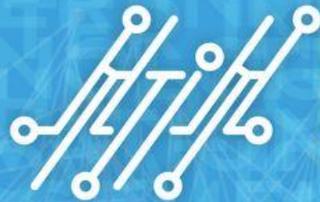




ΠΟΛΥΤΕΧΝΕΙΟ ΚΡΗΤΗΣ
TECHNICAL UNIVERSITY OF CRETE



MASTER IN
TECHNOLOGY &
INNOVATION
MANAGEMENT

**“Towards the development of a Quality
Management System of a small pet grooming
production company.”**

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Abstract

The scope of this thesis is to evaluate and identify whether a young and small company has the ability to meet and work under the quality standards as described in ISO 9001:2015. We will analyze and report the presence of various Quality Management tools with particular reference to the Company named "TOP DOG" and clarify the readiness of this Company to acquire the ISO 9001:2015 certification based on the requirements of the standards. Additionally to the registration of the procedures that are already being followed by the Company and the analysis of the Company's current situation against requirements, we will also mention all other requirements that TOP DOG should include in its procedures in order to acquire the ISO 9001:2015 certification.

TOP DOG is a local start-up company that was founded in Chania, Crete, in 2012, and its business activity is the production and distribution of pet grooming products. The Company had been developing its formulas for the first 3 (three) years; thus, the only department operating until 2015 was the R&D department. TOP DOG entered the Greek market in 2015 and by now has managed to become one of the leading companies in Greece in the area of pet grooming products with a presence in more than 600 selected stores all over the country.

The Company is interested in selling internationally, therefore, is trying to conduct its business under the requirements of ISO 9001:2015 standard. However, it is a very small and young company operating in an unfavorable economic and political environment that faces multiple barriers in setting standard quality practices. This thesis will identify the complexity or the simplicity for a young production company to comply with ISO 9001:2015 standards and answer the question of whether TOP DOG has the capability to conform to this qualitative tool regardless of local economic, environmental, and political restrictions, or if it is too complicated and extensive, requiring multiple working hours to implement, thus making the Standard even more challenging to follow.

List of Acronyms and Abbreviations

ERP: Enterprise Resource Planning

ISO: International Standards Organization

HLS: High-Level Structure

R&D: Research and Development Department

QMS: Quality Management System

SWOT: Strengths, Weaknesses, Opportunities, and Threats

PDCA: Plan - Do - Check – Act

Chapter 1.

Introduction

ISO international standards may be characterized as the most widely accepted set of business-oriented quality standards in the world. The Organization has developed many types of management system standards related to quality to try and cover any business activity, whether involved in the production of consumer products or provision of services. ISO seems to provide standards with simplified procedures, and any organization that chooses to operate a management system can easily meet its requirements. ISO standards seem to be understandable, accessible, and simple to use and implement. More particularly, the Organization itself claims (about ISO 9001:2015) that “all its requirements are generic and are intended to be applicable to any organization, regardless of its type or size, or the products and services it provides.”

This thesis will help us evaluate whether such a statement is solid taking into consideration the efforts of a young enterprise with limited financial and manpower resources to actually function under the basic quality management requirements set in the aforementioned Standard. Such analysis is important for understanding the difficulties a local start-up company might have to operate under international quality management standards while operating under an unfavorable and continuously changing economic and political environment.

In order to achieve the objectives of this study, I have collected relevant implementation and certification processes of the quality management system ISO 9001. This study has been conducted using the research method of participant observation since I am an employee of Top Dog and I am responsible for the Commercial Management of the Company. The empirical data was gathered from observations, interviews, and document studies. This methodology will provide an accurate insight into the Company’s functionality and procedures, therefore a clear view with regard to this thesis.

This study can avail as an example for similar situations while helping Managers to understand their impact on the quality management system. It might also provide an insight to other companies to handle ISO-standard aspects and requirements more effectively and help them conclude a better implementation process for ISO 9001 certification. This study may even light up any possible demanding or complex requirements that can drive the ISO organization to a possible reevaluation at future editions.

Chapter 2.

The structure of the report

The scope of this thesis is to practically identify the flexibility of the ISO 9001 when implemented in a small-sized business and define the key elements of the world's most popular management system standard.

The structure of this thesis is based on 4 (four) sections that are the following:

- 1) Initially, there will be a short overview of the concept of quality and Quality Management Systems in general and the history of how quality principles evolved along the centuries leading to what quality means in modern-day business. We will also identify the advantages and disadvantages of adopting a quality management system. Still, there will be no further analysis on the theoretical and academic background of the Quality Management Systems in order to focus on the practical enforcement of the ISO 9001 standard.
- 2) The 2nd section is an overview of the monitored Company named Top Dog (including basic information on its products, activities, market, and a timeline of its history so far), but most importantly, I will mention the reasons why should Top Dog comply with ISO 9001 and whether the Company has ever made any efforts towards quality management certification.
- 3) The third and most significant section analyzes the ISO requirements in contrast to the Company's established procedures. There will be a detailed report based on the structure and fundamentals set by the ISO standard 9001:2015. The analysis will be performed clause by clause towards establishing a QMS system that will lead the Company to its accreditation. This report will have the form of a self-assessment checklist where I will analyze step by step each clause according to the below framework:
 - a) First of all, the number and title of the clause will be mentioned
 - b) Short description of the clause's meaning according to the ISO 9001 management system standard
 - c) Comments on the Company's present status on each particular clause
 - d) Finally, further analysis of the Company's current procedures and how it applies each clause including possible suggestions for the fulfillment of the clause.
- 4) The final section describes the outcomes and conclusions of this report, analyzed to the possible extent that will include :
 - a) An outline of the whole study (purpose, methodology of development, development).
 - b) A summary of the main findings and conclusions with respect to the aim and scope that have been determined in the Introduction.
 - c) Proposals for the extension and/or continuation of the study in the future.

Chapter 3.

Overview of Quality Management Systems

3.1. The concept of quality

Quality may seem like a relative concept that can be evaluated differently by individuals, customers, users, organizations, etc. However, increased levels of competition have resulted in quality becoming a significant issue in the business world.

Quality in everyday conversation is used in the absolute sense. People use it to describe expensive restaurants and luxury cars. In the absolute sense, quality is associated with the nature of good, beauty, and truth. In the absolute definition, things that have quality present high standards, which cannot be surpassed. Quality products are distinguished by perfection; they have value and grant prestige to those who own them. Rarity and accuracy are two of the quality characteristics in this definition. However, the literal meaning of high quality has nothing to do with the philosophy of Total Quality Management (Zavlanos, 2006).

The term quality is often confusing because it is interpreted in different ways depending on the point of view from which it is examined. According to Plato, quality was linked to man's virtue, moral, spiritual, and physical superiority. Today, quality is considered to be the sense of excellence that gives the acquisition of a good, fully recognizable, for its excellent characteristics.

Abbot and Feigenbaum defined quality as value-based criteria. This value is determined by the quality of the product or service provided and the price offered, which are criteria for acceptance or rejection for the customer (Vastardi, 2005).

According to Gilmore, quality is compliance with specifications. This concept of quality refers to whether the technical specifications of a product are met so as to avoid any loss in order to achieve better quality at a lower cost.

The catalyst for the customer-centric definition of quality has been many public and private companies in the United States, which have seen quality as synonymous with meeting customer expectations. Respectively, Crosby (1979) determines the quality according to the degree of satisfaction of the customer's requirements, while Juran (2000) considers that the concept of quality is intertwined with "suitability for use" (Vastardi, 2005).

Finally, Deming (1993) sees quality as an imperfect cycle of continuous improvement. According to this method, before a process is implemented, the results are planned, executed, studied, and appropriate actions are taken towards a new cycle of improvement.

According to the definition contained in the ISO 9001 standard, quality is the set of characteristics of a product or service that refers to its ability to meet both the given and the expected needs (Fameli, 2005).

3.2. History of Quality in the Modern Era

Juran (1995) extensively analyses in his book "A History of Managing for Quality" how quality was managed over the centuries in some specific civilization or country. Since quality is a timeless concept, it is impossible to identify the exact origins of the human approach to

managing quality. However, if we are to identify the broad trends of the chronological sequence that led to the maturity of the Quality movement, we could claim that the initial quality management can trace its roots back in the late 13th century, where craftsmen were organized into unions called guilds that were responsible for developing strict rules for product and service quality and were marking flawless goods with a special mark or symbol. However, it was at the beginning of the 20th century where “processes” were systematically included in quality practices worldwide.

I hereby include a short history chart that describes the major quality systems that were developed and implemented mainly in the United States of America.

Table 1.

Late 13 th century	Early 19 th century	Late 19 th century	Early 20 th century	WWII	1946	Mid 20 th century	Late 20 th century	21 st century
Craftsmanship and Guilds	Industrial Revolution Factory System	The Taylor System	Quality Processes and SQC	Sampling and Standards	ASQ (then ASQC) formed	Company-wide Quality Control in Japan	Total Quality Management in the U.S.	Quality 4.0

Available at <https://asq.org/quality-resources/history-of-quality>, (Accessed 16 June 2020)

3.3. Quality in the early 20th century

Available at <https://asq.org/quality-resources/history-of-quality>, (Accessed 16 June 2020)

“The beginning of the 20th century marked the inclusion of "processes" in quality practices. A "process" is defined as a group of activities that takes an input, adds value to it, and provides an output. Walter Shewhart began to focus on controlling processes in the mid-1920s, making quality relevant not only for the finished product but for the processes that created it.

Shewhart recognized that industrial processes yield data. Shewhart determined this data could be analyzed using statistical techniques to see whether a process is stable and in control or if it is being affected by special causes that should be fixed. In doing so, Shewhart laid the foundation for control charts, a modern-day quality tool.”

3.4. Quality in World War II

Available at <https://asq.org/quality-resources/history-of-quality>, (Accessed 16 June 2020)

“After entering World War II, the United States enacted legislation to help gear the civilian economy to military production. During this period, quality became a critical component of the war effort and an important safety issue. Unsafe military equipment was clearly unacceptable, and the U.S. armed forces inspected virtually every unit produced to ensure that it was safe for operation. This practice required huge inspection forces and caused problems in recruiting and retaining competent inspection personnel.

To ease the problems without compromising product safety, the armed forces began to use sampling inspection to replace unit-by-unit inspection. With the aid of industry consultants, particularly from Bell Laboratories, they adapted sampling tables and published them in a military standard, known as Mil-Std-105. These tables were incorporated into the military contracts so suppliers clearly understood what they were expected to produce.

The armed forces also helped suppliers improve quality by sponsoring training courses in Walter Shewhart's statistical quality control (SQC) techniques."

3.5. The history of total quality in America

Available at <https://asq.org/quality-resources/history-of-quality>, (Accessed 16 June 2020)

"The birth of total quality in the United States was in direct response to a quality revolution in Japan following World War II, as major Japanese manufacturers converted from producing military goods for internal use to producing civilian goods for trade.

At first, Japan had a widely held reputation for shoddy exports, and their goods were shunned by international markets. This led Japanese organizations to explore new ways of thinking about quality."

3.5.1. Deming, Juran, and Japan

Available at <https://asq.org/quality-resources/history-of-quality>, (Accessed 16 June 2020)

"The Japanese welcomed input from foreign companies and lecturers, including two American quality experts:

W. Edwards Deming, who had become frustrated with American managers when most programs for statistical quality control were terminated once the war and government contracts came to an end.

Joseph M. Juran, who predicted the quality of Japanese goods would overtake the quality of goods produced in the United States by the mid-1970s because of Japan's revolutionary rate of quality improvement.

Japan's strategies represented the new "total quality" approach. Rather than relying purely on product inspection, Japanese manufacturers focused on improving all organizational processes through the people who used them. As a result, Japan was able to produce higher-quality exports at lower prices, benefiting consumers throughout the world."

3.5.2. The American Total Quality Management Response

Available at <https://asq.org/quality-resources/history-of-quality>, (Accessed 16 June 2020)

"At first, U.S. manufacturers held onto to their assumption that Japanese success was price related, and thus responded to Japanese competition with strategies aimed at reducing domestic production costs and restricting imports. This, of course, did nothing to improve American competitiveness in quality.

As years passed, price competition declined while quality competition continued to increase. The chief executive officers of major U.S. corporations stepped forward to provide personal leadership in the quality movement. The U.S. response, emphasizing not only statistics but approaches that embraced the entire Organization, became known as Total Quality Management (TQM).

Several other quality initiatives followed. The ISO 9000 series of quality-management standards, for example, were published in 1987. The Baldrige National Quality Program

and Malcolm Baldrige National Quality Award were established by the U.S. Congress the same year. American companies were at first slow to adopt the standards but eventually came on board.”

3.6. Beyond Total Quality Management

Available at <https://asq.org/quality-resources/history-of-quality>, (Accessed 16 June 2020)

“As the 21st century began, the quality movement matured. New quality systems have evolved beyond the foundations laid by Deming, Juran, and the early Japanese practitioners of quality.

Some examples of this maturation in quality management include:

- Most recently in 2015, the ISO 9001 standard was revised to increase emphasis on risk management.
- In 2000, the ISO 9000 series of quality management standards was revised to increase emphasis on customer satisfaction.
- Beginning in 1995, the Malcolm Baldrige National Quality Award added a business results criterion to its measures of applicant success.
- Six Sigma, a methodology developed by Motorola to improve its business processes by minimizing defects, evolved into an organizational approach that achieved breakthroughs and significant bottom-line results.
- Quality function deployment was developed by Dr. Yoji Akao as a process for focusing on customer wants or needs in the design or redesign of a product or service.
- Sector-specific versions of the ISO 9000 series of quality management standards were developed for such industries as automotive (QS-9000 and ISO/TS 16949), aerospace (AS9000) and telecommunications (TL 9000) and for environmental Management (ISO 14000).
- Quality has moved beyond the manufacturing sector into such areas as service, healthcare, education, and government.
- The Malcolm Baldrige National Quality Award has added education and healthcare to its original categories: manufacturing, small business, and service. Many advocates are pressing for the adoption of a "nonprofit organization" category as well.”

3.7. Benefits and shortcomings of quality management systems adoption

Available at <https://www.nibusinessinfo.co.uk/content/advantages-quality-management-systems>, (Accessed 16 June 2020)

“Advantages of ISO 9001

Implementing a quality management system, such as the ISO 9001, offers numerous benefits to business owners that can be economic (i.e. the contribution of standards to the creation of economic value) and non economic (i.e. the contribution that standards give to the achievement of social and environmental benefits). General standardization and use of standards typically increases efficiency and productivity, and is likely to give an edge over competitors.

Adopting a quality management system may help a company to acquire the following advantages:

- greater efficiency and less waste
- better and consistent control of major business processes
- a better understanding of customer needs
- regulation of successful working practices
- improved risk management
- increased customer satisfaction
- improved participation of employees
- better internal communication
- greater consistency in the quality of products and services
- differentiation of the business against its competitors
- increased profits
- reduction of costly errors
- exploitation of new markets
- managing growth more effectively
- an embedded culture of quality”

The ISO certification, in particular, is a globally recognized achievement and, as such, may help the Company raise its international profile and increase business overseas.

3.8. Disadvantages of ISO implementation

Available at <https://www.nibusinessinfo.co.uk/content/advantages-quality-management-systems> , (Accessed 16 June 2020)

“Despite the many benefits, possible challenges to implementing the ISO standards include:

- the cost of getting and keeping the certification
- the time involved
- resistance to change from within the business
- high possibility of needing help from an outsourced consultant at an additional cost”

Certification to ISO 9001 isn't mandatory, but in some cases may be a prerequisite to working with certain clients such as public bodies. A company should carefully evaluate if certification makes sense for its business. Many organizations benefit from using the Standard without actually seeking certification.

Chapter 4.

Overview of the TOP DOG Company

4.1. Top Dog in a nutshell

Available at <https://b2b.topdog.gr/> . (Accessed 5 September 2021)

TOP DOG is a family-owned business of young yet experienced experts, guided by love and dedication who want to pioneer and contribute to the improvement of the pet grooming market. The Company innovates and stands out for producing pet grooming products that aim at the best quality of life for pets and focus on the perfect result that every pet guardian wants.

Top Dog utilizes modern technical methods and the beneficial properties of various natural ingredients such as olive oil, aloe vera, herbs, green clay, etc., while at the same time they avoid using ingredients such as parabens, alcohol, colorants, and petrochemicals.

Top Dog's philosophy is to combine the properties and advantages of naturally based ingredients with high-quality novel ingredients and cutting-edge tools in order to enhance these properties and expand the boundaries that natural resources give for maximum performance results.

4.2. Top Dog's Products

Available at <https://b2b.topdog.gr/> . (Accessed 5 September 2021)

Each Top Dog formula contains mild and qualitative raw materials, various active ingredients of natural origin, and essential oils that give the final product unique characteristics and offer amazing results, covering the particular needs of each pet individually. Top Dog provides to the pet guardian a wide range of products to choose from, according to the daily routine and needs of the pet regardless of its breed, hair color or coat type. The product portfolio includes shampoos, fragrances, conditioners & masks, skincare products, styling & coat care products and home care products.

The Company's Research and Development department is constantly updated on new research related to the health and well-being of pets, as their lifestyles have changed significantly in the modern world, as well as on new studies conducted on ingredients that have been proved to be beneficial when included in products that are used by pets.

4.3. History of TOP DOG

Available at <https://b2b.topdog.gr/> . (Accessed 5 September 2021)

2012 : THE STORY BEGINS

"Top Dog Natural Pet Products" was established in 2012 by Konstantinos Mastrantonakis, a brilliant young man who decided to be self-employed while investing by his own means in an

unfavorable economic and political environment. The leading part of this decision was his strong desire to put into practice all that he was taught in his studies in Greece and abroad while developing products that would make a difference.

2015 : ENTERING THE MARKET

2015 was a significant milestone for Top Dog since, after 3 (three) years of Research and Development, it entered the Greek market with a small product range consisting of only 6 (six) pet shampoos and 6 (six) fragrances.

2016 : RAISING NATIONAL AWARENESS

The Company participated for the first time in the exhibition PETSTODAY 2016 and gained national recognition while multiplying its selling points.

2017 : DEVELOPING BREAKTHROUGH PRODUCTS

The product portfolio increased to 57 product codes, some of which are breakthrough products.

2018 : REBRANDING TOWARDS EXTERNALIZATION

In 2018 the Company renewed its branding by creating a more international profile where all the information on the products is in 2 languages Greek and English.

2019 : RISING SALES CALL FOR INCREASED PRODUCTION

At the beginning of 2019, Top Dog signed a contract with a large and well-established distributor in Greece that helped the Company to increase its selling points nationally. Booming sales call for the acquisition of new equipment to increase capacity and to optimize efficiency in production processes.

2020 : A LANDMARK YEAR

It was a landmark year since Top Dog invested in new equipment, tripling its production capacity and making its first openings in foreign countries with its leading brand "Top Dog." The Company also signed some initial contracts for producing Private Label products for third parties.

2021 : HISTORY IS BEING WRITTEN

The Company expanded its product portfolio by adding 5 (five) more products and developed a new product category called "Home Care. " Top Tog also participated in the largest exhibition of the pet sector named Interzoo 2021 that has been held for the last 70 years in Germany. Due to the restrictions of the Covid19 pandemic, the exhibition was digital for the first time. TOP DOG also acquired 3 (three) awards out of the 7 (seven) awards that were given in total in the Pet Awards 2021 in the category of Dog and Cat Grooming Products, which signifies the paramount quality of Top Dog's products.

4.4. Top Dog's activities

Right from the start, Top Dog was characterized by innovative strength. Its main activity is producing innovative grooming products for pets using natural ingredients and new scientific methods.

TOP DOG's philosophy is to use mild and performing ingredients from world-renowned suppliers that offer excellent results and contribute to a better quality of life for pets. The Company's products are of high quality and focus on the demanding needs of professional groomers who need to make a difference.

However, what truly characterizes the Company's profile is that all its products are produced with a primary focus to avoid the use of ingredients that have been identified as harmful or have been scientifically accused of side effects and health issues with respect to the particular needs of the pets such as parabens, colorants, SLS, petroleum derivatives, phthalate esters, etc.

4.5. Top Dog's market

Through the know-how and the passion for the perpetual improvement of its products, the Company managed to lead the Greek market in the field of natural pet care products in just a few years.

Top Dog is one of the few companies operating in Greece as most of the market is served by imported products and the only Company that has focused on producing professional products of international standards, capable of meeting the demanding needs of a pet grooming salon or a veterinary clinic.

4.6. Top Dog in numbers

Top Dog is a family-owned business, small in size and relatively new, that is focused on developing and producing pet grooming products.

Its personnel consists of 5 (five) people, including 2 (two) members of the family that are the Top Management, but it also has handed over some departments to outsourced parties, so the total embedded workforce is around 10 (ten) more people (Marketing & Graphic Designing, Legal Consulting, Technical Consulting, Accounting, Website, and Social Media Management, I.T. support, Mechanical Engineering). At the same time, the Company's official distributor in Greece has a sales force of 10 (ten) Salespeople covering the entire country, so the total workforce of Top Dog increases to around 25 (twenty-five) people.

Its annual turnover rapidly increases each year with astonishing percentages. However, 2021 was a milestone since the Company managed to succeed at a paramount growth rate by doubling its gross sales signifying a new era for the future of the Company.

4.7. The reasons for Top Dog to comply with ISO 9001:2015

Top Dog has strategically decided to adopt a QMS from the very beginning knowing that it will help the Company improve its overall performance and provide a sound basis for its

sustainable development initiatives. However, Top Dog recently decided to implement a FORMAL quality management system after realizing that their customers abroad will want assurance that the offered products will meet their requirements for high quality. Those customers are looking for the confidence that can be provided by an organization offering products and services produced under an effective quality management system, such as one conforming to ISO 9001. For Top Dog, the accreditation by ISO 9001:2015 is a tool that will help the Company penetrate foreign markets easier and make them more accessible.

4.8. Any efforts to date towards quality Management and certification

The Company follows the 9001:2015 quality standards in its daily operations through common practices but never made any effort to systematically follow the procedures and correspondingly to acquire an ISO 9001:2015 certification due to the below factors:

Lack of Capacity: Top Dog is a small-sized company with many different departments that are demanding (R&D, Production, Supply, Sales, Marketing, etc.). The relevant Organization chart is included in the Appendices to confirm the complexity of the business. Considering that the development of a Quality Management System requires intensive work, Top Dog could not devote the needed time to establish it.

Budget: At the same time, the Company did not have the corresponding budget that could lead to the hiring of an additional employee (or even more than one) to lead the project, to pay for an Industry Consultant that would provide knowledge and details about the industry and its use of standards or to cover the expenses for the Third Party Assessment.

Time-Consuming: Top Dog has been trying to quantify the impact of standards in its daily operation, but due to all the above factors, significant progress has not been made.

Chapter 5.

Analysis of TOP DOG’s Quality Management System in contrast to ISO 9001:2015

In this chapter, I will extensively analyze TOP DOG’s implemented Quality Management System in contrast to each requirement described in the ISO 9001:2015 standard. The first 3 (three) clauses of the ISO 9001:2015 are introductory. Therefore, I will start my analysis from Clause 4 (four) where the Company must consider its business environment according to which will form a defined management system.

Each clause begins with the title and name given by the Standard itself, followed by the titles of the relevant sub-clauses beneath. Under the sub-clause title, I use a 2-column table where in the first column I describe the guidelines of the requirement set by the ISO 9001:2015 standard, and in the second column, I declare the Company’s current status. Below the table, I further analyze and comment, where needed, the Company’s status and give possible recommendations for improving the Company’s procedures while conforming to the standard requirements.

5.1. Clause 4 : CONTEXT OF ORGANIZATION

5.1.1. Clause 4.1 Understanding the Organization and its context

ISO 9001:2015 Requirements	Comments on Top Dog’s Status
Clause 4.1 requires the Organization to understand and document its business environment (<i>context</i>). It includes all of the internal and external issues and conditions to be considered that may impact the Management System in terms of its structure, scope, implementation, and operation and can affect the Company’s products.	Top Dog has identified its internal and external factors according to the below table.

Internal Issues	External Issues
Employee Efficiency	Customers Satisfaction
Workforce Wellbeing	Markets & Competitors
Work-life Balance	Regulatory & Statutory Requirements
Company Competency	Supplier Performance / Qualified Suppliers
High Quality Standards	Health, Safety and Environmental Requirements
Capacity	Technology Advances (Materials & Machinery)
Infrastructure	Cultural & Social
Intellectual Property	Local & International Economic Climate

Internal Politics	Location Barriers
Market Share & Development	Contracts / Agreements
Communication	Force Majeure Risks
Continual Improvement	
Business Continuity	

5.1.2. Clause 4.2 Understanding the needs and expectations of interested Parties

ISO 9001:2015 Requirements	Comments on Top Dog's Status
This clause requires the Organization to determine the needs and expectations of "interested parties," both internal and external. An interested party could be a person, group, or Organization that can affect, be affected by, or believe that they are affected by a decision or activity.	Top Dog has identified the needs and expectations of the interested parties and has developed the below table.

Interested Parties	Needs and Expectations
Suppliers	Prompt payment, accurate supply planning, work relationships, and effective communication
Finance	Accurate inventory and sales data in the ERP system, liquidity management
I.T.	Hardware & Software equipment, appropriate & functioning business applications
Sales	Pet products that meet standards
Internal Operations	Work toward established goals set by the Management, acquire the necessary resources to meet company goals and expectations, effective communication within a valued workplace
Customers	High quality & value for money products, expectations for innovation and evolvment, on-time delivery, customer reviews, effective communication, customer support and relationship management, supply continuity, defined lead times, social responsibility
Distributors	Adherence to contractual agreements, product and price awareness, inventory supply, on-time deliveries
Legal & Technical Consultants / Contractors	Adherence to contractual agreements, monitor regulatory developments, prompt payment, health and safety issues
Government relations and public affairs	Adherence to standards and regulations, file permits and licenses on time, pay the fees on time, build valued local and federal

	relationships, effective communication
Insurers	No claims, prompt payment, effective risk management
R&D (Research & Development)	Monitor technological innovations and developments, continuous funding and support for research activities, new product and process development, and product characterization
H.R. (Human Resources)	Organizational culture and attitudes toward an effective and motivated workforce, good and safe work environment, job security, recognition and award, training, effective communication
Marketing	Appropriate product branding, accurate product information and positioning
Production	High-quality products manufactured according to QMS, functioning machinery, productivity
Product Management	Order and sale data; access to cost of goods sold (COG) information, technical support for product development and characterization; market and competitor analysis

5.1.3. Clause 4.3 Determining the scope of the QMS

ISO 9001:2015 Requirements	Comments on Top Dog's Status
The purpose of this clause is to define the boundaries of the QMS and to determine to which parts of the Company the QMS applies.	Top Dog has developed a Corporate Management Manual where all boundaries are clarified, and there is an extensive analysis of where this QMS applies to.

As already mentioned, Top Dog is a manufacturing company focused on the well-being of pets and is producing grooming products for pets such as shampoos, fragrances, skincare, and hair care products. Top Dog also has a strong R&D team that performs new product development for third parties. Top Dog's products and services are provided globally to customers involved in the pet sector, such as veterinarians, pet groomers, pet shops, pet breeders, distributors of pet products, and end-users (pet guardians). In a nutshell, its QMS applies to all the departments of the Company and has been formed in such a way that it does not compromise the Company's ability or responsibility to provide compliant products that enhance customer satisfaction.

5.1.4. Clause 4.4 QMS and its processes

ISO 9001:2015 Requirements	Comments on Top Dog's Status
This clause makes it clear that an ISO 9001 Quality Management System must be a process-based QMS.	In the Corporate Management Manual, Top Dog describes the established and implemented QMS that continually

	maintains and improves in order to deliver the appropriate products, services and performance required under the scope.
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Top Dog has established and implemented a QMS, which is maintained and continually improved according to the requirements of the ISO 9001:2015 standard, including processes needed and their interactions.

In the Corporate Management Manual, the Company has determined the required inputs and desired outputs of the processes, criteria, and methods needed for effective operation and control of these processes, as well as resources needed and responsibilities and authorities for processes.

Top Dog's Head Management evaluates business performance and the QMS in total for continual improvement; however such evaluation lacks the systematic repetition required and is clearly stated in ISO 9001. Further comments will be given on clauses 9-Performance Evaluation and 10-Improvement.

5.2. Clause 5: LEADERSHIP

5.2.1. Clause 5.1 Leadership and commitment

ISO 9001:2015 Requirements	Comments on Top Dog's Status
This clause is about overall leadership, commitment, and the expectations for top Management to thoroughly engage with the critical aspects of the QMS.	Top Dog is a family-owned business that is actively committed to developing and implementing the quality management system and believes in continually improving its effectiveness.

The Top Management of Top Dog:

- a) is responsible for the effectiveness of the QMS
- b) provides the needed means to ensure that the Quality Policy is compatible with the strategic direction and the context of the Company
- c) ensures that QMS requirements are integrated into the business processes, and that is achieving the intended results
- d) communicates to its employees the importance of an effective QMS and
- e) promotes continual improvement

5.2.2. Clause 5.2 Policy

ISO 9001:2015 Requirements	Comments on Top Dog's Status
Quality Policy is an important document to the Organization because it provides the direction and formally establishes goals and	Top Management of the Company communicates to all employees the Quality Policy, and they are assigned to

commitment.	understand the part they have in its deployment.
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Top Dog has defined the Quality Policy in the Corporate Management Manual and is available to employees and the public in general through its official website. This Policy represents the framework for continually improving the QMS and ensuring customer requirements are met.

5.2.3. Clause 5.3 Organization roles, responsibilities, and authorities

ISO 9001:2015 Requirements	Comments on Top Dog’s Status
This clause requires that key responsibilities and authorities are clearly defined among employees and that everybody involved understands their role.	The Company’s Top Management assigns the responsibilities and authorities that are analytically communicated to each employee.

The Company's Top Management controls the resources, systems, and processes by which quality products are produced. They are also responsible for business planning, development, and communication of the Company’s policies, establishment, and deployment of quality objectives, the provision of resources needed to implement and improve the QMS by conducting management reviews.

Responsibilities and authorities for relevant roles are assigned by the Top Management and communicated within the Company to:

- a. Ensure that the QMS conforms to ISO 9001:2015 standards;
- b. Report on the operation of the QMS and any opportunities;
- c. Ensure that continuous improvement is taking place;
- d. Ensure that customer focus is promoted throughout the Organization;
- e. Ensure the integrity of the QMS is maintained during changes;
- f. Ensure that responsibilities and authorities related to the QMS are being communicated and understood.

All employees are responsible for executing the business plan, the quality of their work and implementation of the policies and procedures applicable to the processes they perform. Employees are motivated and empowered to identify and report any known or potential problems and recommend related solutions to aid the corrective action process. Employees are also required to focus on customer satisfaction while improving both the effectiveness and efficiency of key system processes.

5.3. Clause 6 : PLANNING

5.3.1. Clause 6.1 Actions to address risks and opportunities

ISO 9001:2015 Requirements	Comments on Top Dog’s Status
This clause introduces the concept of risk (and opportunity) and is an important addition to the latest version of ISO 9001:2015. The concept of “risk-based	The Company has conducted a SWOT analysis report where all threats and opportunities are identified. This report is updated on an annual basis.

thinking” covers the need for a company to consider all aspects of risk.	
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The Company’s Management determines potential risks and opportunities in a SWOT analysis which, along with the implemented QMS, help achieve intended results, prevent or reduce undesired effects, are compatible with the context of the Organization, and can achieve continual improvement.

Present SWOT analysis has identified 5 (five) opportunities and 6 (six) threats.

Opportunities are:

- 1) Rapidly growing industry related to pet products
- 2) Interest in international / new collaborations
- 3) Clientele growth at national/international level
- 4) Production of white label products
- 5) Ability of the Company to produce products other than pet grooming

Threats are:

- 1) Intense competition from internationally recognized companies in the field
- 2) Change of Legislation
- 3) Possible claim/opposition from a customer
- 4) Accounting type of Company
- 5) Unilateral focus of the Company's products in a specific part of the industry
- 6) Productivity limitation

5.3.2. Clause 6.2 Quality objectives and planning to achieve them

ISO 9001:2015 Requirements	Comments on Top Dog’s Status
Clause 6.2 requires the Company to establish quality objectives and plans, ensuring that these are clear, measurable, monitored, communicated, updated, and resourced.	There are many different types of objectives that could be considered; however, the Company’s Top Management has prioritized them according to the below index:

Quality Objectives	Performance Measurement Indicators
Continuous Satisfaction of Customer Requirements and Expectations	<ul style="list-style-type: none"> ➤ Customers reviews, comments, and complaints ➤ Product failures ➤ Customers retention and development
Improving the Company’s position in the market	<ul style="list-style-type: none"> ➤ Customers retention ➤ Customers development ➤ Strong Social Media presence ➤ Empower relationships with suppliers

International expansion and improved awareness levels	<ul style="list-style-type: none"> ➤ International customers development ➤ Revenue ➤ Participation in international exhibitions ➤ Create valuable digital content distributed through social media networking
Improving working conditions	<ul style="list-style-type: none"> ➤ Occupational accidents ➤ Employee retention ➤ Payroll ➤ Provided training

5.3.3. Clause 6.3 Planning of changes

ISO 9001:2015 Requirements	Comments on Top Dog's Status
Clause 6.3 sets requirements to ensure that needed changes to the QMS are carried out under an organized plan.	Top Management of the Company conducts various evaluations and immediately alters the QMS once it has identified risk or opportunity.

Top Management makes needed changes of the QMS under an organized plan considering the purpose of the changes and potential consequences, integrity of the QMS, and allocation or relocation of responsibilities and authorities.

In addition, Top Management undertakes further evaluation to verify that QMS changes are effectively implemented and communicates to all possible personnel changes which affect their work.

5.4. Clause 7 : SUPPORT

5.4.1. Clause 7.1 Resources

ISO 9001:2015 Requirements	Comments on Top Dog's Status
This clause requires that Company should determine and ensure that needed resources are available in order to establish, implement, maintain, and continually improve the QMS. Company should also consider the capabilities of, and constraints on, existing internal resources; and what needs to be obtained from external providers.	The Management is responsible for ensuring the availability of internal or external resources to develop and maintain the QMS.

The Management of Top Dog determines and provides the needed resources for the establishment, implementation, maintenance, and continual improvement of the QMS.

5.4.2. Clause 7.2 Competence

ISO 9001:2015 Requirements	Comments on Top Dog's Status
"Competence" as described on ISO terminology is about the "ability of employees to apply knowledge and skills to achieve intended results."	This clause actually requires the evidence of competence of the personnel. Top Dog does not keep any data regarding the job description of each job or the training record of the staff though it conducts competence training in-house.

Top Dog Management provides the staff with the needed professional training, knowledge and skills, organizational infrastructure, and financial resources to establish, implement, maintain, and improve the QMS. In addition, in some cases, Top Dog will hire competent external personnel and third parties for the realization of activities for which the Company does not have adequate resources.

However, the Management needs to establish the appropriate tool for ensuring the necessary competencies for roles, responsibilities, and authorities for implementation and control activities within the QMS.

Top Dog should determine to the extent necessary the below elements of its personnel competence that may affect the effectiveness of the QMS.

- initiate job descriptions including specific competency provisions;
- ensure employees are competent based on their education, training, and experience;
- provide job training programs to the extent necessary;
- take actions when necessary to assist employees that exhibit less than desirable results.

5.4.3. Clause 7.3 Awareness

ISO 9001:2015 Requirements	Comments on Top Dog's Status
This clause requires the Company to ensure that all personnel are aware of the quality policy, quality objectives and the effectiveness of the QMS.	The Company communicates to its personnel the Quality Policy, relevant quality objectives, their contribution to the effectiveness of the QMS, and implications of nonconformance with the QMS requirements.

5.4.4. Clause 7.4 Communication

ISO 9001:2015 Requirements	Comments on Top Dog's Status
	Top Dog is a small-sized company; therefore,

The clause emphasizes on the importance of effective internal & external communications.	internal communication among its associates is accessible and immediate. Additionally, its customer-centric approach guarantees effective external communications.
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The Company's Management has ensured that several mechanisms are in place in order to facilitate that relevant communication tools are active.

Top Management and Marketing are responsible for determining external communications relevant to the QMS, product documentation, customer and supplier relations.

Internal communication is facilitated through daily routine and regularly conducted meetings among the employees.

5.4.5. Clause 7.5 Documented information

ISO 9001:2015 Requirements	Comments on Top Dog's Status
In contrast to ISO 9001:2008, the renewed version of 2015 standard no longer mandates the need for documented procedures – it is up to the Organization to decide what is needed.	The Company keeps records that show the QMS is implemented and maintained.

The extent of documented information needed for Top Dog is proportionally great due to:

- its type of activities, processes, and products;
- the complexity of processes and their interactions;
- the competence of personnel, and
- work overload of Top Management.

As mentioned before, Top Tog is a small-sized company, and all business activities depend on a few people that strive to keep records of the Company's daily tasks. A valuable tool contributing to this is the recently installed and operated ERP system.

The Company keeps records for the correct amount of time that can be retrieved as necessary and destroyed when no longer needed.

5.5 Clause 8 : OPERATION

5.5.1. Clause 8.1 Operational Planning and Control

ISO 9001:2015 Requirements	Comments on Top Dog's Status
This clause requires that Company's operations are conducted through previously planned and controlled processes. In addition, products and services	Top Dog defines, documents, controls, and keeps records of all applied processes for each and every category of pet products it manufactures so that a state of control is

requirements should be determined with established criteria of acceptance.	achieved. The Company keeps documented information to have confidence that all processes have been carried out as required.
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Top Dog provides its customers with high-quality grooming products intended for pets. In addition, the Company grows at a fast pace; therefore, it needs to make sure that a state of control is achieved even when intended or unintended changes occur. Keeping records allows the Company to make immediate re-adjustments or correction actions without being exposed to its customers.

5.5.2. Clause 8.2 Requirements for Products and Services

ISO 9001:2015 Requirements	Comments on Top Dog's Status
This clause requires the Company to establish processes that will determine the requirements related to its offered products. These requirements are about : a) the customers b) the Company itself c) the applicable law and regulations	Top Management defines the communication with customers, the process of determining and reviewing the requirements related to products and changes to requirements for products.

- a) Top Dog has defined its requirements since its very beginning, and any possible changes are being conducted upon establishing stricter measures.
- b) Top Dog has a customer-centric philosophy that allows the Company to communicate directly with its clientele, obtaining feedback relating to its products (including customer complaints).
- c) The Company has assigned a third party to consult and propose any legit alterations for the products to conform to updated legal requirements.

5.5.3 Clause 8.3 Design and Development of Products and Services

ISO 9001:2015 Requirements	Comments on Top Dog's Status
8.3 clause is about introducing a systematic approach to create a detailed procedure of designing and developing a final product.	Top Management is responsible for planning, realization, and Management of product design and development and project management.

5.5.4. Clause 8.4 Control of externally provided Processes, Products and Services

ISO 9001:2015 Requirements	Comments on Top Dog's Status
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This clause indicates that the Company needs to apply adequate controls in order to ensure that the purchased processes, products or services can meet its requirements.	Top Dog has specified stringent requirements to control the purchased products/services, outsourced processes, evaluation of suppliers, and the purchasing process.
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Top Dog stores documented information of supplier quotations, purchase orders, contracts, and associated review records. In addition, it has compiled an approved supplier list with determining criteria for selection, evaluation, and re-evaluation of suppliers.

5.5.5. Clause 8.5 Production and Service Provisions

ISO 9001:2015 Requirements	Comments on Top Dog’s Status
Clause 8.5 defines the requirements that a company should implement to ensure that its production provision processes run smoothly.	Top Dog applies several controls in order to ensure its products meet the customer’s requirements, needs, and expectations.

Top Dog has implemented several requirements in order to be able to consistently deliver and meet customer expectations, some of which are the below:

- Documented information on each product that defines its characteristics.
- Traceability achieved by marking the batch number on each product. Records of unique identifications are kept to assist in the event of a recall.
- Periodical maintenance of equipment is recorded.

There are also requirements that are set by the Company but are not being registered, some of which are:

- Production checklists are prepared and completed throughout the works but are not filed
- Use of FIFO method for storing new batches

5.5.6. Clause 8.6 Release of Products and Services

ISO 9001:2015 Requirements	Comments on Top Dog’s Status
The Company must monitor and measure the characteristics of its product to verify that set requirements have been met and maintain evidence of conformity with the acceptance criteria.	Top Dog performs product release testing on each batch (including in-house inspections and test plans combined with conformity tests conducted by a third party) to verify that the product requirements are met.

5.5.7. Clause 8.7 Control of Nonconforming Outputs

ISO 9001:2015 Requirements	Comments on Top Dog's Status
This requirement is about nonconforming products. Any product that does not meet set specifications should trigger a process that will prevent them from further processing, use or delivery.	The Company has set a defect management process that ensures nonconforming products are identified and controlled to prevent unintended use or delivery.

5.6. Clause 9 : PERFORMANCE EVALUATION

5.6.1. Clause 9.1 Monitoring, Measurement, Analysis and Evaluation

ISO 9001:2015 Requirements	Comments on Top Dog's Status
This clause points out the necessity of collecting and analyzing data that will measure the suitability and effectiveness of the implemented QMS and identify potential opportunities for improvement.	The Company understands that the evidence of analysis and the evaluation of key performance data can result in fact-based decision-making; therefore, it conducts various evaluations. However, some of these evaluations are made spontaneously, occasionally, and without any particular action plan. The Company needs to establish a specific mechanism to evaluate its QMS thoroughly.

Top Dog needs to monitor and measure the performance and effectiveness of its QMS and establish a mechanism to ensure it is meeting its policies, objectives, and targets.

In order to meet this requirement, Top Dog should identify the below 4 (four) aspects:

1. WHICH activities have a significant impact or risk, therefore, need to be monitored and measured;
2. WHAT are the key characteristics of the activity to be monitored;
3. HOW are key characteristics to be measured (the method);
4. WHEN should the measurements take place; Top Dog needs to determine the time and frequency of the evaluation;

Once the Company answers the above questions, it then needs to record the data on performance, controls, and conformance with objectives and targets and establish management review and reporting. The Company must retain relevant documented information as evidence of the results. An excellent tool for that would also be the customers' perceptions and feedback on which of their needs and expectations have been fulfilled.

By planning all these aspects, the Company can easily keep a check on its critical processes, understand which of them are functioning properly and which ones need attention, and make the required improvements.

5.6.2. Clause 9.2 Internal Audit

ISO 9001:2015 Requirements	Comments on Top Dog's Status
Internal audits help the Company to assess the effectiveness of the QMS. An audit program needs to be established to ensure that all processes are audited at the required frequency.	Top Dog is a small company, and partial internal audits may take place with relevant information being easily spread among the employees; however, by conducting thorough internal audits at planned intervals, the Top Management will be able to demonstrate conformance and effectiveness of the QMS.

Top Dog is advised to carry out internal audits under an annual program at least once annually. Internal audits can take place at the beginning of each year so that all the activities of the Company are inspected at least once.

A clear objective and scope should be defined for each audit to ensure that internal audits are consistent and thorough.

5.6.3. Clause 9.3 Management Review

ISO 9001:2015 Requirements	Comments on Top Dog's Status
This clause indicates that Company needs to conduct planned intervals to reserve the ongoing suitability, adequacy and effectiveness of the QMS and its alignment with the strategic direction of the Company.	Top Dog does not conduct Management Review of the QMS.

As previously stated, Top Dog has high-quality standards and a strict client-centric approach. Such stature does not allow any half measures. The Company immediately takes action and manages any nonconformity of the QMS. Taking immediate action means that organized or planned Management Reviews of the QMS do not take place.

The Company needs to plan a Management Review that will include, among others;

- a) a follow up to the actions suggested by the previous management review;
- b) Internal Audit findings;
- c) review of progress in the implementation of the Quality Policy and objectives;
- d) changes in external and internal issues that are relevant to the QMS;
- e) effectiveness of provided training;
- f) information on the performance and effectiveness of the QMS;
- g) adequacy of resources;
- h) the effectiveness of actions taken to address risks and opportunities;
- i) opportunities and suggestions for improvement

5.7. Clause 10 : IMPROVEMENT

5.7.1. Clause 10.1 General

ISO 9001:2015 Requirements	Comments on Top Dog’s Status
This clause requires organizations to review their processes, products and Quality Management System results in order to determine and identify opportunities for continual improvement of the QMS.	Top Management determines and selects opportunities for improvement to enhance customer satisfaction.

Top Dog has built a direct communication channel with its customers that are encouraged to freely provide improvement suggestions. These ideas help the Company to prioritize and implement strategic actions to meet customer requirements and enhance customer satisfaction.

These actions include:

- improving performance and quality of products to meet requirements, now and for the future;
- correcting, preventing, or reducing mistakes;
- improving the performance and effectiveness of the QMS.

5.7.2. Clause 10.2 Nonconformity and Corrective Action

ISO 9001:2015 Requirements	Comments on Top Dog’s Status
This clause requires the Company to build the fundamental principles of non-conformities Management in order to eliminate the causes of any undesired effects and to avoid recurrence of those effects.	Top Dog handles all nonconformities directly in order to assess the impact, control, and implement corrective actions. However, the Company does not keep documented information (or records) as evidence of the nonconformities and subsequent actions.

Top Management of the Company takes into consideration all nonconformities, so they make sure that proper corrective actions have been made. Top Management has developed a well-prepared correctional action system to investigate the root cause and actions to correct supplier, internal, and customer-reported nonconformities; however, such measures are not documented or recorded, resulting in the loss of traceability of the events that may result in the repetitiveness of the nonconformity.

Top Dog needs to prepare a form to keep records of all nonconformities and complaints, what actions were taken to resolve them, implement additional measures, etc. Such a report will provide a valued registry to the Company with evidence of the occurrence of nonconformities and the subsequent actions taken.

5.7.3. Clause 10.3 Continual Improvement

ISO 9001:2015 Requirements	Comments on Top Dog's Status
The final clause is about the Continual Improvement of a company which is the fundamental principle of ISO9001:2015.	Top Dog continually improves the suitability, adequacy, and effectiveness of the QMS. However, as indicated in previous clauses, continual improvement needs to be achieved under a programmed agenda on an annual basis.

Top Dog should initiate programmed actions to continually improve the suitability, adequacy, and effectiveness of the QMS. Such actions would be to consider the results of analysis and evaluation, the outputs from annual management reviews, and internal audits to determine if there are needs or opportunities to be addressed. Continual improvement techniques and processes should be applied to areas of the Company that will have a measurable impact on the quality of its products.

Chapter 6. Conclusions

I have analyzed throughout this study the requirements set by ISO 9001:2015 standard in contrast to the efforts of a young enterprise involved in the development and manufacture of pet grooming products with limited financial and workforce resources to comply with these requirements.

This study points out whether a local start-up company has the ability to function under those international quality management standards while operating under an unfavorable and continuously changing economic and political environment.

As stated in the Introduction, this thesis is conducted according to the research method of participant observation, with data being gathered from observations, interviews, and document studies, while I recorded all followed processes up to this date.

This work begins by offering some historical references regarding the evolution of the principal concepts of managing for quality through the centuries that lead to the modern tools of Quality Management Systems and the relevant standards that validate the organizations who implement them.

The following chapter offers the reader insight into the studied Company Top Dog followed by an extensive analysis of the ISO 9001:2015 requirements and the Company's current status. Taking into account that the clauses and requirements of the Standard are all based on the Plan – Do – Check – Act cycle (PDCA cycle), I begin my analysis with “Clause 4 (four) : Context of the Organization” of the ISO 9001:2015 and analytically describe each and every clause from that point up until the final “Clause 10 (ten) : Improvement”.

PLAN : this part includes the most clauses of the Standard; No 4, 5, 6 and 7

Clause 4 : The Company complies fully with clause 4 (four) since it has identified the internal and external factors and conditions that can possibly have an impact on the Company's products, has identified the needs and expectations of the interested parties, has determined the scope of its QMS and the relevant implemented processes. However, what needs to be pointed out here is the small reference at the end of the final paragraph of clause 4 (four) that Top Dog does not systematically evaluate its QMS. This is the first indicator that the implemented QMS might have some deficiencies that can affect the proper operation of the business and its Standard for quality.

Clause 5 : refers to the Leadership of the Company, and all requirements are met. Being a family-owned business, all aspects of business operation are centralized. Top Management is responsible for all critical decisions and promotes building strong bonds with customers, suppliers, and employees.

Clause 6 : is fully integrated with the Company's QMS. The Company has prepared a SWOT analysis to address both risks and opportunities, has identified its quality objectives, and plans possible changes in its QMS systematically.

Clause 7 : This is the final requirement that refers to the PLAN part of the PDCA cycle. Top Dog complies with the requirements set under this clause with a single exception of not keeping any data regarding the job description of each job or the training record of the staff.

Top Management informs each employee of its role, its duties, and the responsibilities they need to fulfill for teamwork to be effective. However, there is no official and documented job description for each job separately. The requirement is partially met since employees are aware of their roles and responsibilities but there has to be evidence of the system being maintained and effective. Therefore the Company needs to register all duties and responsibilities in a written form and hand it over to each employee.

In addition to the above, the Company conducts competence training in-house in order to secure that the efficiency of the personnel meets required standards; however, such training is not documented. The Company needs to develop a form that will contain all training information on each employee.

D.O.: this part includes clause No 8

This clause and its sub-clauses represent the production and operational control parts of the Standard – in other words, the ‘engine house’ of production of the Company. Top Dog is a manufacturing company with a sophisticated R&D department that produces high-quality products; thus, its production protocols are strict and paramount. The Company complies fully with the Standard, and there have been no further recommendations from my side.

CHECK : this part includes clause No 9

Clause no 9 is about “performance evaluation” and is the section of the Standard where the Company needs to promote complementary and corrective actions, not because the Company does not execute any evaluation procedures but rather that they are not performed in a satisfactory manner that promotes continuing suitability, adequacy and effectiveness of the implemented Quality Management System.

More analytically explained, the Standard requires the Organization to monitor, measure, analyze and evaluate the QMS in its daily operations. The Company collects and analyzes several data on a daily basis, but not all data are registered. The Company needs to identify what aspects of its daily operation need to be monitored, measured, and when and how this will be done effectively. Most importantly, it needs to keep records of this.

In addition to the above, the Standard requires the Top Management of the Company to conduct Internal Audits and Management Reviews on a regular basis. At Top Dog, Top Management may conduct a partial Internal Audit, but there is no particular time set for this or audit criteria defined. Correspondingly Management Review does not take place at sufficient intervals, nor is there an established review process. The Top Management needs to establish an Audit Program to ensure that all procedures are audited at the required frequency and a Management Review that will demonstrate potential actions related to opportunities or changes towards the improvement of the QMS. Finally, what should be noted is that the Top Management needs to keep documents to demonstrate that Internal Audits and Management Reviews take place.

ACT : this part includes clause No 10

This is the final clause of the ISO 9001:2015 and refers to the continual “Improvement” of the implemented QMS. Once again, the Company follows the suggested requirements to a large extent, yet some essential data are not being recorded. More specifically, sub-clause 10.2 refers to nonconformities and the relevant corrective actions. The Top Management has established a procedure to address possible nonconformities, but such information is not being registered; this results in potential loss of traceability of the events. In addition, Top Dog continually improves the suitability, adequacy, and effectiveness of the QMS; however, these need to be achieved systematically under a programmed agenda on an annual basis.

In a nutshell, this study concludes that ISO 9001:2015 is a tool with extensive requirements that cover all aspects of an organization's daily operation. The broader a business is, the more complex the Standard becomes since more aspects of the Organization must be considered to implement a viable and appropriate QMS. However, it is shown in this dissertation that an adequately designed QMS is more of a matter of meticulousness and structured functionality of the Organization and less of available resources.

Top Dog is a company that was continuously operating under high-quality standards without ever trying to acquire ISO 9001. After observation and detailed documentation of its operations through the years, we can infer that it was mainly a matter of priority and not competency. Once the Company conducts only a few transformations in its QMS, it will easily be able to acquire the ISO 9001:2015.

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APPENDICES

A. ORGANIZATION CHART

