performance of SMEs based on the model suggested and is evaluated through the perceptions of employees of the respective organizations. A questionnaire survey was conducted for this purpose among the selected employees of the SMEs where test implementation was conducted. The questions were focused to identify the

potential benefits that would expect from the implementation of a lean and sustainability integrated system.

A five point Likert scale was used to collect to response. Randomly 6 persons are selected from SME A and 5 persons from SME- B. The variables of the questionnaire and mean responses of respondentscorresponding to the LSIQMS and modified documented of test implementation are shown in Table 5.3 and 5.4.

Table 5.3 - Mean response from survey on the LSIQMS

Question Number	Variables on LSIQMS standard	Mean response from survey	
		SME - A	SME – B
1	Effectiveness of the LSIQMS	4	4.2
2	Comprehensiveness of Lean principles in LSIQMS	4.3	4.2
3	Comprehensiveness of Sustainability principles in LSIQMS	4.3	4.4
4	Easiness for implementation of LSIQMS in SMEs	4.16	4.6
5	Importance of LSIQMS in SMEs	4.5	3.8

Table 5.4 - Mean response from survey on documentation for test Implementation

Question Number	Variables on the documentation of the system based on LSIQMS	Mean response from survey	
		SME - A	SME – B
6	Comprehensiveness of the documentation of LSIQMS	4.1	4.2
7	Easiness of implementation of QMS	4.3	4.4
8	Effectiveness of the QMS	4.4	4.6
9	Extend of QMS support in adopting Lean practices.	4.4	4.4
10	Extend of QMS in adoption of sustainable practices	4.2	4.6

A Paired t-test was carried out to compare the mean values of two SMEs.Table 5.5 shows the data collection responses based from the survey for SMEs A and B on the ten performance indicators as mentioned in section 6.2, based on 5 point Likert test.

The hypotheses of the t-test were the following

H_0: There is no difference between perceptions of the responses from SMEs A and B taken for case study.

H_1: There is difference between perceptions of the responses from SMEs A and B.

Level of significance used; $p < 0.5$., $p<0.01$.

Table 5.5.- Responses from the survey for SMEs A and B.

Performance indicators	SME - A						SME –B				
1	4	5	4	3	4	4	4	5	4	4	4
2	4	4	5	4	4	4	4	4	5	4	4
3	5	5	4	3	4	5	4	4	4	5	5
4	4	5	4	4	4	5	5	5	5	4	4
5	5	5	4	4	4	5	4	4	4	3	4
6	4	4	5	5	3	4	5	4	4	4	4
7	4	4	4	4	4	5	5	4	4	4	5
8	4	4	4	5	4	5	5	5	4	5	4
9	5	5	4	4	4	5	4	4	5	5	4
10	5	5	4	5	5	5	5	5	4	5	4

The responses were then converted to simulation model values corresponding to each performance indicator using Monte Carlo simulation(refer appendix V and are shown in Table 5.6.

Table 5.6 -Responses of simulation model validation

Performance indicators	SME- A											SME- B											Overall Average
	1	2	3	4	5	6	7	8	9	10	Average	1	2	3	4	5	6	7	8	9	10	Average	
1	5	4	5	4	5	5	4	4	5	4	4.5	4	4	5	5	4	4	4	4	4	5	4.3	4.4
2	4	4	5	5	4	4	4	4	5	5	4.4	4	4	5	4	4	4	4	4	4	5	4.2	4.3
3	5	5	5	3	4	5	5	4	4	5	4.5	4	4	4	4	4	4	4	4	4	5	4.1	4.3
4	5	4	5	4	5	5	4	5	4	4	4.5	5	5	5	4	5	5	4	4	5	4	4.6	4.55
5	5	4	4	5	5	5	4	4	5	4	4.5	4	4	4	4	4	4	4	4	4	4	4	4.25
6	4	5	5	5	3	4	4	4	4	4	4.2	4	4	4	4	4	4	5	5	4	4	4.2	4.2
7	5	4	5	5	4	4	4	4	5	4	4.4	5	4	5	4	5	4	5	5	4	5	4.6	4.5
8	5	4	4	5	4	5	4	4	5	4	4.4	5	4	5	4	5	4	5	5	4	5	4.6	4.5
9	4	4	4	5	4	5	4	4	5	4	4.3	4	5	5	4	5	4	5	4	5	5	4.6	4.45
10	5	5	4	5	4	5	5	5	4	5	4.7	5	5	5	4	5	5	5	5	5	4	4.8	4.75

The validation of results obtained from paired t-test using Non-parametric test with Null hypothesis points to the fact that there is no difference between responses in SMEs A and B, at $p<0.01$. The alternative hypothesis is that there is difference in perceptions.The research findings obtained from paired t- test was validated by Mann-

Whitney U test for attributes. Using Monte Carlo method, stationary response data was generated.

The steps adopted for Mann-Whitney Test are the following.

Step 1: Arranging the median responses for SMEs A and B

Table 5.7 - Median responses for each performance measure

Sl. No.	Performance measures	SME	Median of responses	
			Calculated	Survey
1	Effectiveness of the modified document	A	4.5	4.5
		B	4.0	4
2	Lean principles appended to LSIQMS	A	4.0	4.5
		B	4.0	5
3	Sustainability principles in LSIQMS	A	5.0	3.5
		B	4.0	4
4	Easiness in the implementation in SMEs	A	4.5	4
		B	5.0	5
5	Importance of LSIQMS in SMEs	A	4.5	4
		B	4.0	4
6	New documentation and requirements in LSIQMS	A	4.0	5
		B	4.0	4
7	Practicability of modified QMS	A	4.0	4
		B	5.0	4
8	Effectiveness of the modified QMS	A	4.5	4.5
		B	5.0	4
9	Modified QMS support in adopting Lean practices.	A	4.0	4
		B	5.0	5
10	Modified QMS support in adopting sustainable practices	A	5.0	4.5
		B	5.0	4

The frequency curve for depicting the simulated values of responses and original survey values for SME – A corresponding to each performance indicator is shown in figure 5.1.

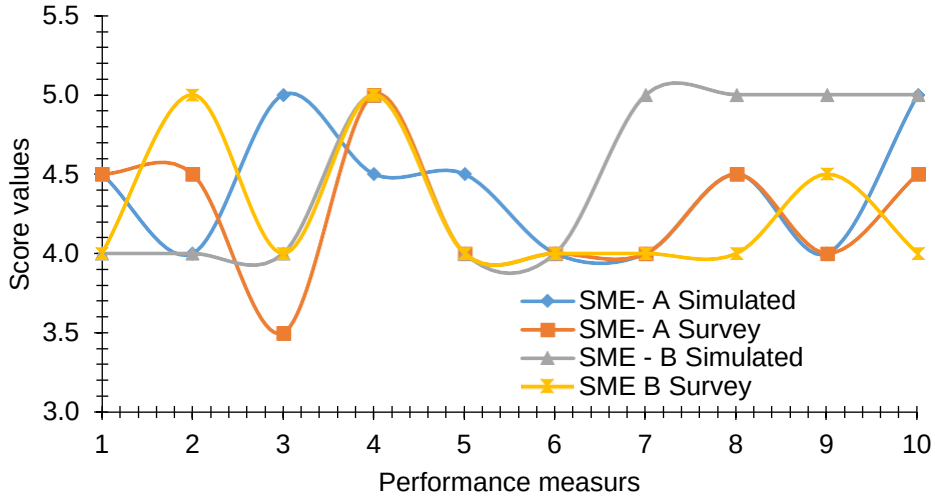

Figure 5.1 Frequency curve for responses of SME – A and B

Step 2: Arranging the calculated values of medians in a different format with respect to SMEs as shown in Table 5.8.

Table 5.8 - Median of responses with respect to SMEs

Performance measures	1	2	3	4	5	6	7	8	9	10
SME - A	4.5	4.0	5.0	4.5	4.5	4.0	4.0	4.5	4.0	5.0
SME - B	4.0	4.0	4.0	5.0	4.0	4.0	5.0	5.0	5.0	5.0

Step 3: From the table 5.8, Ranking is done in the order of their size such as Rank 1 for 4, 1.5 for 4.5 and 2 for 5 and a new table is prepared (table 5.9)

Table 5.9 - Ranking of SMEs

Performance measures	1	2	3	4	5	6	7	8	9	10
SME - A	2	1	3	2	2	1	1	2	1	3
SME - B	1	1	1	3	1	1	3	3	3	3

Step 4:

Sum of Rank for SME – A = 18 = R1

Sum of Rank for SME – B = 20 = R2

Comparing A and B, A is the smallest.

Hence ‘U’ value observed = 18

Step 5:

Expected mean of U = $(n_1 n_2 / 2)$ where $n_1 = 10$ and $n_2 = 10$

Expected Standard deviation of U = $\sqrt{(n_1 n_2(n_1 + n_2 - 1) / 12)}$

= 12.58

Step 6:

Z = (|18-50|) / 12.58

= 32 / 12.58

= 2.46, which is less than the table value 2.56, and $p < 0.05$

Step 7:

It is found that the observed value 2.46 of Z is less than 2.56 table value for p value of 0.01. Hence the Null Hypothesis that there is no difference in perceptions of respondents is acceptable at $p<0.01$.

Step 8:

Results of step 7 are validated the results obtained from paired t- test

The summary of analysis carried out using Paired t-test on the simulated responses (Table 5.6, ten values each) for SMEs A and B are shown in Table 5.10.

Table 5.10 - Results and interpretation

Performance indicators	t_{18} (calculated)	t_{18} (table)	Remarks
1	2.51	2.61	P< 0.01, Not significant
2	0.83	1.73	P< 0.05, Not significant
3	2.50	2.61	P< 0.01, Not significant
4	1.66	2.11	P< 0.05, Not significant
5	2.08	2.11	P< 0.05, Not significant
6	2.50	2.61	P< 0.01, Not significant
7	2.50	2.11	P< 0.01, Not significant
8	1.25	2.11	P< 0.05, Not significant
9	2.50	2.61	P< 0.01, Not significant
10	2.08	2.11	P< 0.05, Not significant

Non parametric test (Mann Whitney test) was administered to the values of responses received from the survey (Table 5.5) to understand whether there was any difference between perceptions. This test did not give statistical validation and hence, for the analysis, simulated values shown in Table 5.6 were used.

5.6 CONCLUSION

The ISO certified SMEs have a clear edge over their non-certified counterparts. ISO 9001:2015 certified organizations have a significantly better manufacturing performance, higher competency, better customer relationship, better leadership and commitment, good quality planning, better resource utilization, operation planning and control, very good evaluation system and continuous improvement, cost reduction practices, performance improvement, better communication, process standardization, lead time reduction, reduced inventory, respect for staff, occupational safety, energy conservation practices, and sustainable innovation and design for the environment is ensured.

The case study sampling results (Table 5.6) justified that the responses from both SMEs in the study were found homogeneous in the acceptance of LSIQMS.The study could thus throw light on the different aspects of implementation of LSIQMS in SMEs to achieve the overall growth in market dynamics, customer satisfaction, financial expenditure, winning harmonious relations, and less wastage with better productivity in the Small and Medium Enterprises.

CHAPTER 6

CONCLUSION

6.1 INTRODUCTION

This research work was undertaken with the objective of identifying the Lean and Sustainability principles from the literature so that the same can be implemented by SMEs. A Quality Management System namely LSIQMS was designed by incorporating these principles in the ISO 9001:2001 QMS.

The first objective of this study was to assess the adoption level of ISO 9001: 2015 quality management system standards in Small and Medium Enterprises (SMEs). An examination of the ISO 9001:2015 QMS being followed by SMEs was carried out initially.

The second objective was to identify the requirements of Lean and Sustainability principles, the level of practical use of Lean and Sustainable manufacturing practices in these industries. The awareness about Lean and Sustainability and its benefits on implementation were studied using a detailed questionnaire survey.

As per the third objective, a Lean and Sustainability integrated QMS model was developed considering the existing ISO 9001:2015 QMS standards.

Finally, to meet the fourth objective, this newly developed LSIQMS model was test implemented in two SMEs and the evaluation was carried out. The results of the implementation study revealed that LSIQMS QMS model can be adopted by SMEs for incorporating Lean and Sustainability principles in their Quality Management System.

6.2 RECOMMENDATIONS

Implementing Lean and Sustainability Integrated QMS is a new process. This often indicates a chance for a big effort that requires a great amount of energy, money, management commitment, employee involvement, and time. This model

developed was used in manufacturing industries in Kerala, and it can also be used for industries in other places since the ISO 9001:2015 QMS was used in abundance to develop this model. This model can even be used for industries located in other countries.

Possibilities for implementation of LSIQMS in other manufacturing concerns not only SMEs but also large units. The influence of the external environment are also to be explored. Generally, industries are different and so is their culture. So it can be modified according to the situations. The ISO 9001 certified SMEs fair better on the Lean and Sustainability implementation as well. First, there is a strong case for the non-ISO certified SMEs to go in for the ISO 9001:2015 certification as there is a direct impact on manufacturing performance as well as the competency of manufacturing performance. Moreover the certified SMEs definitely fair better on the Lean-Sustainability as well. Government, the SME associations and other agencies should give a strong push to the non-ISO certified SMEs to move towards certification. In doing this and also to increase the lean-sustainability integration, the EFQM model is one of the best solutions. Not only is it highly balanced in its approach, it beautifully integrates things like purpose, vision and strategy with the results. It is a model that to a good extent looks like the Balanced Score Card approach that tries to integrate the strategy with financial and non-financial performance of a business. Agencies like the Chambers of Commerce should take the lead in inviting eminent experts in the field of EFQM to India and ask them for the help in developing a highly customized model for SMEs.

6.3 RESEARCH CONTRIBUTIONS

Quality management practices are essential for small and medium-sized enterprises to achieve a competitive advantage. At present very low usage of quality initiatives in Indian SMEs is reported. The reasons for these are the lack of knowledge in the benefits of integrating different initiatives such as Total Quality Management (TQM), Six Sigma, and Lean to ISO as a booster to achieve their performance needs. ISO as an initiative is sufficient enough to meet their business needs. The comparative importance of these factors on the application of quality management practices has never been discussed. The high cost of training is a major barrier to quality initiatives implementation. Lack of resources and lack of top management commitment are other barriers in introducing quality initiatives in SMEs.

SMEs with ISO 9001:2015 certificates use techniques such as overall equipment effectiveness, root cause analysis, and PDCA cycle. Through the systematic application of quality management practices, SMEs can achieve long-term benefits.

Thus, the objective of the study was to examine the manufacturing systems in SMEs from a new perspective, focusing on the key issues faced by SMEs and its solutions. The findings of this study were also able to provide positive results to develop a model for LSIQMS for SMEs.

The model developed will, therefore, provide a stepping stone for the improvement of quality standards for Indian SMEs to assess their performance relative to the QMS standards. The LSIQM may be considered as a tool for improvement of the SMEs in our country. It was evident from the literature review conducted and the responses received through the personal interviews in the case study that SMEs in India at present are facing challenges in their manufacturing processes. The study could establish the necessity of this new system and its favourable acceptance in the selected SMEs in their manufacturing process.

6.4 RESEARCH LIMITATIONS

The implementation of LSIQMS in industries as a part of the study was not possible due to many reasons. The consent for the top management for modifying their system and the cooperation of the people of the organisation was required for the same. Also, the implantation would affect the routine jobs of the people.

One of the limitations for the study was to get information from respondents of the SMEs where implementation studies were conducted. Most of the responses collected were mostly in Nominal and Ordinal scale which was converted to the Likert scale. Only a limited time was available to conduct the study.

Several studies need to be conducted for accepting the LSIQMS as a tool for implementing the principles of Lean and Sustainability.

6.5 CONCLUSION

During the case study of the selected SMEs the following inferences could be made. Main issues faced at present by SMEs in the manufacturing process could be identified and percentages benefits in functional areas could be worked out. A favourable response was found towards the implementation of LSIQMS in these SMEs among workforce in both SMEs. Also based on the studies, it has been found that integrated Lean Sustainable manufacturing system can be defined as a system that creates value for the customers by eliminating wastes consistently and adopting processes that are eco-friendly, economically viable and safe for the employees to produce green products that enhance the social performance.

The proposed model could be implemented in all SMEs as well as in large manufacturing industries in their core business areas to meet the customer satisfaction with a better productivity perspective to the organisation in total.

REFERENCES

1. Rohani, J. M., Mojib, S. and Zahraee, Production Line Analysis Via Value Stream Mapping: A Lean Manufacturing Process Of Color Industry, *Procedia Manufacturing*, Vol. 2, 2015, Pp 6-10.

2 Su, H. C., Dhanorkar, S., and Linderman, K., A Competitive Advantage From The Implementation Timing Of Iso Management Standards. *Journal of Operations Management*, Vol. 37, 2015, Pp 31-44.

3, Schonberger, R.J., Japanese Production Management: An Evolution With Mixed Success. *J Journal of. Operations Management,* Vol. *25*, 2007, Pp 403–419.

4. Ghalib, I., Agha, M H., Hameed, S., and Choudhary, M A., A Survey Of Lean Implementation Gap Analysis In Public Sector Organizations, December 2012, *Life Science Journal,* Vol. 9, Iss. 4, 2012, Pp 1261-1269.

5. Motwani, J., A Business Process Change Framework For Examining Lean Manufacturing: A Case Study. *Industrial Management & Data Systems*, Vol. 103, Iss. 5, 2003, Pp 339-346.

6. Galeazzo, A., and Furlan, A., Lean and Green In Action: Interdependencies And Performance Of Pollution Prevention Projects, *Journal Of Cleaner Production*, Vol. 85, 2014, Pp 191–200.

7. Vinodh, S., Gautham, S G, and Anesh Ramiya R, Implementing Lean Sigma Framework In An Indian Automotive Valves Manufacturing Organisation: A Case Study, *Production Planning And Control,* Vol. 22, Iss. 7, 2011,Pp 708-722.

8. Verrier, B., Rose, B., Caillaud, E., and Remita, H., Combining Organizational Performance With Sustainable Development Issues: The Green And Lean Project Benchmarking Repository. *Journal Of Cleaner Production,* Vol. 85, 2014, Pp 83-93.

9. World Commission On Environment And Development, Report Of The World Commission On Environment And Development, United Nations General Assembly, *Brundtland Report,* 42nd Session, Item 83 (E) Of The Provisional Agenda, 1987, Pp 53-75

10. Moyano-Fuentes, J,. and Martínez-Jurado, P., Lean Management, Supply Chain Management and Sustainability: A Literature Review, *Journal of cleaner production*, Vol. 85, 2014, Pp 134-150

11. Bhanot, N., Paruchuri, V R., and Deshmukh, S G., An Assessment of Sustainability for Turning Process in an Automobile Firm, 23rd CIRP Conference on Life Cycle Engineering, *Procedia CIRP,* Vol. 48, 2016, Pp 538 - 543.

12. Piercy, N and Rich, N, The Relationship Between Lean Operations And Sustainable Operations, *International Journal Of Operations & Production Management*, Vol. 35, Iss. 2, 2015, Pp 282-315.

13., Adebanjo, D., Lee, T., The Impact Of External Pressure And Sustainable Management Practices On Manufacturing Performance And Environmental Outcomes, September 2016, *International Journal Of Operations & Production Management,* Vol. 36, Iss. 9, 2016, Pp 995-1013.

14. Govindan, K., Azevedo, S. G., Carvalho, H., and Cruz-Machado, V., Lean, Green And Resilient Practices Influence On Supply Chain Performance: Interpretive Structural Modeling Approach, *International Journal of Environmental science and Technology,* Vol. 12, Iss. 1, 2015, Pp 15-34.

15. Simpson, D. F., and Power, D., Use The Supply Relationship To Develop Lean And Green Suppliers, January 2005, *Supply Chain Management: An International Journal,* Vol. 10, Iss. 1, 2005, Pp 60-68.

16. Gajendran, S, and Kumar, S, S., Integration Of Lean Compatible Quality Management System, *Journal Of Metallurgical Engineering,* Vol.1, Iss. 2, 2012, Pp 35-45.

17. Nawanir, G., Lim, K. t., and Othman, S. N., Lean Manufacturing Practices In Indonesian Manufacturing Firms: Are There Business Performance Effects? *International Journal of Lean Six Sigma,* Vol. 7, Iss 2, 2016, Pp 149-170.

18. Battisti, M and Perry, M., Walking The Talk? Environmental Responsibility From The Perspective Of Small-Business Owners, Volume18, Iss. 3, 2011, Pp 172-185.

19. Lee, K. H., Why And How To Adopt Green Management Into Business Organizations? The Case Study Of Korean Smes In Manufacturing Industry, *Management Decision journal*, Vol. 47, Iss. 7, 2009, Pp 1101-1121

20. Sáez-Martínez, F. J., Díaz-García, C., * and González-Moreno, A., Factors Promoting Environmental Responsibility In European Smes: The Effect On Performance, Sustainability, Vol.8, 2016, Pp 898 1-14.

21. Shields, J., and shelleman, J., Method To Launch Sustainability Reporting In Smes, The B Corp Impact Assessment Framework, *Journal of Strategic Innovation and Sustainability*, vol. 12, Iss. 2, 2017, Pp 10-19.

22. Drake, D. F., and Spinler, S. Om Forum—Sustainable Operations Management: An Enduring Stream Or A Passing Fancy ? *Manufacturing & Service Operations Management, Vol.* 15, Iss. 4, 2013, Pp 689-700.

23. Fellows, R., Liu, A., Impact Of Participants' Values On Construction Sustainability, *Engineering Sustainability,* Vol.161, Iss. 4, 2008, Pp 219-227.

24. Sekaran, U., and Bougie, J. R. G.,, Research Methods For Business: A Skill Building Approach (5th Edition), 2009, Wiley Publishers.

25. Venkatesh, S. and Muthiah, K., Smes In India: Importance And Contribution, *Asian Journal Of Management Research*, Vol. 2, Iss. 2, 2012, pp 792-796.

26. Rathod, C. B, Contribution Of Indian Small Scale Entrepreneurs To Economic Growth In India: Opportunities And Challenges In Global Economy. *Prabandh-Journal Of Management & Research*, Vol *23*, 2007, Pp 1-12.

27. Lee, N., Sameen, H., and Cowling, M, Access To Finance For Innovative Smes Since The Financial Crisis, Research Policy, Vol. 44, Iss. 2, 2015, Pp. 370-380.

28 Harvie, C., Narjoko, D. A., Oum, T., Firm Characteristic Determinants Of Sme Participation In Production Networks, *Eria Discussion Paper Series,* 2010, Pp 1-51

29 Basu P, Providing Better Access To Finance For Smes In India, *Access Finance*, Issue 2, 2004.

30. Seshasayee, R., Financing Smes: An Industry Perspective, *Cab Calling,* 2006, 24-26.

31. Das, K, Smes In India: Issues And Possibilities In Times Of Globalisation', In Lim, H. (Ed.), Sme In Asia And Globalization, *Eria Research Project Report,* Vol. 5, 2008, Pp 69–97.

32. Nagpal,V. P., Saini, M., and Gupta, S., Problems Faced By Small And Medium Enterprises, Sme In Transitional Economics-Challenges And Opportunities, *Deep And Deep Publications,* 2009, Pp. 566–57

33. Ligthelm, A. A., and Cant, M. C., The Business Success Factor Of Smes Gauteng: A Proactive Entrepreneurial Approach. Bureau Of Market Research, University Of South Africa, 2002.

34. Kyriakidou, O., and Maroudas, L., Taining And Development In British Hospitality, Tourism And Leisure Smes, *Journal Managing Leisure,* Vol 15, Iss. 1-2, 2010, Pp 32-47

35. Wang, C., Walker; E. A., Explaining The Lack Of Strategic Planning In Smes: The Importance Of Owner Motivation, *International Journal Of Organisational Behaviour,* Volume 12 (1), 2011, Pp 1-16

36. Colin Gray, C., and Christopher Mabey, C, Management Development: Key Differences Between Small And Large Businesses In Europe, *International Small Business Journal,* Vol 23, Iss. 5, 2005, Pp 467-485

37. Tustin, Michael R, Ilkka A. Czinkota and Ronkainen, International Marketing Manifesto, Journal Of International Marketing, Vol. 11 Iss. 1, 2003, Pp 13- 27.

38. Adelekan, I. O. Gender, Economic Policy And Domestic Energy Use In Nigeria, *Ibaden Journal of The Social Sciences, Vol. 3*, Iss. 1, 2005, Pp 1– 16.

39. Akinwale A, The Menace Of Inadequate Infrastructure In Nigeria, *Africal Journal Of Science, Technology, Innovation And Development,* Vol 2, Iss. 3, 2010, Pp 207-228.

40. Doe, F., and Asamoah, E. S, The Effect Of Electric Power Fluctuations On The Profitability And Competitiveness Of Smes: A Study Of Smes Within The Acera Business District Of Ghana. *Journal of Competitiveness,* Vol 6, Iss. 3, 2014, 32–48.

41. Yang, Ma Ga Mark, Paul Hong, And Sachin B. Modi, "Impact Of Lean Manufacturing And Environmental Management On Business Performance: An Empirical Study Of Manufacturing Firms", *International Journal Of Production Economics*, Vol. 129, Iss. 2,v2011. Pp 251-261.

42. Jabbour, D, S., and Lopes, A, B., Quality Management, Environmental Management Maturity, Green Supply Chain Practices And Green Performance Of Brazilian Companies With ISO 14001 Certification: Direct And Indirect Effects, *Transportation Research Part E: Logistics And Transportation Review*, Vol. 67, Iss. 1 , 2014, Pp 39-51.

43. Psomas, E. L., The Effectiveness Of The Iso 9001 Quality Management System In Service Companies, *Total Quality Management & Business Excellence*, Vol. 24, Iss. 7, 2013. Pp 768-781.

44. Su, Q., Li, Z., Zhang, S.X., Liu, Y.Y. and Dang, J.X, The Impacts Of Quality Management Practices On Business Performance. An Empirical Investigation From China, *International Journal Of Quality & Reliability Management*, Vol. 25 Iss. 8, 2008, Pp. 809- 823.

45. Mccornac, D. C., The Implementation Of ISO 9000 In Vietnam: Case Studies From The Footwear Industry. *International Business & Economics Research Journal, Vol* 5, Iss. 2, 2006, Pp 77-86.

46. Fotopoulos, C, V., Psomas, E, L., and Vouzas, F, K., Investigating Total Quality Management Practices Inter-Relationships In ISO 9001:2000 Certified Organisations. *Total Quality Management, Vol.* 21, 2010, Pp 503–515.

47. Wahid, R, A., Corner, J., and Tan, P, L., 2011. ISO 9000 Maintenance In Service Organisations: Tales From Two Companies. *International Journal Of Quality & Reliability Management, Vol.* 28, Iss. 7, 2011, Pp 735-757.

48. Chang, D.S. And Lo, L.K. (2005), Measuring The Relative Efficiency of A Firm's Ability To Achieve Organizational Benefits After Iso Certification, Total Quality Management Journal, Vol. 16, Iss. 1, 2005, Pp. 57-69.

49. David Levine and Michael W. Toffel,2010 Quality Management And Job Quality: How The Iso 9001 Standard For Quality Management Systems Affects Employees And Employers, *Management Science, Vol.* 56, Iss.6, 2010, Pp 978-996.

50. Demirbag, M., Tatoglu, E., Tekinkus, M., and Zaim, S., An Analysis Of The Relationship Between TQM Implementation And Organizational Performance: Evidence From Turkish Smes, *Journal Of Manufacturing Technology Management,Vol.* 17, Iss. 6, 2006, Pp 829- 847.

51. Teixeira, Nuno, H., Lopes, I., and Sousa, S., Prioritizing Quality Problems In Smes: A Methodology. *The TQM Journal*, Vol. 27, Iss. 1, 2015, Pp. 2-21.

52. Vinodh, S., Prakash, N.H. And Selvan, K.E, Evaluation Of Leanness Using Fuzzy Association Rules Mining, *International Journal Of Advanced Manufacturing Technology,* Vol. 57 Iss. 1, 2011, Pp. 343-352.

53. Shah, R. and Ward, P.T, Defining And Developing Measures Of Lean Production, *Journal Of Operations Management*, Vol. 25 Iss. 4, 2007, Pp. 785-805.

54. Fullerton, R. R., Mcwatters, C. S., Fawson, C.,. An Examination of The Relationships Between Jit And Financial Performance. *Journal of Operations Management* , Vol. 21, Iss.4, 2003, Pp 383–404.

55. Simpson, D.F., Power, D.J., Use The Supply Relationship To Develop Lean And Green Suppliers. *Supply Chain Management: An International Journal, Vol.* 10 Iss. 1, 2005, Pp 60–68.

56 Motwani, J, A., Business Process Change Framework For Examining Lean Manufacturing: A Case Study, *Industrial Management And Data Systems,* Vol. 103 Iss. 5, 2003, Pp. 339-46.

57. Ghosh, M., Lean Manufacturing Performance In Indian Manufacturing Plants, *Journal of Manufacturing Technology Management*, Vol. 24 Iss 1, 2012, Pp. 113 – 122.

58. Nawanir, G., Lim, K., and Othman, S., Lean Manufacturing Practices In Indonesian Manufacturing Firms: Are There Business Performance Effects? *International Journal Of Lean Six Sigma,* Vol. 7, Iss. 2, 2016,Pp. 149-170.

59. Anand, G. and Kodali, R.,Simulation Model For The Design Of Lean Manufacturing Systems – A Case Study, *International Journal Of Productivity And Quality Management*, Vol. 4, Iss.. 5, 2009, Pp. 691-714.

60. Kumar, S., Singh, B., Qadri, M.A., Kumar, Y.V.S. and Haleem, A., A Framework For Comparative Evaluation of The Lean Performance Of Firms Using Fuzzy Topsis", *International Journal of Productivity And Quality Management*, Vol. 11, Iss. 4, 2013, Pp. 371-392.

61. Paranitharan, K. P., Begam, M. S., Abuthakeer, S.S., and Subha, M. V., Redesigning An Automotive Assembly Line Through Lean Strategy, *International Journal of Lean Thinking*, Vol. 2 Iss. 2, 2011, Pp. 1-14.

62. Hasle, P., Lean Production – And Evaluation Of The Possibilities For An Employee Supportive Lean Practice, *Human Factors And Ergonomics In Manufacturing And Service Industries*, Vol. 24, Iss. 1, 2014, Pp. 40-53.

63 Singh, B., Garg, S. K., Sharma, S. K., and Grewal, C, Lean Implementation And Its Benefits To The Production Industry. *International Journal of Lean Six Sigma*, Vol.1, 2010, Pp 157–168.

64. Holweg, M., The Genealogy Of Lean Production, *Journal Of Operations Management*, Vol. 25, Iss. 2, 2007, Pp. 420-37.

65. Liker, J. K., and Wu, Y. C., Japanese Automakers, Us Suppliers And Supply-Chain Superiority, Sloan *Management Review,* Vol. 42, 2000, Pp 81-93.

66. Mahapatra, S. S., Mohanty, S. R., Lean Manufacturing In Continuous Process Industry, An Empirical Study. *Journal of Scientific & Industrial Research*, Vol. 66, 2007, Pp. 19-27.

67. Saleeshya, P.G., Austin, D. and Vamsi, N., A Model To Assess The Lean Capabilities Of Automotive Industries, *International Journal of Productivity And Quality Management,* Vol. 11, Iss. 2, 2013, Pp. 195-211.

68. Eswaramoorthi, M., Kathiresan, G.R., Prasad, P.S.S. and Mohanram, P.V, A Survey On Lean Practices In Indian Machine Tool Industries, *The International Journal of Advanced Manufacturing Technology*, Vol. 52, Iss. 9-12, 2011, Pp. 1091-1101.

69. Garza-Reyes, J.A., Parkar, H.S., Oraifige, I., Soriano-Meier, H. and Harman To, D. An Empirical-Exploratory Study Of The Status of Lean Manufacturing In India, *International Journal Of Business Excellence*, Vol. 5, Iss. 4, 2012, Pp. 395-412.

70. Achanga, P., Shehab, E., Roy, R., and Nelder, G., Critical Success Factors For Lean Implementation Within Smes, *Journal of Manufacturing Technology Management, Vol.*17, Iss.4, 2006, Pp. 460-471

71. Stamm M.L., Neitzert, Key Performance Indicators (KPI) for the Implementation of Lean methodologies in a Manufacture-To-Order Small and Medium Enterprise, School of Engineering, AUT University, Auckland, New Zealand, 2010, pp 1-14

72. Vinodh, S., Arvind, K.R. and Somanaathan, M, Application Of Value Stream Mapping In An Indian Camshaft Manufacturing Organisation, *Journal Of Manufacturing Technology Management,* Vol. 21 Iss. 7, 2010, Pp. 888-900.

73. Arif-Uz-Zaman, K., A Methodology For Effective Implementation of Lean Strategies And Its Performance Evaluation In Manufacturing Organizations. *Business Process Management Journal,* Vol. 19, Iss.1, 2013, Pp: 169-196.

74. Micklewright, M. Lean ISO 9001: Adding Spark To Your ISO 9001 QMS And Sustainability To Your Lean Efforts, ASQ Quality Press, Milwaukee, 2010.

75. Sullivan, W., Mcdonald, T., and Aken, E, Equipment Replacement Decisions And Lean Manufacturing. *Robotics And Computer Integrated Manufacturing*, Vol. 18, 2002, Pp 255–265.

76. Taj, S., and Berro, L, Application Of Constrained Management And Lean Manufacturing In Developing Best Practices For Productivity Improvement In An Auto-Assembly Plant. *International Journal of Productivity And Performance Management*, Vol. 55, Iss.3/4, 2006, Pp 332–345.

77. Abdulmalek, Fawaz A., and Jayant Rajgopal. Analysing The Benefits Of Lean Manufacturing And Value Stream Mapping Via Simulation: A Process Sector

Case Study, *International Journal Of Production Economics*, Vol. 107, Iss.1, 2007, Pp 223-236.

78. Suárez-Barraza, M. F., Ramis-Pujol, J. and Kerbache, L, Thoughts On Kaizen And Its Evolution. Three Different Perspectives And Guiding Principles, *International Journal And Lean Six Sigma*, Vol. 1, Iss.2, 2011, Pp. 107–129.
79. Bhamu, J., and Sangwan, K. Singh, Lean Manufacturing: Literature Review And Research Issues. *International Journal of Operations & Production Management*, Vol.34, iss. 7, 2014, Pp: 876-940.
80. Aishwarya J. K., Review On Poka-Yoke: A Technique To Prevent Defects, *International Journal Of Engineering Sciences & Research Technology*, Kurhade*, Vol.* 4, Iss. 11, 2015, 652-659.
81. Sujay Biswas, Chakraborty, A., Using Poka-Yoke For The Development of SMEs, *American Journal Of Engineering Research*, Vol. 5, Iss.9, Pp-15-18
82. Hobbs, D. P., Lean Manufacturing Implementation: A Complete Execution Manual For Any Size Manufacturer. *J. Ross Publishing*, 2003.
83. Ioannis, B., Garza-Reyes, J, A., and Vikas Kumar. The Impact Of Lean Methods And Tools On The Operational Performance Of Manufacturing Organisations. *International Journal of Production Research*, Vol. 52, Iss. 18, 2014, Pp: 5346-5366.
84. Zahraee, S. M., Hashemi, A., Ali Abdi, A., Shahpanah, A.,and Jafri Mohd Rohani, J. M., Lean Manufacturing Implementation Through Value Stream Mapping: A Case Study. Journal Technology, Vol. 68, Iss. 3, 2014, Pp: 119-124.
85. Abdulmalek, F., and Rajgopal, J., Analyzing The Benefits of Lean Manufacturing And Value Stream Mapping Via Simulation: A Process Sector Case Study. *International Journal Of Production Economics*, Vol.107, 2007, Pp 223–236.
86. Shih-Lung, Fu., Shou-Yan Chou, Chi-Kuang Chen, and Chi-Wei Wang, Assessment And Cultivation of Total Quality Management Organisational Culture–An Empirical Investigation. *Total Quality Management & Business Excellence*, Vol. 26, Iss. 1-2, 2015, Pp: 123-139.
87. Jain, A., Bhatti, R., and Singh. Harwinder, Total productive maintenance (TPM) implementation practice: A literature review and directions, *International Journal of Lean Six Sigma,* Vol.5, Iss. 3, 2014, Pp 293-323.
88. Demeter, K., and Matyusz, Z. The impact of lean practices on inventory turnover. *International Journal of Production Economics*, Vol.133, Iss. 1, 2011, Pp 154-163.

89. Singh, B., Garg, S. K., Sharma, S. K., and Grewal, C., Lean Implementation benefits to production Industry, international Journal of Six Sigma, Vol. 1, Iss. 2, 2010, Pp. 157-168.

90. Bhasin, S., Performance of Lean in large organisations, Journal of Manufacturing Systems, Vol. 31, Iss. 1, 2012, Pp 349-357

91. Mostafa, S., Dumark, J., Soltan, H., a framework for Lean Manufacturing Implementation, *Production and Manufacturing research,* Vol. 1, 2013, Pp 44-64.

92. Kumar, R., Kumar, V., Barriers In Implementation Of Lean Manufacturing System In Indian Industry: A Survey, International Journal Of Latest Trends In Engineering And Technology, Vol. 4, Iss.2, 2014, Pp 242-251.

93. Mishra, R.. and Napier, R., Linking Sustainability to Quality Management and Firm Performance. *International Journal of Business and Management*, Vol. 10, Iss. 3, 2015, Pp 1-15.

94. Garetti M, and Taisch M., Sustainable manufacturing: trends and research challenges. Prod Plan Control, Vol. 23, Iss. 2, 2012, Pp 83–104.

95. Borangiu, T., Trentesaux, D, Thomas, A., Service Orientation In Holonic And Multi-Agent Manufacturing And Robotics, *Proceedings of SOHOMA 2017.*

96. Gaughran, W., Burke S, and Phelan P., Intelligent Manufacturing And Environmental Sustainability. *Robotic Computer-Integrated Manufacturing* Vol. 23, Iss.6, 2007, Pp 704–711.

97. Isaksson, R., Total Qual. Management For Sustainable Development. Bus. Process Manag. Journal, Vol.12, 2006, Pp 632–645.

98. Yang, M. G., Hong, P., and Modi, S. B., Impact of Lean Manufacturing And Environmental Management On Business Performance: An Empirical Study Of Manufacturing Firms. *International Journal Of Production Economics*, Vol 129, Iss.2, 2011, Pp 251-261.

99. Ellis, T. J., and Levy, Y. The Framework of Problem-Based Research: A Guide For Novice Researchers on The Development of A Research-Worthy Problem. *Information Science: The International Journal of An Emerging Trans-Discipline, Vol.11*, 2008, Pp 18-33

100. Chiarini, A, Sustainable Manufacturing-Greening Processes Using Specific Lean Production Tools: An Empirical Observation From European Motorcycle Component Manufacturers, *Journal Of Cleaner Production*, Vol. 85, 2014, Pp.226–233.

101. Abualfaraa, W., Salonitis, K., Al-Ashaab, A., and Ala'raj, M., Lean-Green Manufacturing Practices And Their Link With Sustainability: A Critical Review, *Sustainability,* Vol. 1, 2019, Pp 1-22

102. Johnson, T.H, Sustainability, And Lean Operations, *Cost Management*, Vol. 20, Iss. 2, 2006, Pp.40–46.

103. Khalili, A., Ismail, M. Y., and Karim, Integration of Lean Manufacturing And Quality Management System Through Structural Equation Modelling, *International Journal of Productivity And Quality Management,* Vol.20, Iss.4, 2017, Pp 534–556.

104. Gajendran S., Sampath Kumar S., Integration Of Lean Compatible Quality Management Systems*, Journal Of Metallurgical Engineering*, Vol.1, Iss.1, 2011, Pp 35–45

105. Mart´Inez-Jurado P.J., Moyano-Fuentes J., Jerez- Gomez P., Human Resource Management In Lean Production Adoption And Implementation Processes: Success Factors In The Aeronautics Industry, *BRQ Business Research Quarterly*, Vo. 17, Iss.1, 2014, Pp 47–68.

106. Ramakrishnan, J. Jayaprakash, C. Elanchezhian, B. Vijaya Ramnath, Implementation of Lean Manufacturing in Indian SMEs-A case study, Materials Today: Proceedings, Volume 16, Part 2, 2019, Pp 1244-1250.

107. Laila Driouach, Khalid Zarbane and Zitouni Beidouri Driouach, Laila & Zarbane, Khalid & Beidouri, Zitouni. Literature Review of Lean Manufacturing in Small and Medium-sized Enterprises. International Journal of Technology. 10(5). 2019, 930.

108. Amine Belhadi, Yusof Bin Mohd Sha'ri, Fatima Ezahra Touriki & Said El Fezazi, Lean production in SMEs: literature review and reflection on future challenges, Journal of Industrial and Production Engineering, 35:6, 2018, pp368-382.

109. Sajan M.P., Shalij P.R., Ramesh A., and Biju Augustine, P. Lean Manufacturing Practices In Indian Manufacturing SMEs And Their Effect On Sustainability Performance*, Journal of Manufacturing Technology Management,* Vol. 28 No. 6, 2016, Pp. 772-793.

110. King, A. and Lenox, M.J, Lean And Green? An Empirical Examination Of The Relationship Between Lean Production And Environmental Performance, *Production And Operations Management*, Vol. 10, Iss. 3, 2001, Pp.244–256.

111. Yang, M. G., Hong, P., and Modi, S. B., Impact of lean manufacturing and environmental management on business performance: An empirical study of manufacturing firms. International Journal of Production Economics, Vol. 129, Iss.2, 2011, Pp 251-261,

112. Saunders, M., Lewis, P., and Thornhill, A., Research Methods For Business Students, *Pearson Education Limited,* 8th Edn., Chapter 4, 2009, Pp 128-174.

113. Creswell; J. W., and Creswell, J. D., Research Design, Qualitative, Quantitative, and Mixed Methods Approaches, Imprint: SAGE Publications, Inc, 5th edn., 2008.

114. Naresh K. Malhotra, David F. Birks, Marketing Research, 4th Edition, Winchester Business School, Peter A. Wills, Pearson, 2012

115. Collis, J. and Hussey, R., Business Research: A Practical Guide for Undergraduate & Postgraduate Students. 3rd ed., 2009, London: Palgrave Macmillan.

116. Perneger , T. V., Courvoisier, D. S., Patricia M Hudelson, and Gayet-Ageron, A., Sample Size For Pre-Tests Of Questionnaires, Vol. 24, Iss.1, 2015, Pp 147-51

117. Leeuw. E., Hox, J., and Dillman, D., International Handbook Of Survey Methodology, 2008,

118. Oosterveld, P., Harrie C.M., Methods For Questionnaire Design: A Taxonomy Linking Procedures To Test Goals, *Quality Of Life Research*, Vol. 28, Iss. 6, 2019, Pp 1-12

119. Brace, I., Questionnaire Design: How To Plan, Structure And Write Survey Material For Effective Market Research, *Kogan Page*, Edn. 4,2018.

120. Cooper, D.R., and Schindler, P.S., Business Research Methods. Mcgraw-Hill Higher Education, *Scientific Research,* 2001.

121. Dawn Iacobucci and Gilbert A. Churchill, Marketing Research: Methodological Foundations, *South-Western Publishing Company*, Edn. 12, 2002.

122. H. Russell Bernard, Research Methods In Anthropology – Qualitative & Quantitative Approaches, *Alta Mira*, 2006

123. Hair, J. F., Black., W. C., Babin., B. J., Anderson., R. E., and Tatham., R., Multivariant Data Analysis. New Jersey: Pearson International Edition, Edn. 7, 2006.

124. Zikmund, W. G., Babin, B,. J., Exploring Marketing Research, *South-Western*, Edn. 10, 2010.

125. Kroese, D,.P., Brereton, T., Thomas Taimre, T., and Zdravko I. Botev, Z. I., Why The Monte Carlo Method Is So Important Today, *Wires Computational Stat*istics Vol. 6, 2014, Pp 386-392.

126. Hastings, W. K., Monte Carlo Sampling Methods Using Markov Chains And Their Applications, *Jstor, Biometrika*, Vol. 57, Iss. 1, 1970, Pp. 97-109

127. George, W., Snedecor and William, G. C., Statistical Methods. Wiley-Blackwell, 8th Ed., 1991.

128n. Siegel, S., Nonparametric Statistics, *The American Statistician*, Vol. 11, Iss. 3, 1957, Pp. 13-19.

APPENDIX - I

SAMPLE OF A FILLED IN QUESTIONNAIRE

QUESTIONNNAIRE ON QMS IMPLEMETATION AND PERCEPTION OF LEAN AND SUSTAINABILITY PRINCIPLES

Dear Sir/Madam,

Please find attached a survey questionnaire form designed to gather information on benefits of quality management systems followed in SMEs along with the understanding the benefits of lean and sustainable practices.

Please before filling in the questionnaire here is a brief background about me;

The definition of Lean used in this survey is "creating more value for customers with fewer resources". It can also be seen as a philosophy or methodology for continuous reduction of waste with an aim of achieving dramatic improvements in quality, cost and time by focusing on process improvement.

The definition of Sustainable manufacturing in this survey is "creation of manufacturedproducts through economically-sound processes that minimize negative environmental impacts while conserving energy and natural resources".

Objective of this questionnaire is to "evaluate the current quality management systems along with the benefits expected from Lean and Sustainability integration with the existing systems".

Please include your views in completing the survey which should take about 15 minutes of your time.

The information provided by you in this questionnaire will be used for research purposes only. All personal information (if provided) will be kept confidential and will not be disclosed to anyone else or used for other purposes.

I look forward to your participation in the same and thank you in advance for sparing your valuable time to answer the questionnaire.

Yours Sincerely,

MANMOHAN C M

Associate Professor in Mechanical Engineering
Govt. Engineering College, Thrissur -9
Mobile: 9447002997
Email id :manmohancm@gectcr.ac.in

Part A : Details of the organisation

1. Name of the organisation : Star Pipes
2. Name of the respondent *(Optional)* : _____
3. Designation : Supervisor.
4. Gender ☐ Male ☑ Female
5. The organisation is ☑ ISO 9001 Certified ☐ Non ISO
6. Organisation is existing for ☐ < 5 years ☐ 5 - 10 years ☑ >10 years
7. Turnover in the last year ☐ < 5 crores ☑ 5 - 75 crores ☐ > 75 crores
8. Number of employees ☐ < 25 ☑ 25 – 50 ☐ > 50

Part B :Survey Questions

Please respond to the following questions by ticking (✓) the appropriate box

		Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree
1	To what extent do you agree that your company mainly focuses on customer requirements and expectations?	1	2	3	4	5 ✓
2	To what extent do you agree that your company has a very good leadership responsible for creating a productive and progressive manufacturing environment?	1	2	3	4 ✓	5
3	To what extent do you agree that your company always provides opportunities for enhancement of skills and knowledge?	1	2	3	4	5 ✓
4	To what extent do you agree that your company follows systematic processes for each work?	1	2	3	4 ✓	5
5	To what extent do you agree that your company always focus on continuous improvement?	1	2	3	4	5 ✓
6	To what extent do you agree that decisions are taken based on real facts, data and information?	1	2	3	4 ✓	5
7	To what extent do you agree that your company is maintaining smooth and healthy relationships with your suppliers.	1	2	3	4	5 ✓
8	To what extent do you agree that lean implementation will motivate the employees?	1	2	3	4	5 ✓
9	To what extent do you agree that product quality will be increased by lean implementation?	1	2	3	4	5 ✓

10	To what extent do you agree that lean implementation will reduce the wastage?	1 2 3 4 5
11	To what extent do you agree that the lean manufacturing will reduce the inventory?	1 2 3 4 5
12	To what extent do you agree that process knowledge will be increased when lean is implemented?	1 2 3 4 5
13	To what extent do you agree that new process technologies will be a part of lean implementation?	1 2 3 4 5
14	To what extent do you agree that lead time will be reduced when lean is implemented?	1 2 3 4 5
15	To what extent do you agree that lean manufacturing will increase the productivity?	1 2 3 4 5
15	To what extent do you agree that lean implementation will result in better understanding on customer needs?	1 2 3 4 5
17	To what extent do you agree that lean implementation will improve the organisation culture?	1 2 3 4 5
18	To what extent do you agree that company's growth will improve by the lean implementation?	1 2 3 4 5
19	To what extent do you agree that sustainable practices will increase the profit of the organisation?	1 2 3 4 5
20	To what extent do you agree that sustainability will improve the company's relationship with people?	1 2 3 4 5
21	To what extent do you agree that organisational performance will be improved by adopting to sustainable practices?	1 2 3 4 5
22	To what extent do you agree that sustainability practice will increase customer delight?	1 2 3 4 5
23	To what extent do you agree that sustainable practices will reduce operating costs?	1 2 3 4 5
24	To what extent do you agree that sustainable practices will improve leadership qualities?	1 2 3 4 5
25	To what extent do you agree that sustainable practices will preserve the environment?	1 2 3 4 5
26	To what extent do you agree that improving people's health and opportunities for a good life contribute to sustainable development?	1 2 3 4 5

APPENDIX II

LEAN AND SUSTAINABILITY INTEGRATED QUALITY MANAGEMENT SYSTEM - REQUIREMENTS

1 Scope

The scope is intended as a means by which organisations can demonstrate their ability to supply products and services that consistently meet customer and applicable statutory and regulatory requirements. It sets out the intended results of a *lean and sustainable integrated* quality management system which are specific and should be aligned with the context of the organisation (see clause 4):

a) needs to demonstrate its ability to consistently provide products and services that meet customer and applicable statutory and regulatory requirements, and

b) aims to enhance customer satisfaction through the effective application of the system, including processes for improvement of the system and the assurance of conformity to customer and applicable statutory and regulatory requirements.

All the requirements of this standard are generic and are intended to apply to any organization, regardless of its type or size, or the products and services it provides.

NOTE 1 In this standard, the terms " products and services" or "service" only apply to products and services intended for, or required by, a customer.

NOTE 2 Statutory and regulatory requirements can be expressed as legal requirements.

2 Normative references

Provides details of the reference standards, relevant to the particular standard. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

3 Terms and definitions

Details terms and definition applicable to the specific standard, in addition to any formal related terms and definitions standard. For this document, the terms and definitions given in ISO 9000:2015apply.

4 Context of the organization

This clause is broken down into four separate sub-clauses which address the scope of the organisation's lean and *sustainability integrated QMS* with particular emphasis on the needs and expectations of interested parties.

4.1 Understanding the organization and its context

The organization shall determine external and internal issues that are relevant to its purpose, *Environmental Impacts* and its strategic direction and that affect its ability to achieve the intended result(s) of its *lean and sustainable integrated* quality management system.

The organization shall monitor and review information about external and internal issues.

NOTE 1: Issues can include positive and negative factors or conditions for consideration.

NOTE 2: Understanding the external context can be facilitated by considering issues arising from legal, technological, political, competitive, market, cultural, social, economic, environmental, whether international, national, regional or local.

NOTE 3 Understanding the internal context can be facilitated by considering issues related to values, culture, knowledge and performance of the organization.

4.2 Understanding the needs and expectations of interested parties

Due to their effect or potential effect on the organization's ability to consistently provide products and services and services that meet customer and applicable statutory and regulatory **customer requirements**, the organization shall determine:

a) the interested parties that are relevant to the *lean and sustainable integrated* quality management system;

b) the requirements of these interested parties that are relevant to the *lean and sustainable integrated* quality management system.

The organization shall monitor and review information about these interested parties and their relevant requirements.

4.3 Establishing the scope of the quality management system

The organization shall determine the boundaries and applicability of the *lean and sustainable integrated* quality management system to establish its scope.

When establishing this scope, the organization shall consider:

a) the external and internal issues referred to in 4.1;

b) the requirements of relevant interested parties referred to in 4.2;

c) the products and services of the organization.

The organization shall apply all the requirements of this standard if they are applicable within the determined scope of the *lean and sustainable integrated* quality management system.

The scope of the organization's *lean and sustainable integrated* quality management system shall be available and be maintained as documented information. The scope shall state the types of products and services covered, and justify any requirement of this standard that the organization determines does not apply to the scope of its *lean and sustainable integrated* quality management system.

Conformity to this standard may only be claimed if the requirements determined as not being applicable do not affect the organization's ability or responsibility to ensure the conformity of its products and services and the enhancement of customer satisfaction.

4.4 Quality management system and its processes

4.4.1 The organization shall establish, implement, maintain and continually improve the *lean and sustainable integrated* quality management system, including the processes needed and their interactions, by the requirements of this International Standard.

The organization shall develop the processes needed for the lean and sustainability integrated quality management system and their application throughout the organization, and shall:

a) determine the inputs required and the outputs expected from these processes;

b) determine the sequence and interaction of these processes;

c) determine and apply the criteria and methods (including monitoring, measurements and related performance indicators) needed to ensure the effective operation and control of these processes;

d) determine the resources needed for these processes and ensure their availability;

e) assign the responsibilities and duties for these processes;

f) address the risks and opportunities as determined by the requirements of 6.1;

g) evaluate these processes and implement any changes needed to ensure that these processes achieve their intended results;

4.4.2 To the extent necessary, the organization shall:

a) maintain documented information to support the operation of its processes;

b) retain documented information to have confidence that the processes are being carried out as planned.

5 Leadership

Clause 5 comprises of three sub-clauses:

5.1 Leadership and commitment

5.1.1 General

Top management shall demonstrate leadership and commitment concerning the *lean and sustainable integrated* quality management system by:

a) taking accountability for the effectiveness of the *lean and sustainable integrated* quality management system;

b) ensuring that the quality policy and quality objectives are established for the *lean and sustainable integrated* quality management system and are compatible with the context and strategic direction of the organization;

c) ensuring the integration of the *lean and sustainable integrated* quality management system requirements into the organization's business processes;

d) promoting the use of the process approach and risk-based thinking;

e) ensuring that the resources needed for the *lean and sustainable integrated* quality management system are available;

f) communicating the importance of effective quality management and of conforming to the *lean and sustainable integrated* quality management system requirements;

g) ensuring that the *lean and sustainable integrated* quality management system achieves its intended results;

h) engaging, directing and supporting persons to contribute to the effectiveness of the *lean and sustainable integrated* quality management system;

i) promoting improvement;

j) supporting other relevant management roles to demonstrate their leadership as it applies to their areas of responsibility;

k) ensuring employee engagement and respecting all persons within the organisation.

NOTE: Reference to "business" in this International Standard can be interpreted broadly to mean those activities that are core to the purposes of the organization's existence, whether the organization is public, private, for-profit or not for profit.

5.1.2 Customer focus

Top management shall demonstrate leadership and commitment to customer focus by ensuring that:

a) customer and applicable statutory and regulatory requirements are determined, understood and consistently met;

b) the risks and opportunities that can affect the conformity of products and services and the ability to enhance customer satisfaction are determined and addressed;

c) focus on enhancing customer satisfaction and *customer delight are* maintained.

5.2 Policy

5.2.1 Establishing the quality policy

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

a) is appropriate to the purpose and context of the organization and supports its strategic direction;

b) provides a framework for setting *lean and sustainable integrated* quality objectives;

c) includes a commitment to satisfy applicable requirements;

d) includes a commitment to the improvement of the *lean and sustainable integrated* quality management system.

5.2.2 Communicating the quality policy

The quality policy shall:

a) be available and be maintained as documented information;

b) be communicated, understood and applied within the organization;

c) be available to relevant interested parties, as appropriate.

5.3 Organizational roles, responsibilities and duties

Top management shall ensure that the responsibilities and duties for relevant roles are assigned, communicated and understood within the organization.

Top management shall assign the responsibility and duties for:

a) ensuring that the *lean and sustainable integrated* quality management system conforms to the requirements of this standard;

b) ensuring that the processes are delivering their intended outputs;

c) reporting on the performance of the quality management system and opportunities for improvement, in particular, to top management;

d) ensuring the promotion of customer focus throughout the organization;

e) ensuring that the integrity of the quality management system is maintained when changes to the *lean and sustainable integrated quality management system* are planned and implemented;

6 Planning

This clause is all about how the organisation will prevent or reduce undesired effects. Clause 6 includes three sub-clauses:

6.1 Actions to address risks and opportunities

This requires organisations to adopt a risk-based approach when planning the workflow.

6.1.1 When planning for the quality management system, the organization shall consider the issues referred to in 4.1 and the requirements referred to in 4.2 and determine the risks and opportunities that need to be addressed to:

a) give assurance that the quality management system can achieve its intended result(s);

b) enhance desirable effects;

c) prevent, or reduce, undesired effects;

d) provide problem-solving methods;

d) achieve improvement;

f) sustainable plan that can help to reduce undesirable business issues;

g) automated technology concerned with the use of electronic, mechanical and computer-based systems to operate and control manufacturing.

6.1.2 The organization shall plan:

a) actions to address these risks and opportunities;

b) how to:

i) integrate and implement the *lean and sustainability* factors into its quality management system processes (see 4.4);

ii) evaluate the effectiveness of these actions.

Actions taken to address risks and opportunities shall be proportionate to the potential impact on the conformity of products and services and services.

NOTE 1: Options to address risks can include avoiding risk, taking the risk to pursue an opportunity, eliminating the risk source, changing the likelihood or consequences, sharing the risk, or retaining risk by informed decision.

NOTE 2: Opportunities can lead to the adoption of new practices, launching new products and services, opening new markets, addressing new customers, building partnerships, using new technology, and other desirable and possibilities to address the organization's or its customers' needs.

6.2 Quality objectives and planning to achieve them

6.2.1 The organization shall establish quality objectives at relevant functions, levels and processes needed for the *lean and sustainable integrated* quality management system.

The quality objectives shall:

a) be consistent with the quality policy;

b) be measurable;

c) take into account applicable requirements;

d) be relevant to the conformity of products and services and enhancement of customer satisfaction;

e) be monitored;

f) be communicated;

g) be updated as appropriate.

6.2.2 When planning how to achieve its quality objectives, the organization shall determine:

a) what will be done;

b) what resources will be required;

c) who will be responsible;

d) when it will be completed;

e) how the results will be evaluated.

6.3 Planning of changes

When the organization determines the need for changes to the *lean and sustainable integrated* quality management system, the changes shall be carried out in a planned manner (see 4.4).

The organization shall consider:

a) the purpose of the changes and their potential consequences;

b) the integrity of the quality management system;

c) the availability of resources;

d) the allocation or reallocation of responsibilities and duties;

7 Support

Clause 7 consists of five sub-clauses:

7.1 Resources

7.1.1 General

The organization shall determine and provide the resources needed for the establishment, implementation, maintenance and improvement of the lean and sustainable integrated quality management system.

The organization shall consider:

a) the capabilities of, and constraints on, existing internal resources;

b) what needs to be obtained from external providers;

c) utilization of natural resources without disturbing the ecosystem balance and ecosystem equilibrium;

d) education and training.

7.1.2 People

The organization shall determine and provide the persons necessary for the effective implementation of *lean and sustainable integrated* quality management system and the operation and control of its processes.

The organization shall ensure

a) Employee involvement in aspects related to internal and external systems

b) workforce management to improve productivity

b) Social sustainability

7.1.3 Infrastructure

The organization shall determine, provide and maintain the infrastructure necessary for the operation of its processes and achieve conformity of products and services.

NOTE: Infrastructure can include:

a) buildings and associated utilities;

b) equipment, including hardware and software;

c) transportation resources,

d) information and communication technology.

7.1.4 Environment for the operation of processes

The organization shall determine, provide and maintain the environment necessary for the operation of its processes and achieve conformity of products and services.

The organization shall ensure

a) organisation of workplace to improve productivity; and

b) environmental policies of the organisation.

The work environment should be managed to ensure compliance with requirements.

7.1.5 Monitoring and measuring resources

7.1.5.1General

The organization shall determine and provide the resources needed to ensure valid and reliable results when monitoring or measuring is used to verify the conformity of products and services to requirements.

The organization shall ensure that the resources provided:

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

b) are maintained to ensure their continuing fitness for their purpose

The organization shall retain appropriate documented information as evidence of fitness for purpose of the monitoring and measurement resources.

When measurement traceability is a requirement or is considered by the organization to be an essential part of providing confidence in the validity of measurement results, measuring equipment shall be:

a) calibrated or verified, or both, at specified intervals, or before use, against measurement standards traceable to international or national measurement standards; when no such standards exist, the basis used for calibration or verification shall be retained as documented information;

b) identified to determine their status;

c) safeguarded from adjustments, damage or deterioration that would invalidate the calibration

status and subsequent measurement results.

The organization shall determine if the validity of previous measurement results has been adversely affected when measuring equipment is found to be unfit for its intended purpose, and shall take appropriate action as necessary.

7.1.6 Organizational knowledge

The organization shall determine the knowledge necessary for the operation of its processes and to achieve conformity of products and services.

This knowledge shall be maintained and be made available to the extent necessary.

When addressing changing needs and trends, the organization shall consider its current knowledge and determine how to acquire or access any necessary additional knowledge and required updates.

NOTE 1: Organizational knowledge *and culture are* knowledge specific to the organization; it is generally gained by experience. It is information that is used and shared to achieve the organization's objectives.

NOTE 2: Organizational knowledge can be based on:

a) internal sources (e.g. intellectual property; knowledge gained from experience; lessons learned from failures and successful projects; capturing and sharing undocumented knowledge and experience; the results of improvements in processes, products and services);

b) external sources (e.g. standards; academia; conferences; gathering knowledge from customers or external providers).

NOTE 3: Organizational culture is developed through policies of the organisation while dealing with the stake holders. Organisational knowledge and culture helps globalisation of the activities in order to improve sustainability.

7.2 Competence

The organization shall:

a) determine the necessary competence of person(s) doing work under its control that affects the performance and effectiveness of the *lean and sustainable integrated* quality management system;

b) ensure that these persons are competent based on appropriate education, training, or experience;

c) where applicable, take actions to acquire the necessary competence, and evaluate the effectiveness of the actions taken;

d) retain appropriate documented information as evidence of competence.

e) device strategies that help improve competence of the organisation

NOTE: Applicable actions can include, for example, the provision of training to, the mentoring of, or the reassignment of currently employed persons; or the hiring or contracting of competent persons.

7.3 Awareness

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

a) the *lean and sustainable integrated* quality policy;

b) relevant quality objectives;

c) their contribution to the effectiveness of the lean and sustainable integrated quality management system, including the benefits of improved performance;

d) the implications of not conforming with the lean and sustainable integrated quality management system requirements.

7.4 Communication

The organization shall determine the internal and external communications relevant to the lean and sustainable integrated quality management system, including:

a) on what it will communicate;

b) when to communicate;

c) with whom to communicate;

d) how to communicate;

e) who communicates.

7.5 Documented information

7.5.1 General

The organization's quality management system shall include:

a) documented information required by this standard;

b) documented information determined by the organization as being necessary for the effectiveness of the *lean and sustainable integrated* quality management system.

c) a clear and compelling vision which intends to achieve and how that vision responds to a real need in the community.

NOTE: The extent of documented information for the *lean and sustainable integrated* quality management system can differ from one organization to another due to:

— the size of the organization and its type of activities, processes, products and services;

— the complexity of processes and their interactions;

— the competence of persons.

7.5.2 Creating and updating

When creating and updating documented information, the organization shall ensure appropriate:

a) identification and description (e.g. a title, date, study, or reference number);

b) format (e.g. language, software version, graphics) and media (e.g. paper, electronic);

c) review and approval for suitability and adequacy.

7.5.3 Control of documented information

7.5.3.1 Documented information required by the *lean and sustainable integrated* quality management system and by this International Standard shall be controlled to ensure:

a) it is available and suitable for use, where and when it is needed;

b) it is adequately protected (e.g. from loss of confidentiality, improper use, or loss of integrity).

7.5.3.2 For the control of documented information, the organization shall address the following activities, as applicable:

a) distribution, access, retrieval and use;

b) storage and preservation, including preservation of legibility;

c) control of changes (e.g. version control);

d) retention and disposition.

Documented information of external origin determined by the organization to be necessary for the planning and operation of the quality management system shall be identified as appropriate, and be controlled.

Documented information retained as evidence of conformity shall be protected from unintended alterations.

NOTE: Access can imply a decision regarding the permission to view the documented information only, or the permission to view and change the documented information.

8 Operation

The seven sub-clauses of clause 8 are as follows:

8.1 Operational planning and control

The organization shall plan, implement and control the processes (see 4.4) needed to meet the requirements for the provision of products and services and to implement the actions determined in Clause 6, by:

a) establishing the requirements for the products and services;

b) establishing criteria for:

   i) the processes;

   ii) the acceptance of products and services;

c) establishing the resources needed to achieve conformity to the products and services and service requirements;

d) implementing control of the processes under the criteria;

e) establishing, maintaining and retaining documented information to the extent necessary:

   i) to have confidence that the processes have been carried out as planned;

   ii) to demonstrate the conformity of products and services to their requirements.

The output of this planning shall be suitable for the organization's operations.

The organization shall control planned changes and review the consequences of unintended changes, taking action to mitigate any adverse effects, as necessary.

The organization shall ensure that outsourced processes are controlled (see 8.4).

8.2 Requirements for products and services

8.2.1 Customer communication

Communication with customers shall include:

a) providing information relating to products and services;

b) handling enquiries, contracts or orders, including changes;

c) obtaining customer feedback relating to products and services, including customer complaints;

d) handling or controlling customer property;

e) establishing specific requirements for contingency actions, when relevant;

8.2.2 Establishing the requirements for products and services

When establishing the requirements for the products and services to be offered to customers, the organization shall ensure that:

a) the requirements for the products and services are defined, including:

   i) any applicable statutory and regulatory requirements;

   ii) those considered necessary by the organization;

   iii) delivery commitments.

b) the organization can meet the claims for the products and services it offers.

8.2.3 Review of the requirements for products and services

8.2.3.1 The organization shall ensure that it can meet the requirements for products and services to be offered to customers. The organization shall conduct a review before committing to supply products and services to a customer, to include:

a) requirements specified by the customer, including the requirements for delivery and post-delivery activities;

b) requirements not stated by the customer, but necessary for the specified or intended use, when known;

c) requirements specified by the organization;

d) statutory and regulatory requirements applicable to the products and services;

e) contract or order requirements differing from those previously expressed.

The organization shall ensure that contract or order requirements differing from those previously defined are resolved.

The customer's requirements shall be confirmed by the organization before acceptance when the customer does not provide a documented statement of their requirements.

NOTE 1: In some situations, such as internet sales, a formal review is impractical for each order. Instead, the review can cover relevant products and services information, such as catalogues.

8.2.3.2 The organization shall retain documented information, as applicable:

a) on the results of the review;

b) on any new requirements for the products and services.

8.2.4 Changes to requirements for products and services

The organization shall ensure that relevant documented information is amended, and those relevant persons are made aware of the changed requirements when the requirements for products and services are changed.

8.3 Design and development of products and services

8.3.1 General

The organization shall establish, implement and maintain a design and development process that is appropriate to ensure the subsequent provision of products and services.

8.3.2 Design and development planning

In establishing the stages and controls for design and development, the organization shall consider:

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

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

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

d) the responsibilities and duties involved in the design and development process;

e) the internal and external resource needs for the design and development of products and services;

f) the need to control interfaces between persons involved in the design and development process;

g) the need for involvement of customers and users in the design and development process;

h) the requirements for the subsequent provision of products and services;

i) the level of control expected for the design and development process by customers and other relevant interested parties;

j) the documented information needed to demonstrate that design and development requirements have been met.

8.3.3 Design and development inputs

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

a) functional and performance requirements;

b) information derived from previous similar design and development activities;

c) statutory and regulatory requirements;

d) standards or codes of practice that the organization has committed to implement

e) potential consequences of failure due to the nature of the products and services;

Inputs shall be adequate for design and development purposes, complete and unambiguous.

Conflicting design and development inputs shall be resolved.

The organization shall retain documented information on design and development inputs.

8.3.4 Design and development controls

The organization shall apply controls to the design and development process to ensure that:

a) the results to be achieved are defined;

b) reviews are conducted to evaluate the ability of the results of design and development to meet requirements;

c) verification activities are conducted to ensure that the design and development outputs meet the input requirements;

d) validation activities are conducted to ensure that the resulting products and services meet the requirements for the specified application or intended use

e) any necessary actions are taken on problems determined during the reviews, or verification and validation activities;

f) documented information of these activities is retained;

g) creativity and innovation are promoted;

h) maximum possible varieties of products are offered to customers;

i) cost saving measures are incorporated in products and processes;

j) the extension of utility of products are ensured.

NOTE: Design and development reviews, verification and validation have distinct purposes. They can be conducted separately or in any combination, as is suitable for the products and services of the organization.

8.3.5 Design and development outputs

The organization shall ensure that the design and development outputs:

a) meet the input requirements;

b) are adequate for the subsequent processes for the provision of products and services;

c) include or reference monitoring and measuring requirements, as appropriate, and acceptance criteria;

d) specify the characteristics of the products and services that are essential for their intended purpose and their safe and proper provision;

The organization shall retain documented information on design and development outputs.

8.3.6 Design and development change

The organization shall identify, review and control changes made during, or after, the design and development of products and services, to the extent necessary to ensure that there is no adverse impact on conformity to requirements

The organization shall retain documented information on:

a) design and development changes;

b) the results of reviews;

c) the standardisation of the changes;

d) the actions are taken to prevent adverse impacts.

8.4 Control of externally provided processes, products and services

8.4.1 General

The organization shall ensure that externally provided processes, products and services conform to requirements.

The organization shall determine the controls to be applied to externally provided processes, products and services when:

a) products and services from external providers are intended for incorporation into the organization's products and services;

b) products and services are provided directly to the customer(s) by external providers on behalf of the organization;

c) a process, or part of a process is provided by an external provider as a result of a decision by the organization.

The organization shall determine and apply criteria for the evaluation, selection, monitoring of performance, and re-evaluation of external providers, based on their ability to provide processes or products and services under requirements.

The organization shall retain documented information of these activities and any necessary actions arising from the evaluations.

8.4.2 Type and extent of control

The organization shall ensure that externally provided processes, products and services do not

adversely affect the organization's ability to consistently deliver conforming products and services to its customers.

The organization shall:

a) ensure that externally provided processes remain within the control of *lean and sustainable* integrated quality management system;

b) define both the controls that it intends to apply to an external provider and those it intends to apply to the resulting output;

c) take into consideration:

i) the potential impact of the externally provided processes, products and services and services on the organization's ability to consistently meet customer and applicable statutory and regulatory requirements;

ii) the effectiveness of the controls applied by the external provider;

d) determine the verification, or other activities, necessary to ensure that the externally provided processes, products and services meet requirements.

8.4.3 Information for external providers

The organization shall ensure the adequacy of requirements before their communication to the external provider.

The organization shall communicate to external providers its requirements for:

a) the processes, products and services to be provided;

b) the approval of:

i) products and services;

ii) methods, processes and pieces of equipment;

iii) the release of products and services;

c) competence, including any required qualification of persons;

d) the external providers' interactions with the organization;

e) control and monitoring of the external providers' performance to be applied by the organization;

f) verification or validation activities that the organization, or its customer, intends to perform at the external providers' premises.

8.5 Production and service provision

8.5.1 Control of production and service provision

The organization shall implement products and services provision and service provision under controlled conditions.

Controlled conditions shall include, as applicable:

a) the availability of documented information that defines:

i) the characteristics of the products to be produced, the services to be provided, or the activities to be performed;

ii) the results to be achieved;

b) the availability and use of suitable monitoring and measuring resources;

c) the implementation of monitoring and measurement activities at appropriate stages to verify that criteria for control of processes or outputs, and acceptance criteria for products and services, have been met;

d) the use of suitable infrastructure and environment for the operation of processes;

e) the appointment of competent persons, including any required qualification;

f) the validation, and periodic revalidation, of the ability to achieve planned results of the processes for products and service provision, where the resulting output cannot be verified by subsequent monitoring or measurement;

g) the implementation of actions to prevent human error;

h) the implementation of release, delivery and post-delivery activities;

i) reduction in lead-time.

8.5.2 Identification and traceability

The organization shall use suitable means to identify outputs when it is necessary to ensure the

conformity of products and services.

The organization shall identify the status of outputs concerning monitoring and measurement requirements throughout products and service provision.

The organization shall control the unique identification of the outputs when traceability is a requirement and shall retain the documented information necessary to enable traceability.

8.5.3 Property belonging to customers or external providers

The organization shall exercise care with property belonging to customers or external providers while it is under the organization's control or being used by the organization.

The organization shall identify, verify, protect and safeguard customers' or external providers' property provided for use or incorporation into the products and services.

When the property of a customer or external provider is lost, damaged or otherwise found to be unsuitable for use, the organization shall report this to the customer or external provider and retain documented information on what has occurred.

NOTE: A customer's or external provider's property can include materials, components, tools and equipment, premises, intellectual property and personal data.

8.5.4 Preservation

The organization shall preserve the outputs during production and service provision, to the extent necessary to ensure conformity to requirements.

NOTE: Preservation can include identification, handling, contamination control, packaging, storage, transmission or transportation, *environmental sustainability* and protection.

8.5.5 Post-delivery activities

The organization shall meet requirements for post-delivery activities associated with the products and services.

In establishing the extent of post-delivery activities that are required, the organization shall consider:

a) statutory and regulatory requirements;

b) the potential undesired consequences associated with its products and services;

c) the nature, use and intended lifetime of its products and services;

d) customer requirements;

e) customer feedback.

NOTE: Post-delivery activities can include actions under warranty provisions, contractual obligations such as maintenance services, and supplementary services such as recycling or final disposal.

8.5.6 Control of changes

The organization shall review and control changes for production or service provision, to the extent necessary to ensure continuing conformity with requirements.

The organization shall retain documented information describing the results of the review of changes, the person(s) studying the change, and any necessary actions arising from the review.

8.6 Release of products and services

The organization shall implement planned arrangements, at appropriate stages, to verify that the products and service requirements have been met.

The release of products and services to the customer shall not proceed until the planned arrangements have been satisfactorily completed, unless otherwise approved by a relevant study and, as applicable, by the customer.

The organization shall retain documented information on the release of products and services. The documented information shall include:

a) evidence of conformity with the acceptance criteria;

b) traceability to the person(s) studying the release.

8.7 Control of nonconforming outputs

8.7.1 The organization shall ensure that outputs that do not conform to its requirements are identified and controlled to prevent their unintended use or delivery.

The organization shall take appropriate action based on the nature of the nonconformity and its effect on the conformity of products and services. This shall also apply to nonconforming products and services detected after delivery of products, during or after the provision of services.

The organization shall deal with nonconforming outputs in one or more of the following ways:

a) correction;

b) segregation, containment, return or suspension of the provision of products and services;

c) informing the customer;

d) obtaining authorasation for acceptance under concession.

Conformity to the requirements shall be verified when nonconforming outputs are corrected.

8.7.2 The organization shall retain documented information that:

a) describes the nonconformity;

b) describes the actions taken;

c) describes any concessions obtained;

d) identifies the suitability deciding the action in respect of the nonconformity.

9 Performance evaluation

Clause 9 contains 3 sub-clauses:

9.1 Monitoring, measurement, analysis and evaluation

9.1.1 General

The organization shall determine:

a) what needs to be monitored and measured;

b) the methods for monitoring, measurement, analysis and evaluation needed to ensure valid results;

c) when the monitoring and measuring shall be performed;

d) when the results from monitoring and measurement shall be analysed and evaluated.

The organization shall evaluate the performance and the effectiveness of the *lean and sustainable integrated* quality management system.

The organization shall retain appropriate documented information as evidence of the results.

9.1.2 Customer satisfaction

The organization shall monitor customers' perceptions of the degree to which their needs and expectations have been fulfilled. The organization shall determine the methods for obtaining, monitoring and reviewing this information.

NOTE: Examples of monitoring customer perceptions can include customer surveys, customer feedback on delivered products and services, meetings with customers, market-share analysis, compliments, warranty claims and dealer reports.

9.1.3 Analysis and evaluation

The organization shall analyse and evaluate appropriate data and information arising from monitoring and measurement.

The results of the analysis shall be used to evaluate:

a) conformity of products and services;

b) the degree of customer satisfaction;

c) the performance and effectiveness of the quality management system;

d) if planning has been implemented effectively;

e) the effectiveness of actions taken to address risks and opportunities;

f) the performance of external providers;

g) the need for improvements to the *lean and sustainable integrated* quality management system.

NOTE: Methods to analyse data can include statistical techniques.

9.2 Internal audit

9.2.1 The organization shall conduct *integrated* internal audits to optimize resources at planned intervals to provide information on whether *the lean and sustainable integrated* quality management system:

a) conforms to:

   i) the organization's requirements for its lean and sustainable integrated quality management system;

   ii) the requirements of this International Standard;

b) is effectively implemented and maintained.

9.2.2 The organization shall:

a) plan, establish, implement and maintain an audit programme(s) including the frequency, methods, responsibilities, planning requirements and reporting, which shall take into consideration the importance of the processes concerned, changes affecting the organization, and the results of previous audits;

b) define the audit criteria and scope for each audit;

c) select auditors and conduct audits to ensure objectivity and the impartiality of the audit process;

d) ensure that the results of the audits are reported to relevant management;

e) take appropriate correction and corrective actions without undue delay;

f) retain documented information as evidence of the implementation of the audit programme and the audit results.

9.3 Management review

9.3.1 General

Top management shall review the organization's *lean and sustainable integrated* quality management system, at planned intervals, to ensure its continuing suitability, adequacy, effectiveness and alignment with the strategic direction of the organization.

9.3.2 Management review inputs

The management review shall be planned and carried out taking into consideration:

a) the status of actions from previous management reviews;

b) changes in external and internal issues that are relevant to the lean and sustainable integrated quality management system;

c) information on the performance and effectiveness of the *lean and sustainable integrated* quality management system, including trends in:

   i) customer satisfaction and feedback from relevant interested parties;

   ii) the extent to which quality objectives have been met;

   iii) process performance and conformity of products and services;

   iv) nonconformities and corrective actions;

   v) monitoring and measurement results;

   vi) audit results;

   vii) the performance of external providers;

   viii) Appraisal of sustainability

d) the adequacy of resources;

e) the effectiveness of actions taken to address risks and opportunities (see 6.1);

f) opportunities for improvement.

9.3.3 Management review outputs

The outputs of the management review shall include decisions and actions related to:

a) opportunities for improvement;

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

c) resource needs.

The organization shall retain documented information as evidence of the results of management reviews.

10 Improvement

Clause 10 has one general and two sub clauses:

10.1 General

The organization shall determine and select opportunities for improvement and implement any necessary actions to meet customer requirements and enhance customer satisfaction.

These shall include:

a) improving *and innovating* products and services to meet requirements as well as to address future needs and expectations;

b) correcting, preventing or reducing undesired effects;

c) improving the performance and effectiveness of the quality management system.

NOTE: Examples of improvement can include correction, corrective action, improvement, breakthrough change, innovation and re-organization.

10.2 Nonconformity and corrective action

10.2.1 When a nonconformity occurs, including any arising from complaints, the organization shall:

a) react to the nonconformity and, as applicable:

i) take action to control and correct it;

ii) deal with the consequences;

iii) problem solving;

b) evaluate the need for action to eliminate the cause(s) of the nonconformity, so that it does not recur or occur elsewhere, by:

i) reviewing and analysing the nonconformity;

ii) establishing the causes of the nonconformity;

iii) establishing if similar nonconformities exist, or could potentially occur;

c) implement any action needed;

d) review the effectiveness of any corrective action taken;

e) update risks and opportunities determined during planning, if necessary;

f) make changes to the quality management system, if necessary.

Corrective actions shall be appropriate to the effects of the nonconformities encountered.

10.2.2 The organization shall retain documented information as evidence of:

a) the nature of the nonconformities and any subsequent actions are taken;

b) the results of any corrective action.

10.3 improvement

The organization shall continually improve the suitability, adequacy and effectiveness of the lean *and sustainable integrated* quality management system.

The organization shall consider the results of analysis and evaluation, and the outputs from management review, to determine if some needs or opportunities shall be addressed as part of improvement.

APPENDIX III

LEAN AND SUSTAINABLE INTEGRATED QUALITY MANAGEMENT SYSTEM DOCUMENT (SME A)

1.0 SME Profile

SME A is a private limited SME located in Thrissur district, Kerala state.

1.1 The mission of the Firm

Our mission is to enhance mobility through innovation, technology and to have a place across the world.

1.2 The vision of the Firm

The SME intent is to work with its customers to grow long term and profitable partnerships.

2.0 SME Scope

Design, development of best quality rubber moulds for floor tiles, wall tiles and pavers. The SME is also specialised in manufacturing of various customised designs. The SME is committed to provide products and services which fully meet the customer's specified contractual requirements.

2.1 Exclusions:

Nil

2.1 Quality Policy

SME A is committed to delivering quality and customised products and services with promised features, which meets and exceeds the needs & expectation of our customers. We promise our valued customer's commitment to excellence in each activity by each employee in the SME by adopting innovative and best in class engineering and management practices with continual improvement in business

and quality management system as a part of our efforts for enhancement in customer satisfaction while assuring 100% quality and quantity.

2.2 Key Objectives

Our objective is to outperform our clients' expectations in terms of customer service, delivery, quality and pricing.

The Quality Manual defines the lean and sustainability integrated QMS, which has been established and adopted as the means for achieving these declared objectives.

3 Definitions

- This document does not introduce any new definitions but rather relies on the following:
    1. Definitions typically used by our customers, stakeholders or marketplace;
    2. Terms typically used in standards and regulations as they relate to our QMS or products and services;
    3. Standard business terminology;

4.0 CONTEXT OF ORGANISATION

4.1 Understanding the SME and its context:

The SME shall establish *a lean and sustainability integrated quality process that is capable of identifying, monitoring, reviewing and resolving anyexternal and internal issues* that are relevant to its purpose and *which could have an effect on its ability to achieve* the intended result(s) through the lean and sustainability integrated quality management system. The SME shall perform an analysis of *the internal and external environments by considering the sustainability concept;* its impact on the SME. *All legal, technological, competitive, market, culture, social, economic and environmental issues shall be closely examined to produce quality products ans services.*

4.2. Understanding the needs and expectations of interested parties

The SME shall establish a procedure for identifying interested parties and their needs, expectations, and interests by considering the quality and environment who are relevant to the lean and sustainability integrated quality management system and the requirement of the interested parties to prevent the potential effect

on the SME's ability to *consistently provide products and services which meet the customer* and applicable statutory and regulatory requirements.

Table 1

Interested parties	Requirements	Monitoring & Review mechanism
External providers	Specification communication. The payment as agreed. On-time Supply of Input material (if any). Technology support.	Defined in the Documented information of External providers control. Review in Management review meetings.
Customer	Quality of product & Service Delivery of product on time Response to complaint Proper Communication.	Defined in the documented information of Marketing & Sales process. Review in Management review meetings.
Statutory & Regulatory Body	Complying with the statutory and regulatory requirements as defined from time to time.	Defined in the documented information of Leadership. Review in Management review meetings.
Bankers / Financiers	Updating of changes in the SME whenever it happened.	Review in Management review meetings.
Employees	Management Support, Payments on time.	Accounting Control of management.

4.3 Determining the scope of the quality management system

SME *shall state* the scope of the lean and sustainability integrated quality management system by considering external and internal issues, the requirement of relevant interested parties and product and service of the SME.
The scope of lean and sustainability integrated quality management system is: Design and development of machinery for Eco-Friendly products and services machine industry and provides customers with immediate and valuable after-sale service and technology support.

Exclusions:

NIL

4.4 Quality management system and its processes

4.4.1 SME A has determined the processes needed for the lean and sustainability integrated quality management system and their application throughout the SME in process map and interactions of processes.

SME A has determined the inputs required and the outputs expected from each process in an individual process map addressed in the documented information of each process.

SME A has determined the sequence and interaction of the processes in Process map and interactions of processes.

The SME A has determined and applied the criteria and methods (including monitoring, measurements and related performance indicators) needed to ensure the effective operation and control of these processes in the documented information of each process.

SME A has determined the resources needed for these processes and ensure their availability in the documented information of Support process.

SME A has assigned the responsibilities and duties for each process.

SME A has addressed the risks and opportunities.

SME A has been evaluating these processes and implementing any changes needed to ensure that these processes achieve their intended results and improve the processes and the quality management system.

Improve the processes and the quality management system by including the current state Value Stream Map in the documentation to comply with the process description requirement. The current-state Value Stream map must be integrated as a complement to the description of the processes and their sequence and interaction, which would lead to actions for the accomplishment of planned results and continuous improvement. Lean metrics should be used together with performance indicators for process monitoring and measurement.

4.4.2 SME A is also maintaining documented information to support the operation of its processes and retaining documented information to have confidence that the processes are being carried out as planned.

5.0 LEADERSHIP

Top management shall demonstrate both leadership and commitment by assuming accountability for the effectiveness of the organisation's lean and sustainability integrated QMS.

5.1 Leadership and commitment

SME A management has demonstrated leadership and commitment concerning the quality management system through;

- Taking accountability for the effectiveness of the lean and sustainability integrated quality management system by periodical review of quality management system through management review meeting, Quality objectives review and providing necessary resources. Management has established the quality policy and quality objectives for the lean and sustainability integrated quality management system and is compatible with the context and strategic direction of the SME.
- Management has determined the SME processes and integrated with the quality management system requirement through process map and interaction this can be demonstrated.
- The established procedure for promoting the use of the process approach and risk-based thinking.
- Ensuring that the resources needed for the lean and sustainability integrated quality management system are available, this is being periodically reviewed through management review meeting.
- Communicating the importance of effective quality management and of conforming to the lean and sustainability integrated quality management system requirements.
- Ensuring that the lean and sustainability integrated quality management system achieves its intended results.
- Engaging, directing and supporting persons to contribute to the effectiveness of the lean and sustainability integrated quality management system by providing training, conducting awareness programs and promoting improvement by introducing the suggestion scheme, Kaizens and conducting meetings. Supporting other relevant management roles to demonstrate their leadership as it applies to their areas of responsibility.

5.1.2 Customer focus

SME A management has demonstrated leadership and commitment concerning customer focus by ensuring that:

- Customer and applicable statutory and regulatory requirements are determined, understood and consistently met.
- The risks and opportunities that can affect the conformity of products and services and services and the ability to enhance customer satisfaction are determined and addressed.
- The focus on enhancing customer satisfaction is addressed *by providing sustainable products and practices..*

5.2 QUALITY POLICY

We promise our commitment to excellence in each activity by each employee in the SME by adopting innovative and best in class engineering and management practices with continual improvement in business and quality management system as a part of our efforts for enhancement in customer satisfaction while assuring 100% quality and quantity. We are also committed to serving society as a whole by generating through sustainable and lean thinking principles to enable continuous improvement of quality. Quality has been of paramount importance for us, since establishment. To attain these objectives, we manufacture our range of machines using high-grade stainless steel procured from an authentic external provider. We conduct stringent quality checks at every production stage to ensure that a flawless range is delivered to the customers.

We have taken various steps to satisfy our customers in the best possible way. Our machinery is offered to the customers at cost-effective prices. We also provide customized packaging of products and services according to the requirements of our customers. Owing to the superior quality of our products and services and customized solutions, we have earned immense market appreciation across India.

5.2.1 Establishing the quality policy

The SME A management shall establish implement and maintain a quality policy that:

- is appropriate to the purpose and context of the SME and supports its strategic direction.
- provides a framework for setting quality objectives.
- includes a commitment to satisfy applicable requirements.
- includes a commitment to continual improvement of the quality management system.

5.2.2 Communicating the quality policy

The quality policy is

- Available and be maintained as documented information
- Communicated, understood and applied within the SME through display, training and periodical review.
- Available to relevant interested parties, as appropriate.

5.3 SME roles, responsibilities and duties

SME A management has ensured that the responsibilities and duties for relevant roles are assigned communicated and understood within the SME. While assigning roles, responsibility, top management has considered and ensured that;

The lean and sustainability integrated quality management system conforms to the requirements of lean and sustainability practices.

The processes are delivering their intended outputs.

Reporting on the performance of the lean and sustainability integrated quality management system and opportunities for improvement, in particular, to top management.

The promotion of customer focus throughout the SME.

The integrity of the lean and sustainability integrated quality management system is maintained when changes to the quality management system are planned and implemented.

6.0 PLANNING

The SME shall monitor and review external and internal issues that could affect the organisation's lean and sustainability integrated quality management and determine if there are any risks and opportunities associated with these issues that should be addressed by their QMS.

6.1 Actions to address risks and opportunities

Describe the process and responsibilities for stakeholder consultation and describe relationship processes to identify and manage impacts, risks, and opportunities arising from economic, environmental, and social issues.

6.1.1 SME A is addressed the issues, requirements the risks and opportunities,

- give assurance that the lean and sustainability integrated quality management system can achieve its intended result(s).

- enhance desirable effects
- prevent, or reduce undesired effects
- achieve improvement

6.1.2 SME A shall plan:

a) actions to address these risks and opportunities,

b) how to

- integrate and implement the actions into its lean and sustainability integrated quality management system processes.
- evaluate the effectiveness of these actions.

Table 2

Interested parties	Requirements	Risks and Opportunities	Effectiveness of actions
External providers	Communication, Payment Terms, On-time supply, Technology support.	Communication gap, payment and delivery terms not in written, Output failure.	Communication like Emails, Phone, Payment & delivery terms, Documented information provided for technical support.
Customer	Sustainable product quality, delivery and service of on-time, Response to the complaint, Proper communication.	Business Loss, Reputation down for the SME.	Defined in the documented information of Marketing & Sales process & Management review meetings.
Statutory & Regulatory Body	SME& product related Statutory and regulatory requirements are kept.	Scarcity of customer acceptable material or loss of business	Defined in documented information & Review in Management review meetings.
Bankers/financiers	All product &SME-related documents are kept.	The SME is facing financial problems.	All product &SME-related documents are kept.
Employees	On-time Payments.	Work is not properly operated.	On-time payments issue to employees.
Marketing	Competitive rates, More amenities, Prime Location,	The SME facing problems in sales, Reputation in market	Market analysis, Competent marketing team.

Externally provided products and services and services	Competitive rates, Sustainable and good quality material, Timely delivery.	The SME facing financial problems, Customer dissatisfied, Reputation in market	Market analysis, Competent Purchase team.

6.2. Quality objectives and planning to achieve them

Top management shall ensure that lean and sustainability integrated quality objectives are achieved.

6.2.1 The organisation shall establish quality objectives at relevant functions, levels and processes needed for the lean and sustainability integrated quality management system.

The quality objectives shall,

- Be consistent with the quality policy
- Be measurable
- improve sustainability
- must include lean thinking strategies
- Be relevant to the conformity of products and services and services and the enhancement of customer satisfaction,
- Be monitored
- Be Communicated
- Be updated as appropriate.

6.2.2 The organisation shall achieve its quality objectives,

- What will be done?
- What resources will be required?
- Who will be responsible?
- When it will be completed
- How the results will be evaluated

Our Quality Objectives are as below:

- Timely completion of projects
- Energy Generation Per Year
- Increase Customer satisfaction
- Reduce Customer Complaint
- Use Sustainable practices

- Follow lean technologies

6.3 Planning of changes

The changes must comply with requirements and seek the creation of synergies in consideration of economic aspects, environment, health and safety of the workers, and SR to improve sustainability performance.

The organisation determines the need for changes to the lean and sustainability integrated quality management system, the changes are carried out in a planned manner

1. the purpose of the changes and their potential consequences
2. the integrity of the quality management system
3. the availability of resources
4. the allocation or reallocation of responsibilities and duties
5. consideration of environmental and economic aspects.
6. health and safety of the workers.
7. *Usage of lean practices.*

The organisation has determined the processes needed for the lean and sustainability integrated quality management system and their application throughout the SME in Process map & Interactions of processes.

7 SUPPORT

7.1 Resources

Top management needs to identify and make available all the resources required to implement and improve its lean and sustainability integrated QMS and its associated quality processes.

7.1.1 General

The organisation shall determine and provide the resources needed for the establishment, implementation, maintenance and continual improvement of the lean and sustainability integrated quality management system. The organisation shall consider

- the capabilities of, and constraints on, existing internal resources
- what needs to be obtained from external providers

The organisation shall determine and provide the resources needed to implement and maintain the lean and sustainability integrated quality management system

and continually improve its effectiveness and to enhance customer satisfaction by meeting customer requirement. The resources will be in the form of;

- Human resources including qualified personnel for verification activities.
- Manufacturing machine tools, testing equipment's other facilities
- Provide sustainable raw material and other inputs.
- Providing funds.

7.1.2 People

The organisation shall determine and provide the persons necessary for the effective implementation of its lean and sustainability integrated quality management system and the operation and control of its processes. The top management ensures the *involvement of employees and management of work force in all areas of activities.*

7.1.3 Infrastructure

The organisation shall determine, provide and maintain the infrastructure necessary for the operation of its processes and achieve conformity of products and services and services. Infrastructure can include

- buildings and associated utilities
- equipment, including hardware and software
- transportation resources
- information and communication technology

7.1.4 Environment for the operation of processes

The organisation shall determine, provide and maintain the environment necessary for the operation of its processes and achieve conformity of products and services and services. A suitable environment can be a combination of human and physical factors

- Social (e.g. non-discriminatory, calm, non-confrontational)
- Psychological (e.g. stress-reducing, burnout prevention, emotionally protective)
- Physical (e.g. temperature, heat, humidity, light, airflow, hygiene, noise).

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7.1.5 Monitoring and measuring resources

7.1.5.1 General

The organisation shall determine and provide the resources needed to ensure valid and reliable results when monitoring or measuring is used to verify the conformity of products and services and services to requirements. The SME shall ensure that the resources provided

- are suitable for the specific type of monitoring and measurement activities being undertaken.
- are maintained to ensure their continuing fitness for their purpose.

7.1.5.2 Measurement traceability

The measurement traceability is maintained if applicable for the instruments or is considered to be an essential part of providing confidence in the validity of measurement results. It is also

- calibrated or verified, or both, at specified intervals, or before use, against measurement standards traceable to international or national measurement standards; when no such standards exist, the basis used for calibration or verification shall be retained as documented information.
- identified to determine their status.
- safeguarded from adjustments, damage or deterioration that would invalidate the calibration status and subsequent measurement results.

7.1.6 Organisational knowledge

The organisation shall determine the knowledge necessary for the operation of its processes and to achieve conformity of products and services and services based on lean and sustainable practices. This knowledge shall be maintained and be made available to the extent necessary. When addressing changing needs and trends, the SME shall consider its current knowledge and determine how to acquire or access any necessary additional knowledge and required updates. SME knowledge is specific to the SME; it is generally gained by experience. It is information that is used and shared to achieve the SME's objectives.

Organisational knowledge can be based on:

Internal sources (e.g. intellectual property; knowledge gained from experience; lessons learned from failures and successful projects; capturing and sharing

undocumented knowledge and experience; the results of improvements in processes, products and services and services);

External sources (e.g. standards; academia; conferences; gathering knowledge from customers or external providers).

7.2 Competence

The organisation shall

- Determine the necessary competence of person(s) doing work under its control that affects the performance and effectiveness of the lean and sustainability integrated quality management system.
- Ensure that these persons are competent based on appropriate education, training, or experience.
- Where applicable, take actions to acquire the necessary competence, and evaluate the effectiveness of the actions taken.
- Retain appropriate documented information as evidence of competence for all employees.

7.3 Awareness

The organisation shall ensure that persons doing work under the SME's control are aware of

- The quality policy.
- Relevant quality objectives.
- Their contribution to the effectiveness of the lean and sustainability integrated quality management system, including the benefits of improved performance.
- The implications of not conforming to the quality management system requirements.

7.4 Communication

The organisation shall determine the internal and external communications relevant to the lean and sustainability integrated quality management system, including

- On what it will communicate
- When to communicate
- With whom to communicate
- How to communicate

- Who Communicates

Communication effectiveness may help the organisation to gain greater visibility and builds support from stakeholders—both external and within the organisation.

Increased communication with employees on the organisation floor is a positive outcome of the lean manufacturing initiative.

7.5 Documented information

7.5.1 General

The organisation's quality management system shall include,

- documented information required by this standard;
- documented information determined by the SME as being necessary for the effectiveness of the *lean and sustainable integrated* quality management system.
- a clear and compelling vision which intends to achieve and how that vision responds to a real need in the community.

7.5.2 Creating and updating

The organisation shall create and update documented information and ensure appropriate

- Identification and description
- Format (e.g. language, software version, graphics) and media (e.g. paper, electronic)
- Review and approval for suitability and adequacy.

7.5.3 Control of documented information

7.5.3.1 Documented information required by the *lean and sustainable integrated* quality management system and shall be controlled to ensure

- It is available and suitable for use, where and when it is needed.
- It is adequately protected (e.g. from loss of confidentiality, improper use, or loss of integrity).

7.5.3.2 For the control of documented information, The organisation shall address the following activities, as applicable

- Distribution, access, retrieval and use
- Storage and preservation, including preservation of legibility

- Control of changes (e.g. version control)
- Retention and disposition.

Documented information of external origin determined by the SME to be necessary for the Planning and operation of the lean and sustainable integrated quality management system as identified as appropriate and is controlled. Documented information retained as evidence of conformity shall be protected from unintended alterations.

8 OPERATION

The SME shall ensure that customer requirements are fully understood, documented and implemented.

8.1 Operational planning and control

The SME shall plan, implement and control the processes (see 4.4) needed to meet the requirements for the provision of products and services and to implement the actions determined in Clause 6, by:

- Determining the requirements for the products and services and services
- Establishing criteria for
  - i) The processes
  - ii) The acceptance of products and services and services
- Determining the resources needed to achieve conformity to the product and service requirements
- Implementing control of the processes following the criteria
- Determining, maintaining and retaining documented information to the extent necessary
  - i) To have confidence that the processes have been carried out as planned
  - ii) To demonstrate the conformity of products and services and services to their requirements

The organisation shall control planned changes and reviews the consequences of unintended changes, taking action to mitigate any adverse effects, as necessary. The organisation shall ensure that outsourced processes are controlled.

8.2 Requirements for products and services

Understanding customer requirements is essential for the creation of a deliverable and for ensuring overall customer satisfaction.

8.2.1 Customer communication

The SME shall ensure that the customer is kept- up-to-date with the progress of their deliverable and that all of their comments and complaints are dealt with a speedy and effective manner.

Communication with customers is include

- Providing information relating to products and services and services
- Handling enquiries, contracts or orders, including changes
- Obtaining customer feedback relating to products and services and services, including customer complaints
- Handling or controlling customer property
- Establishing specific requirements for contingency actions, when relevant.

Customers are communicated regarding the product information through the letter, verbal and/ or through phone, Fax, e-mail. If any amendments in enquiries, purchase orders it will be communicated through Phone, letter & Email. The customer complaints are registered in customer complaint register and the corrective action taken is communicated.

8.2.2 Determining the requirements for products and services and services

When determining the requirements for the products and services and services to be offered to customers, The organisation shall ensure that

- The requirements for the products and services and services are defined, including
  - i) Any applicable statutory and regulatory requirements
  - ii) Those considered necessary by the SME
- The SME can meet the claims for the products and services and services it offers.

At present, the marketing activities are looked after by Marketing in charge and both of them are actively involved in the determination of customer requirements and for each enquiry, he determines the

- Requirements were related to the product in contract review form concerning requirements specified by the customer, including the requirements for delivery and post-delivery activities.
- Requirements not stated by the customer but necessary for the specific or intended use. Statutory and Regulatory requirements related to the product
- Any additional requirements determined by the SME.

8.2.3 Review of the requirements for products and services and services

8.2.3.1 The organisation shall ensure that it can meet the requirements for products and services and services to be offered to customers. The organisation shall conduct a review before committing to supply products and services and services to a customer, to include

- Requirements specified by the customer, including the requirements for delivery and post-delivery activities.
- Requirements not stated by the customer, but necessary for the specified or intended use, when known.
- Requirements specified by the SME.
- Statutory and regulatory requirements applicable to the products and services.
- Contract/order requirements differing from those previously expressed.

The organisation shall ensure that contract or order requirements differing from those previously defined are resolved. The customer's requirements are confirmed by the organisation is before acceptance, when the customer does not provide a documented statement of their requirements

8.2.3.2 The organisation shall retain documented information, as applicable

- On the results of the review
- On any new requirements for the products and services.
- The review ensures that
- the product requirements are defined
- Contract/order requirements differing from those previously expressed in the proposal or quote are resolved.
- Our SME can meet the defined requirements

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8.2.4 Changes to requirements for products and services and services

The organisation shall ensure that relevant documented information is amended, and those relevant persons are made aware of the changed requirements when the requirements for products and services are changed.

8.3 Design and development of products and services

The SME shall plan and control the design and development of its products and services and design, develop and implement a process comprising a number of stages, each of which will be subject to controls and risk analysis.

8.3.1 General

The SME shall establish a multidisciplinary approach to integrate the concept of sustainability into the design and development process of its products and services. Standardization is a way to reduce waste. Aspects of quality and environment shall be considered to integrate the concept of sustainability into the design and development of products and services, and processes.

8.3.2 Design and development planning

The organisation shall consider the stages and controls for design and development, including

- Nature, duration and complexity of the design and development activities
- The required process stages, including application design and development reviews
- The required design and development verification and validation activities
- The responsibilities and duties involved in the design and development process
- The internal and external resource needs for the design and development of products and services and services
- The need to control interfaces between persons involved in the design and development process
- The need for involvement of customers and users in the design and development process
- The requirements for the subsequent provision of products and services and services
- The level of control expected for the design and development process by

customers and other relevant interested parties.

- The documented information needed to demonstrate that design and development requirements have been met.

8.3.3 Design and development inputs

The organisation shall determine the requirements essential for the specific types of products and services and services to be designed and developed. The organisation shall consider

- Functional and performance requirements
- Information derived from previous similar design and development activities
- Statutory and regulatory requirements
- standards or codes of practice that the SME has committed to implement like lean and sustainable practices;
- Potential consequences of failure due to the nature of the products and services and services
- energy-efficient and environment-friendly materials.

Inputs shall be adequate for design and development purposes, complete and unambiguous. Conflicting design and development inputs are resolved. The organisation shall retain documented information on design and development inputs.

8.3.4 Design and development controls

The organisation shall apply controls to the design and development process to ensure that

- The results to be achieved are defined
- Reviews are conducted to evaluate the ability of the results of design and development to meet sustainability requirements,
- Verification activities are conducted to ensure that the design and development outputs meet the input requirements.
- Validation activities are conducted to ensure that the resulting products and services and services meet the requirements for the specified application or intended use as per environmental standards;
- Any necessary actions are taken on problems determined during the reviews, or verification and validation activities.

Documented information of these activities is retained.

8.3.5 Design and development outputs

The organisation shall ensure that design and development outputs

- meet the input requirements
- are adequate for the subsequent processes for the provision of products and services and services
- include or reference monitoring and measuring requirements, as appropriate, and acceptance criteria
- specify the characteristics of the products and services that are essential for their intended purpose and their safe and proper provision.

The organisation shall retain documented information on design and development outputs

8.3.6 Design and development changes

The organisation shall identify, review and control changes made during, or after, the design and development of products and services, to the extent necessary to ensure that there is no adverse impact on conformity to requirements. The organisation shall retain documented information on

- Design and development changes
- The results of reviews
- The standardisation of the changes
- The actions are taken to prevent adverse impacts

8.4 Control of externally provided processes, products and services (Purchase)

8.4.1 General

The organisation shall ensure that externally provided processes, products and services and services conform to requirements, The organisation shall determine the controls to be applied to externally provided processes, products and services and services when,

- Products and services from external providers are intended for incorporation into the SME's products and services.
- Products and services are provided directly to the customer(s) by external providers on behalf of the SME.
- A process, or part of a process, is provided by an external provider as a

result of a decision by the SME.

The organisation shall determine and apply criteria for the evaluation, selection, monitoring of performance, and re-evaluation of external providers, based on their ability to provide processes or products and services by requirements. The SME shall retain documented information of these activities and any necessary actions arising from the evaluations.

8.4.2 Type and extent of control

The organisation shall ensure that externally provided processes, products and services and services do not adversely affect the SME's ability to consistently deliver conforming products and services and services to its customers

The organisation shall:

- Ensure that externally provided processes remain within the control of its quality management system
- Define both the controls that it intends to apply to an external provider and those it intends to apply to the resulting output
- Take into consideration
    - The potential impact of the externally provided processes, products and services and services on the SME's ability to consistently meet customer and applicable statutory and regulatory requirements
    - The effectiveness of the controls applied by the external provider
- Determine the verification, or other activities, necessary to ensure that the externally provided processes, products and services and services meet requirements

8.4.3 Information for external providers

The organisation shall ensure the adequacy of requirements before their communication to the external provider. The organisation shall communicate to external providers its requirements for

- The processes, products and services and services to be provided
- The approval of
    - Products and services and services
    - Methods, processes and equipment
    - The release of products and services and services
- Competence, including any required qualification of persons

- The external providers' interactions with the SME
- Control and monitoring of the external providers' performance to be applied by the SME
- Verification or validation activities that the SME, or its customer, intends to perform at the external providers' premises

8.5 Production and service provision

8.5.1 Control of production and service provision

The organisation shall implement production and service provision under controlled conditions. Controlled conditions include, as applicable

- The availability of documented information that defines
    - The characteristics of the products and services to be produced, the services to be provided, or the activities to be performed
    - The results to be achieved
- The availability and use of suitable monitoring and measuring resources.
- The implementation of monitoring and measurement activities at appropriate stages to verify that criteria for control of processes or outputs, and acceptance criteria for products and services have been met.
- The use of suitable infrastructure and environment for the operation of processes.
- The appointment of competent persons, including any required qualification.
- The validation, and periodic revalidation, of the ability to achieve planned results of the processes for production and service provision, where the resulting output cannot be verified by subsequent monitoring or measurement;
- The implementation of actions to prevent human error.
- The implementation of release, delivery and post-delivery activities.

8.5.2 Identification and traceability

The organisation shall use suitable means to identify outputs when it is necessary to ensure the conformity of products and services. The organisation has identified the status of outputs concerning monitoring and measurement requirements throughout production and service provision. The organisation shall control the unique identification of the outputs when traceability is a requirement and shall retain the documented information necessary to enable traceability. All material are identified including inspection and test status inappropriate manner from receipts at stores through various stages of production. The final product is

transferred to finished goods area before delivery to the customer as detailed in work procedures for storage, packing & dispatch procedure. Traceability is provided, if required by the customer or decided for some products and services to identify finished products and services by providing punch mark/tag/batch code. For such products and services, proper records are maintained also the main packages are traceable through the barcode system.

8.5.3 Property belonging to customers or external providers

The organisation shall exercise care with property belonging to customers or external providers while it is under the SME's control or being used by the SME.

The organisation shall identify, verify, protect and safeguard customers' or external providers' property provided for use or incorporation into the products and services.

When the property of a customer or external provider is lost, damaged or otherwise found to be unsuitable for use, the SME shall report this to the customer or external provider and retain documented information on what has occurred,

- Any arrangement of Customer Supplied raw materials, components, tooling, returnable packaging, measuring instruments etc., are identified during the contract review and communicated to the people concerned.
- All such products and services are uniquely identified after proper verification and properly stored and maintained. Any such product that is lost damaged or is otherwise unsuitable for use shall be recorded and reported to the Customer by the customer representative.
- It shall be the responsibility of QA personnel to verify the quality of such a product even if it has been supplied by the Customer.

8.5.4 Preservation

The organisation shall preserve the outputs during production and service provision, to the extent necessary to ensure conformity to requirements. Preservation includes identification, handling, contamination control, packaging, storage, transmission or transportation, and protection. At all stages of production, appropriate material/product handling, storage, packing of products and services, preservation and delivery of products and services established viz.. The material in storage – are preserved by packing in Gunny bags. In-process – the material is stored in Bins and Air Bubble bags. Finished goods – All parts are surface coated & packed in Bins with Plastic coverage.

8.5.5 Post-delivery activities

The organisation shall meet requirements for post-delivery activities associated with the products and services.

The organisation shall consider in determining the extent of post-delivery activities that are required,

- statutory and regulatory requirements
- the potential undesired consequences associated with its products and services and services
- nature, use and intended lifetime of its products and services and services
- customer requirements
- customer feedback

8.5.6 Control of changes

The organisation shall review and control changes for production or service provision, to the extent necessary to ensure continuing conformity with requirements. The organisation shall retain documented information describing the results of the review of changes, the person(s) and any necessary actions arising from the review.

8.6 Release of products and services

The organisation shall implement planned arrangements, at appropriate stages, to verify that the product and service requirements have been met. The release of products and services to the customer shall not proceed until the planned arrangements have been satisfactorily completed, unless otherwise approved by a relevant authority and, as applicable, by the customer.

The organisation shall retain documented information on the release of products and services. The documented information includes

- Evidence of conformity with the acceptance criteria

To ensure that the products and services meet the quality requirements of customer fully, a systematic approach for inspection and testing at all stage viz. incoming, in the process and final are demonstrated. At each stage, the activity is performed according to documented procedures.

8.7 Control of nonconforming outputs

8.7.1 The SME shall establish procedures for identifying non-conforming product at Stores and stages of production/inspection as well as at the final inspection stage. The non-conforming materials are identified by the production operator/ QA personnel at these stages and suitably identified. Responsibility andauthority are assigned for segregation, review and disposition of the non-conforming product. Documented information of segregation, review and suitable disposition of non-conforming materials are maintained by QA Personnel.

The SME shall deal with nonconforming outputs in one or more of the following ways:

a) correction;

b) segregation, containment, return or suspension of the provision of products and services;

c) informing the customer;

d) obtaining authorization for acceptance under concession.

Conformity to the requirements shall be verified when nonconforming outputs are corrected.

8.7.2 The SME shall retain documented information that:

a) describes the nonconformity;

b) describes the actions taken;

c) describes any concessions obtained;

d) identifies the authority deciding the action in respect of the nonconformity

9 PERFORMANCE EVALUATIONS

9.1 Monitoring, measurement, analysis and evaluation

9.1.1 General

The organisation shall evaluate the performance and the effectiveness of the lean and sustainable integrated quality management system. The organisation shall retain appropriate documented information as evidence of the results.

The SME shall determine:

- What needs to be monitored and measured;
- The methods for monitoring, measurement, analysis and evaluation needed to ensure valid results;
- When the monitoring and measuring shall be performed;
- When the results from monitoring and measurement are analysed and evaluated.

9.1.2 Customer satisfaction

The organisation shall monitor customers' perceptions of the degree to which their needs and expectations have been fulfilled. The organisation shall determine the methods for obtaining, monitoring and reviewing this information. Customer satisfaction shall include the collection of authentic data, frequency and validity of the analysis. The trend and major elements affecting customer satisfaction and key indicators of customer dissatisfaction will be monitored supported by objective evidence. Wherever data available, the level of customer satisfaction will be compared with those of our competitors & relevant action plan will be evolved. A customer satisfaction analysis survey will be conducted once in 12 months. Review of customer satisfaction will be taken by top management during Management Review Meeting as described in Procedure.

9.1.3 Analysis and evaluation

The organisation shall analyze and evaluate appropriate data and information arising from monitoring and measurement. The results of the analysis are used to evaluate

- Conformity of products and services and services
- The degree of customer satisfaction;
- The performance and effectiveness of the quality management system;
- If planning has been implemented effectively;
- The effectiveness of actions taken to address risks and opportunities;
- The performance of external providers;
- The need for improvements to the lean and sustainable quality management system.

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9.2 Internal audit

Procedures are established for a system of planned and documented internal quality audits to verify that the Quality Management System conforms to the planned arrangements as per requirements and effectively implemented and maintained.

9.3 Management review

9.3.1 General

Top management shall review the SME's quality management system, at planned intervals, to ensure its continuing suitability, adequacy, effectiveness and alignment with the strategic direction of the SME. Management review will be conducted once in six months to ensure continuing suitability and effectiveness in satisfying the requirements of the stated quality policy and objectives.

9.3.2 Management review inputs

The management review is planned and carried out taking into consideration;

- The status of actions from previous management reviews
- Changes in external and internal issues that are relevant to the quality management system;
- Information on the performance and effectiveness of the quality management system, including trends in:
    1. customer satisfaction and feedback from relevant interested parties;
    2. the extent to which quality objectives have been met;
    3. process performance and conformity of products and services and services;
    4. nonconformities and corrective actions;
    5. monitoring and measurement results;
    6. audit results;
    7. the performance of external providers
- The adequacy of resources;
- The effectiveness of actions taken to address risks and opportunities;
- Opportunities for improvement

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9.3.3 Management review outputs

The outputs of the management review shall include decisions and actions related to:

- Opportunities for improvement;
- Any need for changes to the quality management system;
- Resource needs.

The organisation shall retain documented information as evidence of the results of management reviews.

10 IMPROVEMENT

The SME shall ensure that they continually evaluate opportunities for improvements that will better enable the organisation's capability of meeting customer requirements and enhancing customer satisfaction.

10.1 General

The organisation shall determine and select opportunities for improvement and implement any necessary actions to meet customer requirements and enhance customer satisfaction. These include

- Improving products and services to meet requirements as well as to address future needs and expectations.
- Correcting, preventing or reducing undesired effects;
- Improving the performance and effectiveness of the quality management system.

Improvement is included correction, corrective action, continual improvement, breakthrough change, innovation and re-SME.

10.2 Nonconformity and corrective action

10.2.1 When a non-conformity occurs, including any arising from complaints, the organisation shall;

- investigate all nonconformities relating to product, process and quality system and the results are recorded. While investigating the causes of non-conformances & deciding corrective actions, the team identifies other products and services /situations where the same or similar non-conformance can occur.

- corrective actions for nonconforming products and services and processes, detected in the SME are recorded; analyzed, reviewed and necessary actions are taken.

Corrective actions are taken on customer complaints; by analyzing the causes of the complaints and taking suitable action to prevent their reoccurrence. The effectiveness of the identified corrective action is monitored through customer feedback and also the customers are kept aware of the corrective actions initiated, with each identified corrective action.

10.3 Continual improvement

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

APPENDIX IV

LEAN AND SUSTAINABILITY INTEGRATEDQUALITY MANAGEMENT SYSTEM DOCUMENT - (SME - B)

Document Number: QM-01

Document Title: Quality Manual (Documented Information)

1 SME INTRODUCTION

SME B was established in 2003. Since then it has improved to become a leading manufacturer and supplier eco-friendly, disposable and paper products manufacturing machines.

The SME supplies a comprehensive range of machinery for the application in the day-to-day life, especially eco-friendly, disposable and paper products manufacturing machinery. The SME continuously strives to provide the customer with the leading edge and quality product solutions with competitive prices and prompt delivery services. The SME is equipped with modernized facilities and a team of qualified engineers to provide fast and efficient quality machining works and gives much importance to the research and development activities, which are greatly promoted in innovating phase now.

2 QUALITY MANAGEMENT SYSTEM

The SME recognises that in order to provide and maintain a consistently high quality in the work it undertakes, an effective Quality management System (QMS) is necessary so as to ensure that proper communication, work control and accountable documented information is generated and retained for all work undertaken. The SME is totally committed to setting and achieving quality standards that are capable of meeting the specified requirements and reasonable expectations of customers.

This Quality Manual document specifies the requirements for **SME B** according to lean and sustainability integrated QMS standard. Adequate and qualified

personnel are assigned to perform various activities as defined in the **QMS.** Quality records are generated to demonstrate the effectiveness of the **QMS**.

3 POLICY AND OBJECTIVES

3.1 Quality Policy

It is the policy of **SME-B** to provide high-quality products and services that are consistently meet the needs and expectations of the customer *by means of a formalised system of lean and sustainability integrated QMS.*

By ensuring all products manufactured and services provided meet customer requirements and continually improving the efficiency and effectiveness of the lean and sustainability integrated Quality Management System.

Our quality policy goes parallel with the need to manage the effective costing, thus we procure high-grade raw material from standardised vendor who are at the forefront of the industry. Our experts are well versed with the intricacies of quality norms and make sure that our developed machinery is complaint with the standards and reliable to be dispatched.

We consider that the employees of an organization act as the supporting pillars of the firm. The major driving force of any SME is the manpower relying upon this we have employed a highly skilled and experienced workforce that is fully hardworking and dedicated. Further, our professionals work in close-synchronization to offer high-quality machines to our clients as per their requirements.

Given continual improvement, we have established objectives, targets and improvement programmes consistent with this policy to improve our QMS. We shall provide resources required to achieve our policy and objectives. Our policy shall be reviewed annually, or as and when necessary, to ensure its suitability and effectiveness. Additionally, our policy shall be communicated to all personnel working in and on behalf of the organization.

3.2 Quality Objectives

The quality objectives shall be consistent with the quality policy and ensure that the requirements for products and services are met.

We are positioned as an enterprise that has gained recognizance for understanding the needs and ongoing technologies. Our uncompromising focus to quality led us to achieve the key milestone of excellence at every stage from production to distribution. Additionally, our team works hard to bring forth the best-

in-class technology in our manufactured printing rollers that carry around the cost-effective benefits and add value to our distinguished clients' business.

Our objectives documented and shall be reviewed annually to ensure its suitability and effectiveness. Additionally, our objectives shall be communicated to all personnel working in and on behalf of the organization.

4: CONTEXT OF THE ORGANIZATION

4.1 Understanding the organization and its context

We have determined external (technological, market, legal and regulatory and economic/competitive environments, whether international, national, regional or local) and internal (values, culture, knowledge, infrastructure and cost incurred of our organization) issues that are relevant to our purpose and our strategic direction and that affect our ability to achieve the intended result(s) of our lean and sustainability integrated QMS. We monitor and review the information about these external and internal issues.

Our external issues are:

- Customer's trustworthiness concerning payment term
- Supplier's commitment to delivery and quality of service and product
- Competitor's products and services that can give the customer to look for an alternate source
- Legal or regulatory requirements

Our internal issues are:

- Staff’s knowledge and attitude (commitment)
- Storage space and holding cost for material

4.2 Understanding the needs and expectations of interested parties

Due to their effect or potential effect on our ability to consistently provide products and services that meet customer and applicable statutory and regulatory requirements, we have determined:

- The interested parties that are relevant to our lean and sustainability integrated QMS.
- The requirements of these interested parties that are relevant to our lean and sustainability integrated QMS.
- We shall monitor and review the information about these interested parties and their relevant requirements.

4.3 Determining the scope of the quality management system

We have determined the boundaries and applicability of the lean and sustainability integrated QMS to establish its scope. In determining this scope, we have considered external and internal issues referred to in section 4.1, the requirements of relevant interested parties referred to in section 4.2 and the products and services of the organization.

Where a requirement of lean and sustainability integrated QMS within the determined scope can be applied, it is applied by the organization. If any requirement(s) of lean and sustainability integrated QMS cannot be applied, we shall ensure it does not affect the organization's ability or responsibility to ensure conformity of products and services. Our scope is available and maintained as documented information in section 1 of this manual, stating our products and services covered by the lean and sustainability integrated QMS and justification for any instance where a requirement of this International Standard cannot be applied.

4.4 Quality management system and its processes

We have established, implemented, maintained and continually improved a lean and sustainability integrated QMS, including the processes needed and their interactions, following the requirements of ISO 9001:2015.

We have determined the processes needed for the lean and sustainability integrated QMS and their application throughout the organization and have:

- Determined the inputs required and the outputs expected from these processes
- Determined the sequence and interaction of these processes
- Determined and applied the criteria, methods (including monitoring, measurements and related performance indicators) needed to ensure the effective operation, and control of these processes
- Determined the resources needed for these processes and ensured their availability
- Assigned the responsibilities and duties for these processes
- Addressed the risks and opportunities as determined by the requirements
- Evaluated these processes and implemented any changes needed to ensure that these processes achieve their intended results
- Improved the processes and the lean and sustainability integrated QMS

We have maintained documented information to the extent necessary to support the operation of processes and retained documented information to the extent necessary to have confidence that the processes are being carried out as planned.

5: LEADERSHIP

Top management shall endeavour-at all times-to create an environment where people are fully involved and in which the organisation's QMS can operate effectively.

5.1 Leadership and commitment

5.1.1 General

Our Top Management has demonstrated its leadership and commitment concerning our lean and sustainability integrated QMS by:

- Taking account of the effectiveness of the lean and sustainability integrated QMS.
- Ensuring that the lean and sustainability integrated QMS policy and objectives established for the QMS are compatible with the context and strategic direction of the organization
- Ensure integration of lean and sustainability integrated QMS requirements into our organization's business processes
- Promoting the use of the process approach and risk-based thinking
- Ensuring resources needed for lean and sustainability integrated QMS are available
- Communicating the importance of effective quality, management and of conforming to the QMS requirements
- Ensuring that lean and sustainability integrated QMS achieved its intended results
- Engaging, directing and supporting persons to contribute to the effectiveness of the lean and sustainability integrated QMS
- Promoting improvements
- Supporting other relevant management roles to demonstrate their leadership as it applies to their areas of responsibility

5.1.2 Customer Focus

Our top management demonstrates its leadership and commitment concerning customer focus by ensuring that:

- Customer and applicable statutory and regulatory requirements are determined, understood and consistently met
- The risks and opportunities that can affect the conformity of products and services and the ability to enhance customer satisfaction are determined and addressed
- The focus on enhancing customer satisfaction is maintained

5.2 Policy

The SME shall establish a high-level managerial statement concerning the organisation's quality policies and quality objectives in order to provide a general focus for the organisation.

5.2.1 Developing the Quality policy

Our top management has established, reviewed and maintained a quality policy that is appropriate to the purpose, risks and context of the organization and supports its strategic direction. This policy attests to our commitment to customer satisfaction and continual improvement of the effectiveness of our lean and sustainability integrated QMS and performance and conformance to ISO 9001:2015.

Our policy also includes a commitment to legal and other requirements to which our SME subscribes. The policy provides a framework for which objectives have been set and reviewed.

Refer to Section 3.1

5.2.2 Communicating the Quality policy

The Quality policy is made available as documented information in Section 3.1 of this manual. It is communicated, understood and applied within the organization. It is made available to relevant interested parties, as appropriate. The policy shall be displayed at appropriate work areas to promote awareness. The policy shall be communicated to all staff through an awareness briefing New staff shall be briefed on the quality, health and safety policy during induction. The policy shall be communicated to all suppliers, contractors and customers as applicable.

It is reviewed periodically and/ or during management review to ensure it is suitable, relevant and appropriate. *Refer to Section 3.1*

5.3 Organizational roles, responsibilities and duties

Top management undertakes the responsibility of the lean and sustainability integrated QMS. Respective roles and responsibilities have been assigned for each of the positions on the organizational chart and are reviewed and approved by top management for adequacy. These responsibilities and obligations are communicated to appointment holders. Personnel with management responsibility shall ensure continual improvement of Quality performance, while other personnel shall be responsible for lean and sustainability integrated QMS which they have control.

We have appointed a Responsible Personnel, who irrespective of other responsibilities has the main responsibility and authority for establishing, implementing, and maintaining the lean and sustainability integrated QMS and ensure its conformance with standards. The identity of the Responsible Personnel is made known to all.

The Responsible Personnel shall evaluate the effectiveness of the lean and sustainability integrated QMS and quality performance to ensure that processes are delivering their intended outputs and reporting to management as and when and during management review. This shall be used as a basis for continual improvement. The Responsible Personnel shall also ensure that employees are aware of the importance of meeting customer requirements and consequences of deviations. He shall ensure that the integrity of the QMS is maintained when changes to the lean and sustainability integrated QMS are planned and implemented.

The top management is ultimately responsible for all actions within the SME that affect its performance and operations. Where necessary, responsibility and study for specific actions or business areas can be delegated to another person, with all employees being communicated about this.

SECTION 6: PLANNING

The SME shall monitor and review external and internal issues that could affect the organisations lean and sustainability integrated quality management and determine if there are any risks and opportunities associated with these issues that should be addressed by their QMS.

6.1 Actions to address risks and opportunities

6.1.1 When planning for lean and sustainability integrated QMS, we have considered issues referred to in 4.1 and the requirements referred to in 4.2 and determine the risks and opportunities that need to be addressed to:

- Give assurance that the lean and sustainability integrated QMS can achieve its intended result(s)
- Enhance desirable effects
- Prevent, or reduce undesirable effects
- Achieve improvement

In identifying our threats and opportunities, we have conducted a SWOT analysis concerning the macro areas of our SME and business as follow (sample):

Additionally, we have conducted an Enterprise Risk Assessment (ERA)and documented as a record for review as needed for our SME business processes.

6.1.2 We have planned actions to address these risks and opportunities, including how to integrate and implement the actions into our lean and sustainability integrated QMS processes and evaluate the effectiveness of these actions. Actions taken to address risks and opportunities shall be proportionate to the potential impact on the conformity of products and services.

Options to address risks and opportunities can include: avoiding risk, taking the risk to pursue an opportunity, eliminating the risk sources, changing the likelihood or consequences, sharing the risk, or retaining risk by informed decisions.

Opportunities can lead to the adoption of new practices, launching new products, opening new markets, addressing new clients, building partnerships, using new technology and other desirable and viable possibilities to address the organization's or its customers' needs.

6.2 Quality Objectives, Targets, Programmes and Planning to achieve them

6.2.1 We have established, implemented and maintained Quality objectives, targets and management programmes at relevant functions, levels and processes. Based on the risks, legal and other requirements, technological options, financial, operational and business requirements and views of the interested parties, the Quality objectives and targets have been formulated. The consistencies with the Quality policy have also been considered during the establishment of objectives and targets. The objectives and targets would be reviewed and revised after the

completion and new objectives and targets would be set to ensure continual improvement. The objective & targets set must be specific, measurable, achievable, realistic & timely. The objective & targets take into account applicable requirements and are relevant to the conformity of products and services and the enhancement of customer satisfaction. It is monitored, communicated and updated as appropriate. We have retained documented information on the objectives.

6.2.2 For all objectives and targets set, the Quality Management Programmes shall be formulated indicating the time frame, responsibility (at various functions and levels, where possible) and the action plan (What will be done, What resources will be required, Who will be responsible, When it will be completed, and How the results will be evaluated) for achieving these objectives and targets. Performance indicators shall be identified to assess the progress of achieving the objectives and targets. The programme considers current activities, products and services as well as planned activities, products and services.

6.3 Planning of changes

Where we determine the need for change to the lean and sustainability integrated QMS, the change shall be carried out in a planned and systematic manner. We consider

- The purpose of the change and any of its potential consequences
- The integrity of the lean and sustainability integrated QMS
- The availability of resources
- The allocation or reallocation of responsibilities and duties

SECTION 7: SUPPORT

The SME shall identify and make available the support required to meet customer requirements.

7.1 Resources

7.1.1 General

We have determined and provided the resources needed for the QMS establishment; implementation, maintenance and continual improvement of our lean and sustainability integrated QMS. We have considered the capabilities of,

and constraints on, existing internal resources and what needs to be obtained from external providers.

7.1.2 People

We have determined and provided the persons necessary for the effective implementation of our lean and sustainability integrated QMS and for the operation and control of our processes.

7.1.3 Infrastructure

We have determined, provided and maintained the infrastructure for the operation of its processes to achieve conformity of products and services. Infrastructure can include:

- Buildings and associated utilities
- Equipment including hardware and software
- Transportation resources
- Information and communication technology

7.1.4 Environment for the operation of processes

We have determined, provided and maintained the environment necessary for the operation of its processes and to achieve conformity of products and services. Environment for the operation of processes can include physical, social, physiological environment and other factors (such as temperature, humidity, ergonomics and cleanliness.)

7.1.5 Monitoring and measuring resources

7.1.5.1 General

We have determined and provided the resources needed to ensure valid and reliable results when monitoring or measuring is used to verify the conformity of products and services to requirements. We have ensured that the resources provided are suitable for the specific type of monitoring and measurement activities being undertaken and are maintained to ensure their continuing fitness for their purpose. We have retained appropriate documented information as evidence of fitness for purpose of the monitoring and measurement resources.

7.1.5.2 Measurement traceability

For measurement traceability which is a requirement of the organization operation requirement in providing confidence in the validity of measurement results, measuring equipment shall be:

- Calibrated or verified, or both, at specified intervals, or before use, against measurement standards traceable to international or national measurement standards; when no such standards exist, the basis used for calibration or verification shall be retained as documented information;
- Identified to determine their status;
- Safeguarded from adjustments, damage or deterioration that would invalidate the calibration status and subsequent measurement results.

7.1.6 Organizational Knowledge

We have determined the knowledge (information such as intellectual property and lessons learned, etc.) necessary for the operation of its processes and to achieve conformity of products and services. This knowledge is maintained and made available to the extent necessary.

When addressing changing needs and trends, we have considered current knowledge and determined how to acquire or access the necessary additional knowledge. To obtain the knowledge required, we consider internal sources (e.g. learning from failures and successful projects, capturing undocumented knowledge and experience of topical experts within the organization) and external sources (e.g. Standards, academia, conferences, and gathering knowledge with customers or providers).

7.2 Competence

We have determined the necessary competence of person(s) doing work under its control that affects the performance and effectiveness of the lean and sustainability integrated QMS.

A procedure to identify training needs and provide ongoing training or other actions (mentoring of, or the reassignment of currently employed persons; or the hiring or contracting of competent persons) to the people whose work may create significant risks has been established, implemented and maintained. It is to ensure that all personnel (those working on behalf of the SME) performing tasks are competent to carry out the tasks based on appropriate education, training and/or

experience. The effectiveness of the actions taken is evaluated. The associated documented information and records shall be retained.

7.3 Awareness

We have ensured that persons doing work under the organization's control are aware of the Quality policy, relevant objectives, their contribution to the effectiveness of the QMS, including the benefits of improved performance and the implications of not conforming with the lean and sustainability integrated QMS requirements.

7.4 Communication

The procedure for internal communication on QMS related issues from top to bottom and vice versa has been established, implemented and maintained to ensure effective dissemination of information. We have also determined the internal and external communications relevant to the lean and sustainability integrated QMS, including:

- On what we will communicate
- When to communicate
- With whom to communicate
- How to communicate
- Who communicates

An effective communication system to receive, to document and to respond to the requests of external interested parties, has been implemented and maintained. Our procedure or policy also includes participation and consultation of employees on lean and sustainability integrated QMS matters.

7.5 Documented Information

7.5.1 General

Our QMS includes documentation to control the processes and systems required to implement the lean and sustainability integrated QMS. These documents include the Quality policy and objectives, Quality manual, documented procedure required, work instructions and records and forms as required by the standards and necessary for the effective planning, control and operation of our processes.

The documentation has been established on four as shown below based on the complexity, interaction of the processes and nature of our SME;

Level 1: Quality Manual provides an overview of the QMS and describes the

elements of the lean and sustainability integrated QMS and its associated documents including the scope, documented procedures established and the interaction of the processes.

Level 2: System Procedures describe common processes, including documented procedures required by the standards, applicable to the SME. These procedures are required to effectively implement the lean and sustainability integrated QMS and represent core elements of the standard.

Level 3: Operational Procedures (If applicable) describe the specific department processes and sub-processes that shall be controlled to ensure product and performance requirements.

Level 4: Records (Documented Information that needs to be retained) deemed necessary to demonstrate product conformance and conformance to standards.

7.5.2 Creating and updating

When creating and updating documented information, we ensure appropriate:

- identification and description (e.g. a title, date, study, or reference number)
- format (e.g. language, software version, graphics) and media (e.g. paper, electronic)
- review and approval for suitability and adequacy.

7.5.3 Control of documented information

7.5.3.1 Documented information required by the lean and sustainability integrated QMS and International Standard shall be controlled to ensure it is available and suitable for use, where and when it is needed and it is adequately protected (e.g. from loss of confidentiality, improper use, or loss of integrity).

7.5.3.2 For the control of documented information, we have addressed the following activities, as applicable: distribution, access, retrieval and use, storage and preservation, including preservation of legibility, control of changes (e.g. version control) and retention and disposition.

Procedure for controlling all lean and sustainability integrated QMS documents has been established. The procedure addresses the creation and modification of the various types of documents. Procedure for the identification, storage, protection, retrieval, retention and disposal of records has been established, implemented and maintained. The records shall be and remain legible, identifiable and traceable to the activity, product and service involved. Documented information of external origin determined by the organization to be necessary for the planning and operation of the lean and sustainability integrated QMS shall be

identified as appropriate, and be controlled. Documented information retained as evidence of conformity shall be protected from unintended alterations.

8: OPERATION

8.1 Operational planning and control

We have planned, implemented and controlled the processes needed to meet the requirements for the provision of products and services and to implement the actions determined by:

- determining the requirements for the products and services
- establishing criteria for:
- the processes
- the acceptance of products and services
- determining the resources needed to achieve conformity to the product and service requirements
- implementing control of the processes by the criteria
- determining and keeping documented information to the extent necessary:
- to have confidence that the processes have been carried out as planned
- to demonstrate the conformity of products and services to their requirements

The output of this planning is suitable for our organization's operations.

We control planned changes and review the consequences of unintended changes, taking action to mitigate any adverse effects, as necessary. Outsourced processes are controlled.

Procedures are documented for operational control (if needed) to ensure that there are no deviations from the policy, objectives and targets. A relevant requirement has been communicated to the suppliers and contractors to ensure that the lean and sustainability integrated QMS aspects related to their activities, products and services for our SME are effectively controlled.

8.2 Requirements for products and services

8.2.1 Customer communication

Communication with customers includes providing information relating to products and services

(i.e. contracts or SME website), handling enquiries (sales hotlines and sales representatives), contracts or orders, including changes, obtaining customer feedback relating to products and services, including customer complaints, handling or controlling customer property and establishing specific requirements for contingency actions, when relevant.

8.2.2 Determining the requirements related to products and services

When determining the requirements for the products and services to be offered to customers, our sales and contracts department ensures that the requirements for the products and services are defined, including any applicable statutory and regulatory requirements and those considered necessary by our organization. We ensure we can meet the claims for the products and services we offer.

8.2.3 Review of requirements related to products and services

8.2.3.1 We ensure that we can meet the requirements for products and services to be offered to customers. We conduct a review before committing to supply products and services to a customer, to include:

- requirements specified by the customer, including the requirements for delivery and post-delivery activities;
- requirements not stated by the customer, but necessary for the specified or intended use, when known;
- requirements specified by the organization;
- statutory and regulatory requirements applicable to the products and services;
- contract or order requirements differing from those previously expressed.

We ensure that contract or order requirements differing from those previously defined are resolved. The customer's requirements are confirmed by our sales and contracts department before acceptance when the customer does not provide a documented statement of their requirements.

8.2.3.2 We retain documented information, as applicable on the results of the review and any new requirements for the products and services.

8.2.4 Changes to requirements for products and services

We ensure that relevant documented information is amended, and that relevant personnel are made aware of the changed requirements when the requirements for products and services are changed.

8.3 Design and development of products and services

The SME shall plan and control the design and development of its products and services, which shall include;

- Stage reviews;
- Verification and validation activities;
- Identification of responsibilities and duties;
- Provision for effective communication;
- Clarity of responsibilities;

8.4 Control of externally provided processes, products and services

8.4.1 General

We shall ensure that externally provided processes, products and services conform to requirements. We have determined the controls to be applied to externally provided processes, products and services when:

- products and services from external providers are intended for incorporation into the SME's products and services
- products and services are provided directly to the customer(s) by external providers on behalf of the organization
- a process, or part of a process is provided by an external provider as a result of a decision by the organization

We have determined and applied criteria for the evaluation, selection, monitoring of performance, and re-evaluation of external providers, based on their ability to provide processes or products and services following requirements. We have retained documented information (a record) of these activities and any necessary actions arising from the evaluations.

8.4.2 Type and extent of control

We shall ensure that externally provided processes, products and services do not adversely affect our ability to consistently deliver conforming products and services to our customers.

We ensure that externally provided processes remain within the control of our quality management system. We define both the controls that we apply to an external provider and the resulting output. We take into consideration the potential

impact of the externally provided processes, products and services on our ability to consistently meet customer and applicable statutory and regulatory requirements and the effectiveness of the controls applied by the external provider. We also determine the verification, or other activities, necessary to ensure that the externally provided processes, products and services meet requirements.

8.4.3 Information for external providers

We shall ensure the adequacy of requirements before their communication to the external provider. We communicate to external providers its requirements for:

- the processes, products and services to be provided
- the approval of products and services and/ or methods, processes and equipment
- the release of products and services
- competence, including any required qualification of persons
- the external providers' interactions with our organization
- control and monitoring of the external providers' performance to be applied by our organization
- verification or validation activities that we, or our customer, intends to perform at the external providers' premises

8.5 Production and Service provision

8.5.1 Control of Production and Service provision

We shall implement production and service provision under controlled conditions. Controlled conditions shall include, as applicable:

- the availability of documented information that defines the characteristics of the products to be produced, the services to be provided, or the activities to be performed and the results to be achieved
- the availability and use of suitable monitoring and measuring resources
- the implementation of monitoring and measurement activities at appropriate stages to verify that criteria for control of processes or outputs, and acceptance criteria for products and services, have been met
- the use of suitable infrastructure and environment for the operation of processes
- the appointment of competent persons, including any required qualification
- the validation and periodic revalidation does not apply to the SME as all the product (from the processes output) supplied by the SME will be tested and

inspected to ensure meeting customer requirements before shipping out

- the implementation of actions to prevent human error
- the implementation of release, delivery and post-delivery activities

8.5.2 Identification and traceability

We use suitable means to identify outputs when it is necessary to ensure the conformity of products and services. We shall control the unique identification of the outputs when traceability is a requirement and retain the documented information necessary to enable traceability. Appropriate identification (work order number) traceable to customer purchase order established for all work in progress to finished product. Finished product failed testing or inspection shall be separated from the testing and inspection and stored in an assigned location until rectified and re-test and re-inspection done.

8.5.3 Property belonging to customers or external providers

We exercise care with property belonging to customers or external providers while it is under our control or being used by us. We identify, verify, protect and safeguard customers' or external providers' property provided for use or incorporation into the products and services.

When the property of a customer or external provider is lost, damaged or otherwise found to be unsuitable for use, we report this to the customer or external provider and retain documented information on what has occurred. A customer's or external provider's property can include material, components, tools and equipment, premises, intellectual property and personal data. All personal data is also protected following the Personal Data Protection Act.

8.5.4 Preservation

Raw material and finished-products received are subjected to proper storage and inspection for the following:

1. Part/product by the purchase order to ensure the correct product received or shipped.
2. Visual and Packaging inspection to ensure no clear and visual damaged.

We Ltd shall ensure raw materials have proper identification and sound inventory control established and finished good have proper identification statue.

8.5.5 Post-delivery activities

We meet requirements for post-delivery activities (actions under warranty provisions, contractual obligations such as supplementary services such as recycling or final disposal, etc) associated with the products and services. In determining the extent of post-delivery activities that are required, we consider:

- statutory and regulatory requirements
- the potential undesired consequences associated with its products and services
- nature, use and intended lifetime of its products and services
- customer requirements
- customer feedback

8.5.6 Control of changes

We shall review and control changes for production or service provision, to the extent necessary to ensure continuing conformity with requirements. We have retained documented information describing the results of the review of changes, the person(s) organizing the change, and any necessary actions arising from the review.

8.6 Release of products and services

We implement planned arrangements, at appropriate stages, to verify that the product and service requirements have been met. The release of products and services to the customer shall not proceed until the planned arrangements have been satisfactorily completed, unless otherwise approved by a relevant studyity and, as applicable, by the customer. We retain documented information on the release of products and services including evidence of conformity with the acceptance criteria (through our testing or commissioning report) and traceability to the person(s) organizing the release.

8.7 Control of nonconforming outputs

8.7.1 We ensure that outputs that do not conform to their requirements are identified and controlled to prevent their unintended use or delivery. We take appropriate action based on the nature of the nonconformity and its effect on the conformity of products and services. This shall also apply to nonconforming products and services detected after delivery of products, during or after the provision of

products and services. We deal with nonconforming outputs in one or more of the following ways:

- correction
- segregation, containment, return or suspension of the provision of products and services
- informing the customer • obtaining organization for acceptance under concession

Conformity to the requirements shall be verified when nonconforming outputs are corrected.

8.7.2 We retain documented information that:

- describes the nonconformity
- describes the actions taken
- describes any concessions obtained
- identifies the suitability deciding the action in respect of the nonconformity

9: PERFORMANCE EVALUATION

The SME shall make available procedures to ensure conformity, improvement the analysis of customer satisfaction and the control of products, services and processes.

9.1 Monitoring, measurement, analysis and evaluation

9.1.1 General

We have determined what needs to be monitored and measured, the methods for monitoring, measurement, analysis and evaluation needed to ensure valid results, when the monitoring and measuring shall be performed and when the results from monitoring and measurement shall be analysed and evaluated.

We evaluate the performance and the effectiveness of the lean and sustainability integrated QMS and retain appropriate documented information as evidence of the results. This includes statistical methods to monitor and analyze processes.

A process has been established to monitor and measure quality performances including the extent to which objectives are met, qualitative and quantitative measures, proactive and reactive measure of quality performance and monitoring of equipment. Records are maintained. Results of such evaluations are recorded.

9.1.2 Customer satisfaction

Customer satisfaction is determined to monitor customers' perceptions of the degree to which their needs and expectations have been fulfilled. Customer satisfaction is obtained using customer communications with sales and administrative personnel, customer feedbacks/ complaints received and customer satisfaction survey. The customer satisfaction survey is conducted annually for a selected sample size of our customers.

9.1.3 Analysis and evaluation

We analyse and evaluate appropriate data and information arising from monitoring and measurement. The results of the analysis are used to evaluate:

- conformity of products and services
- the degree of customer satisfaction
- the performance and effectiveness of the lean and sustainability integrated QMS.
- if planning has been implemented effectively
- the effectiveness of actions taken to address risks and opportunities
- the performance of external providers
- the need for improvements to the QMS

9.2 Internal audit

9.2.1 An internal audit program has been established to ensure that the QMS conforms to the ISO 9001:2015 requirements and to ensure the QMS is effectively implemented and maintained.

9.2.2 This internal audit program shall include the objective, scope, criteria, methodology and this internal audit shall be conducted at least once a year (frequency). In formulating the internal audit program, the importance of the process, risks and the results of previous audits shall be considered.

It is the lead auditor's responsibilities and requirements for planning the audit program, ensuring the impartiality of auditor and reporting the audit results to management and documented in the management review and retaining associated records. It is the auditor's responsibility to conduct the audit and reporting the results to the lead auditor and to ensure appropriate correction and corrective actions are address timely (as guide 2weeks) and closure taken.

9.3 Management review

9.3.1 General

The QMS is reviewed at least once a year to ensure its continuing suitability, adequacy, effectiveness and alignment with the strategic direction of our organization.

9.3.2 Management review inputs

The reviewing agenda includes:

a) results of internal and external audits b) results of participation & consultation c) relevant communication(s) from external interested parties, including complaints d) information on the performance and effectiveness of lean and sustainability integrated QMS) the extent to which objectives and targets have been met f) status of nonconformities, corrective and preventive actions.

9.3.3 Management review outputs

The outputs from the management reviews shall include any decisions and actions related to possible changes to lean and sustainability integrated QMS policy, objectives, targets, opportunities for improvement, any need for changes to the management system and other elements of the lean and sustainability integrated QMS, consistent with the commitment to continual improvement. We shall maintain the record in the form of minutes of the review meetings.

SECTION 10: IMPROVEMENT

10.1 General

We determine and select opportunities for improvement and implement any necessary actions to meet customer requirements and enhance customer satisfaction. This includes improving products and services to meet requirements as well as to address future needs and expectations, correcting, preventing or reducing undesired effects and improving the performance and effectiveness of the lean and sustainability integrated QMS.

10.2 Nonconformity and corrective action

10.2.1 When nonconformity or potential nonconformity occurs, including any arising from complaints, we react to the nonconformity and, as applicable take action to control and correct it and deal with the consequences.

We also evaluate the need for action to eliminate the cause(s) of the nonconformity or potential nonconformity, so that it does not recur or occur elsewhere by:

- reviewing and analysing the nonconformity or potential nonconformity;
- determining the causes of the nonconformity or potential nonconformity;
- determining if similar nonconformities exist, or could potentially occur;
- implement any action needed;
- review the effectiveness of any corrective or preventive action taken;
- update risks and opportunities determined during planning, if necessary;
- make changes to the lean and sustainability integrated QMS, if necessary.

Corrective actions shall be appropriate to the effects of the nonconformities or potential nonconformities encountered.

10.2.2 We retain documented information of the nature of the nonconformities and any subsequent actions taken and the results of any corrective action. Necessary changes to the documentation or processes shall be made if applicable.

10.3 Continual improvement

We shall continually improve the suitability, adequacy and effectiveness of the lean and sustainability integrated QMS. The organization shall consider the results of analysis and evaluation, and the outputs from management review, to determine if some needs or opportunities shall be addressed as part of continual improvement.

APPENDIX V

SAMPLE CALCULATIONS OF SIMULATED RESPONSES USING MONTE CARLO METHOD

PERFORMANCE INDICATOR : 1 -

For SME – A

Survey values	Probability	Cumulative probability	Random interval	Random number	Simulated value
4	0.17	0.17	1 - 16	22	5
5	0.21	0.38	17 - 37	15	4
4	0.17	0.55	38 - 54	32	5
3	0.13	0.68	55 - 57	41	4
4	0.17	0.85	58 - 84	17	5
4	0.17	1.00	85 - 99	24	5
				08	4
				19	4
				28	5
				43	4

SME – B

Survey values	Probability	Cumulative probability	Random interval	Random number	Simulated value
4	0.19	0.19	1 - 18	04	4
5	0.24	0.43	19 - 42	17	4
4	0.19	0.62	43 - 61	28	5
4	0.19	0.81	62 - 80	41	5
4	0.19	1.00	81 - 99	66	4
				78	4
				08	4
				52	4
				14	4
				29	5

Calculation of 'd'

SME- A	SME- B	d
5	4	1
4	4	0
5	5	0
4	5	1
5	4	1
5	4	1
4	4	0
4	4	0
5	4	1
4	5	1
		6

Paired t-test.

Null Hypothesis – No difference in Perception

Alternative Hypothesis – Difference in perception

SME - A

$n_1 = 10$

mean value = $\bar{x}_1 = 5$

Range (σ_1) = 1.01

SME - B

$n_2 = 10$

mean value = $\bar{x}_2 = 4$

Range (σ_2) = 1

$t_{cal} = (d /(\sigma d/\sqrt{n_1+n_2-2}))$

$\sigma d = 101$

$\bar{d} = (d/n_1) = (6/10) =$ **0.6**

$t = 0.6/ (1.01/\sqrt{18})$

= **2.51** and < 2.61 (Value from the table) at $p < 0.01$

Thus the Null hypothesis is accepted.

LIST OF PUBLICATIONS

1. Manmohan, C. M., and Shalij, P. R., Influence of Lean on Quality Management Performance in Small and Medium Enterprises, *International Journal of Mechanical and Production Engineering Research and Development* (IJMPERD) ISSN(P): 2249–6890; ISSN(E): 2249–8001, Vol. 9, Special Issue, Aug 2019, 68–74 (Scopus Indexed).

2. Manmohan, C. M., and Shalij, P. R., A Literature review on the effect of Lean and Sustainability on Quality Management Systems for SMEs, *International Journal of Science and Research*, Vol. 9, ISS. 2, February 2020, 1618-1623, Research Gate Impact Factor (2018): 0.28 | SJIF (2018): 7.426, ISSN 2319: 7064, DOI: 10.21275/SR20224172131.

3. Manmohan, C. M., Shalij, P.R., Integration of Lean and Sustainability In ISO 9001:2015 Certified SMEs In India, International Journal of Control and Automation, Science and Engineering Research Support Society. ISSN: 2005-4297, Vol. 13, No. 3, 2020, pp. 169-180 (Scopus Indexed).