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A DISSERTATION SUBMITTED IN PARTIAL FULFILMENT

OF THE REQUIREMENTS FOR THE DEGREE OF ACADEMIC MASTER IN

« Quality Management »

The contribution of the internal audit within the context of ISO 9001:2015 certification preparation.

Case of study: INAMED Group

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ABSTRACT:

The importance of internal audit within an organization is apparent, as it plays a critical role in assessing and enhancing operational effectiveness and ensuring compliance with regulatory requirements. The objective of this work is primarily to conduct an internal audit in accordance with the requirements of ISO 9001:2015 within the company INAMED . Using a qualitative approach, we conducted semi-structured interviews with the employees to understand stakeholders' influence and interests, complemented by documentary analysis, observation, and an observation grid. Our findings detail the process of the internal audit of the Quality Management System and the subsequent actions taken to implement it effectively.

Keywords: Internal Audit, Quality management system, ISO 9001, ISO 19011, Nonconformity, quality

الملخص:

أهمية التدقيق الداخلي داخل المؤسسة واضحة، حيث يلعب دوراً حاسماً في تقييم وتعزيز الكفاءة التشغيلية وضمان الامتثال لمتطلبات التنظيمات الرقابية. هدف هذا العمل بشكل أساسي هو إجراء تدقيق داخلي وفقاً لمتطلبات المعيار ISO 9001:2015 داخل شركة INAMED. باستخدام نهج نوعي، قمنا بإجراء مقابلات شبه منظمة مع الموظفين لفهم تأثير واهتمامات أطراف المهتمة، مدعومة بتحليل وثائقي وملاحظة ميدانية وشبكة مراقبة الملاحظة. تفصل نتائجنا عملية التدقيق الداخلي لنظام إدارة الجودة والخطوات التالية المتخذة لتنفيذه بفعالية.

الكلمات المفتاحية:التدقيق الداخلي ،نظام إدارة الجودة ISO 9001، ISO 19011، عدم المطابقة، الجودة.

Résumé :

L'importance de l'audit interne au sein d'une organisation n'est plus à prouver, car il joue un rôle essentiel dans l'évaluation et l'amélioration de l'efficacité opérationnelle et la conformité aux exigences réglementaires. L'objectif de ce travail est principalement de réaliser un audit interne conformément aux exigences de la norme ISO 9001 :2015 au sein de l'entreprise INAMED. En utilisant une approche qualitative, nous avons mené des entretiens semi-structurés avec les employés pour comprendre l'influence et les intérêts des parties prenantes, complétés par une analyse documentaire, une observation et une grille d'observation. Nos résultats détaillent le processus d'audit interne du Système de Management de la Qualité et les actions subséquentes prises pour le mettre en œuvre de manière efficace.

Mots clés : Audit interne, système de management de la qualité, ISO 9001, ISO 19011, Non-conformité, qualité.

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Table of contents

LIST OF TABLES

LIST OF FIGURES

ABBREVIATION LIST

ISO: International Standards Organization.
QMS: Quality Management System.
TQM: Total Quality Management.
QC : Quality control.
QA: Quality Assurance.
PDCA: Plan Do Act Check.
IMS: Integrated Management System.
IMM: Integrated Management Manager
SWOT: Straights,Weaknesses, Opportunities and threats.
SMEs: Small and medium-sized enterprises.

INTRODUCTION

The quality management system is an essential tool for companies to enhance through documented procedures, facilitates continuous measurement of quality, ensures corrective and preventive actions, and ultimately leads to reduced defect rates and lower production costs. It helps organizations detect and correct problems early, thereby minimizing costs, and aids new employees in becoming effective quickly. Through these mechanisms, a quality management system enables companies to maintain or increase their market share and competitiveness. their competitiveness and ensure economic success. (J anis, 2012)

The ISO 9001 certifications enable organizations to meet the needs of customers and stakeholders while following regulatory requirements. They enhance customer satisfaction, by committing to quality and continuous improvement, organizations with these certifications achieve higher productivity, better resource management, and improved employee morale, gaining a competitive advantage across various industries.(Jappreet Kaur, 2021)

Planning and conducting internal audits are crucial steps in evaluating the effectiveness of the Quality Management System. This involves meticulously scheduling the audits, selecting and training auditors, and thoroughly assessing all aspects of the quality management system against ISO 9001:2008 and ESG standards. During these audits, any non-conformities or areas for improvement are identified. Addressing these findings requires a structured approach to propose and implement corrective actions, ensuring that the issues are resolved and improvements are made. The successful implementation of the quality management system goes beyond mere formal compliance; it must be deeply integrated into the organization's processes and culture. This integration is essential for the quality management system to be beneficial, as it aligns with the organization's objectives and significantly enhances the quality of education, leading to better outcomes for students and stakeholders.(Kráľová, 2015)

The study context:

The dissertation focuses on the application of internal audits within INMAED, a Mediterranean agric-food company. The research aims to explore the implementation of internal audits as part of the QMS, diagnose the current state of the organization’s processes, and develop an action plan to address identified non-conformities. The methodological approach adopted in this study includes action research, which combines practical problem-solving with the generation of new knowledge through iterative cycles of planning, action, observation, and reflection.

The dissertation is structured to provide a comprehensive understanding of the internal audit process, starting with an overview of the theoretical framework and methodology. The interpretive paradigm is employed to delve into the complexities of organizational systems and practices, emphasizing the importance of qualitative insights and subjective interpretations in understanding non-conformities and stakeholder perspectives.

Through detailed documentation and analysis, this study aims to contribute to the existing body of knowledge on internal auditing and quality management. By highlighting the practical application of ISO standards in a real-world setting, the research underscores the significance of internal audits in driving continuous improvement and ensuring organizational excellence.

To conduct our work, we will aim to address the following research question:

«How to successfully conduct an internal audit in accordance with the guidelines for auditing management systems and address the non-conformities within the company INAMED ?»

To elucidate our research topic, we have formulated the following sub-questions:

- How can the existing quality management system be effectively diagnosed in compliance with the requirements of the ISO 9001 standard?
- What is the appropriate action plan to be executed post-audit report within INAMED?

Therefore, to answer our research question, we structured our dissertation into three chapters:

Chapter One : begins with a literature review that explores various methodologies and practices for conducting internal audits, the limitations organizations face, and the advantages of these audits in terms of efficiency and improvement. Key studies are examined to highlight the strategic benefits of implementing quality management system , the performance impacts of ISO 9001 certification, and the motivations, benefits, and barriers experienced by companies in adopting the ISO 9001:2015 standard.

Additionally, the conceptual framework delves into the internal audit process itself, outlining the sequential steps involved, from initiating the audit to conducting follow-up actions. This includes defining the purpose, scope, and objectives of the audit, preparing for the audit, conducting the audit activities, preparing and distributing the audit report, and completing and following up on the audit. Each step is crucial for ensuring a thorough, effective, and

systematic audit process that provides valuable insights and drives improvements within the organization.

Chapter two: we explored the implementation of a Quality Management System at INMAED through a qualitative, action research methodology. The research employs the 5W1H method to structure the project, aiming to diagnose non-conformities and enhance the quality management system in accordance with ISO 9001 standards. Data collection methods include semi-structured interviews with process drivers, checklists, and observations. Guided by the interpretivist paradigm, this research acknowledges the subjective and socially constructed nature of organizational realities. The chapter provides an in-depth overview of INMAED's history and organizational structure, culminating in a comprehensive analysis designed to ensure continuous improvement and adherence to quality standards.

Chapter three: is divided into two comprehensive sections. In the first section, we initiate a thorough audit of the existing Quality Management System. This internal audit involves evaluating compliance with ISO 9001 standards, identifying non-conformities, and assessing areas for improvement. The results of this audit are then meticulously analysed and presented in a detailed report, which serves as the foundation for an action plan aimed at addressing the identified issues and enhancing the overall system. The second section of the chapter focuses on the implementation phase, detailing the specific actions, strategies, and projects undertaken to establish and integrate an improved Quality Management System.

CHAPTER 01: SYNTHESIS OF REASEARCHERS AND THEORICAL FRAMEWORK

Internal Quality audits are a critical component of the ISO 9001 standard that ensure an organization's processes comply with the requirement and that QMS is effectively implemented and maintained.

Section 01: Synthesis of researchers

The literature review explores the role and impact of internal quality audits within the framework of QMS, It examined the methodology and practices with conducting internal audits, the limits organizations face and the advantages of audits in terms of efficiency and improvement by synthesizing findings from numerous studies to provide us a comprehensive understanding of our work

1. Quality management system

The paper *«Implementation of Quality Management System ISO 9001 in the World and its Strategic Necessity 'discusses the strategic importance of implementing the ISO 9001 Quality Management System (QMS) globally.»* .(Priede, 2012) Begins by explaining the significance of quality management as a crucial factor for enhancing the competitiveness of economies. Which defines competitiveness in terms of productivity, prosperity, and economic growth. This work highlights that economies with higher productivity levels tend to generate higher income. The researcher delves into the strategic benefits of implementing quality management systems like ISO 9001 for companies. It underscores that well-documented procedures improve consistency, quality measurement, and corrective actions, ultimately reducing defect rates and production costs. It is important to mention that the researcher point out that ISO 9001 certification is perceived as a strategic tool for improving processes and accessing foreign markets.

(Mehmet Sıtkı İlkay, 2012) Published *«the effect of the ISO 9001 quality management system on the performance of SMEs»* aiming to determine whether there is a difference in performance between ISO 9001 certified and non-certified small and medium-sized enterprises (SMEs) in Turkey, to do so a survey was conducted with 255 SMEs, encompassing certified, seeking certification, and non-certified companies, examining motivations for certification, quality practices, and performance. The data collected was analyzed using one-way analysis of variance to compare between the variables, the researchers found that there is no significant difference in terms of performance between certified and non-certified companies whereas higher quality practices were exhibited by certified companies, likewise it was detected that those seeking certification for intrinsic

benefits showed partially higher performance than the ones seeking certification for external pressures or benefits.

(Laura Bravi, 2019) In his titled work *«The ISO 9001:2015 Quality Management System Standard: Companies' Drivers, Benefits, and Barriers to Its Implementation»* discusses the motivations, benefits, and barriers experienced by Italian companies in implementing the ISO 9001:2015 standard. Based on a survey of 493 companies, the study finds that the main motivations for adopting the standard are internal improvements and external market pressures. The benefits include enhanced quality management and customer satisfaction, while barriers include excessive costs and bureaucratic hurdles. The study emphasizes the importance of a quality culture, particularly in Northern Italy. t also investigated at how companies interpreted their transition from ISO 9001:2008 to ISO 9001:2015, highlighting the value put on continuous improvement, risk management, and ease of interaction with other standards

2. Internal audit

- A research paper titled The determinates on internal audit quality , Aiming to examine the behaviour of internal audit and investigate if there is factors that influence audit quality ,(Samagaio & Teresa Felicio, 2023) used partial least squares (PLS-SEM)to analyze the data collected from a web-based survey questionnaire submitted to Portuguese internal auditors from 3 moths yielding a total of 187 responses with a sample of112 responses , the variables were measured as follow ; "Perceived Organizational Support ,Organizational Commitment , Risk Profile and Organizational Independence were measured using a seven-point Likert-typescale ranging between one (strongly disagree) and seven strongly agree) "

Thus, first it was determined that the Organizational Commitment have a negative effect on reduced audit quality practices hence the researchers found that it is persuasive for organizations to prioritize addressing problems that influence internal auditor's identity , involvement and loyalty .On the contrary perceived Organizational Support has a positive impact , After a little research attention it's appear that according to (Rittenberg & LE, 2015) the profession ordinarily draws people with high individual and ethical standards . Recognizing the esteem of internal auditing in advancing organizational administration might anticipate internal auditors from feeling undervalued in their work, they may prioritize their proficient satisfaction in completing tasks appropriately and proficiently over the esteem set due to their generosity. Moreover, reduced audit quality increase depends on time factor. In addition, this work ensures that the determinants of internal audit quality are the ones associated with both the individual and the entity .Sustaining this paper. (Cheng.RH &

Engstrom, 2002)In their published work, stated that knowledge and behaviorare the two main factor of the auditor's proficiency

-To illustrate and demonstrate how the internal audit contribute in improving the global performance of a company. A published work *«STUDY OF THE INFLUENCE OF INTERNAL AUDIT ON THE COMPANIES OVERALL PERFORMANCE IN SOUSS MASSA REGION»* utilized a questionnaire conducted to sixty: medium and large-sized enterprises in Food-processing sector, Industry, Buildings / construction. Applying PLS (Partial least square),

As a result,(Mustapha &Samia, 2019)proved that:

- An internal auditor's qualifications significantly impact social and economic performance.
- The internal audit background could enhance the company's performance.
- The qualifications and the criteria of an internal audit assist in evaluating the economic performance.

Noted: The researchers faced a limitation due to sample size.

-Based on forgoing (E. CHRISTENSEN, STEVEN M., OMER, &MARJORIE, 2016) argued that a strong audit quality depends the characteristics and the behavior of auditor after conducting a survey to both auditors and investors, done in 2012. To illustrate the precise definition of audit quality and to offer supplementary perspectives about what has been found, the researchers use what we called "Follow-up interviews "on their published paper.

-The study of factors affecting the internal audit effectiveness in public administration (BOUTHACH & Taouab) . the objective of this research is to provide empirical evidence of the effectiveness of internal audit, the researchers used a quantitative method through a

questionnaire with a sample of 43 Companies in Morocco, as findings it was determined that internal audit is independent approach argued and the support of the first management has a significant impact on the realization and effectiveness of the entire process.

Within the current period, a few researchers have turned their research lens on the added value on internal audit

- (Masoud, 2021) picked to discuss the effect of internal audit and how it can impact the performance, for this matter they have employed a quantitative method (a questionnaire was distributed to 712 heads of departments from three units in Dar salaam – Tanzania but only 258 were selected , to study the degree of agreement of the respondents therefor they were

asked to give a number from 1 to 5 as this work used 5 point Likert scales :(1= strongly disagree) , (5=strongly agree)to three expression suggested .after discussing the result it was determined that internal audit does have influence the procurement performance , and detect risks , by the end of the paper the researches recommended that the organization case of study should guarantee all the essential requirements for internal auditors to deliver a high-quality audit .

3. Internal quality audit

The article titled *«The Role of Internal Quality Auditing in Improving Process Performance Under Applications of ISO 9001 - A Field Study in Cement Company SCAEK»* investigates how internal quality audits contribute to continuous improvement in companies that have adopted quality management systems. The study focuses on SCAEK, a prominent Algerian cement company that has achieved ISO 9001 certification، indeed (Kechat, 2019) The data collection tool that (Kechat, 2019) used was a questionnaire survey This survey was distributed in two sections to the process leaders at SCAEK .in order to gather insights from those directly involved in the internal auditing process and its impact on process performance. to analyses the received result (17 over 19 respondent) the researcher used using SPSS model .

The literature consistently shows that:

- Internal quality auditing is a strategic tool for organizations to drive continuous improvement.
- Internal quality auditing help maintain the effectiveness of the quality management system
- SCAEK provides all the essential elements to execute an internal quality audit frequently; this involves regular evaluations and updates to maintain the effectiveness of the quality management system.
- SCAEK considers the audit process a tool for controlling processes. This ensures that the company's operations align with the ISO 9001 standards and continually improve.

-The article *«Total Quality Management and Its Relationship with the Internal Audit»,* (Haronet, 2012) published in the Australian Journal of Basic and Applied Sciences, explores the intricate relationship between Total Quality Management (TQM) and internal audit functions. The study emphasizes that TQM systems are widely implemented because they allow internal audit departments to focus on overall objectives, thereby improving

performance and maintaining quality standards. which has become a top priority. This transformation necessitates internal auditors to develop new skills, including understanding TQM theoretical aspects and statistical quality control methods. The internal auditor's role evolves from an independent reviewer to a cooperative participant and consultant, working closely with production management to ensure quality. The study underscores the importance of continuous improvement, adherence to high ethical standards, and alignment with organizational goals through TQM. The incorporation of IT systems and the human element in quality control is seen as crucial for the effectiveness of TQM and internal audit functions. Recommendations include updating methods and standards to evaluate internal audit performance in relation to overall quality and fostering a collaborative environment for achieving long-term organizational.

(Al-Mahawili, 2023) The document explores the Internal Audit Quality Management System (QMS) at the Iraqi Drilling Company (IDC) in Baghdad, specifically evaluating its conformity with the ISO 9001: 2008 standards and the ISO 19011: 2002 guidelines. The research highlights notable weaknesses in IDC's implementation and documentation of its QMS. It aims to diagnose these issues and suggest corrective and preventive measures to enhance quality management. IDC, which holds an ISO 9001: 2008 certification , has committed to regular internal audits to identify non-conformities and opportunities for improvement. However, the study finds that while IDC’s QMS largely meets the ISO 9001: 2008 standards, it does not fully adhere to the ISO 19011: 2002 guidelines during internal audits, revealing specific areas for improvement. The research concludes that stricter compliance with ISO 19011: 2002 is necessary to strengthen IDC’s internal audit processes and ensure continuous improvement in its QMS.

-The article *«The Impact of the Internal Audit for Quality Management System on Improving the Quality Management System in Companies that Obtained the ISO 9001/2015 Certificate in the Energy Sector in Sudan»* by Dr. Mohammed Al-Amin Ahmed Al-Mahi explores the influence of internal audits on continuous improvement in Sudan's energy sector. The study, involving 38 internal auditors, found that while internal audit practices are highly implemented according to ISO 19011:2018 standards—including audit implementation, preparation, planning, auditor qualification, and follow-up—the level of continuous improvement remains low. Internal audits positively impact continuous improvement, with 69.2% of audit procedures showing a strong positive correlation. Specifically, a one-degree increase in internal audit levels results in a 47.8% enhancement in continuous improvement.

Auditor qualifications have a significant effect, with a 60.8% positive correlation, where a one-degree increase in qualifications leads to a 36.9% improvement. Audit preparation also significantly impacts continuous improvement with a 54.8% positive correlation. However, audit planning does not show a significant statistical impact on continuous improvement. Recommendations from the study include enhancing follow-up on non-conformities, developing comprehensive improvement plans, focusing on internal audit processes to uncover improvement opportunities, and improving auditor training and qualifications to better leverage internal audits for continuous improvement.

-Our current study distinguishes itself from previous research by concentrating on the methodology of internal audits within quality management systems, as specified by ISO 19011:2018 standards. This investigation delves deeply into the internal audit process, specifically within the context of quality management systems. While prior research has addressed related themes, such as the critical role of internal quality audits in ensuring compliance with ISO 9001 standards, driving continuous improvement, and enhancing overall organizational performance, this study aims to elucidate the intricacies of internal audit methodology within the ISO 19011:2018 framework.

Internal quality audits are pivotal in identifying non-conformities, facilitating improved internal communication, and contributing to more efficient process control. Although studies present mixed results regarding the direct impact of ISO 9001 certification on performance, they consistently highlight the strategic benefits of quality management, including enhanced customer satisfaction and greater access to international markets. However, significant challenges such as excessive costs, bureaucratic hurdles, and the necessity of a strong quality culture remain.

Effective internal audits demand qualified auditors, robust documentation, and regular evaluations. Emphasizing continuous improvement is essential for maintaining the effectiveness of a Quality Management System (QMS) and achieving long-term organizational goals.

By concentrating on these aspects, this study enhances the understanding of internal audit practices within quality management systems, aligning with contemporary ISO standards. Additionally, internal audits serve as a crucial first step in visualizing the state of an organization, thereby significantly aiding in the effectiveness of its improvement efforts.

Section 02: Theoretical Framework

1. Presentation of quality management

Quality management is a systematic approach that ensures products or services meet or exceed customer expectations through meticulous planning, continuous monitoring, and consistent improvement of processes. It encompasses key components such as quality, quality control, quality assurance, and quality improvement. Quality control involves operational techniques to fulfil quality requirements, while quality assurance focuses on systematic activities to maintain standards. Quality improvement drives continuous enhancement of products, services, and processes. ISO 9001, a widely recognized QMS standard, provides requirements for effective quality management, emphasizing a process-oriented approach, the Plan-Do-Check-Act cycle, and risk-based thinking. This section explores the theoretical aspects of quality management, essential for organizations aiming for sustained success.

1.1Quality

1.1.1Definition of Quality :

There is a variety of definitions, here are a few that seem more appropriate:

- ISO 8402 define Quality as *«The totality of features and characteristics of a product or service that bear on its ability to satisfy stated or implied needs»*(ISO 8402 , 1994)

- *«The uniform level of the quality of the products that we wish to produce to provide our customers with what they expect with understanding that we are costly working to improve quality, but always remaining competitive »*(Gould, 2013)
- Deming *«Good quality means a predictable degree of uniformity and dependability with the quality standard suited to the customer».*

In simple words quality ensure to meet explicit or implicit customer requirements. It encompasses a consistent level of excellence and reliability, aligning with customer expectations while acknowledging the ongoing pursuit of improvement and competitiveness within cost constraints.

1. 1.2Quality evaluation

(Garvin, 1988) Stated that the era of quality management relates to time, from the Inspection period to the Statistical Quality Control Era, Quality Assurance Era, and the most recent Strategic Quality Management Era.

Quality evolution can be traced back to the 1920, guided by a statistical theory Related with the quality of products.

-Shewhart invented an innovative approach in the field of statistical processes in 1924, which recently marked its 100th anniversary: the 'control chart'.

However, his method encountered substantial obstacles since it was not possible to detect all the defects draining effort, time and operational personnel started to ignore the chart, later his work was developed by Deming. In early 1950s the quality management was spread in Japan.
Deminghas tough Japanese engineers and executive methods and control quality to help advancing the industry and adopt quality commitment, by then in 1970 Japanese companies made a leapfrogging in production and importing their products to USA and Europe.
Adherents to (Bedaida, 2024) the evolution of quality lead us to two concepts of quality management: quality assurance and total quality management.
To continue with the mainstream of quality, (Ellis, 1993) stated that the term quality is associated with:

- **Quality control**

Quality control is a key element on quality assurance as it is a process to correct the errors in product.
And ISO (ISO 8402 , 1994) define it as *«the operational techniques and activities that are used to satisfy quality requirement»*
In a simpler word, Quality control is the process of verifying, evaluating a products or service whether it is conform to requirements.
-A quality control process must be developed and implemented to track all activities in a survey's life cycle before getting to the point of assessing potential issues and to propose potential solutions.
-The first worldwide quality control conference, held in Tokyo in 1969, was sponsored by Japan, America, and Europe. Feigenbaum first used the term "total quality" referring to a range of issues such as planning, organisation, and managerial accountability. Ishikawa gave a presentation outlining the differences between "total quality control" in Japan and

"companywide quality control," as well as how all employees, from top management to employees, must study and engage in quality control. By the late 1970s, Japanese firms had implemented company-wide quality management. (The Evolution of Qality)

- **Quality assurance**

An approach for preventing mistakes and defects in goods or services by guaranteeing that quality standards have been adhered to.

-*«Quality refers to the standards the must be met to achieve specified purposes to the satisfaction of customers»*(Ghobadian, 1993)

-*«Quality assurance is a methodology used in the development of products or services that ensure a level of quality in production»*(journaldunet)

-Quality assurance: *«All those planned and systematic actions necessary to provide adequate confidence that a product or service will satisfy given requirements for quality»* (ISO 8402 , 1994)

Quality is defined as the adherence to standards designed to fulfil specific purposes and meet customer expectations, ensuring that the end product or service delivers the promised value and satisfaction, on the other hand quality assurance is a comprehensive methodology applied during the development of products or services to maintain and control quality throughout the production process, ensuring consistency and reliability .This involves a series of planned and systematic activities necessary to provide confidence that a product or service will satisfy given quality requirements. These activities include monitoring and controlling the production process, implementing preventive measures to avoid defects, and ensuring continuous improvement. By integrating these practices, organizations can achieve higher standards of quality, enhancing customer satisfaction and achieving long-term success.

- **Total quality management**

(Powell, 1995) Confirms that "TQM's origins can be traced to 1949, when the Union of Japanese Scientists and Engineers formed a committee of scholars, engineers, and government officials devoted to improving Japanese productivity, and enhancing their post-war quality of life" and "American firms began to take serious notice of TQM around 1980."

To express the breadth of TQM, several theories have first put in the picture quality gurus contribution to the movement,Deming (1986), Juran (1979), Crosby (1979), Feigenbaum (1983).

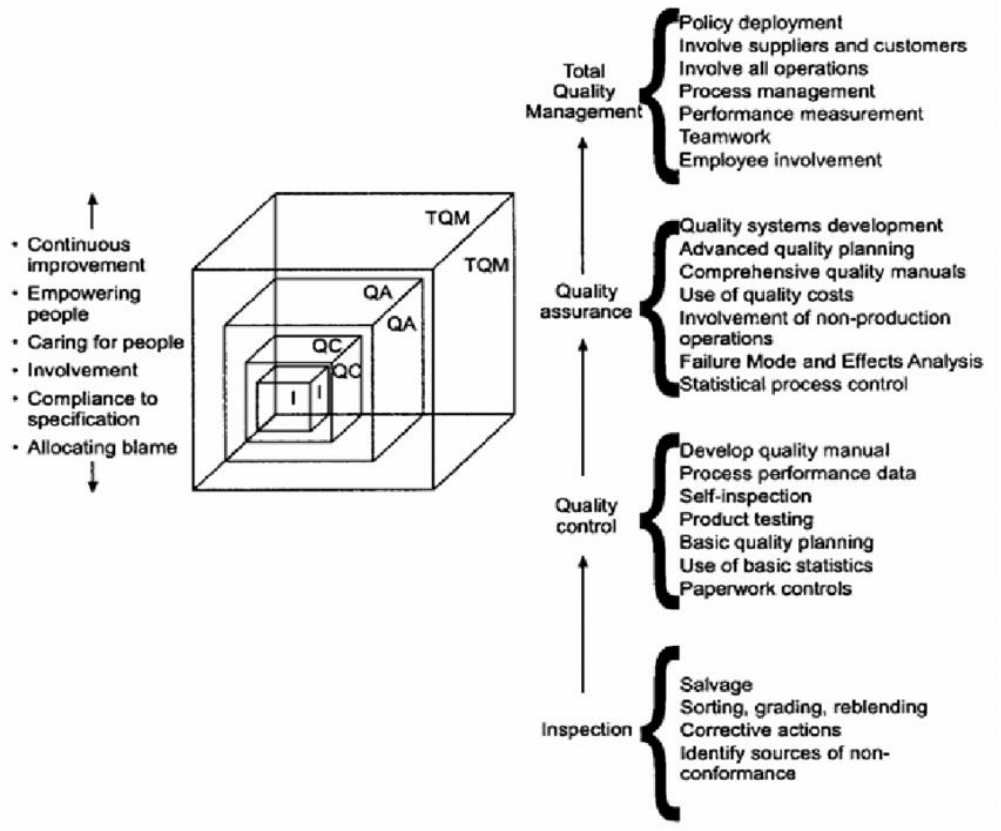
-Deming Proposed 14 points and it considered as a core concept on implementing TQM. In short is asset of management practices to help companies increasetheir quality and productivity.

‘TQM is a structured attempt to refocus the organization's behaviour, planning and working practices towards a culture which is employee driven, problem solving, customer oriented, and open and fear-free. Furthermore, the organization's business practices are based on seeking continuous improvement, devolution of decision making, removal of functional barriers, eradication of sources of error, team working, and fact-based decision making “(Ghobadian, 1993)

“TQM is a holistic management philosophy that strives for continuous improvement in all functions of an organization, and it can be achieved”.(Kaynak, 2003)
It cab argued that TQM is the responsibility of providing good services and quality products to ensure full client satisfaction lies with every employee, from the lower level to the upper level, through complete and organized activities called “total quality management.”

Total Quality Management (TQM) is an all-encompassing management philosophy focused on achieving continuous improvement in every aspect of an organization to ensure high quality and customer satisfaction. Pioneers of the TQM movement include renowned quality experts such as Deming, Juran, Crosby, and Feigenbaum. Deming's 14 points, which are fundamental to TQM implementation, provide a framework of management practices designed to improve quality and productivity. TQM seeks to reshape organizational behavior, planning, and work practices toward a culture that is employee-driven, oriented around problem-solving and customer needs, and characterized by openness. It prioritizes continuous improvement, decentralized decision-making, elimination of functional barriers, eradication of errors, teamwork, and decisions based on factual data. By adopting these principles, organizations can elevate their quality standards, enhance customer satisfaction, and achieve sustained success.

Figure 1 : the four levelsevaluation of the quality management



Source:(Shahin, 2004)

The figure delineates the hierarchical progression of quality management, encompassing four distinct levels: Inspection, Quality Control (QC), Quality Assurance (QA), and Total Quality Management (TQM). At the foundational level, Inspection focuses on defect identification, corrective measures, and compliance verification. Advancing to QC, the scope broadens to include the development of quality manuals, implementation of basic statistical methods, and product testing. The QA level introduces sophisticated techniques such as Statistical Process Control (SPC), Failure Mode and Effects Analysis (FMEA), and comprehensive quality systems that integrate non-production operations and quality cost analysis. At the apex, TQM embodies a holistic approach, emphasizing continuous improvement, process management, performance measurement, and extensive stakeholder involvement, including suppliers and customers. This evolution signifies a paradigm shift from reactive inspection and blame allocation to proactive, systemic quality enhancement and employee empowerment.

1.1. Quality management system

1.2.1Definition of Quality management system :

The quality management system is “the element of the organization's management system that focuses on achieving results, based on quality objectives, to satisfy, as appropriate, the needs, expectations or requirements of interested parties “(Audit Interne - Qualite , 2004)

According to (ISO 9000, 2015) A Quality Management System (QMS) is a framework through which an organization identifies objectives, determines and manages the processes and resources needed to achieve desired results, optimizes resource use taking taken into consideration long and short-term impacts, and addresses both intended and unintended consequences in providing products and services to interested parties.

Quality management has been demonstrated as “philosophy or an approach to management” made up of a “set of mutually reinforcing principles, each of which is supported by a set of practices and techniques”

Based on these definitions : A Quality Management System (QMS) is a comprehensive framework within an organization's management system that focuses on achieving quality objectives to meet the needs, expectations, and requirements of interested parties. It identifies objectives, manages processes and resources, optimizes resource use considering both long and short-term impacts, and addresses intended and unintended consequences in providing products and services. It is based on a philosophy or approach to management comprising a set of mutually reinforcing principles supported by specific practices and techniques.

1.2.2Evaluation of ISO 9001

The adoption of a quality management system and subsequent certification has been significantly influenced by internal motivations, objectives, and policies. Initially, the introduction of ISO 9001 certification emerged prominently in Europe, where it was first adopted. European companies, recognizing the strategic advantage of certification, began to encourage their global suppliers to pursue ISO 9001 certification as well. At that time, ISO 9001 certification was viewed as a crucial tool to mitigate trade barriers and facilitate smoother international trade.

This proactive approach by European firms created a ripple effect, compelling numerous countries to implement ISO 9001 standards. The drive for certification was largely fueled by competitive pressures and the desire to meet client demands within international supply

chains. Companies saw the certification to gain a competitive edge—adopting the mindset that if a competitor was certified, they too needed to achieve certification to remain viable and attractive in the market. Additionally, downstream clients in the global supply chain increasingly demanded ISO 9001 certification from their suppliers, further intensifying the pressure on companies to comply.

As a result, the widespread implementation of ISO 9001 standards became a common business practice, driven by both the need to stay competitive and the necessity to meet evolving client expectations in the international marketplace. This trend highlights the interconnected nature of global trade and the role of quality management systems in enhancing business operations and fostering international cooperation (Corbett, Luca, & Pan, 2003). (Corbett, Luca, & Pan, 2003)

1.2. Audit :

1.3.1Origin and evolution

Back in the 1990s, with the spread of international ISO 9000 family. The quality auditing process was utilized for companies with elevated risk activates to provide additional assurance and security,

The quality audit was carried out in accordance with the quality assurance thatemphasizes documentation and formalization.

From 1995 to 2000, there was less formalization and a focus on the content of writing rather than the quality of documentation. On the other side, we have shifted from methodical to introspective writing.

In 2ooos The ISO 9001 standard shifted our focus from quality assurance to quality management systems. This standard directs the company to:

- Focus on the customer;
- Employee empowerment;
- Management as leadership;

((Christophe), 2003)

1.3.2Definition of Audit :

It has been argued that there is a wide and varied definitions of Audit whether it's internal or external yet they all share common ideas.

Regardless of its type according to (CAMBRIDGE Dictionary)

Audit *: «to make an official examination of the accounts of a business and produce a report »*

In The organizations: «*Systematic, independent and documented process for obtaining audit evidence and evaluating it objectively to determine the extent to which the audit criteria are fulfilled»*(ISO 19011 : 2018)

To gain insight into an organization's efficiency and performance (Eden & Moriah , L, 1996) Suggest that internal audits within necessary actions.

(CLAUDE, 2009)*« A monitoring tool that will enable the enterprise to maintain in the right direction , its QMS and the use made of it. In the right direction. It is a quality management tool, and a tool for improvement. »*

(FEY, 1991)*«A quality audit is a methodical examination of a system with a view to rapidly verifying its degree of conformity or suitability. to rapidly verify its degree of conformity or suitability, and then to gather, if necessary, all the data needed to draw up recommendations for action to prevent, reduce or eliminate prevent, reduce or eliminate the causes of non-quality »*

Audit is a structured process aimed at evaluating and verifying the financial records, operational procedures, and overall performance of a business or organization. It involves systematically examining accounts and operations to ensure compliance with established criteria or standards. Audits are conducted independently and documented to provide an objective assessment of the extent to which the audit criteria are met.

1.3.3 The objectives of a quality audit:

- Evaluate Compliance: Assess the ability of the quality management system (QMS) to ensure adherence to specified quality requirements.
- Integration Measurement: Determine the extent to which the QMS is integrated within the company, ensuring it is known, understood, and applied by personnel.

- Deviation Assessment: Identify any discrepancies between the QMS and the established quality audit criteria.
- Improvement Identification: Detect sensitive areas and potential opportunities for improvement within the QMS.
- Resource Verification: Verify that the organization has the necessary resources to achieve its quality objectives.
- Effectiveness Check: Evaluate the effectiveness of the QMS by determining whether the quality objectives are being met.
- Continuous Improvement Monitoring: Ensure that the QMS is continually improving and operating satisfactorily.(n.d)

1.3.4 The distinguishing features of approaches generally used in conducting audits

Auditing approaches vary widely in their methodologies, objectives, and scope, each tailored to address specific aspects. The following table presents an overview of the key characteristics of various auditing approaches, highlighting their unique attributes and applications.

Table 1: features of approachesused in the audit activity

Audit activity	Features of approaches			
	The element approach	The departmental Approach	The task-based Approach	The process approach
Planning the audit	The auditor uses the elements of the governing Standard ,eg ISO9000:2000, as the basis for planning and conducting The audit. The audit schedule may not follow the elements in numerical order as this will depend upon location and timing,	The auditor starts with the organisation's departments and seeks conformity with those requirements of the Standard that apply to each department. The audit plan is based	The auditor identifies the work areas to visit and on arrival seeks to establish what tasks are performed there. The plan starts with customer requirements proceeds through all the works areas that	The auditor examines the way processes are managed to achieve results and improve performance. The plan is based on processes and not on elements. The organisation structure is useful only in identifying who to interview. The plan

	but, in principle, each element is matched with the person or department within the organisation**.**	on the organisation chart, with those departments that come within the scope of registration.	lead to completed output, regardless in which department they were located .	shows a path through main processes that cut across departmental boundaries.
Preparing the checklist	The checklist tends to be complied by taking each 'shall' statement and rewriting the requirement of the standard in the form of a question.	Checklist cites questions taken from the requirement of the Standard, but will pick up additional questions from the departmental procedures.	A flaw chart is used in planning the checklist, either taken from the organisation's procedure or drawn by the auditor.	The process approach does not require a detailed checklist, as the framework used can be adapted to any process.
Conducting the audit	The auditors tend to look for specific evidence in the belief that, if they find it, the organisation is compliant	The objective is to establish whether the department staff follows the documented procedures	The auditor uses a task element framework as the basis for revealing evidence.	The audit starts with top management and examines all main processes first and make linkages.
Reaches the conclusions	The auditor seeks non-conformity and reaches a conclusion on the number of non-conformities found in the simples taken. Non-conformities are classified on the basis that if a requirement	If the evidence presented in response to the questions conforms to the procedure, the procedure is assumed to be implemented	The auditor reveals not only whether the procedures have been followed, but whether the procedures adequately address the requirement of the governing	The auditor is looking for evidence that the organisation's processes are being managed effectively and in doing so will touch almost every requirement in ISO

	of the Standard has not been met.	and effective.	Standard.	9001:2000 Standard.

Source:(Kaziliūnas, 2008)

The comparative analysis delineates four distinct audit methodologies: element-based, departmental, task-oriented, and process-centric, with each approach evaluated across key audit phases including planning, checklist formulation, execution, and conclusion. The element-based approach synchronizes audit planning with fundamental elements, constructing checklists from imperative 'shall' statements and scrutinizing specific evidence of conformity. In contrast, the departmental approach conducts audits by department, employing checklists amalgamated from standard requisites and departmental protocols, with a focus on procedural adherence. The task-oriented methodology orchestrates audit planning around discrete work areas and tasks, utilizing flowcharts to structure checklists and assessing task-specific evidence. Conversely, the process-centric approach accentuates process management, employing adaptable checklists, commencing audit activities with senior management involvement, and appraising cross-departmental processes for efficient management, thereby encompassing a broad spectrum of ISO 9001:2000 stipulations.

1.3.5Different types of audits :

Table presents an overview of several types of audits categorized into first-party, second-party, and third-party audits, as outlined in ISO 19011:2018.

Table 2: Different types of audits

1 st party audit	2nd party audit	3 rd party audit
Internal audit	External provider audit	Certification and /or accreditation audit
	Other external interested party audit	Statutory , regularity and similar audit

Source:(ISO 19011 : 2018)

- ✓ **First-party audit:** This type of audit, also known as an internal audit, is conducted by or on behalf of the organization itself to assess its own management systems, processes, and performance.

- ✓ **Second-party audit:** External provider audits fall under this category, where audits are performed by entities external to the organization but are directly engaged by the organization, such as suppliers or contractors. These audits typically assess conformance to contractual requirements or supplier agreements.
- ✓ **Third-party audit:** This category includes certification and/or accreditation audits, conducted by independent external auditors. Certification audits determine if an organization's management system conforms to specified requirements, while accreditation audits assess the competence and impartiality of certification bodies themselves.

2. Internal Audit

2.1Origin :

For many authors, internal audit's appearance is associated with United States 1929 great economic depression**.**

Back to the past, the British, whose nations were occupying American land, introduced investments that helped establish the practice of external auditing in the United States throughout the 19th century. The United States' external audit function began when these English external auditors imposed their methods and procedures, was going through the 1929 economic crisis; American corporations were experiencing a recession during the 1929 Great Depression. At the time, American businesses wanted to save as much money as possible, thus accounts were closely examined to cut expenses. Large American companies were already using external auditing firms.(Renard, 2017)

Almost all over the country, they were searching for methods to cut expenses and discovered that the external auditors needed to complete several preparation activities, such as account analysis and other types of inventory, before they could begin their audit job. If these responsibilities were delegated to outside audit firms, American businesses would suffer significant financial losses. These would be extremely costly for American corporations to outsource to outside auditing firms, on top of the fact that they are already facing a crisis. So it made sense to recommend that some of these setup duties be completed by corporate personnel.

These internal auditors, who were employees of the company, at the time since they were conducting audit work in the traditional sense and were considered "internal" since they were full members of the team.

Once the economic meltdown ended, internal auditors were still employed by US corporations.

After that, in 1941, the Institute of Internal Auditors was founded, “The mission of The Institute of Internal Auditors is to provide dynamic leadership for the global profession of internal auditing "(The Insititute of Internal Auditors)

Due to this historical background as (JacquesRENARD, 2010) mentioned in his book “Many still think in function of finance and accounting, when we talk about internal audit “

Over time, the internal audit concept has developed with various categories:”

- Financial audit
- Operational audit
- Tax audit
- IT audit
- Technical audit
- Legal audit
- Quality audit “ (Boudriga, 2012)

2.2 Definition of internal audit :

From then Published definition in 1947 by the Institutes of internal auditors

Internal auditing serves as an independent evaluation process conducted within an organization, aimed at reviewing accounting, financial, and operational functions. Its purpose is to provide management with both protective and constructive insights. Acting as a control mechanism, it assesses the efficiency of various control methods. While its focus is predominantly on accounting and financial domains, it can also extend to operational areas..(Boudriga, 2012)

The second edition of Guidelines for auditing management system ISO 19O11 :2011

«Internal audit can form the basis for an organization’s self-declaration of conformity. In many cases, particularly in small organizations, independence can be demonstrated by the freedom from responsibility for the activity being audited or freedom from bias and conflict of interest»

(ISO 19011 : 2011 Guidelines for auditing management system, 2009 / 2008) .

Building upon IIA’s International Professional Practices Framework

«Internal auditing is an independent, objective assurance and consulting activity designed to add value and improve an organization’s operations. It helps an organization accomplish its

objectives by bringing a systematic, disciplined approach to evaluate and improve the effectiveness of risk management, control and governance processes»(About Internal Auditor):

- Risk management: as the main activates of internal auditors is to facilitate and assessing the implementation of the four phases management (Identifying , analyzing and evaluating the risk)

In short the auditor aim to advance the RM procedures," Internal auditors the company's risk profile and play a key role in identifying areas for risk management " (E, Lindow , & Jill , 2002).

- Internal control:are policies, procedures, and processes designed to protect firm assets and reduce risk. To achieve the company's objective.

The Components of Internal Controls

- governance processes : "To enhance the role of internal audit in corporate governance, emphasis should be placed on the capability of internal audit in providing assurance to management and the board on the integrity of information flows, including the monitoring of all internal systems which generate information "(Leung, Cooper, & Robertson).

From these definitions, it is evident that internal auditing is a multifaceted function that encompasses independence, appraisal, and advisory roles within organizations. It operates as an independent appraisal activity directed at assessing accounting, financial, and operational processes, serving both protective and constructive functions by assessing control effectiveness. Moreover, internal audit serves as the foundation for an organization's self-declaration of conformity, which is particularly pertinent for smaller entities, where independence is demonstrated by the absence of responsibility for audited activities or biases. Additionally, internal auditing is distinguished by its objective assurance and consulting functions, aimed at enhancing organizational operations through systematic evaluation and improvement of risk management, control, and governance processes, thereby contributing to the attainment of organizational objectives.

2.3 The approach of internal audit

-Audit client

Is the person or organization requesting an audit.

Following to the guidelines of ISO 19011 this definition is followed with note in Case of internal audit:

-The audit client can also be the auditee or the person, managing the audit

-Auditee: 'Organization being audited '

-Auditee responsibilities

- Share pertinent information with auditors, answering questions clearly.
- Comprehend the standard which the audit client we be ask and evaluate about
- Preparing documents to facilitate the audit process
- Implanting corrective action plans

-Auditor: «person who conduct an audit»

Noted that an auditor may only audit beyond his\her processes.

-Audit team:means a team or a group of auditors. The audit team number is not set, it could differ depending on multiple factors.

And it may be also ‘supported if needed by technical experts “ (ISO 19011 : 2018)

In Line With (Bamber, 1983) “an audit is usually conducted by an audit team, which is characterized by a hierarchical structure and division of labor.” Observer and technical expert do not act as auditors. Each team has a leader, thus an auditor should be appointed as one.

2.4 The principals of internal audit

In accordance with (The Institute of Internal Auditors : INTERNATIONAL STANDARDS FOR THE PROFESSIONAL PRACTICE OF INTERNAL AUDITING (STANDARDS) , 2016)"the internal audit activity must be independent, and internal auditors must be objective in performing their work."

- **Independence**

“Independence is the freedom from conditions that threaten the ability of the internal audit activity to carry out internal audit responsibilities in an unbiased manner. To achieve the degree of independence necessary to effectively carry out the responsibilities of the internal audit activity, the chief audit executive has direct and unrestricted access to senior management and the board" Ibid

- **Objectivity**

The objectivity of internal audit is related to the professionalism of auditors. They must perform audits in such a manner that they evaluate and communicate all processes objectively, and they won't be influenced by anything or anyone.

Objectivity is an unbiased mental attitude that allows internal auditors to perform engagements in such a manner that they believe in their work product and that no quality compromises are made. Objectivity requires that internal auditors do not subordinate their

judgment on audit matters to others. Threats to objectivity must be managed at the individual auditor, engagement, functional, and organizational levels" Ibid

- **Universality**

Internal auditing can be performed in organizations of all sizes, all sorts of businesses, and all sectors.

- **Continuity**

An organization regularly performs internal auditing, which is a permanent and continuous activity.

As previously mentioned, an internal auditor is already employed by the company and cannot audit their own processes.

-Jacques RENARD "It's worth pointing out at this point that the permanent nature of the internal auditor's work means that he or she is ineligible for any operational responsibilities outside the auditing function. This rule is both a practical necessity and a professional ethics requirement. "

It's a practical necessity, because you can't be both judge and jury, auditor and operational manager. It is also a deontological requirement, since it is imposed by the need to audit everything, and to do so without any subjectivism."(Jacques RENARD, 2010)

However this audit has six main stages mentioned in the standard:

I. 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;

II. Define the audit criteria and scope for each audit.

III. Select auditors and conduct audits to ensure objectivity and the impartiality of the audit process.

IV. ensure that the results of the audits are reported to relevant management.

V. Take appropriate correction and corrective actions without undue delay.

VI. Retain documented information as evidence of the implementation of the audit programme and the audit results. Ibid

2.5 Audit according to Guidelines for auditing management systems ISO 19011: 2018

These guidelines emphasize a structured approach to auditing, including planning, conducting, reporting, and following up on audits. The standard highlights the importance of impartiality, competence, and confidentiality in audit activities, ensuring that audits are conducted objectively and with integrity. ISO 19011:2018 encourages auditors to adopt a risk-based approach, tailoring audit processes to the organization's context and objectives while considering the significance of risks and opportunities. By promoting consistency and effectiveness in audit practices, this standard facilitates the enhancement of organizational performance and the achievement of strategic objectives.(ISO 19011 : 2018)

2.5.1Internal audit planning and preparation

Internal audit planning and preparation are crucial steps in the internal audit process, ensuring that audits are conducted efficiently and effectively. This phase involves defining the scope and objectives of the audit, identifying the resources required, and developing a detailed audit plan. Preparation includes gathering relevant information, understanding the organization's processes and controls, and establishing clear communication with auditees. Thorough planning and preparation help auditors identify key areas of risk, allocate resources appropriately, and set a structured framework for conducting the audit, ultimately leading to more accurate and valuable audit outcomes.

-Audit programme

Adherence to ISO 9000 An audit programme “is a set of one or more audits planned over a certain timeframe with a specific objective” (ISO 9000, 2015)

This definition emphasizes that each quality management audit must be carefully prepared, involving preparation, approval, and implementation stages. The audit programme is distinct from an annual audit plan, as it encompasses more than just planning; it includes monitoring compliance and ensuring the qualification of insourced or outsourced processes in response to the continuously changing environment and audit practices

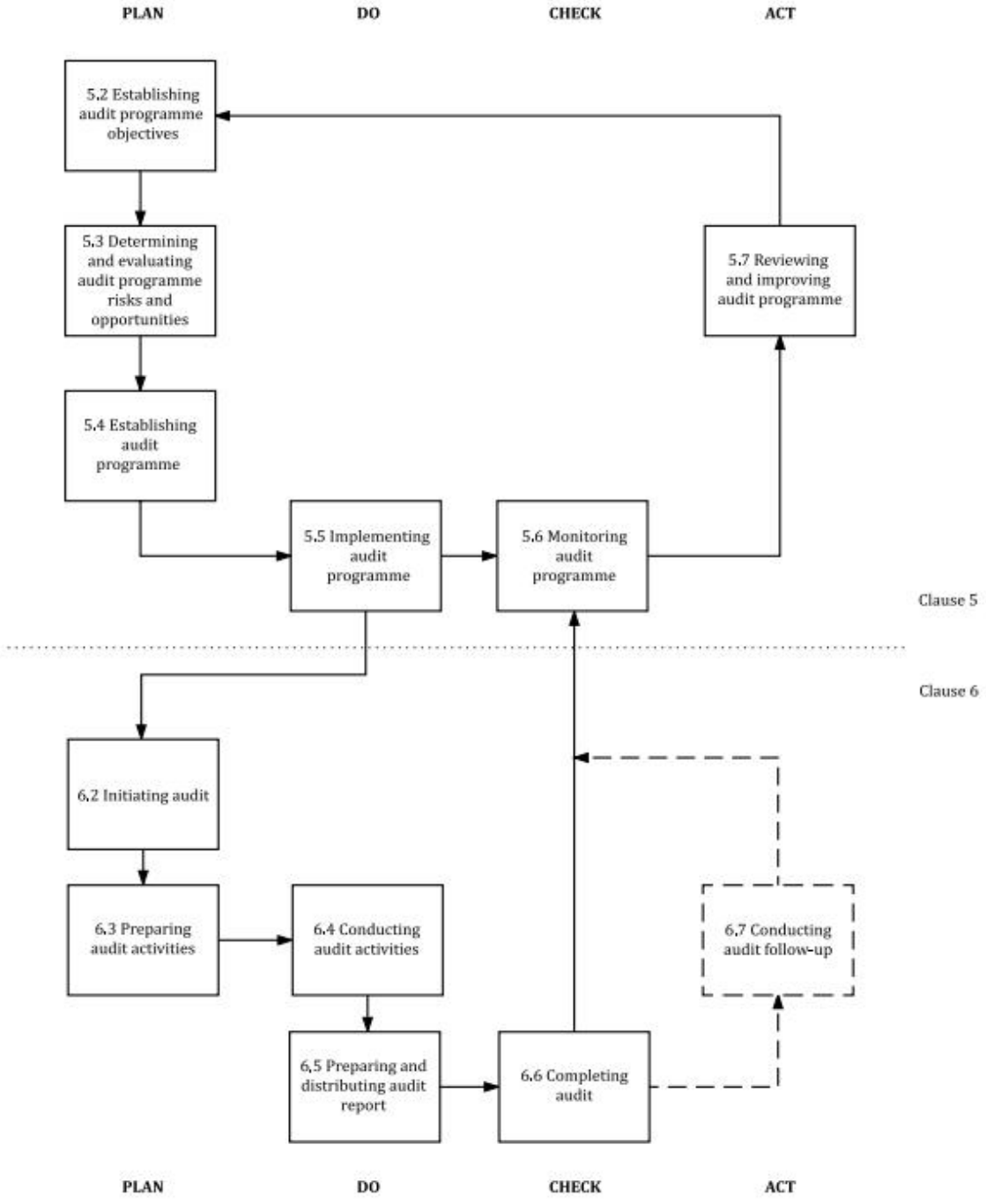
The elements constituting the internal audit (IA) program must be determined based on the strategic objectives of the company, its operational context, and the opportunities and threats it faces. This involves a thorough assessment of internal and external factors, including regulatory requirements, stakeholder expectations, market trends, and industry-specific risks. The audit program should be aligned with the company's vision and mission, while incorporating measures to identify and leverage opportunities for continuous improvement

and proactive risk management. Furthermore, it is crucial to consider the available resources, necessary competencies, and appropriate technologies to effectively and efficiently conduct audits, while ensuring compliance with international standards such as ISO 9001.

Adhering to the (ISO 19011 : 2018) : The audit program should detail and identify resources to ensure audits are conducted effectively and efficiently within specified time frames. It should include the audit program's objectives, associated risks and opportunities with actions to address them, the scope of each audit (including extent, boundaries, and locations), the audit schedule (number, duration, and frequency), audit types (internal or external), audit criteria, methods to be employed, criteria for selecting audit team members, and relevant documented information

➢ The process flow for the management of an audit programme

Figure 2: The process flow for the management of an audit programmere



Source : (ISO 19011 : 2018)

This figure illustrate the audit programmes stages split into two parts : the overall audit programme clause 5 and individual audits clause 6 . In clause 5 , it starts with setting objectives and assessing risks Plan , then running the audit programme Do , monitoring progress Check , and making improvements Act . clause 6 details the audit steps : starting and preparing for the audit Plan , conducting the audit Do , writing and sharing the report , and finishing the audit Check .

- Establishing audit programme objectives

The audit client should ensure that the objectives of the audit program are established to guide the planning and execution of audits, ensuring effective implementation. These objectives should align with the audit client's strategic direction and support the management system policy and objectives. They can be based on the needs and expectations of relevant interested parties (both external and internal), the characteristics and requirements of processes, products, services, and projects (including any changes to them), management system requirements, the need for evaluation of external providers, the auditee's performance level and management system maturity (as indicated by relevant performance indicators, nonconformities, incidents, or complaints), identified risks and opportunities for the auditee, and the results of previous audits.(ISO 19011 : 2018)

- Determining and evaluating audit programme risks and opportunities

The individuals managing the audit program should identify the risks and opportunities and present them to the audit client, along with resource requirements, to ensure they are properly addressed. Risks may include: inadequate planning, such as failing to set relevant audit objectives or determine the extent, number, duration, locations, and schedule of audits; insufficient resources, including time, equipment, or training; inappropriate selection of the audit team, leading to a lack of overall competence; ineffective communication processes; poor implementation, such as inadequate coordination of audits or neglecting information security and confidentiality; ineffective control of documented information, including determining necessary information and protecting audit records; and inadequate monitoring, reviewing, and improving the audit program. Additional risks include the availability and cooperation of the auditee and the availability of evidence to be sampled.

- Establishing the audit programme

This encompasses delineating the roles and responsibilities of the individual overseeing the audit program, as well as assessing the competence of the person managing the audit program. It also involves defining the expertise required for the audit program and determining the necessary resources for its implementation.

- Implementing audit programme

The implementation phase follows the planning stage, where the plans devised are executed to achieve the predetermined objectives of the internal audit program. This phase involves putting into action all the strategies and plans developed during the planning phase. It includes conducting the actual audits based on the defined scope, criteria, and methods, ensuring that the audit team adheres to the established schedule and resource allocations.

During this phase, the audit team collects and analyzes data, interacts with auditees, and verifies compliance with relevant standards and regulations. The goal is to systematically evaluate and document findings to provide an accurate assessment of the auditee's processes and controls, thereby fulfilling the objectives set forth in the audit program. Additionally, in this phase, objectives, scope, and criteria are determined, methods are selected, responsibilities of the internal audit team leaders are assigned, and audit results are managed.

- Monitoring audit programme

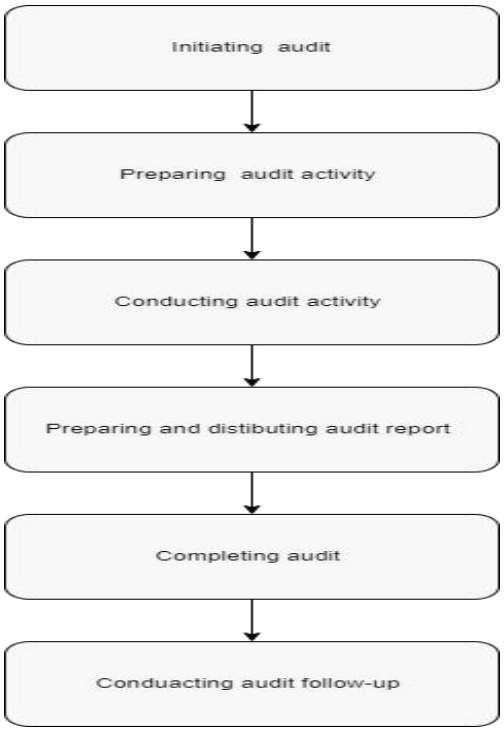
The individuals managing the audit program should evaluate whether schedules are being met and objectives achieved, assess the performance of audit team members including the team leader and technical experts, and ensure the audit teams can implement the audit plan effectively. They should also gather feedback from audit clients, auditees, auditors, technical experts, and other relevant parties, and verify the sufficiency and adequacy of documented information throughout the audit process. Modifications to the audit program may be necessary due to changes in audit findings, the effectiveness and maturity of the auditee's management system, the effectiveness of the audit program, the audit scope or program scope, the auditee's management system, relevant standards and requirements, external providers, identified conflicts of interest, and the audit client's requirements.

- Reviewing and improving audit programme

The individuals managing the audit program and the audit client should review the program to assess if its objectives have been met, using lessons learned for future improvements. They should ensure a thorough review of the audit program's overall implementation, identify areas and opportunities for improvement, apply necessary changes, and review the continual professional development of auditors. Additionally, they should report the audit program results and review findings with the audit client and relevant interested parties as appropriate.

2.5.2 Conducting internal audit

Figure 3: ***Conducting audit***



Source : Elaborated by our care, inspired by ISO 19011

The figure outlines the sequential steps involved in an audit process. Here's a detailed explanation of each step:

- Initiating Audit

- This is the first step where the audit process begins. It involves defining the purpose, scope, and objectives of the audit. The audit manager will establish the audit plan, identify the resources needed, and notify the relevant parties about the upcoming audit.

- Preparing Audit Activity

- During this phase, the audit team prepares for the audit by gathering relevant information about the auditee's operations, processes, and previous audit reports. This step includes the development of detailed audit checklists and work programs, and the allocation of tasks among audit team members.

- Conducting Audit Activity

- This is the core of the audit process where the audit team conducts the audit as per the plan. Activities include collecting evidence through interviews, observations, and document

reviews, assessing compliance with standards and regulations, and evaluating the effectiveness of the auditee's processes and controls.

- Preparing and Distributing Audit Report

- After the audit activity is conducted, the audit team compiles their findings, conclusions, and recommendations into an audit report. This report is reviewed for accuracy and completeness before it is distributed to the audit client and other relevant stakeholders.

- Completing Audit

- This step involves finalizing the audit documentation and ensuring that all audit activities have been properly documented. The audit manager reviews the entire audit process and ensures that all objectives have been met and all findings have been appropriately addressed.

- Conducting Audit Follow-up

- The last step is the follow-up audit, which occurs after the initial audit report has been distributed. The purpose of the follow-up is to verify that the auditee has taken the corrective actions recommended in the audit report and to ensure that these actions have been effective in resolving identified issues.

Each of these steps is crucial for ensuring a thorough, effective, and systematic audit process that can provide valuable insights and drive improvements within the audited organization.

Conclusion:

The conclusion of Chapter 1 emphasizes the critical role of internal audit in ensuring the effective implementation and continuous improvement of quality management systems (QMS). It highlights the necessity for systematic and well-planned audit processes, as detailed in the ISO 19011:2018 framework, which includes setting clear objectives, identifying risks and opportunities, and executing audits in a structured manner. The chapter underscores the importance of auditor competence, thorough documentation, and regular review and improvement of audit programs. By adhering to these guidelines, organizations can enhance their compliance with standards, ensure the effectiveness of their QMS, and foster an environment of ongoing quality improvement. This comprehensive approach to internal auditing not only helps in identifying and rectifying non-conformities but also in aligning the QMS with the strategic goals of the organization, thereby driving overall performance excellence.

CHAPTER 02: METHODOLOGICAL FRAMEWORK &ORGANIZATIONAL CONTEXT

In this chapter, we will present the methodology of our research, specifying the framework of the project and detailing the action research method we have employed .We further examine the different data collection methods utilized, along with the tools applied for collecting and processing the data.

Section 01 : Epistemological approach

«Epistemology is the philosophical underpinnings of researchers' beliefs regarding the nature of knowledge and how it is derived or created. The particular belief represents a person's epistemological position » (Yin, 2016)

1. Key epistemological approaches in research:

- **Positivism**

According to (Yoon, Lars, & Anthony, 2020) "*Positivism relies on the hypothetic condeductive method to verify a priori hypotheses that are often stated quantitatively, where functional relationships can be derived between causal and explanatory factors (independent variables) and outcomes (dependent variables)"*

Post-positivism delineates an epistemological stance that diverges from the positivist notion of absolute objectivity, instead recognizing the nuanced interplay of subjectivity, values, and socio-cultural context in knowledge production. It accentuates the interpretative essence of reality, the inherent theoretical preconceptions shaping observations, and underscores the imperative of situating knowledge within its contextual and historical comprehension in knowledge acquisition. Post-positivism advocates for critical inquiry and reflexivity in research, prompting researchers to contemplate their biases, assumptions, and theoretical frameworks.(Hollis, 2018)

From the previous definitions, we can extract that:

Post-positivism delineates an epistemological stance that diverges from the positivist notion of absolute objectivity, emphasizing the interpretative essence of reality and the recognition of subjectivity, values, and socio-cultural context in knowledge production.

- **Constructivism and interpretivism**

represent convergent streams of thought that challenge the notion of a single reality or truth, instead asserting that reality is subject to interpretation. They tend to favor the use of

qualitative methods to apprehend these multiple realities. Put simply, the nature of reality is determined by the subject and object of study, based on the intentionalist hypothesis that "the world is made of possibilities" that are not predefined. Although these two paradigms share similarities, they differ in certain aspects. Interpretivism emphasizes knowledge construction through initial understanding of facts followed by interpretation, while constructivism emphasizes active knowledge construction with the aim of achieving a specific objective. (BEDAIDA, 2024)

- **Interpretivism research philosophy**

The following table outlines the key principles and characteristics of the interpretivism approach, highlighting its focus on qualitative methods, the importance of context.

Table 3: Interpretivism Research Philosophy

Ontology (nature of really or being)	Epistemology (what constitutes acceptable knowledge)	Axiology (role of values)	Typical methods
Complex,rich Socially constructed through culture and language multiple meanings , interpretations , realities Flux of processes Experiences, practices.	Theories and concepts too simplistic. Focus on narratives, stories, perceptions and interpretations New understandings and worldviews as contribution	Value-bound research Researches are part of what is researched , subjective Researcher Interpretations key to contribution Researcher reflexive	Typically inductive. Small samples , in depth investigations , Qualitative methods of analysis , but a range of data can be interpreted

Source:(Husam Helmi Alharahsheh, 2020)

The table presents the interpretivism research philosophy, detailing its perspectives on ontology, epistemology, axiology, and typical methods. From an ontological standpoint, interpretivism perceives reality as complex and socially constructed, shaped by culture and language, allowing for multiple interpretations. Epistemologically, it challenges simplistic theories, focusing instead on narratives and perceptions to foster new understandings. In terms

of axiology, it recognizes the value-laden nature of research, with researchers' subjectivity and reflexivity being essential. Methodologically, interpretivism leans towards inductive reasoning, employing small sample sizes and qualitative analysis for comprehensive, in-depth investigations.

We have chosen the interpretive paradigm to address the research context, and this choice can be justified For several reasons.

-Interpretivism acknowledges the multifaceted nature of reality, recognizing that organizational processes and practices are socially constructed and influenced by various contextual factors. In conducting a diagnostic audit, we delve into the complexities of organizational systems, striving to comprehend factors contributing to non-conformities.

- Interpretivism values subjective interpretations and qualitative insights, which are crucial in uncovering the root causes of non-conformities and understanding the perspectives of stakeholders involved. By utilizing qualitative methods such as interviews, observations, and document analysis, we aim to capture the rich context surrounding non-conformities, allowing for a deeper understanding beyond mere compliance.

- Interpretivism emphasizes reflexivity and acknowledges the role of the researcher in shaping the research process. our commitment to critically reflecting on our own biases and assumptions throughout the audit process aligns with the interpretive approach, enhancing the credibility and validity of your findings.

Overall, this work adheres to the principles of interpretivism, recognizing the subjective nature of organizational realities and the importance of qualitative insights in uncovering meaningful insights.

2. Presentation of the research methodology:

2.1 The framework of the project:

To structure our work comprehensively and systematically, we utilized the 5W1H method, a well-established approach commonly used in problem-solving and situational analysis. This method enabled us to thoroughly address the critical questions of Who? What? Where? When? Why? and how?, ensuring a detailed and organized framework for our research.

The 5W1H method is based on the principles : if you don't ask, you won't find out" and "a problem well described is a problem half-solved." This technique is utilized for describing

and analyzing a given issue by systematically answering five key questions starting with W (What, Where, When, Who, Which) and one starting with H (How). (Knop & Mielczarek, 2018)

Table 4: The framework of the project

What	Implementing internal audit as part of the contribution of setting up a Quality Management System According to ISO 90001
Who	Integrated management system manager Consultant Expert Trainee
Where	INMAED , a Mediterranean Agro-food company
When	During our internship
How	In our work, we will adopt an action research (AR) approach, relying on interviews, observation, documentary analysis, and a checklist (ISO 9001). This approach has been deemed suitable for establishing an analytical framework and guiding the selection of research methods to be employed.
Why	An internal audit to evaluate the effectiveness of the QMS (Quality Management System). Through conducting an internal audit of the Quality Management System (QMS) following the guidelines of the 19011:2018 standard.

Source: elaborated by our care based on 5 W1H method .

2.2 Research methodology : Action research

To conduct a study, the researcher must carefully select and employ a precise, well-defined, and suitable methodology for the subject under study .

Research methods encompass all the techniques and procedures used to conduct research, whereas research methodology refers to the comprehensive approach used to address research problems. It is the study of how research is systematically conducted. In this context, the researcher outlines the various steps typically taken to investigate a research issue. Therefore, the scientific approach employed in conducting research is known as methodology (SHANTI & SHASHI, 2017)

In this dissertation, we gravitate toward action research as our study methodology, which is particularly relevant for improving our practices and generating new knowledge on our subject of study. This participatory and iterative method combines scientific research with practical action to solve concrete problems. By actively involving participants and repeating cycles of planning, action, observation, it ensures directly applicable and relevant solutions.

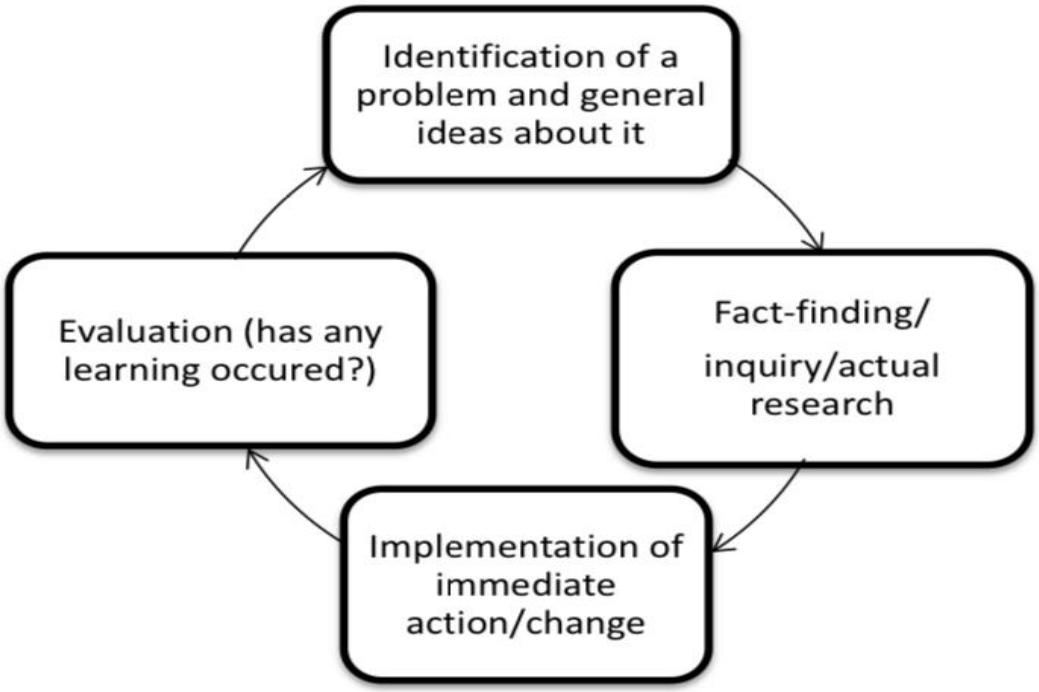
According to **Source spécifiée non valide.** « *the purpose of action research is not only to generate knowledge about a topic, but also enable individual and organizational development* »

Action research is a qualitative research approach aimed to solve a specific problem, actively involves researchers within businesses to address specific on-the-ground problemsIn addition to offering practical solutions, this approach aims to enrich the body of scientific knowledge. It relies on the voluntary action of a researcher in an organization that has accepted their intervention. (LAFFITTE, 2009)

(P, 2008) Suggest that action research is A participatory process aiming to acquire practical knowledge to achieve significant human goals. It aims to combine action and reflection, as well as theory and practice, in collaboration with others, to find concrete solutions to urgent challenges and, more broadly, to promote the flourishing of individuals and their communities.

In accordance with (SHANTI & SHASHI, 2017) «Qualitative research, is concerned with qualitative phenomenon, i.e., relating to quality or variety. Such type of research is typically descriptive and harder to analyze than quantitative data. Qualitative research involves looking in-depth at non-numerical data. It is more naturalistic or anthropological.»

Figure 4: A Cyclical action research process.



Source: Lewin,K (1951) Field Theory in social sciences ,Harper & Row ,New York

This figure above illustrates acyclical action research process. It starts with identifying a problem and forming initial ideas, followed by thorough investigation and data collection. The findings then guide the implementation of practical actions to address the issue. Finally, the outcomes are evaluated to assess effectiveness and gather lessons learned, often leading back to the problem identification phase, thus creating a continuous improvement loop.

We provide rationale for the selection of adopting a qualitative research-action methodology in our study as outlined below:

-It is pertinent to underscore our involvement in the ISO 9001 implementation and certification project at INAMED during our internship tenure.

-Qualitative studies provide insights into the determinants shaping individuals' opinions, their selection of practices, and their construal of the surrounding milieu. This qualitative approach yields nuanced perspectives often beyond the purview of quantitative inquiries, thus furnishing a more holistic and enlightened framework for prospective foresight.

- Numerous of articles previously mentioned in our literature review used the qualitative approach

- In our work, we employed various tools and methods for data collection, including observation, documentary analysis, interviews, and checklists. All these methods are integral parts of action research.

This will facilitate the comparative analysis between the operational procedures involved in conducting an internal audit and the stipulated guidelines outlined in the ISO 19011:2018 standard.

2.3 Data collection:

In this work, our emphasis lies in diagnosing the company's adherence to ISO 9001 standards, which are crucial for ensuring quality management and continuous improvement., we aim to first identify areas of non-conformance, followed by pinpointing areas for improvement. Subsequently, we offer effective recommendations to enhance overall quality and operational efficiency.. By systematically assessing compliance with ISO 9001 requirements we employ a range of tools to provide a comprehensive evaluation of the company's processes and performance including: document study, observation, interviews, and checklists. It is crucial to highlight that these methods have been thoughtfully chosen considering the subject under study and the specific context.

2.3.1 Documentary analysis:

In order to enhance the credibility of our work, we have adopted a documentary or bibliographic research approach. This involves consulting several types of existing internal documents of the host company (such as process sheets, procedures, and records), as well as ISO 9001 and ISO 19011 standards. This method helps us understand the existing context, identify gaps, and determine the best approach for our research. It can be used in conjunction with other research methods, such as interviews and observations.

2.3.2 Observation:

Observing involves voluntary attention and intelligence, guided by a final or organizing objective, and directed towards an object to gather information. (Jean & Xavier)

- **Participant observation:**

(Bernard, 1994) found that participant observation involves some degree of deception and impression management. He points out that most anthropologists must maintain objectivity by keeping a certain distance. Participant observation, he explains, is the process of building rapport within a community and learning to behave in a way that allows one to blend in, so that community members act naturally. Subsequently, the observer withdraws from the setting to analyze the data and gain a deeper understanding of the community, which they then document. This process encompasses more than just observation; it includes natural conversations, several types of interviews, checklists, questionnaires, and unobtrusive methods. Key characteristics of participant observation include maintaining an open, nonjudgmental attitude, having a genuine interest in learning about others, and being aware of the likelihood of experiencing culture shock and making mistakes, most of which can be overcome.

- **Participatory or direct observation:**

Direct observation involves collecting information through sensory perception, allowing for the documentation of activities, behaviors, and physical aspects of a situation without relying on people's willingness or accuracy in responding to questions. This method is particularly useful when understanding an ongoing process, behavior, or unfolding event, when there is visible physical evidence or outcomes, or when written or other data collection methods are deemed inappropriate.(How to plan and conduct direct observation)

During my internship, I had the opportunity to engage as a participant observer. This approach was chosen due to my presence in quality management system implementation project, providing me with the chance to conduct a diagnostic audit in collaboration with a consulting expert. Together, we identified non-conformities and gaps in each process, which facilitated a comprehensive understanding of the company's current state. Additionally, I participated in specific actions alongside a colleague as part of the quality management system implementation. This immersion enabled me to utilize a variety of data collection tools, including interviews, checklists, and questionnaires.

2.3.3 Interview:

«The interview is an important data gathering technique involving verbal communication between the researcher and the subject. Interviews are commonly used in survey designs and in exploratory and descriptive studies. There is a range of approaches to interviewing, from completely unstructured in which the subject is allowed to talk freely about whatever they wish, to highly structured in which the subject responses are limited to answering direct questions.» (Nigel, Nick, & Amanda, 2000)

In short the interview is a vital method for gathering data through verbal interaction between the researcher and the participant. It's widely employed in survey designs as well as exploratory and descriptive studies. Interviews can vary from completely unstructured, where the participant freely discusses any topic, to highly structured, where responses are restricted to specific questions.

There is three main types : structured , semi structured and unstructured

- **Types of interviews:**

There is three main types : structured , semi structured and unstructured (Nigel, Nick, & Amanda, 2000)

- **Unstructured or in depth interviews:**

Unstructured or in-depth interviews, also known as qualitative interviews, are termed this way because they lack a defined structure. The interviewer conducts the interview intending to explore a limited number of topics, sometimes only one or two, and formulates subsequent questions based on the interviewee's previous answers. Even though only one or two topics are addressed, they are examined in great depth

- **Semi-structured interviews:**

Semi-structured interviews are similar to structured interviews in that the topics or questions are planned. However, instead of closed questions, semi-structured interviews use open-ended questions.

These interviews are valuable for gathering attitudinal information on a large scale or when it is difficult to create a list of potential pre-codes due to limited knowledge about the subject area. Nevertheless, semi-structured interviews are more time-consuming than structured ones

because they require the development of coding frames and conducting content analysis on numerous interviews. Responses can be either tape-recorded or noted down by the interviewer.

❖ **Structured or standardized interviews:**

Structured interviews allow the interviewer to pose the same questions to each respondent in a consistent manner. Utilizing a rigidly structured schedule of questions, akin to a questionnaire, the approach is often intended to facilitate quantitative data analysis. In many structured interviews, not only are the questions predetermined, but so are the possible answer choices. Pre-coded responses are essential for enabling comparison across all respondents. Typically, all responses are recorded or written down on the questionnaire. By minimizing open-ended responses, the time required for coding and content analysis is significantly reduced, and often the data can be directly entered into a computer for analysis.

❖ **Research Sample:**

In a qualitative approach, the sampling method relies on the rigorous selection of groups of representative elements linked to the research objectives, ensuring the acquisition of relevant and reliable responses. In the context of our study, we deliberately chose a sample composed of process drivers, considered key actors directly involved in the operational management of activities. This selection aims to gather comprehensive and pertinent data on the implementation of quality practices within the organization. I opted for a semi-directive interview approach to foster in-depth and targeted exchanges on opinions, motivations, and quality-related practices with the process drivers. Details regarding the participants as well as the interview schedule are listed in the table below.

Figure 5: ***the interviewed actors***

N :	Interviewee	Function	Date	Duration ofthe interview
1	I.H	Procurement and supply chain manager	March 31, 2024	45 min
2	Y.A.M	quality controller	April 1, 2024	30min
3	D.B	commercial manager	March 31, 2024	30 min
4	Z.B	Human Resources Director	April 4 , 2024	30 min
5	M.B	Industrial Director	April 4 , 2024	45 min

Source : elaborated by our care .

2.4 The Data collection tools :

2.4.1 Check-list:

The initial phase of our quality management system is conducting an internal audit. This step is of paramount importance as it will facilitate the implementation , Concurrently, we must adhere to the requirements of the ISO 9001 standard, thereby enabling the identification of non-conformities and detect deviations from specified requirements or customer expectations. To accomplish this, we will develop a checklist encompassing the relevant requirements of this standard, which must be met in accordance with specified requirements or customer expectations. The check-list see appendix 3

2.4.2 Observation grid:

An observation grid is a structured tool used in research and evaluation to systematically record and categorize observations of behaviours, events, or phenomena in the work place . It

helps ensure consistent data collection by providing predefined criteria and categories for observers to use when noting their observations. During our internship period, we developed an observation grid to systematically document our observations over the three months at INAMED **.**

2.4.3 Interview Guide:

We intend to conduct five interviews, during which we will pose specific questions regarding the stakeholders, their needs and expectations, as well as an assessment of their power and interest. These interviews are designed to meet the requirements of ISO 9001, chapter 4.2. The interview guide we have developed aims to collect information on factors that may influence the attainment of objectives for each process, in compliance with the requirements of ISO 9001, chapter 4.1. **(see Appendix9).**

2.4.4 The self-assessment grid ISO 9001 :

The ISO 9001 grid , developed in Excel and based on an evolution scale , allows for assessing the conformity rate to new requirements and effectively detecting critical items within INAMEDs quality management system .

2.5 Analysis method:

The information gathered through interviews, observation, and documentary analysis has allowed us to identify the stakeholders of INAMED, as well as their power and interests.

- **Table of The interested parties :**

We've updated a table listing the stakeholders of INAMED, their needs, interests, and evaluated the power of each stakeholder.

Section 02: Organizational Context.

1. Presentation of the company INAMED:

1.1 History of the company

INAMED was founded in 1998 by FERRADJI family and several other shareholders. The company, originally known as YOPI MILK, made its market debut with a "La Délicieuse" production line, a "Ferlait" milk and leben production line, and a "SUNNY DRINK" fruit juice production unit.

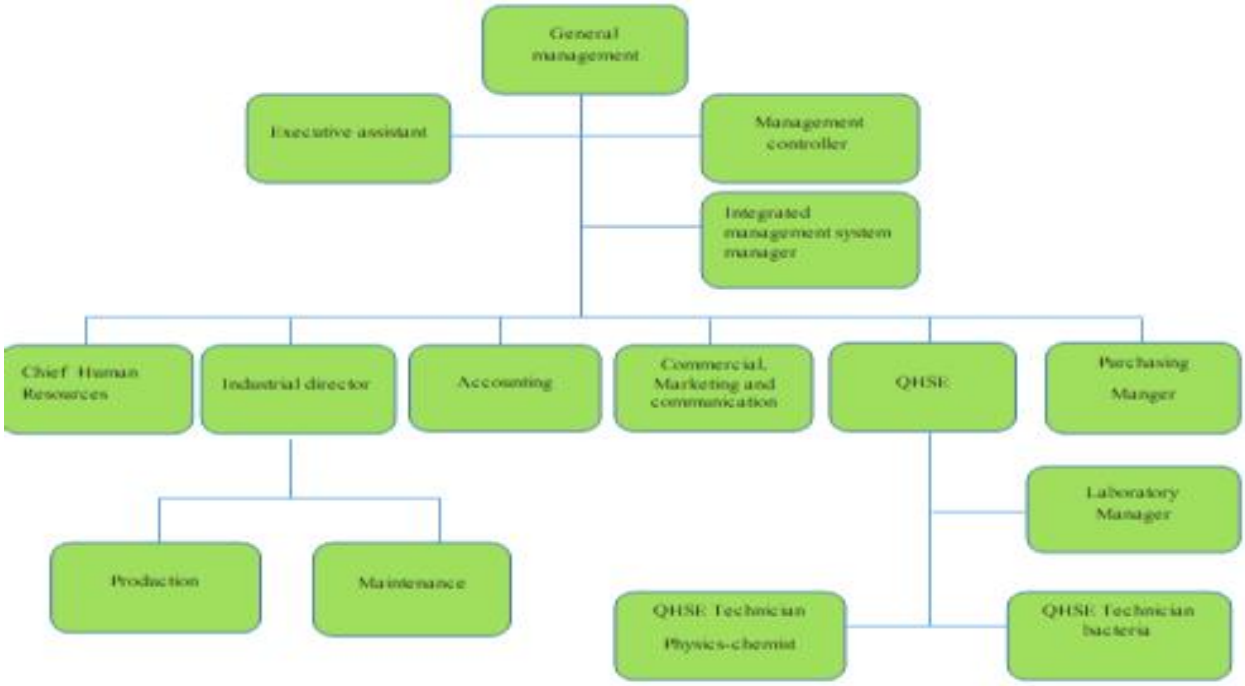
- In 2008, Mr. FERRADJI El-Hachemi acquired 100% of the shares in YOP MILK, and appointed an external manager to manage the company.
- In 2012, and on retiring so many years of experience, the manager handed over his position to Ms. Ferradji Amira, who joined the company with the one sole aim of developing, modernizing, and ensuring the growth of this business.

Today, members of the FERRADJI family have assumed the management of INAMED and are determined to ensure the transition to a modern, profitable operation in every aspect, and to optimize the company's resources to take advantage of major market opportunities.Furthermore, they agreed to include milk production in their new investments, to launch soft drinks, and to diversify away from their competitors by offering new products in high demand on the national market, particularly tomato sauce, classic white sauce (bechamel sauce), sour cream and liquid cream (fastmovers),

- In addition, and with a view to growing the Group and optimizing INAMED's costs, it was decided to enter a second phase, in partnership with SH Biogeaud, in production of fruit and vegetable concentrates. The aim was to expand the unit vertically, thereby integrating the entire business process for better cost and quality control

2. Organizational chart:

Figure 6: Organizational chart



Source: Internal document

This organizational chart illustrates a hierarchical structure with the General Management at the top, supported by an Executive Assistant, Management Controller, and Integrated Management System Manager. Below them are key functional areas including Chief Human Resources, Industrial Director, Accounting, Commercial/Marketing/Communication, QHSE (Quality, Health, Safety, and Environment Maintenance, while the QHSE manages QHSE Technicians specializing in Physicochemical and), and Purchasing Manager. The Chief Human Resources oversees Production and Bacteria analysis. The Purchasing Manager supervises the Laboratory Manager. Each role supports the company's overall objectives, ensuring effective coordination and communication across departments.

3. Corporate profile:

Table 5: Identity card

Name	**INAMED**
Logo	
Creation Date	1998
activity	Food and Beverage
Legal status	Limited liability company
Address	Kolea –Tipaza
Number of employees	55
Share capital	70.000.000 DZD
Executives	FERRADJI Sif-Eddine , FERRADJI Amira , FERRADJI Slim
Phone number	23550118
Email	Sconso@inamed-dz.com
Web site	https://inamed-dz.com

Source: elaborated by our care based on internal document

4. Values, and objectives:

4.1 Values:

- **Excellence**

Quality is a priority at **INAMED**. Respecting the current production and manufacturing standards is a matter of honour. Respecting the environment and our consumers' health is paramount in making our decisions.

This value is reflected in the rigorous choice of our equipment and our raw materials. We are committed to being a company of excellence to guarantee the best quality-price ratio.

Taste, easy use, nutritional value and various other features are gradually studied to satisfy our customers.

Taste, ease of use, nutritional value and many other aspects are studied step by step for the pleasure of our consumers.

- **Commitment**

As a family-owned company, **INAMED** invests highly in its lucrative and non-lucrative projects. Creating wealth is one of the group's existence priorities. Its management policy relies on all its employees' career evolution. Every new employee is important, and we make, by all means, their integration comfortable. We also look after their actualization, because we honestly believe that a happy employee is a successful employee.

Trust, Loyalty, integrity, transparency and tolerance are the columns on which lean our professional relationships with our stakeholders (partners, costumers, and collaborators).

- **Authenticity**

INAMED has always been faithful to its values that are reflected in all its services and products. We are not just industrialists, but real partners who listen constantly to consumers. That's why all our strategies are set carefully to provide reliable solutions and a better lifestyle.

Distinctive brands, flawless availability and healthy recipes are the highlights of our products. Our secret? We are close to our customers and we know their tastes!

- **Innovation**

Innovation is a key word of our policy. We are always seeking perfection. To innovate means to improve something and we aim to improve the way you eat! That's why we invest in the best in-service training programs that our partners can benefit from. That learning keeps them up to date and make them always surprise you with recipes as original as each other.

42 bjectives:

- Make tasty recipes in the respect of oneself, of people and of life in general.
- Secure food balance for all citizens: parents who are concerned by their children' food, athletes who wish to improve their performances, or seniors who wish to grow old healthily.
- Diversify the local market by introducing "made in bladi" products that are in no way inferior to the imported ones.

5. INAMED Products & BRANDS:

INAMED strive to meet the needs of its client, through quality produced products and beverages. Here we present the proposed products.

Table 6: INAMED Products & BRAND*S*

	El-Boustene	Tomato Sauce	
		Pizza Sauce	
		classic white sauce	
		(Bechamel)	
	Kidoo	Kidoo Potes	applesauce
			Pear-apple Compote
			apple-apricot compote
			Orange
		P 'tit Kidoo	Cocktail
			Chocolate milk
	Fakya	Sary	Orange
			Cocktail

Source: elaborated by our care based on INAMEDs website.

CONCLUSION:

The present chapter is divided in two main sections, in the first one we have detailed the research methodology employed to investigate the research problem, emphasizing the use of action research within the context of quality management systems. By utilizing a qualitative approach, The integration of various data collection methods, including observation, interviews, documentary analysis, and checklists. This methodological rigor not only ensures the validity and reliability of our findings but also enhances the practical applicability of our recommendations.

The second section highlights a general presentation of company case of study, objectives and values. By presenting INAMED identity card, organizational chart, brands and products.

CHAPTER 3: RESULTS& DISCUSSION

During our internship at INAMED, we conducted an internal audit approach in collaboration with a consulting expert to conduct a comprehensive evaluation of the company's quality management system. The audit aimed to assess the system's effectiveness and its level of implementation within the company, in accordance with the requirements of the ISO 9001 standard. This international standard is essential for ensuring that the company's products and services consistently meet customer expectations and regulatory requirements.

The audit included an exhaustive evaluation of all quality-related processes and procedures, from resource management to production, including staff training and customer satisfaction. We worked with the consulting expert to analyze the existing documentation, quality records, to identify strengths and areas needing improvement.

This phase is crucial for identifying gaps between the company's current practices and the requirements of the ISO 9001 standard. The audit results will enable the development of a precise action plan to address non-conformities and strengthen the quality management system.

Section 01: Conducting the Internal audit of the company INAMED

1. Internal audit Action plan:

we outline the proposed action plan for conducting an effective and thorough internal audit. The purpose of this plan is to ensure a comprehensive evaluation of the organization's internal controls, risk management processes, and governance structures. By detailing the steps and strategies involved, this action plan aims to provide a clear roadmap for achieving audit objectives, identifying areas for improvement, and enhancing overall operational efficiency. This systematic approach will facilitate the identification of potential issues, the implementation of corrective measures, and the continuous improvement of internal processes.

Table *7*: Internal Audit Action plan

Step	Action Description	Responsible	Deadline
1	Audit preparation	Audit team leader	06/03/2024
2	Information collection	Audit team members	06/03/2024
3	Analysis of collected information	Analysis team	06/03/2024
4	Planning meeting	Audit team leader and stakeholders	06/03/2024
5	Defining audit objectives and criteria	Audit team leader	06/03/2024
6	Development of audit plan	Audit team	07/03 /2024
7	Review and approval of audit plan	Audit team leader and stakeholders	07/03/2024
8	Implementation of on-site audit	Audit team	07/03 /2024
9	Collection and analysis of audit results	Audit team	07/03/2024
10	Drafting the audit report	Audit team leader	11/03/2024
11	Review and approval of the audit report	stakeholders	11/03/2024
12	Distribution of the final audit report	AUDIT team leader	11/03/2024

Source : elaborated by our care .

In this section, we implemented our action plan, as outlined in the previous table, to contribute to the completion of an internal audit within the company " INAMED", with the aim of auditing the quality management system .

1.1 Managing an audit programme:

The first step entailed the integrated management manager contacting the audit expert to schedule the audit date. Following this, we worked together with Expert Consulting to establish a schedule, covering: objectives of the audit program; scope ; schedule; types of

audits; audit criteria; methods to be employed during the audit; and relevant documented information. **SeeAppendix1**

❖ **The objectives of this audit were:**

- Ensure the management system meets all audit standard requirements.
- Verify the organization has effectively implemented its planned arrangements.
- Confirm the management system can achieve the organization's policy objectives.
- Audit the management system documentation
- Review the scope of application
- Identify non-conformities, positive points, and opportunities for improvement

Upon approval of the audit plan by the manager of INAMED, the Integrated Management Officer (RMI) transmitted it via email to all process pilots to inform them and enable them to prepare adequately. Additionally, the expert, in collaboration with our team, conducted a thorough review of the documentation related to each audited process. This documentation included quality policies, process sheets, operational procedures and any relevant documents. This process aimed to ensure that each process complied with the requirements of the quality management system. See Appendix 1

Acquire an understanding of the organization's context, its environment, the socioeconomic framework, the system's parameters, and the profession's characteristics.

1.2 The opening meeting:

The opening meeting, chaired by the consulting expert, took place as scheduled on March 7, 2024, at 8:30 AM. It was attended by INAMED manager and all process leaders and lasted for 30 minutes. The meeting was conducted under favorable conditions. Expert Consulting facilitated the meeting, adhering to the audit plan to outline the program's procedures. During the meeting, the audit objectives were presented, and the scope and criteria of the audit were clarified. Additionally, the schedule and responsibilities of each participant were defined. Both auditors and auditees also discussed communication methods and any potential logistical constraints.

Held at the mission site, involves the following participants:

- The manager of the audited entity
- The audit team
- Trainee
- The points to be addressed during this meeting are as follows:
- Introduce the auditors, their experience, their roles
- Request a representative to introduce the audited individuals and their roles
- Recap the scope and objectives of the audit
- Outline the audit process: presentation of the audit plan, methods, communication channels
- Office location, working hours, phone line.
- Determine and agree what office facilities are available and normal working hours.

1.3 Conducting of Internal Audit :

The opening meeting is followed by conducting interviews with the auditees . For collecting objective evidence and evaluating non-conformities in INAMED's processes. We interview employees at various levels and examine relevant documents to ensure compliance with the ISO 9001 standard. The aim is to identify gaps between the defined processes and best practices.

1.4 Conducting Interviews:

The utilized methodologies included interviews, activity observation, and documentation and records review. The audit structure adhered to the attached audit plan see appendix .The auditor commenced the interview by requesting the auditee to outline their activities within INAMED to understand the processes and guide questions towards specific points, all while documenting the discussion .We reviewed and analyzed process sheets and activity reports. The concluding step involved analyzing the audit findings and discussing them with the auditee, backed by evidence, with the goal of evaluating the effectiveness of the process for identifying non-conformities, risks, and opportunities related to the objectives.During the internal audit, we meticulously observed the conduct of activities, the work environment, and the working conditions. We also paid particular attention to the relationships between process managers, the interactions between different processes, and the communication tools utilized. Additionally, we examined the methods

of information sharing and display to ensure clear and effective understanding among all team members.

1.5 Conducting closing meeting :

The auditor held the closing meeting in adherence to the predetermined schedule outlined in the audit plan, with the attendance of all participants who duly signed an attendance record . Within this forum, the auditor provided an overview of the audit's progression, commencing with expressions of gratitude towards all attendees for their invaluable contributions. Subsequently, a comprehensive recapitulation of the audit's objectives, criteria, and scope was delivered, supplemented by elucidations on identified instances of non-conformance. The auditor inform to formulate a corrective and preventive action plan to address all identified non-conformities. Subsequently, a conclusion was delivered. action plan aimed at rectifying all identified non-conformities. Finally, the session culminated in the presentation of conclusive remarks.

The Lead Auditor has also conveyed to the auditees and other participants that the audit report will be issued on 11/03/2024.

- **Positive observations of QMS in INAMED :**

  - A highly engaged employees
  - The company demonstrates exemplary proficiency in the marketing of its products.
  - Well managed horizontal diversification
  - Products offered of better quality.
  - Significant investment has been made in the automation of production machinery.

- **Audit findings:**

  1. 01 major non-conformity
  2. 06 minor non-conformities
  3. NA minor/major non-conformities unresolved from the previous audit.

1.6 Preparing and distributing audit report:

- **Preparing audit report:**

The audit team leader reported the audit conclusions in accordance with the audit plan. The report contains a comprehensive record of the audit, encompassing details such as the audit objectives, scope (particularly the identification of the organization, INAMED, and the audited functions or processes), audit team and auditee participants, dates and locations of audit activities, audit criteria, findings, evidence, and conclusions. It also includes a statement on the degree to which the audit criteria have been fulfilled, a summary of audit conclusions, main findings supporting them, and any identified good practices. a clear description of identified non-conformities supported by formal evidence referencing relevant documents and standards chapters and corrective Actions. Appendix 2

- **Distributing audit report:**

After preparing the audit report and ensuring the accuracy of findings, it was carefully reviewed to ensure it encapsulated all relevant observations and recommendations. Following this thorough review process, the report was officially distributed on the agreed-upon date of 10/03/2024 A copy of this audit report was sent to the Integrated management system .

1.7 Conducting audit follow-up:

The outcome of the audit, as outlined in ISO 19011, was based on its objectives in INAMED, where the aim was to conduct an internal audit as a diagnostic tool for assessing the current situation. Upon completing the audit, the report indicated the need for corrections, corrective actions, and opportunities for improvement. Therefore, we developed an action plan to address the non-conformities identified. It is worth mentioning that we diagrammed the results of our audit report using a self-assessment grid recommended by the auditor, in compliance with the requirements of the ISO 9001:2015 standard. Additionally, we managed and addressed the audit findings through non-conformity forms to identify root causes and propose corrective actions. Finally, we created a tracking table for non-conformities to ensure traceability of reported issues.

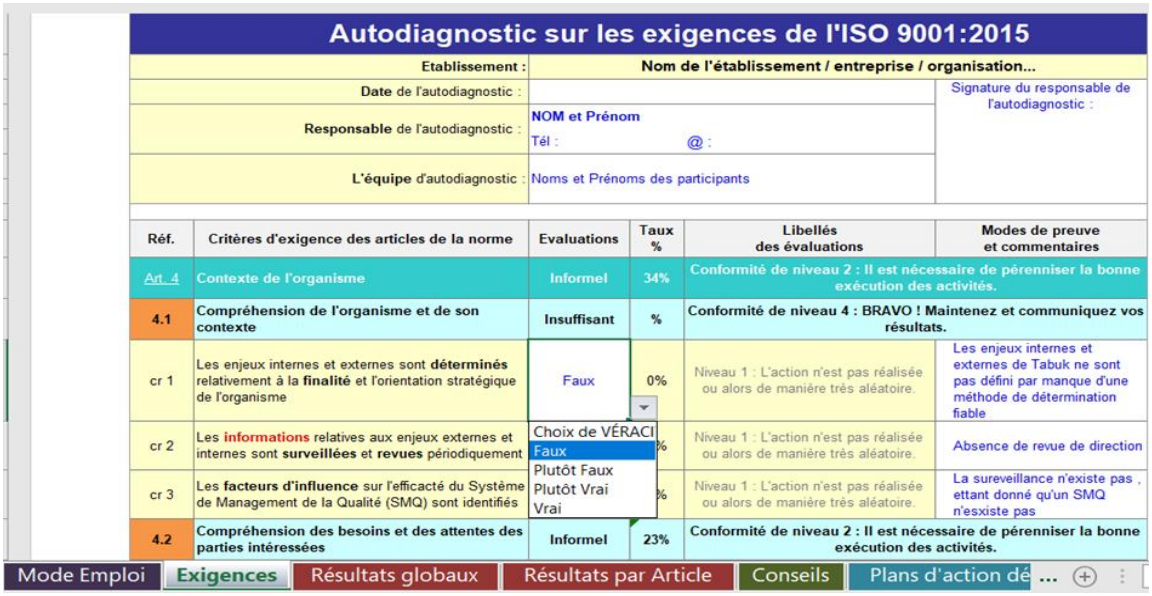
Section 2 : Audit Report Analysis and monitoring of results :

1. Audit Report Analysis:

As we analyze our audit report at INAMED, this process will assist us in assessing the Quality Management System within INAMED. Additionally, this analysis will enable us to identify the processes exhibiting the highest number of non-conformities, allowing us to devise an action plan to address these issues and improve the QMS.

Using the grid allow us to evaluate conformity to requirements and detect non-conformities. It also contains the standard's requirements reformulated and classified into articles and sub-articles. For each sub-article, a level of conformity is provided, including the following propositions: false, rather false, rather true. Consequently, the overall results of each are presented in the form of a radar diagram, representing the level of conformity of the articles to the requirements of the ISO 9001 standard.

The table below illustrates the correspondence between levels of truthfulness and levels of compliance.



Autodiagnostic sur les exigences de l'ISO 9001:2015

Etablissement :	**Nom de l'établissement / entreprise / organisation...**				
Date de l'autodiagnostic :					Signature du responsable de l'autodiagnostic :
Responsable de l'autodiagnostic :	**NOM et Prénom** Tél : @ :				
L'équipe d'autodiagnostic :	Noms et Prénoms des participants				
Réf.	**Critères d'exigence des articles de la norme**	**Evaluations**	**Taux %**	**Libellés des évaluations**	**Modes de preuve et commentaires**
Art. 4	**Contexte de l'organisme**	**Informel**	**34%**	**Conformité de niveau 2 : Il est nécessaire de pérenniser la bonne exécution des activités.**	
4.1	**Compréhension de l'organisme et de son contexte**	**Insuffisant**	**%**	**Conformité de niveau 4 : BRAVO ! Maintenez et communiquez vos résultats.**	
cr 1	Les enjeux internes et externes sont **déterminés** relativement à la **finalité** et l'orientation stratégique de l'organisme	Faux	0%	Niveau 1 : L'action n'est pas réalisée ou alors de manière très aléatoire.	Les enjeux internes et externes de Tabuk ne sont pas défini par manque d'une méthode de détermination fiable
cr 2	Les **informations** relatives aux enjeux externes et internes sont **surveillées** et **revues** périodiquement	Choix de VÉRACI Faux Plutôt Faux Plutôt Vrai Vrai	%	Niveau 1 : L'action n'est pas réalisée ou alors de manière très aléatoire.	Absence de revue de direction
cr 3	Les **facteurs d'influence** sur l'efficacté du Système de Management de la Qualité (SMQ) sont identifiés		%	Niveau 1 : L'action n'est pas réalisée ou alors de manière très aléatoire.	La sureveillance n'existe pas , ettant donné qu'un SMQ n'esxiste pas
4.2	**Compréhension des besoins et des attentes des parties intéressées**	**Informel**	**23%**	**Conformité de niveau 2 : Il est nécessaire de pérenniser la bonne exécution des activités.**	

Mode Emploi | Exigences | Résultats globaux | Résultats par Article | Conseils | Plans d'action dé ...

Source : elaborated by our care.

Table 8: The evaluation scale

False	Insufficient
Rather false	Informal
Rather true	Convincing
True	Complint

Source : ISO 9001 self-assessment grid

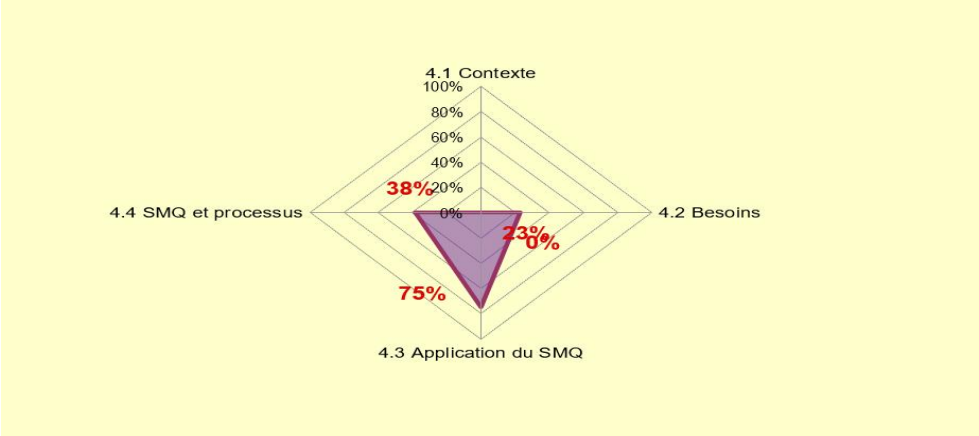
1.2 Audit results :

1.2.1 Results by chapter :

After conducting a audit of the quality management system in collaboration with expert consultants within LLB INAMED and compiling a comprehensive audit report, we proceeded to conduct a detailed evaluation of each chapter of the ISO 9001 standard. This evaluation enabled us to determine the level of compliance and the degree of performance of the company in quality management. For each chapter and sub-chapter, we accurately calculated the level and rate of compliance. The results of this evaluation were presented in the form of radar diagrams, created from the ISO 9001 self-assessment grid. All the detailed results see appendix 3

A. Chapter 04: Context of the organization

Figure 7: Presents the results of Chapter 4



Source : Developed by our care based on the self-assessment grid

The figure represents a radar chart illustrating the compliance rates for four sub-chapters of Chapter 4 of the ISO 9001:2015 standard within a company. The four axes of the chart are:

1. **Context (4.1)** - with a compliance rate of 0%
2. **Needs (4.2)** - with a compliance rate of 23%
3. **Application of QMS (4.3)** - with a compliance rate of 75%
4. **QMS and processes (4.4)** - with a compliance rate of 38%

- **Comments on the figure:**

Context (4.1):

The compliance rate is 0%, indicating significant gaps in understanding and integrating the organizational context into the Quality Management System (QMS). This means the company has failed to identify or analyze the internal and external factors that could influence its QMS, a key requirement of ISO 9001:2015.

Needs (4.2):

The compliance rate is 23%, showing that the company needs to better understand and meet the needs and expectations of interested parties. Improving the processes for collecting and analyzing customer and stakeholder needs is essential to increase this compliance rate.

Application of QMS (4.3):

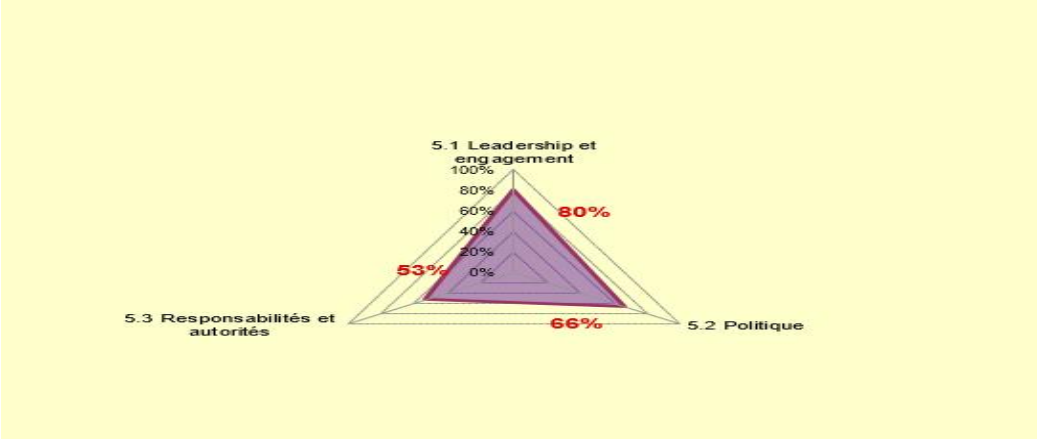
The compliance rate is 75%, the highest among the evaluated sections. This indicates that the company has relatively strong practices for applying the QMS. However, there is still room for improvement to achieve full compliance.

QMS and processes (4.4):

The compliance rate is 38%, suggesting moderate difficulties in establishing and maintaining QMS processes. These processes need optimization and better structuring to be more effective and contribute better to overall quality.

B. Chapter 05: Leadership

Figure 8: Presents the results of Chapter 5



Source: Developed byour care based on the self-assessment grid

The figure represents a radar chart illustrating the compliance rates for three sections of Chapter 5 of the ISO 9001:2015 standard within a company. The three axes of the chartare:

1. **Leadership and commitment (5.1)** - with a compliance rate of 80%
2. **Policy (5.2)** - with a compliance rate of 66%
3. **Responsibilities and authorities (5.3)** - with a compliance rate of 53%

- **Comments on the figure**:

1. **Leadership and commitment (5.1)**:

The compliance rate is 80%, which is relatively high. This indicates that the company has implemented strong practices in leadership and commitment according to ISO 9001:2015 requirements. This means the management is actively engaged in the quality management system and plays a key role in promoting and continuously improving it.

2. **Policy (5.2)**:

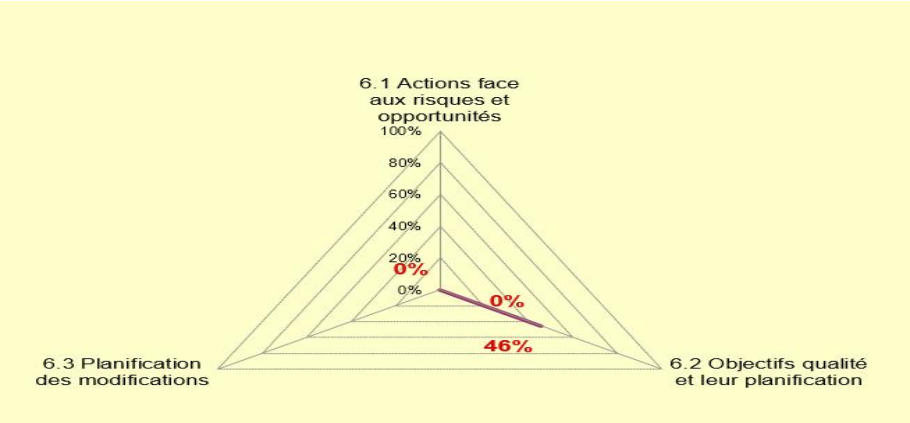
The compliance rate is 66%, showing that the company meets most of the quality policy requirements but still has areas to improve. This might involve better communication of the quality policy, greater employee involvement in its implementation, or adjustments to align the policy with the company's strategic objectives.

3. **Responsibilities and authorities (5.3)**:

The compliance rate is 53%, the lowest among the three evaluated sections. This indicates significant gaps in defining and assigning responsibilities and authorities within the company. To improve this rate, the company should clarify employee roles and responsibilities, ensure these roles are well understood, and delegate the necessary authority to manage quality processes effectively.

C. **Chapter 06: Planning**

Figure 9 : presents the results of Chapter 6



Source: Developed by ourcare based on the self-assessment grid

The figure represents a radar chart illustrating the compliance rates for three sections of Chapter 6 of the ISO 9001:2015 standard within a company. The three axes of the chartare:

1. **Actions to address risks and opportunities (6.1)** - with a compliance rate of 0%
2. **Quality objectives and planning to achieve them (6.2)** - with a compliance rate of 46%
3. **Planning of changes (6.3)** - with a compliance rate of 0%

➢ **Comments on the figure**:

1. **Actions to address risks and opportunities (6.1)**:

The compliance rate is 0%, indicating that the company has not implemented the necessary actions to identify, assess, and address risks and opportunities. This is a critical gap because managing risks and opportunities is essential for ensuring the sustainability and continuous improvement of the Quality Management System (QMS).

2. **Quality objectives and planning to achieve them (6.2)**:

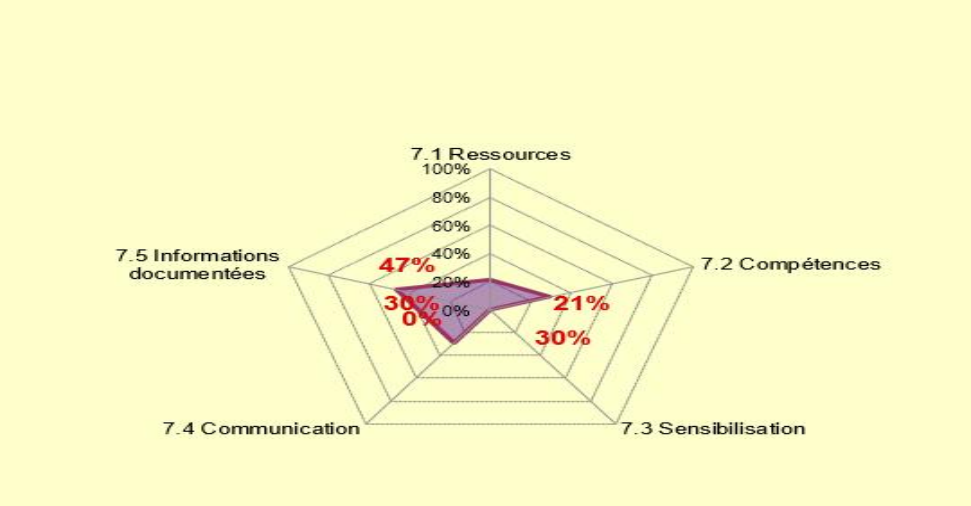
The compliance rate is 46%, showing that the company has partially established and planned its quality objectives. While there are efforts in this direction, improvements are needed to ensure the quality objectives are clearly defined, measurable, achievable, relevant, and time-bound. This alignment will help the company better achieve its strategic quality objectives.

3. **Planning of changes (6.3)**:

The compliance rate is 0%, revealing that the company does not effectively plan changes. Proper change planning is crucial to ensure that any changes are well-thought-out, coordinated, and implemented to minimize risks and maximize benefits. Lack of change planning can lead to disruptions and a decline in product or service quality.

D. **Chapter 07:** Support

Figure 10: presents the results of Chapter 7



Source: Developed by ourcare based on the self-assessment grid

The following figure represents a radar chart illustrating the compliance rates for five sections of Chapter 7 of the ISO 9001:2015 standard within a company. The evaluated sections and their compliance rates are as follows:

1. **Resources (7.1)** - with a compliance rate of 21%
2. **Competence (7.2)** - with a compliance rate of 30%

3. **Awareness (7.3)** - with a compliance rate of 0%
4. **Communication (7.4)** - with a compliance rate of 30%
5. **Documented information (7.5)** - with a compliance rate of 47%

- **Comments on the figure**:

1. **Support and resources (7.1)**:

The compliance rate is 21%, indicating that the company needs to make significant efforts to ensure that the necessary resources (human resources, infrastructure, work environment, monitoring and measuring resources) are adequately identified and provided. Improving this section is essential for the company to operate effectively and achieve its quality objectives.

2. **Competence (7.2)**:

The compliance rate is 30%, indicating that the company needs to improve the management of employee competencies. It is crucial to identify competency needs, adequately train personnel, and maintain appropriate competency levels to ensure the quality of products or services.

3. **Awareness (7.3)**:

The compliance rate is 0%, revealing that the company has not implemented effective measures to raise employee awareness about the importance of their contribution to quality and the objectives of the QMS. Awareness is essential to ensure that all personnel are aligned and motivated to achieve quality objectives.

4. **Communication (7.4)**:

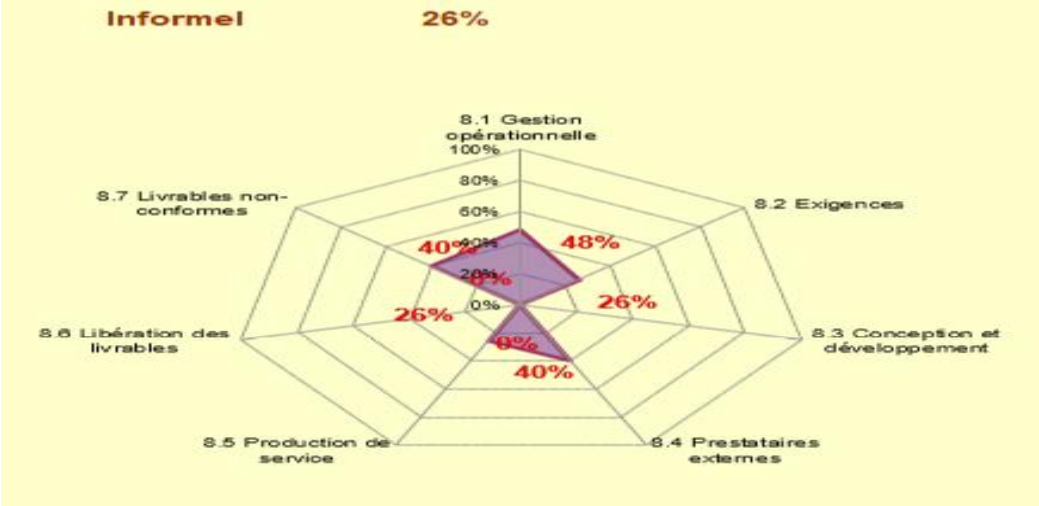
The compliance rate is 30%, showing that there are gaps in internal and external communication within the company. Effective communication is vital to ensure that relevant QMS information is exchanged in a timely and appropriate manner.

5. **Documented information (7.5)**:

The compliance rate is 47%, the highest among the evaluated sections. While this rate is relatively better, it still indicates that improvements are needed in managing documented information, including the creation, updating, control, and distribution of documents and records relevant to the QMS.

E. Chapter 08: Operation

***Figure* 11: presents the results of Chapter 8**



Source: Developed by ourcare based on the self-assessment grid

The following figure represents a radar chart illustrating the compliance rates for five sections of Chapter 8 of the ISO 9001:2015 standard within a company. The evaluated sections and their compliance rates are as follows:

1. **Planning and operational control (8.1)**:

The compliance rate is 48%, showing that the company has relatively solid planning and operational control practices in place, but there are still improvements needed to fully comply with the requirements of ISO 9001:2015.

2. **Requirements for products and services (8.2)**:

The compliance rate is 26%, indicating that the company needs to improve its processes for determining, understanding, and meeting customer requirements for products and

services. Effective processes are necessary to correctly capture customer requirements and ensure their satisfaction.

3. **Control of externally provided processes, products, and services (8.4)**:

The compliance rate is 40%, indicating that the company has practices in place to control the contributions of external providers, but there is still room for improvement in managing these external processes.

4. **Production and service provision (8.5)**:

The compliance rate is 26%, showing that the company needs to improve its production and service provision processes to ensure that products and services meet specified requirements.

5. **Release of products and services (8.6)**:

The compliance rate is 0%, revealing major weaknesses in the final control of products and services before delivery to the customer. It is crucial for the company to implement rigorous procedures to verify that all products and services meet requirements before their release.

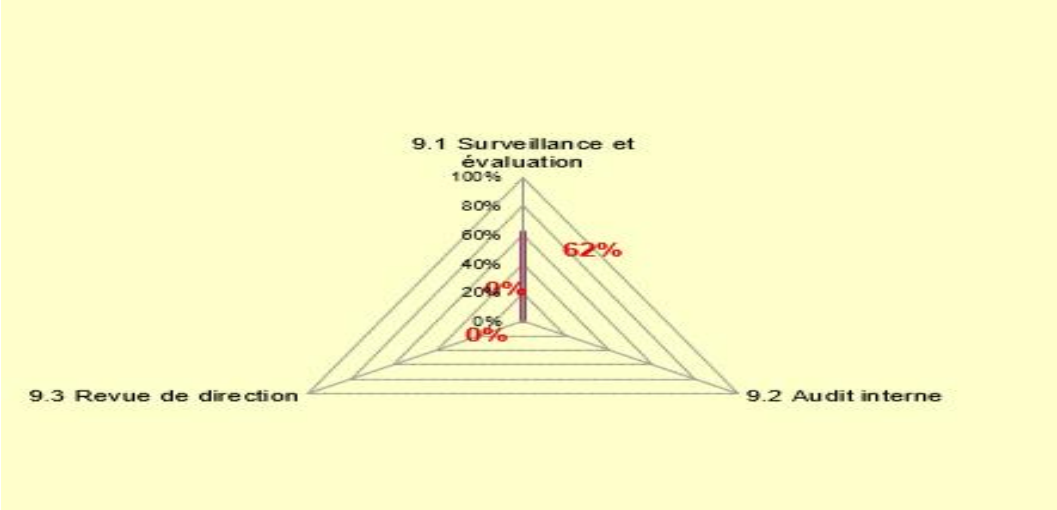
6. **Control of nonconforming outputs (8.7)**:

The compliance rate is 40%, showing that the company has practices in place to control nonconforming products and services, but there are still opportunities for improvement to ensure effective management of nonconformities.

Note: Sub-chapter 8.3 is excluded because INAMED does not engage in design activities

F. Chapter 9: Performance Evaluation

Figure 12: presents the results of Chapter 9



Source: Developed by ourcare based on the self-assessment grid

The following figure represents a radar chart illustrating the compliance rates for the sections of Chapter 9 of the ISO 9001:2015 standard within the company. The evaluated sections and their compliance rates are as follows:

1. **Performance evaluation (9.1)** - with a compliance rate of 62%
2. **Internal audit (9.2)** - with a compliance rate of 0%
3. **Management review (9.3)** - with a compliance rate of 0%

- **Comments on the figure**:

1. **Monitoring, measurement, analysis, and evaluation (9.1)**:

The compliance rate is 62%, indicating that the company has relatively solid practices in place for monitoring, measurement, analysis, and evaluation. However, improvements are needed to achieve full compliance with the requirements of ISO 9001:2015. This section is crucial to ensure that processes are effective and that quality objectives are met.

2. **Internal audit (9.2)**:

The compliance rate is 0%, revealing critical gaps in conducting internal audits. Internal audits are essential for evaluating the effectiveness of the quality management system

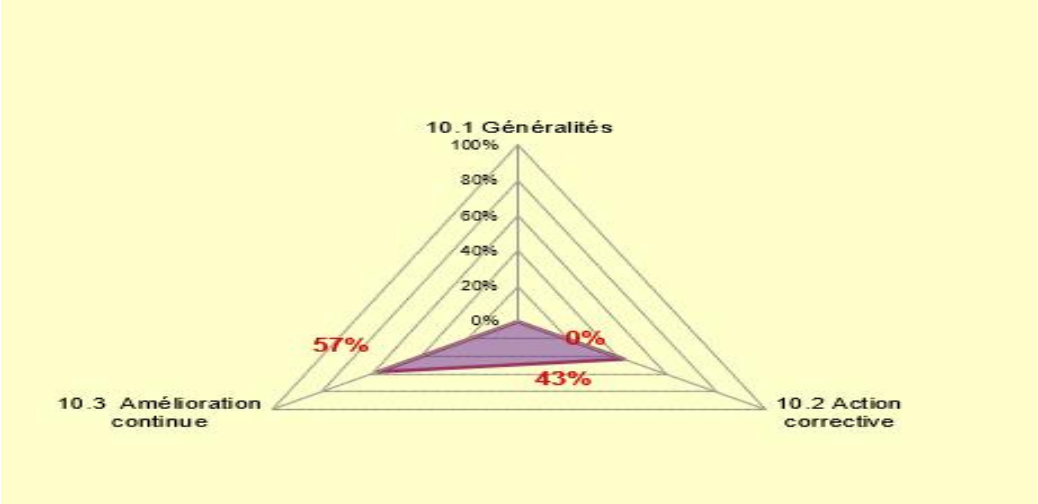
(QMS) and identifying areas needing improvement. It is imperative for the company to implement a regular and systematic internal audit program.

3. **Management review (9.3)**:

The compliance rate is 0%, indicating that the company has not established an effective process for management review. Management review is a key requirement of ISO 9001:2015, as it ensures that the QMS remains relevant, adequate, and effective. Regular management review meetings are necessary to assess the QMS performance and make data-driven decisions.

G. **Chapter 10: Improvement**

Figure 13: presents the results of Chapter 10



Source: Developed by ourcare based on the self-assessment grid

The following figure represents a radar chart illustrating the compliance rates for the sections of Chapter 10 of the ISO 9001:2015 standard within the company. The evaluated sections and their compliance rates are as follows:

1. **General (10.1) -** with a compliance rate of 0%
2. **Nonconformity and corrective actions (10.2) -** with a compliance rate of 43%
3. **Improvement (10.3) -** with a compliance rate of 57%.

- **Comments on the figure**:

1. **General (10.1)**:

The compliance rate is 0%, indicating that the company has not implemented an effective process for continuous improvement. This section is essential to ensure that the quality management system (QMS) constantly evolves to better meet requirements and expectations. The company must establish regular evaluation and improvement practices to identify optimization opportunities.

2. **Nonconformity and corrective actions (10.2)**:

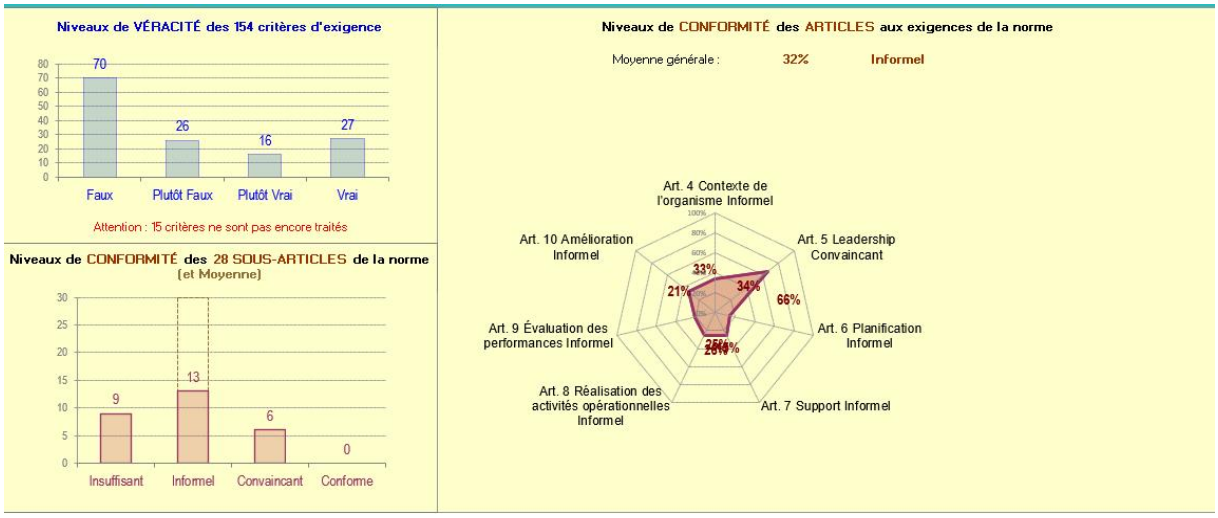
The compliance rate is 43%, indicating that the company has practices in place to manage nonconformities and corrective actions, but there is still room for improvement. It is crucial to have a rigorous system to identify, document, and address nonconformities to prevent their recurrence.

3. **Improvement (10.3)**:

The compliance rate is 57%, showing that the company has relatively effective improvement processes in place. However, additional efforts are necessary to achieve full compliance with the requirements of ISO 9001:2015. A culture of continuous improvement must be integrated at all levels of the organization.

Overall results of the internal audit with respect to the requirements of the ISO 9001:2015 standard:

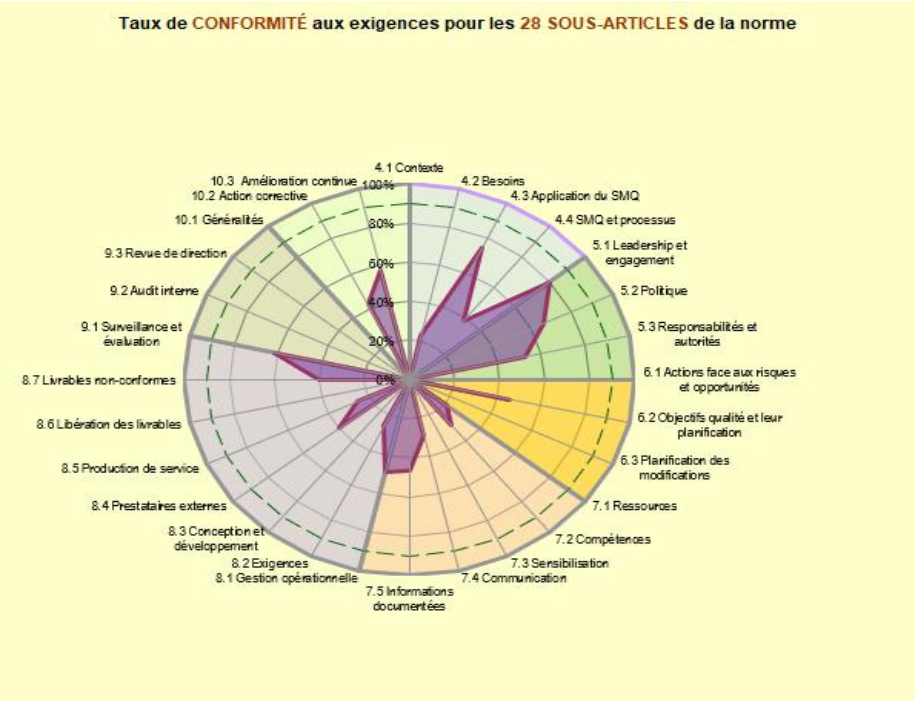
Figure 14: RADAR diagram presents the overall results of our report



Source: Developed by ourcare based on the self-assessment grid.

The figure presents an overview of the quality management system of the INAMED Group through a radar diagram and several histograms, illustrating the levels of compliance and accuracy of the requirements of the ISO 9001:2015 standard. The radar diagram reveals that the overall compliance of the articles is only 32%, characterized as informal, with notable weaknesses in the areas of improvement (Chapter 10) and the execution of operational activities (Chapter 8). The histograms show that 70 criteria out of 154 are considered "False," while only 27 are "True," and that 13 sub-articles out of 28 are deemed informal. These results indicate that the current system requires significant improvements to achieve an acceptable level of compliance and ensure effective performance in line with the standards of the ISO 9001:2015 standard.

Figure 15: Radar Diagram Illustrating Compliance Rates with Respect to the 28 Requirements



Source: Developed by ourcare based on the self-assessment grid.

The radar diagram figure illustrates the compliance rates of the quality management system of the INAMED Group with respect to the 28 sub-chapters (requirements) of the ISO 9001:2015 standard. The results show varied compliance levels with notable strengths in the areas of management commitment (Chapter 5.1), quality policy (Chapter 5.2), and communication (Chapter 7.4), reaching nearly 100%. However, significant gaps remain in

management review (Chapter 9.3), internal audit (Chapter 9.2), and corrective action management (Chapter 10.2), indicating critical areas requiring major improvements to achieve full compliance and ensure the effectiveness of the quality management system.

2. Results-based monitoring :

2.1 Interpretation of the observation grid :

As previously mentioned, we designed a structured observation grid to systematically and objectively collect data during our internship. This grid facilitates the precise and detailed recording of behaviors, events, or conditions observed within a specific context. Below is our observation grid:

Table 9 :observation grid

Observation Criteria	**Description**
Motivation of Employees	Employees are motivated to obtain ISO 9001 certification but are reluctant to perform additional tasks.
Execution of HR Tasks	The HR process pilot is partially committed because they also work for another company.
Certification of the Logistics Process	The logistics process, although important for exports and imports, is not included in the certification plan.
Reliability of Equipment	The equipment is exceptionally reliable and high-tech.
Quality of RawMaterials	The raw materials used are of excellent quality.
Training and Knowledge of Employees	Training and knowledge are limited to certain employees (regarding the quality management system).

Absence Management	Absence management is inadequate, which affects the continuity of processes
responsibilities and authorities	If the production process pilot is absent, the production line is paralyzed because they are the only one authorized to initiate production. However, the production process pilot is not always available as he resides in Tunisia.

Source: Elaborated by our care

The organization displays a mix of strengths and areas for improvement across its operational and management aspects. While employee motivation towards ISO 9001 certification is commendable, their reluctance to undertake additional tasks may hinder adaptability. The partial commitment of the HR process pilot due to external commitments raises concerns about resource allocation and compliance. Excluding the logistics process from the certification plan could affect overall quality management comprehensiveness. The reliability of high-tech equipment and the use of good-quality raw materials are positive, but limited training on the quality management system and inadequate absence management present risks. Dependency on a single production process pilot residing abroad poses operational challenges. Addressing these issues, particularly through comprehensive training, effective absence management, and contingency planning for critical roles, will strengthen the organization's quality management system and overall operational resilience.

2.2 Proposed action plan:

Following the completion of the internal audit, we identified discrepancies with the ISO 9001:2015 standards. We will develop a comprehensive action plan order to address the gaps identified. The action plan will function as a roadmap, guiding the execution of necessary actions and ensuring that all required measures are implemented. Additionally, it will provide a mechanism for tracking progress and ensuring accountability in accordance with the ISO 9001 standard.

Action plan **See appendix 4**

2.2.1 Result of the Interviews :

We conducted 5 interviews. The purpose of these interviews was to:

- Identify the interested parties.

- Examine the needs and expectations of the interested parties /relevant stakeholders:

Table 10 :The interested parties

Process	**Stakeholders**	**Their needs**	**Interest**	**Power (influence)**
Commercial	Consumers	Quality of products , Competitive prices	**3**	**3**
	Distributors	Access to sufficient stock , Promotional support	**2**	**2**
Procurement	Suppliers	Payment terms , Order forecast	**3**	**3**
	Banks / Financial institutions	Solvency , Credit guarantees	**2**	**2**
	Governmental authorities		**1**	**3**
	Transport company	Transport conditions	**2**	**2**
Quality control	Client	Compliant product	**3**	**3**

	State		**1**	**3**
	Laboratory	Representative samples	**3**	**1**
	Suppliers	Compliant product , traceability	**3**	**3**
Human resources	Organization / Training	Training opportunities , course contract	**2**	**1**
	Syndicate	Collective bargaining , Respect for rights	**3**	**3**
	Recruitment agency	Job offer , Contractual relationships	**2**	**1**
Production	Clients	High quality product, Deadlines	**3**	**3**
	Subcontractor	Clear instructions , timely payment	**2**	**2**
	Materials Supplier	Regular order , sustainable contracts	**2**	**2**

Source : elaborated by our care

Table *11*: The evaluation scale

1	**low relevance**
2	**strong relevance**
3	**very strong relevance**

Source: Elaborated by our care

2.2.2 The process of resolving non-conformity:

In this section, we outline the procedural steps taken to address the recurrent non-conformities within the management process of LLC INAMED. The resolution of these non-conformities will not only enhance the management process but also augments the overall efficacy of INAMED. Root cause analysis was conducted, followed by the implementation of appropriate corrective measures.

- ✓ **The non-conformity to be addressed**

After our audit, one major non-conformity and six minor non-conformities were identified within the quality management system. To record and track the identified non-conformities, we developed a non-conformity Handling Form (Correction and Corrective Action) to each non –conformity containing information about the nature of the non-conformity, its location, severity, corrective actions to be undertaken, designated responsible parties, and deadlines for corrective actions.

But for our work we will present a non-conformity handling form for the non-conformities identified in Chapter 6 "Planning" and sub-chapter 6.1 "Actions to address risks and opportunities see **appendix 5**

Table 12: Description of Non-Conformity

Non-Conformity	No risk and opportunity analysis has been conducted for each process.
The ISO 9001 standard requirement.	Clauses 6.1. require an organization take action to identify risks and opportunities
Functional Area	Management team

Source: elaborated by our care

- ✓ **Actions to address risks and opportunities:**

Analysis of different process risks and opportunities:

In the audit report, one of the findings pertains to our comprehensive analysis of the available documentation, which revealed a notable absence of risk and opportunity assessments associated with individual processes. Consequently, the absence of corresponding action plans hindered the mitigation of risks and exploitation of opportunities. This deficiency extended to stakeholder monitoring, where the clarity and relevance were notably lacking. In response to this identified non-conformity, we elaborated a Risk and opportunity analysis sheet in collaboration with the integrated management system manager we've implemented the 5*5 risk Matrix see **appendix 6**

Table 10: Identification of risks

N°	Context elements	Source (causes)		Risk	Process	Evaluation			Action Plan	
						P	G	C	Actions	responsibility
1	Non-compliance with purchasing or service requirements by suppliers and service providers	Threats	External .	Stock shortage/outage Production halt n Non-compliant production	Procurement and supply chain m	3	4	12	Determination of purchasing requirements - Communication of purchasing requirements - Supplier selection - Supplier evaluation - Communication of purchasing requirements	Procurement
2	Product shortages in the market	Threats	Internal .	Loss of market share	commercial	3	4	12	Product availability survey on the market according to the customer tracking procedure	Commercial
3	Non-compliance with customer requirements	Threats	External.	Loss of market share	Commercial	2	4	8	Determination of customer requirements Communication of customer requirements Customer satisfaction survey	Commercial
4	Compliance with legal and regulatory requirements	Strengths	Internal .	Strengthening legitimacy towards legal and regulatory authoritie	Management	1	4	4	Regulatory and normative monitoring	Quality control
6	High Turn-over rate	Weaknesses	Internal	Increase in burdens on the company Lack of mastery of processes by new recruits	Human Resources	1	4	4	Verification of working conditions Determining recruitment requirements Assessing the effectiveness of recruitments Developing a career development plan	HR
7	The absence of the training plan	Weaknesses	External / Internal .	Appearance of non-conformities due to lack of mastery of work procedures	Human Resources	2	2	4	Developing a training plan	HR

Source: elaborated by our care

- ✓ **Opportunities of different processes:**

Table 13: Opportunities of INAMED

N:	Context elements	Opportunities	Actions	Responsibility
1	Supplier loyalty	Cost improvement Compliance with requirements	Assessment of external service providers.	Procurement and supply chain
2	Installation of the self-control laboratory	Independence in verifying the compliance of our product parameters at all levels.	Completion of the laboratory construction.	quality control
3	The possibility to correct settings during production.	Reduction of product non-conformities	Staff training Determining process monitoring parameters	Industrial
4	Flexibility of production	Diversification of the	Research and	quality control

	equipment	product portfolio	development of products	

Source: elaborated by our care

2.2.3 The Quality policy:

During our internship, we collaborated with the Integrated Management System manager to review INAMED's quality policy. As part of their commitment to continuous improvement, INAMED has set more ambitious objectives within their Quality Management System (QMS). In addition to refining the quality policy, we ensured its alignment with ISO 9001 standards and communicated these enhanced objectives to all relevant stakeholders, including employees, suppliers, and clients, to ensure comprehensive understanding and adherence. **See appendix 7**

2.2.4 The implementation of the action plan:

Owing to temporal limitations, we encountered difficulty in executing all the actions delineated in the action plan. The subsequent table will enumerate the actions which we were able to cultivate during our tenure of internship at INAMED.

Table 14: Planning

Clauses	Deliverable	Responsible
4.2	Determination of relevant interested parties	Trainee
	Determination of needs and expectations of PI	
5.2	Revise the quality policy and integrate new quality,	Trainee + IMSM
6.1	Risk and opportunity analysis	Trainee + IMSM
	sheet	

Source: Elaborated by our care

2.3 Non-conformance handling table:

Given that we were unable to address all the non-conformities, we have developed a tracking table for the INAMED company. A non-conformity tracking table is a fundamental pillar in quality management within organizations. This table enables INAMED to centralize all encountered non-conformities, providing a comprehensive overview to identify recurring trends and underlying issues. By meticulously documenting the corrective actions taken for each non-conformity, it ensures rigorous tracking, assigning responsibilities and deadlines to guarantee their resolution. Furthermore, it serves as a platform for internal communication, enhancing transparency and alignment among stakeholders regarding ongoing quality challenges and the measures implemented to address them. By analyzing the data from the table and the non-conformity reports we have prepared, we have identified the root causes of the issues, thereby facilitating the implementation of preventive measures to avoid their recurrence**. See appendix 8**

Section 3 :Discussion

The review of literature by(Mehmet Sıtkı İlkay, 2012) investigated the impact of ISO 9001 certification on the performance of SMEs in Turkey, finding no significant performance difference between certified and non-certified companies, but noting higher quality practices in certified companies. Conversely, as our work in INAMED involved conducting an audit to assess their QMS status and identify non-conformities, with the primary goal was achieving ISO 9001 certification to gain market access. Both contexts emphasize the importance of certification in enhancing quality practices, yet differ in their motivations—INAMED's focus is on external market benefits, while the study also considers intrinsic benefits and overall performance impact.

(Laura Bravi, 2019) on the implementation of the ISO 9001:2015 standard in Italian companies reveals that the main motivations are internal improvements and external market pressures, with benefits including better quality management and increased customer satisfaction, but also obstacles such as excessive costs and administrative formalities. Our experience at INAMED reflects similar motivations, as the main objective was to obtain ISO 9001 certification to access new markets. However, either do us encountered specific limitations, which constitute a significant internal barrier. In summary, while the Italian companies studied by Bravi highlight the benefits of continuous improvement, risk management, and synergy with other standards, INAMED shares the same external motivations but faces distinct internal operational challenges.

Both the article "Total Quality Management and Its Relationship with the Internal Audit" (Haronet, 2012) and us as trainee at INAMED recognize the significance of the human element in implementing quality management systems (QMS). Haronet's study underscores the importance of internal auditors developing new skills and transitioning to cooperative roles within TQM frameworks, emphasizing collaboration with production management to ensure quality standards. Similarly, at INAMED, we highlight the pivotal role of the human element in the QMS implementation process. We sensitize employees about quality and certification through interviews and other initiatives. Both contexts emphasize the need for continuous improvement, adherence to high ethical standards, and alignment with organizational goals, aligning with the principles of Total Quality Management. Additionally, we have recognizing their crucial roles in ensuring the effectiveness of TQM and internal audit functions. Overall, while the article provides

theoretical insights into the relationship between TQM and internal audit, during our internship in INAMED we have put practical efforts to sensitize and involve employees in quality management processes, reflecting a hands-on approach to implementing TQM principles within the organization.

(Al-Mahawili, 2023) and the internal audit approach at INAMED prioritize the evaluation and enhancement of quality management systems (QMS) through internal audits based on ISO standards, particularly ISO 19011:2002 guidelines. INAMED appears to prioritize compliance with these standards in its internal audit practices. This suggests that while both entities share a common goal of enhancing QMS through internal audits, they may differ in the extent to which they adhere to ISO guidelines, potentially influencing the effectiveness of their quality management processes.

CONCLUSION

The aim of this research was to perform a thorough internal audit, address any identified non-conformities, and devise a strategic action plan. To achieve this, we incorporated a wide range of theoretical concepts related to internal auditing and quality management systems (QMS), while also assessing the broader impact of internal auditing on businesses. Our qualitative study, utilizing semi-structured interviews, detailed observations, and extensive document analysis, underscored the crucial role of internal auditing in the implementation and optimization of quality management systems. This multifaceted approach allowed us to gain deep insights into the practical and theoretical aspects of the audit process.

We meticulously detailed each step of the internal audit process. Working alongside a consulting expert, we conducted the audit using a specially developed checklist and participatory observations to ensure a rigorous and accurate evaluation. These tools enabled us to collect precise data and formulate relevant recommendations to enhance the company's QMS. The use of a comprehensive checklist ensured that all critical aspects of the QMS were evaluated, leaving no room for oversight and thus providing a solid foundation for improvement.

In our evaluation of INAMED's quality management system (QMS) according to ISO 9001 standards, we conducted an internal audit to assess the system's effectiveness and identify both strengths and areas for improvement. Collaborating with an expert consultant, we meticulously followed an action plan that involved preparation, information collection, on-site audits, and detailed reporting. Our audit revealed significant employee engagement and proficiency in product marketing, along with high-quality product offerings due to substantial investments in automation. These findings highlighted the robust aspects of INAMED’s operations, showcasing its strengths in critical business areas.

However, we identified one major and six minor non-conformities, particularly in understanding the organizational context, addressing risks and opportunities, planning changes, resource management, competence, and communication. This discovery was essential in pinpointing specific areas where INAMED needed to focus its improvement efforts. Through radar diagrams, we visualized compliance levels across various ISO 9001 chapters, such as the context of the organization, leadership, planning, support, and operation. These visual tools not only facilitated a clear understanding of the compliance levels but also helped in communicating the findings effectively to all stakeholders involved. These insights led us to develop corrective action plans and follow-up measures to enhance INAMED's QMS, ensuring continuous improvement and alignment with ISO 9001 standards.

Due to the limited period of the internship, the realization of this dissertation encountered some difficulties. We conducted an internal audit and worked on the non-conformities detected in

chapters 4, 6, and 7 of the ISO 9001 standard. We also elaborated follow-up measures for the treatment of non-conformities for INAMED to address the remaining unresolved issues. This continuous process of follow-up and resolution is crucial for maintaining the integrity and effectiveness of the QMS over time.

Finally, contributing to the internal audit and the implementation of the quality management system at INAMED enriched our understanding of internal audit processes and quality management systems, thereby consolidating our academic training. The hands-on experience gained through this research has not only deepened our theoretical knowledge but also enhanced our practical skills, preparing us for future challenges in the field of quality management and internal auditing

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Appendix

***Appendix 1:** Audit Plan*

Audit Plan March 7th, 2024

1. General Information

Auditor Team	Consulting expert Trainee
Audit Type	internal (first-party)
Audit Standard	ISO 9001
Audit Date	March 7th, 2024
Audit Time	8.30am- 4.00pm

Day 1

Time	Process	Auditor	Activity
08.30	Opening Meeting:	Audit team + Trainee	Opening Meeting: - Recap of the audit scope and its objectives and criteria. - Audit process: presentation of the audit plan, methods, communication channels. - Questions,answers.
09.00	Management Process	Audit team + Trainee	- Scope of the QMS (Quality Management System) - Exclusions and outsourced processes; - Implementation of strategic directions, Quality Policy. - Quality objectives and targets - Customer feedback - Types of communication applied internally/externally (customer feedback) - Status of the documentation system - Internal Audit & Management Review

Time	Process	Auditor	Activity
10.30	Procurement and Supply Process:	Audit team + Trainee	- Planning and implementation of procurements - List of external suppliers - Evaluation and selection of suppliers - Purchase-related information, reception requirements - Verification of purchased product - Identification and traceability of stocks - Control of changes - Determination of risks and opportunities - Quality objectives and action planning to achieve them - Implementation of the improvement loop
10.30	Commercial Process	Audit team + Trainee	- Determination of product requirements. - Order processing -Review of requirements - Contracting and Invoicing - Contract management - Verification of ability to meet requirements - Customer information, customer complaints, and customer satisfaction surveys - Operational control - Communication management - Determination of risks and opportunities - Quality objectives and action planning to achieve them
12.-	Break		

Time	Process	Auditor	Activity
01.00	Human Resources Process	Audit team + Trainee	- Recruitment plan and administrative management. - Training management. - Career management and skills assessments. - Occupational health. - Management of organizational knowledge - Determination of risks and opportunities - Quality objectives and action planning to achieve them - Implementation of the improvement loop
01.00	Production Process:	Audit team + Trainee	-Planning and implementation of operational activities Product requirements Production management -Management of changes in product and service requirements - Post-delivery activities & control of non-conformig products - Verification and improvement - Determination of risks and opportunities - Quality objectives and action planning to achieve them -Implementation of the improvement loop
2.00	Maintenance Process	Audit team + Trainee	-Infrastructure management - Management of the environment associated with PF (Production Floor) storage and packaging - Equipment maintenance and calibration monitoring - Measurement traceability -Identification and traceability

Time	Process	Auditor	Activity
	01.00	Quality Control Process	- Analysis and Release of PF (Finished Products) -Control of PF Environment - Resources for monitoring and measurement -Equipment maintenance and calibration monitoring - Measurement traceability -PF identification and traceability - Determination of risks and opportunities - Quality objectives and action planning to achieve them -Implementation of the improvement loop

5. Release

Auditor Name :R.B

Release Date : 03/06/2024

Auditor Signature

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***Appendix 2:** Audit report*

Audit report :

Organization profile:

Auditor Team	Consulting expert Trainee
Contact person	Yacine Mebarki
General description of audited Organization	INAMED a Mediterranean agric-food company.
Audit Date	March 7th, 2024

Clause Title(s)	Process	POS/ODA/PDA/ NC MIN/NC MAJ	Comment
4.1Understating the organization and its context	Integrated Management system.	ODA	identified internal and external issues affecting its objectives as of November 20, 2019. It is essential torevise the context analysis.
4.2 Understanding the needs and expectations of interested parties		ODA	Relevant Stakeholders identified with their needs and expectations. Update needed formonitoring their requirements.
4.3 Determining the scope of the quality management system		PDA	Presented scope Demonstrates understanding of company's activities. Justifications for exclusions are not founded.
4.4 Quality Management System and Its Processes	Integrated Management System	POS	Process sheets ensure compliance. Recommendations to enrich input elements and establish simplified flowcharts.
5.1 Leadership and Commitment	Integrated Management System	POS	Strong commitment to customer satisfaction and continuous improvement.investment in ICTtechnology and ERP.

5.2 Policy	Integrated Management System	ODA	Quality policy developed by top management, needs better dissemination.
5.3 Organizational Roles, Responsibilities, and Authorities	Integrated Management System	ODA	Communicated job descriptions, need to clearly define roles in accordance with ISO 9001.
6.1 Actions to Address Risks and Opportunities	All processes	NC MAJ	Overall risk analysis done, but no specific risk analysis for each process.
6.2 Quality Objectives and		NCMIN 01	Clear and simplified objectives with measurement indicators needed.
6.2.2 Quality Objectives and	All processes	NC MIN2	Relevant Stakeholders identified with their needs and expectations. Update needed formonitoring their requirements.
7.1.2 Human Resources	HR Process	PDA	Formal recruitment plan exists but is not operational.
7.1.3 Infrastructure	All processes	POS	Adheres to maintenance schedule for Production machines.
7.1.5 Monitoring and Measuring Resources	Quality Control	NC MIN 03	Need for internal reminder system for calibration schedule, calibration certificates required.
7.1.6 Organizational Knowledge	HR Process	ODA	Recommended to integrate a skills matrix.

7.2 Competence	HR Process	NC MIN 04	Training provided but lacks competence evaluation, training plan for 2023/2024, and cold evaluation.
7.3 Awareness	Integrated Management System	ODA	Development and implementation of an awareness plan needed.
7.4 Communication	Integrated Management System	ODA	Communication plan needs improvement by integrating internal process interaction information.
7.5 Documented Information	Integrated Management System	ODA	Regular updates ensured, but some uncodified documents found.
8.1 Operational Planning and Control	All processes	ODA	Operational planning and control is effectively in place.
8.2 Requirements for Products and Services	Commercial process	PDA	The company ensures clear communication with customers regarding product requirements. However, there needs to be better documentation Of these Communications.
8.3 Design and Development of Products and Services			
8.4 Control of Externally Provided Processes, Products, and Services	Procurement and supply	PDA	There is a system to evaluate and monitor suppliers, but it needs to be updated regularly.
8.5 Production and Service Provision			Production processes are well-defined and controlled. However, there are some areas

8.5.1 Control of production and service provision	Process: Production		
8.5.2 Identification and traceability		PDA	Batch numbers are used to ensure better traceability of products from raw material to finished product.
8.5.3 Property of customers or external providers	Process: Integrated Management System	PDA	Although this chapter is excluded from the company's Quality Management System (QMS), the property of providers manifests in various forms. For example, the drums are under the company's responsibility since they are the property of the suppliers
8.5.4 Preservation	Process: Quality Control	PDA	Preservation is currently carried out using manual labels that may deteriorate or be damaged. It is recommended to review the method of labeling preserved products or to opt for the use of non-destructible labels. It is also imperative to subdivide the preservation area for raw material sampling and finished products. Although samples of released batches are preserved to ensure the conformity of the finished products, no preservation duration is defined form whatsoever (procedure, internal note, manual, etc.)
8.5.5 Post-delivery activities	Process: Integrated Management System	PDA	Just as with chapter 8.5.3, it is essential not to exclude this requirement from the company's Quality Management System (QMS). It is in compliance with law 09-03 regarding consumer protection by integrating a phone number printed on the packaging dedicated to consumer service. This directly attests to the company's awareness of post-delivery activities. Documentary reference (evidence): Consumer Service phone number on the packaging of Tomato Sauce PF: 023 51 01 24
8.6 Release of Products and Services	Process: Quality Control	NC MIN 05	The product release complies with the internal procedure of the company; however, it is imperative to work with documented information that attests to the satisfactory execution of all planned criteria before release, for example: batch records, release checklist, intermediate control reports, etc.

8.7 Control of non- conforming Outputs	Process Quality Control	POS	The non-conforming output elements are controlled as required in this chapter.
9 Performance Evaluation 9.1.2 Customer Satisfaction	Sales Process	ODA	It is observed that customer satisfaction surveys should be regularly conducted continuously, using ICT or other adapted methods.
9.1.3 Analysis and Evaluation	All processes	NC MIN 06	No planning has been established, resulting in non-compliance with this requirement for all processes
9.2 Internal Audit			In the process of planning
9.3 Management Review			
10. Improvement 10.2 Non-conformity and corrective action	Process: Integrated Management System	ODA	It is recommended to strengthen the management of non-conformities and corrective actions by establishing an overall tracking status for non-conformities and corrective actions.

POS: Positive finding that deserves to be mentioned as a remarkable effort to improve the effectiveness and/or efficiency of the system.

ODA: An opportunity for improvement is a situation in which the evidence presented indicates that a requirement has been effectively implemented, but based on the auditor's knowledge and experience, additional effectiveness or robustness could be achieved through a modified approach.

PDA: Any critical finding that deserves to be mentioned, including warnings (dangers of future non-conformity, weaknesses in the system, remarks). Anything that requires action from the auditee or, at least, their attention and follow-up by the auditor during their next visit.

NC MIN: Any non-conformity that does not affect the ability of the management system to achieve the desired results.

NC MAJ: This is a non-conformity that affects the ability of the system to achieve the desired results.

Appendix 3: DETAILED RESULTS OF EACH CHAPTER BY REQUIREMENTS

1	Document d'appui à la déclaration première partie de conformité à la norme ISO 9001:2015				Impression sur pages A4 100% en format horizontal	
2	**Autodiagnostic sur les exigences de l'ISO 9001:2015**					
3	Etablissement :	Nom de l'établissement / entreprise / organisation...				
4	Date de l'autodiagnostic :				Signature du responsable de l'autodiagnostic :	
5	Responsable de l'autodiagnostic :	NOM et Prénom				
6		Tél : @ :				
7	Equipe d'autodiagnostic :	Noms et Prénoms des participants				
8						
9						
10	Réf.	Critères d'exigence des articles de la norme	Evaluations	Taux %	Libellés des évaluations	Modes de preuve et commentaires
11	~~Art. 4~~	Contexte de l'organisme	Informel	34%	Conformité de niveau 2 : Il est nécessaire de pérenniser la bonne exécution des activités.	
12	4.1	Compréhension de l'organisme et de son contexte	Insuffisant	%	Conformité de niveau 4 : BRAVO ! Maintenez et communiquez vos résultats.	
13	cr 1	Les enjeux internes et externes sont **déterminés** relativement à la **finalité** et l'orientation stratégique de l'organisme	Faux	0%	Niveau 1 : L'action n'est pas réalisée ou alors de manière très aléatoire.	Les enjeux internes et externes de Tabuk ne sont pas défini par manque d'une méthode de détermination fiable
14	cr 2	Les **informations** relatives aux enjeux externes et internes sont **surveillées** et **revues** périodiquement	Faux	0%	Niveau 1 : L'action n'est pas réalisée ou alors de manière très aléatoire.	Absence de revue de direction
15	cr 3	Les **facteurs d'influence** sur l'efficacité du Système de Management de la Qualité (SMQ) sont identifiés	Faux	0%	Niveau 1 : L'action n'est pas réalisée ou alors de manière très aléatoire.	La sureveillance rlexiste pas , ettant donné qu'un SMQ réxiste pas
16	4.2	Compréhension des besoins et des attentes des parties intéressées	Informel	23%	Conformité de niveau 2 : Il est nécessaire de pérenniser la bonne exécution des activités.	
17	cr 4	Les parties intéressées **pertinentes** sont identifiées dans le cadre du SMQ	Faux	0%	Niveau 1 : L'action n'est pas réalisée ou alors de manière très aléatoire.	les parties intéressées n sont pas identifiées par une méthode précise
18	cr 5	Les **exigences des clients** ainsi que celles **légales et réglementaires** sont prises en considération dans le SMQ	Plutôt Vrai	70%	Niveau 3 : L'action est formalisée et réalisée.	
19	cr 6	Les **informations** sur les parties intéressées et leurs exigences sont **surveillées et revues** périodiquement	Faux	0%	Niveau 1 : L'action n'est pas réalisée ou alors de manière très aléatoire.	absence d'information sur les parties prenantes ainsi que leurs mise a jour
20	4.3	Détermination du domaine d'application du système de management de la qualité	Convaincant	75%	Conformité de niveau 3 : Il est nécessaire de tracer et d'améliorer les activités.	
21	cr 7	Le domaine d'application du SMQ **est établi** en déterminant ses limites et son applicabilité	Vrai	100%	Niveau 4 : L'action est formalisée, réalisée, tracée et améliorée.	domaine d'appliquation du SMQ non établi
22	cr 8	Le domaine d'application du SMQ **prend en compte** les enjeux externes et internes, les exigences des parties intéressées pertinentes et les produits et services de l'organisme	Faux	0%	Niveau 1 : L'action n'est pas réalisée ou alors de manière très aléatoire.	domaine d'appliquation du SMQ non établi
23	cr 9	Une **information documentée** est **disponible** et tenue à jou sur le domaine d'application du SMQ	Vrai	100%	Niveau 4 : L'action est formalisée, réalisée, tracée et améliorée.	absence d'information documentée concernant le domaine d'appliquation du SMQ
24	cr 10	Les exigences **non applicables** sont justifiées et n'impactent ni la conformité des produits et services ni l'amélioration de la satisfaction des clients	Vrai	100%	Niveau 4 : L'action est formalisée, réalisée, tracée et améliorée.	domaine d'appliquation du SMQ non établi
25	4.4	Système de management de la qualité et ses processus	Informel	38%	Conformité de niveau 2 : Il est nécessaire de pérenniser la bonne exécution des activités.	
26	cr 11	Le SMQ est établi, mis en oeuvre, tenu à jour et **amélioré en continu**, y compris les processus et leurs interactions	Plutôt Faux	30%	Niveau 2 : L'action est réalisée quelques fois de manière informelle.	les processus ainsi que leurs interactions ne sont pas déterminés
27	cr 12	Les éléments d'entrée requis et de sortie attendus sont déterminés	Plutôt Vrai	70%	Niveau 3 : L'action est formalisée et réalisée.	Les éléments d'entrée requis et de sortie ne sont déterminés
28	cr 13	Les **ressources** nécessaires sont déterminées et leurs **disponibilités** sont assurées	Plutôt Vrai	70%	Niveau 3 : L'action est formalisée et réalisée.	
29	cr 14	Les méthodes de surveillance et de **mesure de la performance des processus** sont déterminées et appliquées	Faux	0%	Niveau 1 : L'action n'est pas réalisée ou alors de manière très aléatoire.	processus non determinés
30	cr 15	Les **responsabilités et autorités pour le pilotage des processus sont attribuées**	Vrai	100%	Niveau 4 : L'action est formalisée, réalisée, tracée et améliorée.	les processus ainsi que leurs pilotes ne sont pas déterminé
31	cr 16	Les **risques et opportunités** pour l'organisme (cf 6.1) sont pris en compte par le SMQ	Faux	0%	Niveau 1 : L'action n'est pas réalisée ou alors de manière très aléatoire.	
32	cr 17	Les **informations documentées** nécessaires au bon fonctionnement des processus sont **tenues à jour** et **conservées**	Faux	0%	Niveau 1 : L'action n'est pas réalisée ou alors de manière très aléatoire.	absence des fiches processus
33	~~Art. 5~~	Leadership	Convaincant	66%	Conformité de niveau 3 : Il est nécessaire de tracer et d'améliorer les activités.	
34	5.1	Leadership et engagement	Convaincant	80%	Conformité de niveau 3 : Il est nécessaire de tracer et d'améliorer les activités.	
35	cr 18	La direction assume la responsabilité de l'efficacité du SMQ, son intégration avec les processus métiers et l'information nécessaire à la bonne **implication du personnel**	Vrai	100%	Niveau 4 : L'action est formalisée, réalisée, tracée et améliorée.	
36	cr 19	La direction promeut l'amélioration, incite, oriente et **soutient toutes les personnes** pouvant contribuer à l'efficacité du SMQ	Vrai	100%	Niveau 4 : L'action est formalisée, réalisée, tracée et améliorée.	
37	cr 20	La direction s'assure que les **exigences clients et légales et réglementaires** sont maitrisées en permanence	Vrai	100%	Niveau 4 : L'action est formalisée, réalisée, tracée et améliorée.	
38	cr 21	La direction s'assure que les **risques et les opportunités** affectant la qualité ou la satisfaction du client sont maitrisés	Faux	0%	Niveau 1 : L'action n'est pas réalisée ou alors de manière très aléatoire.	
39	cr 22	La direction démontre son engagement à **l'orientation client** en donnant la priorité à **l'accroissement de sa satisfaction**	Vrai	100%	Niveau 4 : L'action est formalisée, réalisée, tracée et améliorée.	
40	5.2	Politique	Convaincant	66%	Conformité de niveau 3 : Il est nécessaire de tracer et d'améliorer les activités.	
41	cr 23	La direction établit, revoit et met à jour périodiquement sa politique qualité en accord avec le contexte et son **orientation stratégique**	Plutôt Vrai	70%	Niveau 3 : L'action est formalisée et réalisée.	Absence d'une politique qualité
42	cr 24	La **politique qualité** est disponible et tenue à jour sous forme d'une **information documentée**	Vrai	100%	Niveau 4 : L'action est formalisée, réalisée, tracée et améliorée.	La politique qualité nest pas documetée
43	cr 25	La politique qualité est **communiquée, comprise et appliquée** au sein de l'organisme	Plutôt Faux	30%	Niveau 2 : L'action est réalisée quelques fois de manière informelle.	La politique qualité nest pas publiée
44	5.3	Rôles, responsabilités et autorités au sein de l'organisme	Convaincant	53%	Conformité de niveau 3 : Il est nécessaire de tracer et d'améliorer les activités.	
45	cr 26	La direction s'assure que les **responsabilités et autorités** sont attribuées, communiquées et **comprises** pour les fonctions pertinentes (pilotes de processus critiques par exemple)	Plutôt Faux	30%	Niveau 2 : L'action est réalisée quelques fois de manière informelle.	
46	cr 27	Les **responsabilités et autorités** associées à la **performance du SMQ et son évolution** sont attribuées	Vrai	100%	Niveau 4 : L'action est formalisée, réalisée, tracée et améliorée.	
47	cr 28	Les responsabilités et autorités associées à la promotion de l'orientation client au sein de l'organisme sont attribuées	Plutôt Faux	30%	Niveau 2 : L'action est réalisée quelques fois de manière informelle.	
48	~~Art. 6~~	Planification	Informel	15%	Conformité de niveau 2 : Il est nécessaire de pérenniser la bonne exécution des activités.	

		attribuées				
48	~~Art. 6~~	**Planification**	Informel	15%	**Conformité de niveau 2 : Il est nécessaire de pérenniser la bonne exécution des activités.**	
49	6.1	**Actions à mettre en oeuvre face aux risques et opportunités**	Insuffisant	0%	**Conformité de niveau 1 : Il est nécessaire de formaliser les activités réalisées.**	
50	cr 29	Les **risques et opportunités** sont pris en compte pour **améliorer la performance du SMQ** en lien avec les enjeux à relever et les exigences à satisfaire	Faux	0%	Niveau 1 : L'action n'est pas réalisée ou alors de manière très aléatoire.	
51	cr 30	L'organisme planifie et met en oeuvre les **actions face aux risques et opportunités** sélectionnés	Faux	0%	Niveau 1 : L'action n'est pas réalisée ou alors de manière très aléatoire.	
52	cr 31	Les actions mises en oeuvre sont **adaptées** à l'impact potentiel sur la conformité des produits et des services	Faux	0%	Niveau 1 : L'action n'est pas réalisée ou alors de manière très aléatoire.	
53	cr 32	L'**efficacité** de ces actions au sein des processus du SMQ est **évaluée**	Faux	0%	Niveau 1 : L'action n'est pas réalisée ou alors de manière très aléatoire.	
54	6.2	**Objectifs qualité et planification pour les atteindre**	Informel	46%	**Conformité de niveau 2 : Il est nécessaire de pérenniser la bonne exécution des activités.**	
55	cr 33	Des **objectifs qualité** sont établis aux fonctions, niveaux et processus nécessaires au bon fonctionnement du SMQ	Vrai	100%	Niveau 4 : L'action est formalisée, réalisée, tracée et améliorée.	
56	cr 34	Les objectifs qualité sont **pertinents, mesurables et cohérents** avec la politique qualité	Vrai	100%	Niveau 4 : L'action est formalisée, réalisée, tracée et améliorée.	
57	cr 35	Les objectifs qualité sont **surveillés, tenus à jour et communiqués**	Faux	0%	Niveau 1 : L'action n'est pas réalisée ou alors de manière très aléatoire.	
58	cr 36	Les **informations documentées** sur les objectifs qualité sont **tenues à jour**	Plutôt Faux	30%	Niveau 2 : L'action est réalisée quelques fois de manière informelle.	
59	cr 37	Pour atteindre les objectifs qualité, l'organisme détermine le **responsable**, les actions, les ressources, les échéances et les modalités d'évaluation des résultats	Faux	0%	Niveau 1 : L'action n'est pas réalisée ou alors de manière très aléatoire.	
60	6.3	**Planification des modifications**	Insuffisant	0%	**Conformité de niveau 1 : Il est nécessaire de formaliser les activités réalisées.**	
61	cr 38	La réalisation des modifications apportée au SMQ est **planifiée** et tient compte de l'intégrité de ce dernier	Faux	0%	Niveau 1 : L'action n'est pas réalisée ou alors de manière très aléatoire.	
62	cr 39	L'organisme détermine les objectifs et les **conséquences possibles** des modifications planifiées	Faux	0%	Niveau 1 : L'action n'est pas réalisée ou alors de manière très aléatoire.	
63	cr 40	L'organisme met à disposition les **ressources** nécessaires à la réalisation des modifications	Faux	0%	Niveau 1 : L'action n'est pas réalisée ou alors de manière très aléatoire.	
64	cr 41	L'organisme attribue les **responsabilités et autorités** nécessaires à la réalisation des modifications	Faux	0%	Niveau 1 : L'action n'est pas réalisée ou alors de manière très aléatoire.	
65	~~Art. 7~~	**Support**	Informel	25%	**Conformité de niveau 2 : Il est nécessaire de pérenniser la bonne exécution des activités.**	
66	7.1	**Ressources**	Informel	21%	**Conformité de niveau 2 : Il est nécessaire de pérenniser la bonne exécution des activités.**	
67	cr 42	L'organisme identifie et fournit les **ressources nécessaires** au SMQ	Plutôt Vrai	70%	Niveau 3 : L'action est formalisée et réalisée.	
68	cr 43	L'organisme prend en compte les **capacités et contraintes** des ressources internes existantes et identifie les prestataires externes potentiels	Plutôt Vrai	70%	Niveau 3 : L'action est formalisée et réalisée.	
69	cr 44	L'organisme détermine et fournit les **ressources humaines nécessaires** au fonctionnement efficace du SMQ et de ses processus	Plutôt Vrai	70%	Niveau 3 : L'action est formalisée et réalisée.	manque d'effecif
70	cr 45	L'organisme détermine, fournit et maintient l'**infrastructure et l'environnement** nécessaires à l'obtention de la conformité des produits et des services	Plutôt Vrai	70%	Niveau 3 : L'action est formalisée et réalisée.	
71	cr 46	L'organisme détermine et fournit les ressources nécessaires pour assurer **la validité et la fiabilité des résultats** de surveillance ou de mesure en lien avec la conformité des produits et services	Faux	0%	Niveau 1 : L'action n'est pas réalisée ou alors de manière très aléatoire.	
72	cr 47	L'organisme s'assure de l'adaptation, de l'adéquation et du **maintien des ressources** fournies pour les activités de surveillance et de mesure	Faux	0%	Niveau 1 : L'action n'est pas réalisée ou alors de manière très aléatoire.	
73	cr 48	Des **informations documentées** pour démontrer l'adéquation des ressources pour la surveillance et la mesure sont **conservées**	Faux	0%	Niveau 1 : L'action n'est pas réalisée ou alors de manière très aléatoire.	
74	cr 49	Les instruments de mesure sont identifiés, protégés, vérifiés et /ou étalonnés **périodiquement**	Faux	0%	Niveau 1 : L'action n'est pas réalisée ou alors de manière très aléatoire.	
75	cr 50	Tout équipement de mesure est **relié aux étalons** nationaux ou internationaux	Faux	0%	Niveau 1 : L'action n'est pas réalisée ou alors de manière très aléatoire.	
76	cr 51	Lorsque ces étalons n'existent pas, la référence utilisée est **conservée** sous forme d'**information documentée**	Faux	0%	Niveau 1 : L'action n'est pas réalisée ou alors de manière très aléatoire.	
77	cr 52	Lorsqu'un équipement de mesure s'avère inadapté à l'usage prévu, la validité des **résultats antérieurs** est vérifiée. Le cas échéant, une action appropriée est mise en oeuvre	Faux	0%	Niveau 1 : L'action n'est pas réalisée ou alors de manière très aléatoire.	
78	cr 53	Les **connaissances clés** pour le bon fonctionnement du SMQ sont identifiées, tenues à jour et partagées	Faux	0%	Niveau 1 : L'action n'est pas réalisée ou alors de manière très aléatoire.	
79	cr 54	L'organisme évalue ses **connaissances actuelles** par rapport aux évolutions et détermine la façon d'acquérir les **connaissances supplémentaires** nécessaires	Faux	0%	Niveau 1 : L'action n'est pas réalisée ou alors de manière très aléatoire.	absence de passation entre les anciens et les nouveaux
80	7.2	**Compétences**	Informel	30%	**Conformité de niveau 2 : Il est nécessaire de pérenniser la bonne exécution des activités.**	
81	cr 55	Les **compétences** nécessaires des personnes dont le travail a une incidence sur les performances du SMQ sont **déterminées**	Plutôt Faux	30%	Niveau 2 : L'action est réalisée quelques fois de manière informelle.	
82	cr 56	Les **compétences** du personnel sont **évaluées** sur la base d'une formation ou d'une expérience appropriée	Plutôt Faux	30%	Niveau 2 : L'action est réalisée quelques fois de manière informelle.	
83	cr 57	L'organisme met en place et évalue l'efficacité des actions pour **acquérir ou renforcer les compétences** nécessaires au bon fonctionnement du SMQ	Plutôt Faux	30%	Niveau 2 : L'action est réalisée quelques fois de manière informelle.	
84	cr 58	Les **informations documentées** sur les compétences du personnel sont **conservées**	Plutôt Faux	30%	Niveau 2 : L'action est réalisée quelques fois de manière informelle.	
85	7.3	**Sensibilisation**	Insuffisant	0%	**Conformité de niveau 1 : Il est nécessaire de formaliser les activités réalisées.**	
86	cr 59	L'organisme s'assure que le personnel est **sensibilisé** à la politique et aux objectifs **qualité**	Faux	0%	Niveau 1 : L'action n'est pas réalisée ou alors de manière très aléatoire.	le personnel n'est pas sensibilisé à la politique , car elle est n'existe pas
87	cr 60	L'organisme s'assure que le personnel est **conscient** de l'importance de son activité, de sa contribution individuelle et collective à la réalisation de ces objectifs	Faux	0%	Niveau 1 : L'action n'est pas réalisée ou alors de manière très aléatoire.	
88	cr 61	Le personnel est **sensibilisé** aux effets bénéfiques d'une amélioration des performances et aux répercussions d'un non respect des exigences du SMQ	Faux	0%	Niveau 1 : L'action n'est pas réalisée ou alors de manière très aléatoire.	
89	7.4	**Communication**	Informel	30%	**Conformité de niveau 2 : Il est nécessaire de pérenniser la bonne exécution des activités.**	
90	cr 62	La pertinence des besoins de communication **interne** est déterminée	Plutôt Faux	30%	Niveau 2 : L'action est réalisée quelques fois de manière informelle.	Absence de plan de communication
91	cr 63	La pertinence des besoins de communication **externe** est déterminée	Plutôt Faux	30%	Niveau 2 : L'action est réalisée quelques fois de manière informelle.	Même observation précedante
92	cr 64	Les modalités de communication **interne** sont déterminées	Plutôt Faux	30%	Niveau 2 : L'action est réalisée quelques fois de manière informelle.	Même observation précedante

91	cr 63	La pertinence des besoins de communication **externe** est déterminée	Plutôt Faux	30%	Niveau 2 : L'action est réalisée quelques fois de manière informelle.	Même observation précedante
92	cr 64	Les modalités de communication **interne** sont déterminées	Plutôt Faux	30%	Niveau 2 : L'action est réalisée quelques fois de manière informelle.	Même observation précedante
93	cr 65	Les modalités de communication **externe** sont déterminées	Plutôt Faux	30%	Niveau 2 : L'action est réalisée quelques fois de manière informelle.	Même observation précedante
94	7.5	**Informations documentées**	Informel	47%	**Conformité de niveau 2 : Il est nécessaire de pérenniser la bonne exécution des activités.**	
95	cr 66	Les **informations documentées** du SMQ comprennent celles exigées par l'ISO 9001 et celles nécessaires à son efficacité	Plutôt Vrai	70%	Niveau 3 : L'action est formalisée et réalisée.	
96	cr 67	Toute **information documentée** est identifiée et décrite de manière compréhensible dans un format et sur un support accessibles	Plutôt Vrai	70%	Niveau 3 : L'action est formalisée et réalisée.	
97	cr 68	Le contenu des **informations documentées** est revu périodiquement en termes de pertinence et d'adéquation à l'usage	Faux	0%	Niveau 1 : L'action n'est pas réalisée ou alors de manière très aléatoire.	
98	cr 69	Les **informations documentées** sont utiles, utilisables et utilisées	Plutôt Faux	30%	Niveau 2 : L'action est réalisée quelques fois de manière informelle.	
99	cr 70	Les modifications des **informations documentées** sont maitrisées (contrôle des versions par exemple)	Vrai	100%	Niveau 4 : L'action est formalisée, réalisée, tracée et améliorée.	
100	cr 71	La gestion des **informations documentées** est bien maîtrisée en termes de distribution, accès, stockage, protection, conservation et élimination	Plutôt Faux	30%	Niveau 2 : L'action est réalisée quelques fois de manière informelle.	
101	cr 72	Les **informations documentées** externes sont identifiées et maitrisées	Plutôt Faux	30%	Niveau 2 : L'action est réalisée quelques fois de manière informelle.	
102	~~Act. 8~~	**Réalisation des activités opérationnelles**	Informel	26%	**Conformité de niveau 2 : Il est nécessaire de pérenniser la bonne exécution des activités.**	
103	8.1	**Planification et maîtrise opérationnelles**	Informel	48%	**Conformité de niveau 2 : Il est nécessaire de pérenniser la bonne exécution des activités.**	
104	cr 73	Les **processus** internes et externes relatifs à la fourniture des produits et services sont **planifiés, mis en œuvre et maîtrisés**	Plutôt Faux	30%	Niveau 2 : L'action est réalisée quelques fois de manière informelle.	
105	cr 74	Les exigences et les critères d'acceptation des **éléments de sortie** des processus (produits et services) sont déterminés	Vrai	100%	Niveau 4 : L'action est formalisée, réalisée, tracée et améliorée.	
106	cr 75	L'organisme assure la maîtrise des processus conformément aux **critères d'acceptation** des éléments de sortie	Plutôt Vrai	70%	Niveau 3 : L'action est formalisée et réalisée.	
107	cr 76	L'organisme détermine les **ressources nécessaires** à l'obtention de la conformité des produits et services	Plutôt Faux	30%	Niveau 2 : L'action est réalisée quelques fois de manière informelle.	
108	cr 77	Des **informations documentées mises à jour** prouvent l'efficacité des processus et la conformité des produits et services	Plutôt Faux	30%	Niveau 2 : L'action est réalisée quelques fois de manière informelle.	
109	cr 78	Les éléments de sortie de la planification sont **adaptés** aux modes de fonctionnement et savoir-faire de l'organisme.	Vrai	100%	Niveau 4 : L'action est formalisée, réalisée, tracée et améliorée.	
110	cr 79	Toute **modification** prévue est maîtrisée, analysée dans ses conséquences et des actions sont menées pour **anticiper tout effet négatif**	Plutôt Faux	30%	Niveau 2 : L'action est réalisée quelques fois de manière informelle.	j'ai pa su répondre
111	cr 80	Les processus **externalisés** sont **maîtrisés**	Choix de la VÉRACITÉ		Libellé du critère quand il sera choisi	
112	8.2	**Exigences relatives aux produits et services**	Informel	26%	**Conformité de niveau 2 : Il est nécessaire de pérenniser la bonne exécution des activités.**	
113	cr 81	Les clients disposent des **informations** relatives aux produits et services attendus, au traitement de leurs retours ainsi qu'à la gestion de leurs propriétés ou aux actions d'urgence le cas échéant	Faux	0%	Niveau 1 : L'action n'est pas réalisée ou alors de manière très aléatoire.	
114	cr 82	L'organisme détermine **toutes les exigences** relatives aux produits et services, y compris celles légales et réglementaires ou celles jugées nécessaires	Vrai	100%	Niveau 4 : L'action est formalisée, réalisée, tracée et améliorée.	
115	cr 83	L'organisme est capable de **répondre aux réclamations clients** relatives aux produits et services	Vrai	100%	Niveau 4 : L'action est formalisée, réalisée, tracée et améliorée.	
116	cr 84	L'organisme mène des revues d'exigences **avant** tout engagement de fourniture des produits et services	Faux	0%	Niveau 1 : L'action n'est pas réalisée ou alors de manière très aléatoire.	absence de revue d'exigences
117	cr 85	La revue d'exigences inclut l'identification de toutes les exigences (client, implicites, spécifiées, légales...) et les écarts éventuels avec le contrat ou la commande	Faux	0%	Niveau 1 : L'action n'est pas réalisée ou alors de manière très aléatoire.	même remarque précédente
118	cr 86	Les **écarts** éventuels détectés entre les exigences sont **résolus**	Faux	0%	Niveau 1 : L'action n'est pas réalisée ou alors de manière très aléatoire.	j'ai pa su répondre
119	cr 87	Si les exigences du client ne sont pas documentées, une **confirmation d'acceptation** est effectuée par l'organisme	Faux	0%	Niveau 1 : L'action n'est pas réalisée ou alors de manière très aléatoire.	j'ai pa su répondre
120	cr 88	Les **informations documentées** relatives aux résultats des revues et aux nouvelles exigences des produits et services sont **conservées**	Faux	0%	Niveau 1 : L'action n'est pas réalisée ou alors de manière très aléatoire.	même remarque précédente
121	cr 89	En cas de modification des exigences des produits et services, les **informations documentées** correspondantes sont **amendées**	Plutôt Faux	30%	Niveau 2 : L'action est réalisée quelques fois de manière informelle.	même remarque précédente
122	cr 90	En cas de modification des exigences des produits et services, le **personnel concerné** en est **informé**	Plutôt Faux	30%	Niveau 2 : L'action est réalisée quelques fois de manière informelle.	
123	8.3	**Exigences relatives aux produits et services**	Insuffisant		**Conformité de niveau 1 : Il est nécessaire de formaliser les activités réalisées.**	
124	cr 91	Un processus de conception et développement est **établi, mis en œuvre et tenu à jour** pour assurer la fourniture des produits et services	Choix de la VÉRACITÉ		Libellé du critère quand il sera choisi	
125	cr 92	Les **étapes** ainsi que les ressources nécessaires à la conception et au développement sont **déterminées**	Choix de la VÉRACITÉ		Libellé du critère quand il sera choisi	
126	cr 93	L'organisme détermine les activités nécessaires pour la **vérification et validation** du processus de la conception et de développement, en impliquant, si nécessaire des clients et des utilisateurs	Choix de la VÉRACITÉ		Libellé du critère quand il sera choisi	
127	cr 94	La phase de conception et de développement prend en compte les exigences relatives à la **fourniture ultérieure** des produits et services	Choix de la VÉRACITÉ		Libellé du critère quand il sera choisi	
128	cr 95	L'organisme maîtrise les **interfaces** entre les personnes impliquées en conception et développement, définit les **responsabilités et autorités** et implique les parties intéressées dans ce processus	Choix de la VÉRACITÉ		Libellé du critère quand il sera choisi	
129	cr 96	Des **informations documentées** prouvent que les exigences de conception et développement ont été satisfaites	Choix de la VÉRACITÉ		Libellé du critère quand il sera choisi	
130	cr 97	Les exigences fonctionnelles et de performance, les exigences légales et réglementaires, les normes et règles de l'art, les retours d'expérience sont pris en compte comme **éléments d'entrée** en conception et de développement	Choix de la VÉRACITÉ		Libellé du critère quand il sera choisi	
131	cr 98	Les éventuels **éléments conflictuels** en entrée de conception et de développement sont **résolus**	Choix de la VÉRACITÉ		Libellé du critère quand il sera choisi	
132	cr 99	Les **résultats attendus** de conception et de développement sont définis et des **revues, vérification et validation** sont menées régulièrement	Choix de la VÉRACITÉ		Libellé du critère quand il sera choisi	
133	cr 100	Les **éléments de sortie** de conception et de développement sont **conformes** aux attentes et correctement informatifs sur l'usage des produits et services	Choix de la VÉRACITÉ		Libellé du critère quand il sera choisi	

132	cr 99	Les **résultats attendus** de conception et de développement sont définis et des **revues, vérification et validation** sont menées régulièrement	Choix de la VÉRACITÉ		Libellé du critère quand il sera choisi	
133	cr 100	Les **éléments de sortie** de conception et de développement sont **conformes** aux attentes et correctement informatifs sur l'usage des produits et services	Choix de la VÉRACITÉ		Libellé du critère quand il sera choisi	
134	cr 101	Les **informations documentées** relatives aux trois phases " entrée, maîtrise et sortie" de la conception et du développement sont **conservées**	Choix de la VÉRACITÉ		Libellé du critère quand il sera choisi	
135	cr 102	L'organisme identifie, revoit et maîtrise les **modifications** pour assurer qu'elles n'aient **pas d'impact négatif** sur la conformité aux exigences	Choix de la VÉRACITÉ		Libellé du critère quand il sera choisi	
136	cr 103	Des **informations documentées** prouvent la maîtrise des modifications et leur autorisation	Choix de la VÉRACITÉ		Libellé du critère quand il sera choisi	
137	8.4	**Maîtrise des processus, produits et services fournis par des prestataires externes**	Informel	40%	**Conformité de niveau 2 : Il est nécessaire de pérenniser la bonne exécution des activités.**	
138	cr 104	Des **critères** pour l'évaluation, la sélection, la surveillance des performances et la réévaluation des **prestataires externes** sont établis et appliqués	Faux	0%	Niveau 1 : L'action n'est pas réalisée ou alors de manière très aléatoire.	
139	cr 105	Les **risques** relatifs à l'externalisation des processus, produits et services sont **évalués**	Choix de la VÉRACITÉ		Libellé du critère quand il sera choisi	pas de determination ni d'évaluation des risques relatif a l'externalisation des processus , produits et services
140	cr 106	L'organisme vérifie la **conformité** des processus, produits et services fournis par des **prestataires externes**	Vrai	100%	Niveau 4 : L'action est formalisée, réalisée, tracée et améliorée.	
141	cr 107	L'organisme s'assure de l'adéquation des exigences spécifiées et les communique aux prestataires externes	Vrai	100%	Niveau 4 : L'action est formalisée, réalisée, tracée et améliorée.	
142	cr 108	Les **informations documentées** sur les résultats du contrôle, de la vérification, de la surveillance et de l'évaluation des prestataires externes sont **conservées**	Faux	0%	Niveau 1 : L'action n'est pas réalisée ou alors de manière très aléatoire.	
143	8.5	**Production et prestation de service**	Informel	26%	**Conformité de niveau 2 : Il est nécessaire de pérenniser la bonne exécution des activités.**	
144	cr 109	**Les informations documentées** nécessaires à la production et prestation de service sont **disponibles, ainsi que les ressources** appropriées à la surveillance et la mesure	Plutôt Faux	30%	Niveau 2 : L'action est réalisée quelques fois de manière informelle.	
145	cr 110	La surveillance et la mesure des processus de production se fait par un **personnel compétent et qualifié**	Faux	0%	Niveau 1 : L'action n'est pas réalisée ou alors de manière très aléatoire.	
146	cr 111	L'organisme valide périodiquement l'**aptitude des processus** de production à obtenir les résultats prévus, à anticiper les erreurs humaines, à libérer et à livrer les produits et services	Faux	0%	Niveau 1 : L'action n'est pas réalisée ou alors de manière très aléatoire.	
147	cr 112	Des **informations documentées** de traçabilité sont **conservées** sur l'identification des produits et services et de leurs niveaux de conformité aux exigences de surveillance et de mesure	Faux	0%	Niveau 1 : L'action n'est pas réalisée ou alors de manière très aléatoire.	
148	cr 113	Les **propriétés** des clients et prestataires externes sont **conservées** et **protégées** en cas d'utilisation. Toute perte ou détérioration des propriétés est notifiée à la partie concernée.	Vrai	100%	Niveau 4 : L'action est formalisée, réalisée, tracée et améliorée.	
149	cr 114	Au cours de la production ou de la prestation de service, les **éléments de sortie** sont **préservés** autant que de besoin pour assurer leur conformité aux exigences	Faux	0%	Niveau 1 : L'action n'est pas réalisée ou alors de manière très aléatoire.	
150	cr 115	Les **activités post-livraison** répondent aux exigences réglementaires et tiennent compte des informations nécessaires, usages, risques, garanties ou retours exprimés par des clients.	Faux	0%	Niveau 1 : L'action n'est pas réalisée ou alors de manière très aléatoire.	
151	cr 116	Toute modification relative à la production et prestation de service est revue et maîtrisée.	Faux	0%	Niveau 1 : L'action n'est pas réalisée ou alors de manière très aléatoire.	
152	cr 117	Des **informations documentées** concernant les résultats de la revue de modification, les responsables d'autorisation et les actions induites sont conservées.	Vrai	100%	Niveau 4 : L'action est formalisée, réalisée, tracée et améliorée.	
153	8.6	**Libération des produits et services**	Insuffisant	0%	**Conformité de niveau 1 : Il est nécessaire de formaliser les activités réalisées.**	
154	cr 118	**Avant la libération** des produits et services, l'organisme vérifie leur conformité aux exigences préalablement définies	Faux	0%	Niveau 1 : L'action n'est pas réalisée ou alors de manière très aléatoire.	
155	cr 119	Aucune libération ne se fait **sans la validation** de toutes les dispositions planifiées, sauf approbation par une autorité compétente et, le cas échéant, par le client	Faux	0%	Niveau 1 : L'action n'est pas réalisée ou alors de manière très aléatoire.	
156	cr 120	**Des informations documentées** prouvent et tracent la conformité, l'acceptation et les autorisations jusqu'à la libération des produits et services	Faux	0%	Niveau 1 : L'action n'est pas réalisée ou alors de manière très aléatoire.	
157	8.7	**Maîtrise des éléments de sortie non conformes**	Informel	40%	**Conformité de niveau 2 : Il est nécessaire de pérenniser la bonne exécution des activités.**	
158	cr 121	Les éléments de sortie **non-conformes** aux exigences applicables sont identifiés et maîtrisés pour en **empêcher tout mauvais usage**	Faux	0%	Niveau 1 : L'action n'est pas réalisée ou alors de manière très aléatoire.	
159	cr 122	Des actions appropriées sont menées pour **chaque non-conformité** détectée, même après livraison des produits et services	Vrai	100%	Niveau 4 : L'action est formalisée, réalisée, tracée et améliorée.	
160	cr 123	Les **éléments de sortie non conformes** sont **traités** en termes de correction, d'isolement, de retour, d'information au client ou d'usage par dérogation autorisée	Vrai	100%	Niveau 4 : L'action est formalisée, réalisée, tracée et améliorée.	
161	cr 124	Les **éléments de sortie corrigés** sont vérifiés en terme de conformité aux exigences	Faux	0%	Niveau 1 : L'action n'est pas réalisée ou alors de manière très aléatoire.	
162	cr 125	**Les informations documentées** décrivant la non-conformité, les actions menées, les dérogations obtenues et les autorités décisionnaires sont **conservées**	Faux	0%	Niveau 1 : L'action n'est pas réalisée ou alors de manière très aléatoire.	
163	~~Art. 9~~	**Évaluation des performances**	Informel	21%	**Conformité de niveau 2 : Il est nécessaire de pérenniser la bonne exécution des activités.**	
164	9.1	**Surveillance, mesure, analyse et évaluation**	Convaincant	62%	**Conformité de niveau 3 : Il est nécessaire de tracer et d'améliorer les activités.**	
165	cr 126	L'organisme établit les **critères et les modalités** de surveillance pour assurer la **validité des résultats**	Plutôt Vrai	70%	Niveau 3 : L'action est formalisée et réalisée.	surveillance qui se fait rarement
166	cr 127	L'organisme **planifie** la surveillance et la mesure ainsi que l'analyse et l'évaluation des résultats	Plutôt Vrai	70%	Niveau 3 : L'action est formalisée et réalisée.	même remarque précédente
167	cr 128	Des **informations documentées** sont **conservées** et prouvent les résultats sur la performance obtenue et l'efficacité du SMQ	Plutôt Vrai	70%	Niveau 3 : L'action est formalisée et réalisée.	
168	cr 129	Le niveau de **satisfaction des clients** est **surveillé** par des méthodes définies, mises en œuvre et revues périodiquement	Vrai	100%	Niveau 4 : L'action est formalisée, réalisée, tracée et améliorée.	Absence d'enquet de satisfaction clients
169	cr 130	Les données issues de la surveillance et de la mesure sont évaluées et analysées pour **progresser** à tous les niveaux (clients, produits, processus, prestataires, résultats...)	Faux	0%	Niveau 1 : L'action n'est pas réalisée ou alors de manière très aléatoire.	surveillance qui se fait rarement
170	9.2	**Audit interne**	Insuffisant	0%	**Conformité de niveau 1 : Il est nécessaire de formaliser les activités réalisées.**	
171	cr 131	Les audits internes sont **planifiés, établis et mis en œuvre à des intervalles déterminés**	Faux	0%	Niveau 1 : L'action n'est pas réalisée ou alors de manière très aléatoire.	

170	9.2	Audit interne	Insuffisant	0%	Conformité de niveau 1 : Il est nécessaire de formaliser les activités réalisées.	
171	cr 131	Les audits internes sont **planifiés, établis** et **mis en œuvre à des intervalles déterminés**	Faux	0%	Niveau 1 : L'action n'est pas réalisée ou alors de manière très aléatoire.	
172	cr 132	Les **critères** et le **périmètre** de chaque audit sont définis	Faux	0%	Niveau 1 : L'action n'est pas réalisée ou alors de manière très aléatoire.	
173	cr 133	Les auditeurs sont **sélectionnés** en **s'assurant** de l'objectivité et de l'impartialité du processus d'audit.	Faux	0%	Niveau 1 : L'action n'est pas réalisée ou alors de manière très aléatoire.	
174	cr 134	Les résultats des audits sont **communiqués à la direction** concernée et les actions correctives nécessaires sont mises en place sans délai indu	Faux	0%	Niveau 1 : L'action n'est pas réalisée ou alors de manière très aléatoire.	
175	cr 135	Des **informations documentées** sont **conservées** comme preuves de la mise en œuvre du **programme d'audit** et de ses résultats.	Faux	0%	Niveau 1 : L'action n'est pas réalisée ou alors de manière très aléatoire.	
176	9.3	Revue de direction	Insuffisant	0%	Conformité de niveau 1 : Il est nécessaire de formaliser les activités réalisées.	
177	cr 136	La revue du SMQ est **réalisée** à des intervalles planifiés pour s'assurer de son **efficacité** et **adéquation** avec la stratégie de l'organisme	Faux	0%	Niveau 1 : L'action n'est pas réalisée ou alors de manière très aléatoire.	Absence de revue de direction
178	cr 137	La revue de direction exploite des **éléments d'entrée pertinents et complets** (bilans, résultats, enquêtes, efficience, analyses, prestataires...)	Faux	0%	Niveau 1 : L'action n'est pas réalisée ou alors de manière très aléatoire.	Même observation précedante
179	cr 138	La revue de direction fournit des **décisions et actions** sur les opportunités d'amélioration, le besoin de modifier le SMQ et le besoin en ressources	Faux	0%	Niveau 1 : L'action n'est pas réalisée ou alors de manière très aléatoire.	Même observation précedante
180	cr 139	Les **éléments de sortie** des revues de direction sont **conservés** sous forme d'**informations documentées**.	Faux	0%	Niveau 1 : L'action n'est pas réalisée ou alors de manière très aléatoire.	Même observation précedante
181	~~Art. 10~~	Amélioration	Informel	33%	Conformité de niveau 2 : Il est nécessaire de pérenniser la bonne exécution des activités.	
182	10.1	Généralités	Insuffisant	0%	Conformité de niveau 1 : Il est nécessaire de formaliser les activités réalisées.	
183	cr 140	Toutes les **opportunités d'amélioration** sont déterminées et sélectionnées	Faux	0%	Niveau 1 : L'action n'est pas réalisée ou alors de manière très aléatoire.	
184	cr 141	Des actions sont menées pour satisfaire les exigences du client et accroître sa **satisfaction présente ou future**	Faux	0%	Niveau 1 : L'action n'est pas réalisée ou alors de manière très aléatoire.	
185	cr 142	L'organisme anticipe, corrige, prévient et réduit les éventuels **effets indésirables** de ses produits et services	Faux	0%	Niveau 1 : L'action n'est pas réalisée ou alors de manière très aléatoire.	
186	cr 143	L'organisme améliore la **performance** et l'**efficacité de son SMQ**	Faux	0%	Niveau 1 : L'action n'est pas réalisée ou alors de manière très aléatoire.	
187	10.2	Non-conformité et action corrective	Informel	43%	Conformité de niveau 2 : Il est nécessaire de pérenniser la bonne exécution des activités.	
188	cr 144	L'organisme **traite toute forme de non-conformité** y compris les réclamations	Faux	0%	Niveau 1 : L'action n'est pas réalisée ou alors de manière très aléatoire.	
189	cr 145	L'organisme **réagit à chaque non-conformité** pour la corriger, la maîtriser et prendre en charge les conséquences	Faux	0%	Niveau 1 : L'action n'est pas réalisée ou alors de manière très aléatoire.	
190	cr 146	L'organisme évalue la nécessité de traiter **les causes** des non-conformités	Faux	0%	Niveau 1 : L'action n'est pas réalisée ou alors de manière très aléatoire.	
191	cr 147	L'organisme met en œuvre, suit et évalue **l'efficacité** de toutes les **actions correctives** requises pour gérer ces non conformités	Plutôt Faux	30%	Niveau 2 : L'action est réalisée quelques fois de manière informelle.	pas de suivi réel
192	cr 148	Si nécessaire, les **risques et opportunités** définis lors de la planification sont **mis à jour** après l'exécution des actions correctives	Plutôt Vrai	70%	Niveau 3 : L'action est formalisée et réalisée.	
193	cr 149	Si nécessaire, le **SMQ est modifié**	Vrai	100%	Niveau 4 : L'action est formalisée, réalisée, tracée et améliorée.	
194	cr 150	Des **informations documentées** sur la nature des non-conformités, des actions menées et de leurs résultats sont **conservées**	Vrai	100%	Niveau 4 : L'action est formalisée, réalisée, tracée et améliorée.	
195	10.3	Amélioration continue	Convaincant	57%	Conformité de niveau 3 : Il est nécessaire de tracer et d'améliorer les activités.	
196	cr 151	L'organisme s'engage à **améliorer en continu** la pertinence, l'adéquation et la performance du SMQ	Vrai	100%	Niveau 4 : L'action est formalisée, réalisée, tracée et améliorée.	
197	cr 152	L'organisme **détermine les besoins et les opportunités** d'amélioration continue	Plutôt Vrai	70%	Niveau 3 : L'action est formalisée et réalisée.	
198	cr 153	Les **résultats de l'analyse et de l'évaluation** sont pris en compte pour identifier les besoins et opportunités d'amélioration continue	Plutôt Faux	30%	Niveau 2 : L'action est réalisée quelques fois de manière informelle.	Absence de suivi et d'évaluation
199	cr 154	Les **éléments de sortie de la revue de direction** sont pris en compte pour identifier les besoins et les opportunités d'amélioration continue	Plutôt Faux	30%	Niveau 2 : L'action est réalisée quelques fois de manière informelle.	Absence de revue de direction

Appendix 4 : Action plan

JALON		ACTION	HOW	WHO	WHEN
Update of context analysis	1	Raising awareness of the orgnism context	See awareness plan	RMI	Week 3 April
	2	Determination of internal and external issues	Brainstorming (AGENDA)	RMI + PP	Week 4 April
Update of needs and expectations of PI	3	Determination of needs and expectations of PI	1-to-1 session	RMI + PP	Week 3 April
	4	Determination of relevant interested parties	1-to-1 session	RMI + PP	Week 4 April
Scope of application INAMED	5	Review of excluded requirements	Session with consultant	RMI + consultant	Completed
	6	Document modification and coding	Session with consultant	RMI	Completed
Process and interaction sheets	7	Review & update input and output data		PP	Week 2 May
	8	Organizing EAs and ES in the SIPOC tool		RMI	Week 2 May
	9	Review of the correspondence between process logigrams and doucments		PP	Week 2 May
	10	General review of Process Data Sheets		PP	Week 2 May
Quality policy	12	Internal dissemination of quality policy	Display - welcome booklet - screensavers	RMI + RH + IT	Week 1 April
	14	Raising awareness of quality policy	See awareness plan	RMI	Week 3 April
Action for risks and opportunities	20	Raising awareness of risks and opportunities	See awareness plan	RMI	Week 3 April
	21	Analyze the company's overall risks and opportunities	Brainstorming	RMI + PP	Week 1 May
	22	Set up an action plan: deal with risks and seize opportunities	Brainstorming	PP	Week 1 May
	23	Analyze the risks and opportunities associated with each process	1to1 session	RMI + PP	Week 1 May
	24	Set up an action plan: deal with the risks and seize the opportunities associated with each process	1to1 session	PP	Week 1 May
	25	Implement a plan to monitor the needs/expectations of interested parties	1to1 session	RMI + PP	Week 1 May
Quality objectives and actions to achieve them	26	Review targets, calculation methods and target thresholds		PP	Week 2 May
	27	Set up an action plan to determine how to achieve objectives		RMI + PP	Week 3 May
	28	Monitor progress towards objectives	Drawing up dashboards and determining KPIs	RMI + PP	Week 3 May
Company resources	41	Pilot awareness plan - for employees		RMI +HSE	Week 3 April
Communication & documented information	42	Update communication plan	1to1 session	RMI + all relevant profiles	
	43	Raising awareness of the communication plan and the need to respect it	Meeting	RMI + General Management	
	44	Mapping of all process documents and coding of documents lacking cartridges		Yacine + PP	Week 3 April

Surveillance planning	58	Planning an internal audit	Set up an audit program	RMI + Consultant	
	59	Planning a management review		RMI + Consultant	
Continuous improvement	60	Raising awareness of continuous improvement and N.C. treatment		RMI	Week 3 April
	61	Fill in and track the document: non-conformity follow-up report and corrective actions		RMI	Completed
	62	Draw up an action plan table for corrective action on non-conformities		RMI	Completed
System planning and ISO certification	63	Finalize quality management system action plan (responsible and deadlines)	Meeting with PPs + general management	RMI	
	64	Finalization of the QMS plan in a GANTT chart with estimated total project duration		RMI	
	65	Use a certification body to plan a certification audit program		RMI + Consultant + General Management	

Appendix 5: Non-conformity Handling form

INAMED Group	Record	Code : ENG-SMI-03
		Version : 00
	Non-Conformity Handling Form (Correction and Corrective Action)	Date :11/03/2024
		Page :1 sur 1

Date: March 11, 2024	Issuing Service: QMS Issuer's Name: Y.M	N° fiche : SMI017

OBSERVATION (with details):
No risk and opportunity analysis has been conducted for each process.

☐ Non-conformité système ☐ Non-conformité produit

TYPE :	Reference Documents/ Records :
☐ Customer Complaint ☐ Internal Non-conormity ☐ CCP orPRPo * ☒ Internal / external Audit	Audit report

CORRECTION :

	Description of the correction	Effectiveness Evaluation of the Correction	Documents / Records :
☐ Reprocessing ☐ Destruction ☐ Other	Conduct brainstorming sessions to determine the analysis of issues .	The Document has properly filled out	Context analysis (SOWT)

Name of the person Responsiblefor th correction : Date :04 /04 / 2024 Visa	Name of the person responsiblefor the evaluation Date :04 /04 / 2024 Visa

Corrective Actions :	Details of corrective actions :
Root cause Analysis (Based on the 5 Whys) Method : the review of INAMEs issues is not planned	Proposed Actions *(selected actions are underlined)* : Integrate the review (update) of the context analysis into the management review plan .

Name of the responsible person : Y.M Department : Integrated management	signature :	Date :	Deadline:

Evaluation of the corrective action : Effictive ☐ Not Effective☐

Closure / report : … /……/…… **IMM signature :**

Observations :

** : When it concerns a product NC affecting a CCP or PRPo: the product is potentially dangerous.*

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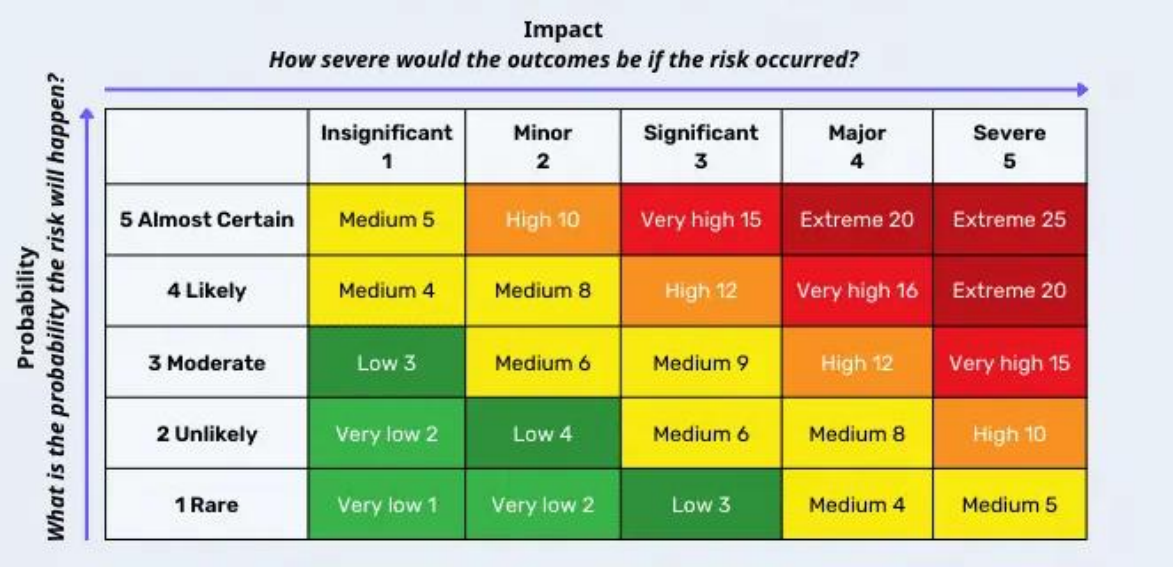
Appendix 6: *5*5 Risk Matrix*



	Insignificant 1	Minor 2	Significant 3	Major 4	Severe 5
5 Almost Certain	Medium 5	High 10	Very high 15	Extreme 20	Extreme 25
4 Likely	Medium 4	Medium 8	High 12	Very high 16	Extreme 20
3 Moderate	Low 3	Medium 6	Medium 9	High 12	Very high 15
2 Unlikely	Very low 2	Low 4	Medium 6	Medium 8	High 10
1 Rare	Very low 1	Very low 2	Low 3	Medium 4	Medium 5

Appendix7: Quality policy of INAMED

INAMED Group

POLITIQUE DE LA QUALITE ET DE LA SECURITE DES DEMREES ALIMEMTAIRES

A l'ère de la mondialisation et l'ouverture du marché, toutes les entreprises, quelles que soient leurs tailles se trouvent confrontées à une concurrence de plus en plus vive.
Dans ce contexte, seules les entreprises qui réussissent à répondre et à devancer les attentes de leurs clients, ont une chance de survivre.

C'est pourquoi, INAMED, a mis en place un système de management de la qualité et de la sécurité des denrées alimentaires conformément aux exigences des normes ISO 9001 et ISO 22 0000, qui permettra de donner au client de l'entreprise l'assurance que l'établissement, de par son organisation, ses processus, ses moyens humains et matériels, est capable de lui fournir des produits conformes à ses exigences ainsi qu'aux exigences légales et réglementaires applicables.

De ce fait notre politique se base sur les objectifs suivants :

1. Assurer la conformité des produits aux exigences des clients etaux exigences légales et réglementaires applicables.
2. Accroître la Satisfaction de nos clients et des parties intéressées
3. Améliorer les compétences de nos collaborateurs
4. Améliorer la communication interne et externe
5. Améliorer l'efficacité de notre système de management dela qualité et de la sécurité des denrées alimentaires
6. Améliorer les conditions d'hygiène à tous les niveaux

Aux fins de l'atteinte de ces objectifs, la direction générale d'INAMED est tenue de veiller à leur compatibilité avec son orientation stratégique, tout en tenant compte :

- De ses enjeux internes et externes ;
- Des attentes et besoins des parties intéressées pertinentes.

Nous nous engageons à mettre à disposition les moyens nécessaires au déploiement des objectifs, au respect des exigences légales et réglementaires et à l'amélioration continue de notre système de management de la qualité et de la sécurité des denrées alimentaires.

La Direction

SARL INAMED Route de la Briqueterie Bir Touta Tél. 024.47.01.19 Fax. 024.57.01.18 N°: 93 B 0004461-16/00

Inamed Group.
260 Route des vaches
Koléa W. Tipaza, Algérie
www.inamed-dz.com

Appendix 8:Non-conformity handiling follow up

INAMED Group	LIST	Code : ENG-SMI-04	
		Version : 00	
	Non-conformity handling follow-up - March	Date : 12/03/2024	
		Page : 1/1	

N° de Fiche NC	relevant struc	Non-conformity	Correction/ Action corrective	Date of opening	Planned closing date	closing date	Discrepancy	Efficacité (Yes/No)
	MS MANGER	No risk and opportunity analysis has been conducted for each process	**Correction:** Organize a brainstorming session to determine an opportunities analysis. **Corrective action:** Schedule the analysis of the context during management reviews.	11/03/2024	DONE			
2	All processes	plan for achieving quality objectives	Plan who, when, and with what resources the objectives should be achieved	11/03/2024	26/03/2024	24/03/2024	-2	
3	QHSE	plan for measuring instruments	The implementation of the calibration procedure for measuring instruments	11/03/2024	11/04/2024	01/06/2024	51	Not Efficien
4	HR	Absence of skills assessment	Planning hot and cold training evaluations and annual staff evaluations	11/03/2024	18/03/2024	01/06/2024	75	Not Efficien
5	QHSE	Absence of documentation for product release	- Creation of a checklist for the release of finished product batches. - Intermediate verification audits for blocked	11/03/2024	18/03/2024	17/03/2024	-1	Efficient
6	All processes	conduct analysis and evaluation due to	Ensure planning of activities to subsequently evaluate their effectiveness	11/03/2024	11/04/2024	09/04/2024	-2	Efficient

***Appendix 4:** Interview Guid*

	Interview Guide	

The national higher school of management
Quality Management
Student: Makhloufi Nesrine

Objective:

We are Master's students in Quality Management at the National School of Management.
This questionnaire is part of our qualitative study aimed at identifying stakeholders in each process, understanding their expectations and needs, and determining the communication channels and means of information transmission between them. The interview will be exclusively used for scientific purposes within the framework of our research project.

Identification of Stakeholders	-What are the interested parties related to your activity?
Identification ofNeeds	-What are the needs that connect you to this interested party?
Evaluation of Power and Interest	1. What are the needs that connect you to this stakeholder? (What does this stakeholder want?) 2. Evaluate the power of this stakeholder on a scale from 1 to 3 3. What score from 1 to 3 would you give to your interest in this stakeholder?
Communication Channels	What are the main channels and means you use to communicate with your interested parties?
Frequency	How often do you have exchanges or communications with your interested parties?