

Original Article

A Structured Evaluation of ISO 10009:2024 Quality Tools in Supporting ISO 9001-Based Quality Management Systems

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Abstract: This study evaluates the applicability and effectiveness of quality tools in ISO 10009:2024 for supporting ISO 9001-based Quality Management Systems (QMS). The objective is to bridge the gap between standard-based guidance and practical industrial implementation. The research employs a document analysis approach, focusing exclusively on the ISO 10009:2024 standard to systematically examine the characteristics, scope, and usability of its quality tools. A multi-dimensional classification framework is developed based on functional role, data requirements, PDCA alignment, area of use, and improvement stage. The results indicate that although ISO 10009 provides a comprehensive repository of tools, their effectiveness is highly context-dependent, influenced by organizational maturity, data capability, and resource availability. Basic tools are widely applicable, while advanced tools face adoption barriers due to complexity. This study contributes by reframing ISO 10009 as a decision-support toolbox and providing a structured classification framework that enhances tool selection and supports context-driven implementation.

Keywords: ISO 10009:2024, Quality Tools, Continuous Improvement, PDCA Cycle, Operational Excellence, ISO 9001.

I. INTRODUCTION

With an extremely competitive industrial landscape, organizations are bound to expand their quality, efficiency, and operational performance. This helps to ensure the structures in place for any improvement initiative are both robust and sustainable, and are implemented through quality management systems (QMS), especially those aligned with international standards. In the last few decades, methods like Lean, Six Sigma, and Total Quality Management (TQM) [1] have achieved tremendous benefits for operational excellence, mainly based on structured quality tools [2,3]. ISO 9001 is one of the best-known quality management systems and a proven method in industry. It is designed as a systematic approach that organizations can use to ensure they consistently meet product quality and customer satisfaction requirements and to harness continual improvement [4]. Its successful uptake across a number of sectors demonstrates its flexibility and relevance to different types of organisational contexts [5]. However, the effectiveness of ISO 9001 is highly determined by the connection between its principles and practical implementation, especially at the level of turning documented procedures into operational performance improvements [6].

The recently published ISO standard ISO 10009:2024 is designed to assist organizations in optimally utilizing quality tools within their quality management systems. It offers an orderly, specific group of 53 tools as a resource to help organizations in selecting, implementing and assessing suitable methods for enhancing processes and decision making [7]. It serves as a guidance standard, fostering a common and appropriate use of quality tools that improve performance, strengthen problem-solving, and facilitate data-driven decision-making. ISO 10009:2024 supplements ISO 9001 by closing the loop between requirements and real-world implementation. It provides a non-prescriptive, flexible guidance that allows organizations to implement quality management principles through the structured selection and application of tools. The standard covers tools from using simple methods, such as flowcharts and Pareto analysis, to advanced methods, such as Failure Mode and Effects Analysis (FMEA) and Quality Function Deployment (QFD).

Perhaps the most significant strength during the development of ISO 10009:2024 is that it is a true guideline on the usage of tools and not prescriptive requirements or validation of their performance in certain industrial environments. Thus, its most valuable use case is serving as a tangible reference to support your continuous improvement efforts. So far, the literature has explored the benefits of individual quality tools; they have shown that these have the potential to improve process performance, lower defects, and make better decisions [7] 8. But, these studies are usually disparate, not a generalisable mindset and often specific to industries or methodologies. For that reason, little integrated knowledge exists as to how particular groups of integrated tools operate across different industrial domains [5], [6].

From a practical standpoint, the quality tool implementation is also linked with different challenges such as resource logistics, data availability and varying levels of organizational maturity. Theoretically strong tools end up being rendered impotent when applied without adequate skill or support structures 10. Additionally, organizations focus on a narrow range of



tools, but many others are used by only a few. This gap between the demonstrated potential value of quality tools and their actual realized usage in industrial practice is well-known.

While implementation challenges cannot be eliminated, quality tools' limitations need critical assessment. Some are qualitative, allowing for a degree of subjectivity and bias; others tend to require large amounts of data as well as technical expertise, meaning they can only be used by powerful institutions. Additionally, the prevalent deployment of digital technologies and Industry 4.0 approaches poses challenging concerns about the appropriateness or flexibility of traditional quality methodologies to suit contemporary data-driven landscapes. Simultaneously, the increasing sustainability challenges—ranging from environmental to social and governance (ESG) aspects and the transition into a circular economy further increase their complexity. These pressures have put forward the need for organizations to not only achieve process efficiency and quality improvement but also link their attribute practice under the umbrella of sustainability. This study attempts to address these lacunae by developing a critical assessment of ISO 10009:2024 through an evaluation of the benefits, advantages, drawbacks and problems along with the future scope of enhancement pertaining to quality essential tools as provided by standards in industrial scenarios. This research contributes to the literature by bridging the gap between standard-based guidance and practical implementation based on a structured review approach that provides theoretical contributions as well as recommendations for practice towards organizational improvements in deploying quality tools effectively. This research represents one of the first systematic assessments of ISO 10009:2024, building on a multi-dimensional classification framework to improve tool selection and functionality.

II. LITERATURE REVIEW

A) *Quality Tools in Quality Management*

Quality tools have been acknowledged as prerequisites for continuous improvement in relation to most quality management systems (QMS) for decades. Well-known tools of basic quality management like Pareto charts, check sheet, cause-and-effect diagrams, and flow charts have been widely accepted because of their simplicity in detecting the inefficiencies in processes and detecting the problems regarding quality [12]. Various tooAdvanced tools like Failure Mode and Effects Analysis (FMEA) [13], Statistical Process Control (SPC) [14], as well as Quality Function Deployment (QFD)[15], offer more advanced analytic capabilities for risk analysis, control of variation and customer-centric design improvement. This increased usefulness in industrial settings is based on their incorporation within structured methodologies, for example, Lean Six Sigma [16]. Research has revealed that the systematic application of quality methods can remarkably increase operational efficiency, decrease defects, and ensure wider decisions [17][19]. They are, however, largely dependent on their context in terms of organizational capability [3], the availability/receptiveness of data [4] and process complexity.

B) *Relationship between ISO 10009:2024 and ISO 9001:2015*

ISO 10009:2024 is a new ISO higher-level structure (HLS) standard developed to complement and work in harmony with ISO 9001:2015, one of the prominent quality management standards belonging to the ISO 9000 family. However, they significantly differ in their scope and functioning. ISO 9001:2015 lays out the requirements for a Quality Management System (QMS), while ISO 10009:2024 provides guidance on how to choose and use quality tools to successfully implement those requirements. Agenda 2030 further diversifies its principles, establishing a process-based approach, risk-based thinking. ISO 9001:2015 directs organizations to manage processes and maintain the consistency in product and service quality while continuing to improve performance over [20]. On the other hand, ISO 10009:2024 is a supplementary standard [21] which provides an organised suite of tools to cover specific clauses in support of the implementation and comprehensiveness of ISO 9001. Regarding implementation, ISO 10009:2024 complements ISO 9001:2015 by converting abstract requirements into tangible processes and techniques. For instance, clauses related to monitoring and measuring (Clause 9), analysis and evaluation, and improvement (Clause 10) of ISO 9001 can be successfully implemented using Statistical Process Control (SPC), root cause analysis, and FMEA. Thus, ISO 10009 is a kind of toolbox that helps organizations to better meet the requirements of ISO 9001.

ISO 10009:2024 is in accordance with the philosophy of continuous improvement as part of ISO 9001, including programs such as PDCA (Plan–Do–Check–Act). Several widely accepted quality tools recommended in ISO 10009 can be mapped across every phase of the PDCA cycle so organizations are able to identify problems (Plan), institute solutions (Do), track performance (Check) and standardise improvements (Act). This alignment strengthens the practical applicability of ISO 10009 in processing an ISO 9001-based QMS. Yet, in spite of that complementary bond—the nursing nature of the instinct—a significant limitation lies. ISO 10009 is focused more on what tools are available and not on how to choose, integrate and evaluate these tools in the context of ISO 9001. This can result in poor alignment between the tools and some of the specific QMS needs – for tool usage, organizations must either outgrow their data capabilities or have the right level of process maturity.

C) Benefits and Advantages of Quality Tools

The literature points out numerous advantages in the implementation of quality tools [6]. Second, organizations can quickly detect root causes of defects and inefficiencies by using quality tools that improve process visibility [22]. Tools like Pareto analysis and root cause analysis have long been reported to aid data-driven decision-making and prioritization of improvement initiatives [8]. Secondly, quality tools support formalized problem solving and standardization which is necessary to maintain improvements. For example, SIPOC and process mapping help in establishing how processes interact and where they end or begin, while tools like 5S and Kaizen assist companies in developing a culture of continuous improvement at the ground level. The reason these tools work so well is because they are simple in nature and relatively easy to implement, making them widely applicable in most industries.

By establishing a standard analytical framework for responding to quality-related issues, quality tools reduce ambiguity and improve coordination of decisions impacting both front-line operations and the work function across an organization, enhancing organizational communication and cross-functional integration. It is especially important because ISO 9001 is principle-based and does not provide prescriptive operational detail, and standards become a key practice for successful operation. This level of abstraction often leads to gaps in implementation at the operational level. Here, ISO 10009:2024 serves a bridging purpose by offering systematic guidance on the choice and use of quality tools, translating principles of quality management at a high level into practical mechanisms. However, the ease, versatility and relevance of these tools provide broad applicability across a variety of industrial contexts ranging from manufacturing to services; thus, their effectiveness generally relies on contextual alignment, competence and organizational level of maturity. Without these conducive features of the context, tool standardisation will end up merely satisfying some form of requirements rather than actually producing significant effects on performance.

D) Limitations of Quality Tools in Practice

However, although quality tools have some advantages, they also have many limitations when applied in the real-world industrial contexts. A noteworthy shortcoming is excessive dependence on qualitative assessment, particularly in methodologies like brainstorming, SWOT analysis, and fishbone diagrams that are fundamentally subjective and biased. The absence of supporting quantitative data may undermine the outcome reliability. Moreover, more advanced tools: Failure Mode and Effects Analysis (FMEA) and Quality Function Deployment (QFD) can often be linked with high implementation complexity needing expertise, time and resources. This limitation restricts their use, especially among weaker SMEs with limited capabilities that either avoid them altogether or apply them superficially and in a vague way, which reduces their overall impact [11] [24]. While the literature on the benefits of quality tools is vast and well-established, their appropriateness in a present-day industrial context shaped by both rapid digitalisation and sustainability demands has been insufficiently investigated. The current literature focuses mainly on operational and economic benefits of specific tools; the application of the tools in different contexts is still less explored, along with their integration with digital systems and overall contribution to sustainability goals. Moreover, ISO 9001 forms a basis for quality management but is too abstract and principle-based for practical use; additional guidance on how to implement it side by side with more detailed requirements is needed. While ISO 10009:2024 aims to fill this gap by providing guidance on the selection and application of quality tools, not enough critical evaluation exists about its practical relevance, implementation challenges (within different industrial contexts) and effectiveness.

E) Implementation Challenges

There are several pragmatic challenges that make the successful implementation of quality tools difficult. The challenges are many, but the most important one is organizational readiness in terms of qualified resources and a quality culture. Even tried and tested tools, when not adequately trained or if management shows little commitment, can be disappointing [25,26]. Another major issue is data availability from primary resolution or satellite sources. Most of the modern quality tools are highly dependent on accurate and sufficient data for analysis, but, in practice Organizations get stuck with data which is incomplete or untrustworthy. Additionally, with the growing complexity of industrial systems and the move toward digital and data-driven environments, it becomes even more difficult to incorporate traditional quality tools with advanced industrial technologies.

III. RESEARCH METHOD

The study employs a systematic document analysis with conceptual evaluation to explore the suitability of quality tools described in ISO 10009:2024. The document analysis is a qualitative research method where existing and standardised documents are analysed in a systematic way to identify common themes and patterns [27]. The main analysis source in this research is the ISO 10009:2024 standard, which outlines a comprehensive set of quality tools along with guidelines for implementing them within a quality management system. This encompasses the systematic review of some tools evaluated, describing their main characteristics, scope of application and complexity. Tools are described and positioned on different dimensions such as functional role, data requirements, PDCA alignment, area of use and improvement stage (strategic, tactical and operational). This multi-dimensional approach to classification aligns with conceptual research techniques that seek to organize and understand

complex types of systems [28]. The evaluation occurs by combining these dimensions into patterns, practical relevance and potential implementation challenges across distinct industrial contexts. Such an approach would facilitate a systematic and robust review of ISO 10009:2024, which aspires to improve the practicality and applicability of its quality tools in accordance with ISO 9001-based Quality Management Systems. Conceptual analysis enables the development of theory and framework in empirical data-scarce areas.

IV. RESULTS AND DISCUSSION

A) Descriptive Analysis of Quality Tools in ISO 10009:2024

The pie chart (Fig 1.a) illustrates the distribution of quality tools based on effort level. A majority of the tools (57%) fall under the “Easy” category, indicating that more than half can be implemented with minimal effort and basic understanding. Examples of these include flowcharts, brainstorming, checklists, Pareto charts, and 5S, which are simple, visual, and require limited data or training (Table 1). The “Medium” category accounts for 36%, showing a significant portion requires moderate training and structured application. Only 8% are classified as “Difficult,” meaning few tools demand advanced expertise and extensive resources.

Distribution of Quality Tools by Effort Level

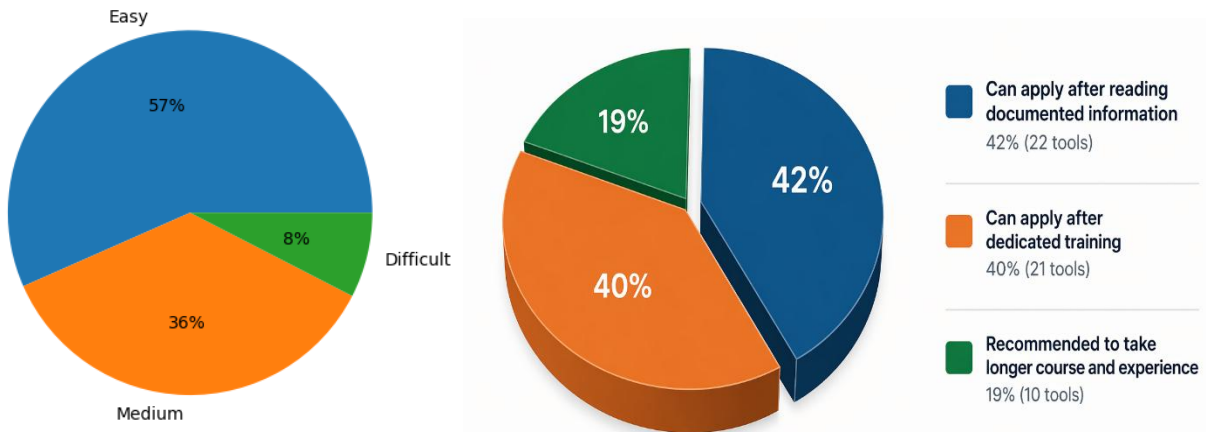


Figure 1. (a). Distribution Tools by Effort Level. 1 (b). Distribution Tools by Capability

This implies that most tools are accessible, enabling organizations to quickly adopt and embed quality practices without significant barriers or high initial investment. Consequently, organizations can start using the easy part and achieve early improvements, build confidence among teams, and create a strong foundation for continuous improvement before advancing to more complex and data-intensive tools.

Table 1: Tools Set Based on Effort

Category	Toos
Easy	SWOT, SIPOC/COPIs, Turtle Diagram, Flowchart, RACI, Risk Register, Heat Map, Brainstorming, Quality Circles, Affinity Diagram, Five Whys, Fishbone Diagram, Is/Is Not Analysis, Process Wastes, Spaghetti Diagram, 5S, Kanban, JIT, Error Proofing, Visual Aid, Box Plot, Pie Chart, Pareto Chart, NPS, Pugh Matrix
Medium	PESTLE, Vision & Mission, Control Plan, SWIFT, Kaizen, MBO, Kano Model, VSM, ToC, Production Levelling, OEE, COQ, Radar Chart, Pre-control, Decision Tree, Benchmarking, Six Thinking Hats
Difficult	FMEA, Six Sigma Program TQM, Porter’s Five Forces, Hoshin Kanri, CTQ, FTA

The pie charts (Fig. Sections 1b) echo the focus of ISO 10009:2024 on practical use and incremental capability in selecting quality tools. This preference towards the “Easy” tools (42 %) illustrates that one of the guiding principles of the standard is accessibility, enabling organizations to easily start making improvements with minimal experience. The Medium category (40%) is structured; you train on the tools and support your systematic improvement efforts. On the other hand, only 19% of ‘Difficult’ tools can be observed, which means these advanced tools are reserved for large-scale problems with a higher level of maturity of systems (Table 2). This distribution fits with the intent of ISO 10009 to help carry organizations from basic application through progressively more competency-related tasks while avoiding depletion of resources and/or need for immediate specialism in higher-order work. This also means that most tools do not require top-notch team capability for adoption, enabling wider cross-functional collaboration and quicker implementation within organizations. It allows employees at all levels to collaborate and take ownership using basic tools such as flow charts, brainstorming or checklists. This inclusiveness facilitates an overall development of organizational learning, a bolstered problem-solving culture and allows teams to implement standout methods

gradually as their skill sets improve alongside their confidence. Figures 1(a), distribution by effort level, and (b) distribution by capability show organizations that implementation should start with “Easy” tools and low capability ones as well. Having such tools in their toolkits from the very beginning prevents frustrations coming from easy-to-use, little training required, and fast-applied solutions that one Team member gets frustrated with. This ensures you win early, gain traction and confidence in the solution quickly - ensuring participation on a broader scale across your organization. With low-effort and low-capability tools at the outset, organizations may lay a reasonable foundation for quality improvement without resource or personnel overload. With experience and familiarity, teams can slowly move towards more advanced tools that require increased capability and effort. Such a phased approach enables sustainable deployment and continuous enhancement, consistent with the spirit of ISO 10009:2024.

Table 2: Tools Set Based on Capability

Capability	Tools
Basic (Low Capability)	SWOT, SIPOC/COPIS, Turtle Diagram, Flowchart, RACI, Risk Register, Heat Map, Brainstorming, Quality Circles, Affinity Diagram, Five Whys, Fishbone Diagram, Is/Is Not Analysis, Process Wastes, Spaghetti Diagram, 5S, Kanban, JIT, Error Proofing, Visual Aid, Box Plot, Pie Chart, Pareto Chart, NPS, Pugh Matrix
Intermediate (Need Training)	PESTLE, Vision & Mission, SWIFT, Kaizen, MBO, Kano Model, VSM, ToC, Production Levelling, OEE, COQ, Radar Chart, Pre-control, Decision Tree, Benchmarking, Six Thinking Hats
Advanced (High Capability)	FMEA, Six Sigma Programme, TQM, Porter’s Five Forces, Hoshin Kanri, CTQ, FTA, Control Plan, QFD, GR&R

B) Classification of ISO 10009:2024 Quality Tools

The quality tools outlined in ISO 10009:2024 can be systematically classified into four main categories based on their functional purpose, level of analytical complexity, and typical application context in industrial practice. This classification aims to provide a more structured understanding of how different tools contribute to quality management activities, ranging from basic problem identification to advanced strategic decision-making. Specifically, the classification is developed using the following criteria:

1. Functional Role: The primary purpose of the tool (e.g., problem identification, process mapping, data analysis, or decision support)
2. Data Requirement: The extent to which the tool relies on qualitative judgment versus quantitative data
3. Classification Based on Area of Use
4. Application Context: PDCA
5. The typical stage of use within improvement initiatives (operational, tactical, or strategic level)

Based on these criteria, ISO 10009:2024 quality tools are classified into the following four categories (Table 1):

- Fundamental Tools: Tools with low complexity, primarily used for basic problem identification and visualization
- Process & Mapping Tools: Tools designed to understand, analyze, and visualize process flows and system interactions
- Analytical & Statistical Tools: Data-driven tools used for quantitative analysis, variation control, and performance evaluation
- Advanced & Strategic Tools: High-level tools used for risk assessment, decision-making, and strategic planning

a. Classification Based on Functional Role

Tools classification based on Functional Role (Table.3) not only enhances the interpretability of ISO 10009:2024 but also highlights the relationship between tool characteristics and their practical applicability in industrial environments. Importantly, it reveals a critical gap between the availability of advanced tools and their actual usability, particularly in organizations with limited analytical capabilities.

Table 3: Tools Classification Based on Function Role

Classification	Characteristic	Tools Set
Fundamental Tools	Simple, visual, easy to use, and requiring low skill levels	Check Sheet; Histogram; Pareto Chart; Cause-and-Effect Diagram (Fishbone/Ishikawa); Scatter Diagram; Control Chart (basic level); Flowchart (basic process flow); Stratification; Run Chart
Process and Mapping Tools	Understanding the system, workflow, and process interactions.	SIPOC Diagram; Value Stream Mapping (VSM); Process Mapping; Swimlane Diagram; Turtle Diagram; Workflow Diagram; Spaghetti Diagram; Business Process Model and Notation (BPMN); Service Blueprint; Input-Output Analysis

Analytical & Statistical Tools	Analytical and Statistical Tools	Statistical Process Control (SPC); Process Capability Analysis (Cp, Cpk); Regression Analysis; Hypothesis Testing; Design of Experiments (DoE); Measurement System Analysis (MSA); Correlation Analysis; Time Series Analysis; Sampling Techniques; ANOVA (Analysis of Variance); Reliability Analysis; Trend Analysis
Advanced & Strategic Tools	Complex, high-level decision-making, and integrative	Failure Mode and Effects Analysis (FMEA); Fault Tree Analysis (FTA); Quality Function Deployment (QFD); Benchmarking; SWOT Analysis; Risk Analysis; Multi-Criteria Decision Analysis (MCDA); TRIZ (Innovation Problem Solving); Scenario Analysis; Cost of Quality (CoQ) Analysis; Balanced Scorecard; Decision Tree Analysis

b. Classification Based on Data Requirement

The classification of quality tools in ISO 10009:2024 can also be viewed through the lens of data requirements (Table 4), specifically the extent to which each tool relies on qualitative judgment versus quantitative data. This perspective is particularly important in industrial contexts where data availability and analytical capability vary significantly across organizations.

Based on this criterion, quality tools can be grouped into three main categories (Table 2):

Table 4: Classification of Tools Based on Data Requirement

Classification	Criteria	Tools Set
Qualitative-Based Tools:	Expert judgment, experience, and subjective assessment	Cause-and-Effect Diagram (Fishbone/Ishikawa); Flowchart (basic process flow); SIPOC Diagram; Process Mapping; Swimlane Diagram; Turtle Diagram; Workflow Diagram; Spaghetti Diagram; Business Process Model and Notation (BPMN); Service Blueprint; Brainstorming; SWOT Analysis; TRIZ (Innovation Problem Solving); Scenario Analysis
Mix-Tools: (Quantitative & Qualitative)	Combine qualitative judgment with structured or partial data	Check Sheet; Pareto Chart; Histogram; Scatter Diagram; Run Chart; Stratification; Failure Mode and Effects Analysis (FMEA); Fault Tree Analysis (FTA); Benchmarking; Risk Analysis; Multi-Criteria Decision Analysis (MCDA); Balanced Scorecard; Decision Tree Analysis
Quantitative-Based Tools	Fully data-driven and statistically grounded	Statistical Process Control (SPC); Control Chart; Process Capability Analysis (Cp, Cpk); Regression Analysis; Hypothesis Testing; Design of Experiments (DoE); Measurement System Analysis (MSA); Correlation Analysis; Time Series Analysis; Sampling Techniques; ANOVA (Analysis of Variance); Reliability Analysis; Trend Analysis; Cost of Quality (CoQ) Analysis

c. Classification Based on Area of Use

The clustering of ISO 10009:2024 quality tools by improvement areas reflects a relatively formal assortment but provides insights into how such tools can enrich an organization in Table 5. Then, tools such as Kanban, JIT and Value Stream Mapping are categorized under efficiency and flow improvement, where their primary goal is to optimize processes and eliminate waste, while control-oriented tools like control charts, Pareto charts and visual aids help in the evaluation of quality over time for continued stable operations. Tools that help to prevent defects include Poka-Yoke, FMEA, CTQ and Cost of Quality analysis, which aim to reduce errors by focusing on design robustness. Similarly, problem-solving tools like root cause analysis, Five Whys and Fishbone diagrams allow for systematic diagnosis of process issues, while process mapping tools like SIPOC, BPMN and service blueprint promote a better understanding (and resulting transparency around processes. Some tools like the SPC, regression, and ANOVA are more analytical in nature to promote data-driven decision-making, while these strategic and innovative-oriented analysis methods focus on long-term improvement initiatives such as TRIZ, benchmarking and Balanced Scorecard. Collaborative tools, from brainstorming to quality circles, promote the family constellations of continuously improving within organizations ending up as organization wide transformation tools such as Six Sigma or TQM. This cluster analysis also shows that while ISO 10009:2024 provides functional classification of tools, it also implicitly exhibits shifts in focus from operational process interventions to strategic transformation interventions.

Table 5: Classification of Tools Based on Area of Use

Cluster	Tools
Efficiency & Flow Improvement	Kanban; JIT; Spaghetti Diagram; Value Stream Mapping (VSM); Workflow Diagram
Quality Control & Monitoring	Control Chart; Pre-control; Run Chart; Pareto Chart; Box Plot; Pie Chart; Radar Chart; Visual Aid
Defect Reduction & Prevention	Error Proofing (Poka-Yoke); FMEA; CTQ; COQ Analysis
Problem Solving & Root Cause Analysis	Root Cause Analysis; Five Whys; Fishbone Diagram; Fault Tree Analysis (FTA); Is/Is Not Analysis; Decision Tree

Process Understanding & Mapping	SIPOC Diagram; Process Mapping; Swimlane Diagram; Turtle Diagram; BPMN; Service Blueprint; Input-Output Analysis
Data Analysis & Statistical Improvement	SPC; Regression Analysis; Hypothesis Testing; ANOVA; Correlation Analysis; Time Series Analysis; Sampling Techniques; Process Capability Analysis; MSA; Reliability Analysis; Trend Analysis
Innovation & Strategic Improvement	TRIZ; Scenario Analysis; SWOT Analysis; Benchmarking; MCDA; Balanced Scorecard
Collaboration & Continuous Improvement Culture	Brainstorming; Affinity Diagram; Quality Circles; Six Thinking Hats
Organizational Excellence & Transformation	Six Sigma Programme; TQM

d. Classification Based on PDCA Concept

ISO 10009:2024 offers a systematic approach for identifying and using quality tools and techniques within the PDCA (Plan–Do–Check–Act) cycle (Table). This is done systematically for solving problems, leading to continuous improvement (6). The Plan phase employs analytical and strategic tools like SWOT, PESTLE, AHP, and FMEA to understand context, risks and objectives. The Do phase focuses on action, where operational tools such as SIPOC, Value Stream Mapping, Kanban and Work Breakdown Structure are used for implementing processes and collecting data. This leads to controlled and structured execution of activities, which can be relied upon for further assessment. During the Check phase, tools used for Performance Appraisal, such as Balanced Scorecard, Cost of Quality, Heat Maps and cause-and-effect analysis methods like Fishbone Diagram and Five Whys, are employed to evaluate process effectiveness and deviations. This helps you build a tool set for strategic decision making, corrective actions, and innovative decisions (e.g., benchmarking; Lewin’s Force Field Analysis; Six Thinking Hats) standardization. In summary, ISO 10009 stresses that tools should not be used as a stand-alone but incorporated into the PDCA cycle to support data-based decision-making and process capability to drive continuous improvement both operationally and strategically.

Table 6: Classification of Tools Based on PDCA

Plan	DO	Check	Action
Analytical Hierarchy Process (AHP)	Cycle Counts	Balanced Scorecard	Balanced Scorecard
Affinity Diagrams	Cost of Quality (CoQ)	Brainstorming	Benchmarking
BCG Matrix	FMEA	Cost of Quality	Dynamic Work Design
Benchmarking	Five Whys Analysis	Decision Tree	House of Quality
Brainstorming	Heat Maps	Kanban	Lewin’s Force Field Analysis
Decision Tree	House of Quality (QFD)	Management by Objectives	Management by Objectives
Is/Is Not Analysis	Inventory Turns	Net Promoter Score	PESTLE
Kaizen	Ishikawa / Fishbone Diagram	Process Wastes	Porter’s Five or Six Forces
Management by Objectives (MBO)	Kano Model	Robotic Process Automation	Potential Gain in Customer Value
Net Promoter Score (NPS)	Management by Objectives (MBO)	Six Sigma	Production Levelling
Overall Equipment Effectiveness (OEE)	Mystery Shopper	Six Thinking Hats	RACI
PESTLE	Process Wastes (Muda)	Solution Effect	Radar Chart
Porter’s Five/Six Forces	Risk Register	SWIFT	Risk Register
Six Sigma	SIPOC	Theory of Constraints	Solution Effect
SWOT	Six Sigma	Work Breakdown Structure	SWOT
Total Quality Management (TQM)	Turtle Diagrams		Visual Aids
Visual Aids	Value Stream Mapping (VSM)		
	Vision and Mission		

e. Classification Based on The Typical Stage

Classification based on the common use phase within improvement initiatives categorize tools into strategic, tactical and operational levels (Table 7). At the strategic stage, Balanced Scorecard, SWOT and PESTLE are the tools used for setting direction, aligning objectives and prioritizing improvement initiatives. The tactical stage, on the other hand, emphasizes organized analysis and problem-solving with tools such as FMEA or SIPOC (or both) by finding root causes and creating designs. In the operation stage, operational tools like control charts, check sheets and visual management are utilized to track daily performance, stabilize processes and maintain improvements. This classification helps in aligning the organizational

goals and execution activities. The fact that improvement tools are classed as strategic, tactical and operational means organizational aims will be consistent with actually doing it. Strategic tools: define direction and priorities with a time span of several years (Balanced Scorecard, SWOT, PESTLE). Tactical tools are often used within improvement projects to allow for more structured analysis and solution development (ex, FMEA, SIPOC, Five Whys). Shop floor level operational tools like OEE, Kanban and Value Stream Mapping are implemented to control processes and maintain improvements. This layered approach allows organizations to translate strategy into action, ensuring data-driven improvement initiatives that are well-coordinated and continuously monitored for performance and long-term organizational efficacy.

Table 7: Classification of Tools Based on Improvement Stage

Stage	Tools
Strategic:	Analytical Hierarchy Process (AHP), Balanced Scorecard, BCG Matrix, Benchmarking, Dynamic Work Design, House of Quality (QFD), Lewin’s Force Field Analysis, Management by Objectives (MBO), Net Promoter Score (NPS), PESTLE, Porter’s Five/Six Forces, Potential Gain in Customer Value, SWOT, Theory of Constraints, Vision and Mission, Total Quality Management (TQM)
Tactical:	Affinity Diagrams, Brainstorming, Decision Tree, FMEA, Five Whys Analysis, Heat Maps, Kano Model, Risk Register, SIPOC, Six Sigma, Six Thinking Hats, SWIFT, Work Breakdown Structure, RACI, Solution Effect, Cost of Quality (CoQ), Mystery Shopper
Operational:	Cycle Counts, Cost of Quality, Inventory Turns, Ishikawa / Fishbone Diagram, Is/Is Not Analysis, Kaizen, Kanban, Process Wastes (Muda), Production Levelling, Overall Equipment Effectiveness (OEE), Robotic Process Automation, Radar Chart, Turtle Diagrams, Value Stream Mapping (VSM), Visual Aids

C) Relation ISO 10009:2024 and ISO 9001

Figure 2 illustrates the structure of the Quality Management System (QMS) within the PDCA (Plan–Do–Check–Act) cycle as defined in ISO 9001. Central to the system is leadership (Clause 5), which ultimately connects planning (Clause 6), support and operation (Clauses 7-8), performance evaluation (Clause 9), and improvement (Clause 10) into an integrated, closed-loop system. In each case, external inputs (organizational context and stakeholder requirements Clause 4) are the basis for strategic direction, and outputs align with customer satisfaction and the delivery of desired products or services that meet specified quality standards.

The PDCA is cyclical in nature, assuring that strategic objectives are continuously aligned with operational execution. This way, each phase reinforces the other, allowing for a systematic approach to performance monitoring, evaluation, and continuous process improvements. It fosters evidence-based decision-making, process efficiency, and continuous improvement through this dynamic interaction. Consequently, the QMS adapts and evolves as needed to ensure continuous improvement of organizational performance in a rapidly moving environment.

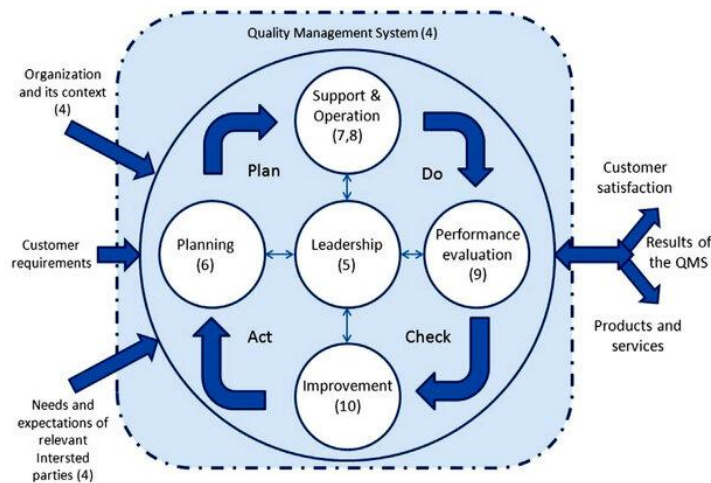


Figure 2. Structure of ISO 9001:2015 in PDCA cycle (ISO 9001:2015 Quality Management System Standard, 2015)

ISO 10009:2024 is fundamentally a reinforcing element to ISO 9001 in building an efficient, data-enabled Quality Management System (QMS). ISO 9001 specifies what organizations must implement through its risk-based thinking and the PDCA structure [29], while ISO 10009 gives practical guidance on how to operationalise these requirements in a systematic way using a suite of quality tools and techniques. Meanwhile, in the Plan phase (Clauses 4–6), tools such as SWOT, PESTLE, FMEA and QFD address and identify organizational context, risks and customer requirements. The Do phase (Clauses 7–8) takes that plan and executes it using SIPOC, Value Stream Mapping, Kanban and Kaizen to ensure process reliability and efficiency. Check

(Clause 9) assesses performance with some KPIs, Cost of Quality, and Balanced Scorecard so that outcomes can be reviewed in a data-driven manner. In this phase, the organizations standardize tools like visual aids, control chart, corrective actions and plans for continual improvement based on benchmarking and TQM practices (Clause 10). The location of the PDCA phase in the ISO 9001 clause for corresponding quality tools in Table 6. In some cases, without ISO 10009, implementation of quality management principles is likely to be driven by compliance and a focus on documentation. On the other side, just applying quality tools themselves without any organized management system would be rather a property of strategy. Hence, this integration enables a synergistic framework that not only enhances organizational agility but also helps in facilitating evidence-based decision-making and accelerates operational excellence.

Figure 3 depicts this integration within the Plan-Do-Check-Act cycle of ISO 9001, whereby leadership (Clause 5) integrates planning, doing, checking and acting in a closed-loop manner. External input-organizational context and stakeholder needs (Clause 4) hold power over the system, and rather than outputs, concern customer satisfaction and quality performance. Such cyclical bases confirm an ever-evolving alignment of strategy with operations and underpin systematic improvement on a sustainable basis.

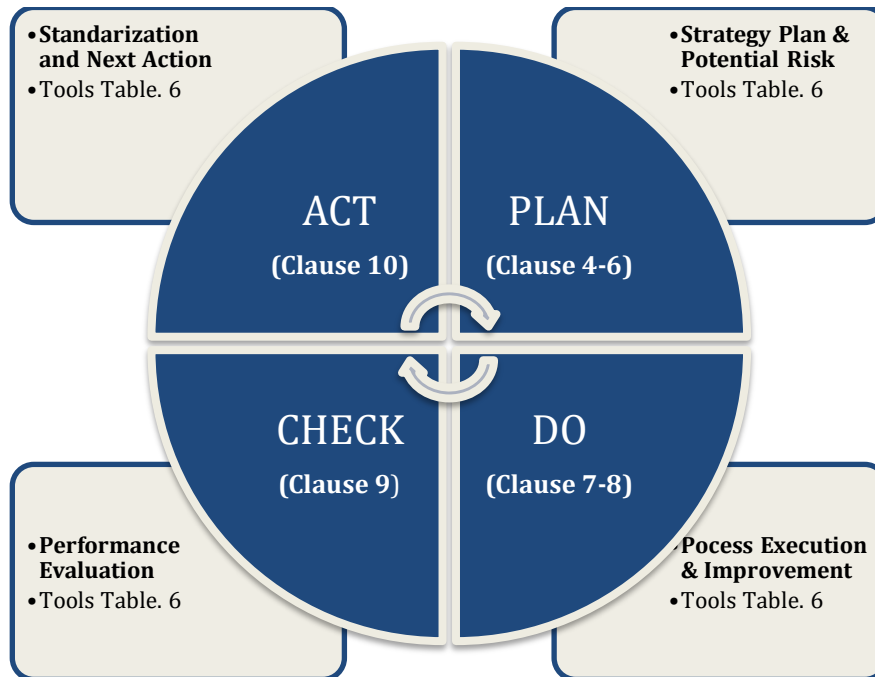


Figure 3. Integration of ISO 10009:2024 and ISO 9001 by the Author

D) Strengths of ISO 10009 Tool Structure

One of the major strengths identified is that you cover a wide array of tools. The standard successfully combines both traditional tools and advanced state-of-the-art instruments that make it possible for organizations to tackle a diversity of quality-related issues. A key strength is its versatility of application. Most of the tools used in these implementations might not be specific to industries, thus making them a shelf life portion usable across both manufacturing and services sectors. Pareto charts and flowcharts are particularly useful basic tools, since they produce widespread engagement without substantial investments. Most tools (57% in Fig 1A and 1B) are low-effort, low-capability-based tool sets, meaning they can be executed with almost no previous expertise or minimal training. This feature reduces the entry barrier for organizations and allows employees to participate at various levels. This suggests that companies can learn and improve quickly, find early wins and help teams grow in trust with one another. This is particularly useful for small and medium enterprises (SMEs), which frequently lack the resources and expertise. All of the tools can very much be utilized for service, and service-based industries as well—not just limited to manufacturing! This makes ISO 10009:2024 broadly applicable, enhancing the relevance of this standard in diverse organizational contexts as well as supporting continuous and scalable approaches to quality improvement.

E) Limitations and Gaps

a. Tool-Centric Approach

ISO 10009:2024 has a primarily tool-centred focus, encouraging lists and descriptions of quality tools but providing too little guidance on how to select or use them. Consequently, for organizations that are short on resources or less mature and

thus may lack the ability to discern which the best tooling is in the specific operational context they find themselves in. Some tools at the basic level are GOOD. This limitation lowers the practicality of the standard and could result in inefficient or unwise tool adoption.

b. Lack of Integration Guidance

Another major limitation is the lack of clear and direct integration guidelines between GRC and existing management systems, particularly ISO 9001. Conceptual integration can be demonstrated through frameworks (e.g., Figure 3 in conjunction with the tools provided in Table 6); however, there is no formal definition within the standard to incorporate such tools across a structured Quality Management System (QMS). As a result organizations struggle to harmonize their tool choices with process-based approaches, in turn limiting the effectiveness of implementation.

c. Inconsistency in Mapping QC Tools in Correlation with PDCA-Cycle Steps

Lack of consistency between existing quality tools for mapping to the PDCA cycle steps under the total quality management framework. In standard PDCA methodology for continuous improvement, 30 tools used for root-cause analysis of problems (such as the Ishikawa diagram and Five Whys) are typically placed in the PLAN phase, since they help identify problems and conduct causal analysis before implementation. However, the fact that such tools fall under the DO phase in some parts of the standard (e.g., Annex A tables) is ambiguous for practical application. This inconsistency can also be very confusing for shopfloor employees, where a solid line between analysis and execution is needed. Consequently, the processes for problem-solving can become fragmented, and solutions may be implemented before confirming the root cause of a problem. This gap highlights how aligning standard interpretation and operational practice is crucial to keeping PDCA simple, consistent, and actionable at all levels of the organization.

d. Lack of Integration with Quality 4.0 and Sustainability Principles

The standard allows limited consideration of sustainability dimensions, in terms of environmental and social (categories are well-controlled and established), governance metrics data, and green quality practices. It is not aligned with the Quality 4.0 concepts, such as real-time data analytics, digital integration, artificial intelligence and automation interface capabilities. Consequently, the standard does not provide a clear direction on how conventional quality tools can be tailored or advanced for digitally-enabled ecosystems that truly align with sustainability goals. This limits its relevance in the current industrial contextualization where organizations are confronted with achieving a merger of operational excellence, digital transformation and sustainable performance. ISO 10009 is still based on conventional methodologies and needs clarity in its alignment to Quality 4.0 & sustainability frameworks that help with data-based decision making, predictive quality management and environment-friendly operations.

F) Implementation Challenge

The complexities of challenges to implement ISO 10009:2024 quality tools are amplified by trends in digital transformation, sustainability requirements and differences in maturity along organizations. One of the major difficulties lies in the fusion between traditional quality tools with IoT, big data, and artificial intelligence, since organisations experience barriers such as system interoperability, digital infrastructure limitations, or data availability. As a result, you often see tools in play in a piecemeal and reactive way rather than as part of an end-to-end real-time decisioning framework. The second most important issue is the integration of sustainability in quality practices. Organizations feel the heat to deliver against environmental and social impacts, but most quality tools were never built to account for sustainability performance without added metrics, data systems, and strong cross-functional alignment. This adds more complexity to the implementation of applications, especially within resource-constrained systems. Also, the gap in skills and knowledge is too large. While the deployment of these advanced tools requires applicable expertise in areas such as data analytics, digital systems and sustainability at operational and managerial levels, that is largely lacking. Moreover, lack of support from leadership and resistance to change impede successful implementation. Finally, the lack of specific guidance on which tools to use and how to integrate them in ISO 10009 could lead to tool misuse or limitation. Confronting these challenges will require a concerted digital enablement, workforce development and tighter alignment of strategy to execution.

V. CONCLUSION

Although ISO 10009:2024 provides a structured, comprehensive repository of quality tools, this study illustrates that its practical effectiveness is largely context-dependent and contingent on the level of maturity and data capability in organizations. Even with more availability in advanced tools, there is a strong gap between what is available to use and the real-world application – many high-end tools are based on niche expertise and require expensive resources. ISO 10009 should be used as a context-dependent decision-support toolbox from a managerial perspective, rather than as a mere prescriptive checklist, based on specific operational needs and considerations regarding available resources for the organization when prioritizing and selecting tools to be utilized. Meaning for academics: This study contributes by presenting a new multi-dimensional classification framework, which will improve the applicability and interpretability of quality tools across different industrial contexts. Nonetheless, the standard is still

mainly anchored in traditional approaches and lacks sufficient integration of more recent paradigms (Quality 4.0; sustainability). The lack of integration with digital technologies, real-time analytics, and ESG-oriented performance metrics confines it as a relevant concept to the present-day industrial landscape. One limitation of this study is the conceptual and literature-based approach. Tipology of methods. Future research must focus on empirical validation, approaches for selection of quality tools, and developing systems where quality tools are interfaced with digital and sustainability frameworks to improve the efficacy and the industry impact margin. You can expect future integration of AI-driven quality analytics, IoT-enabled monitoring and sustainability performance indicators.

Recommendations

Due to the global pressure on sustainable development and ESG (Environmental, Social and Governance) and rapid digitalization including IoT (Internet of Things), it is inevitable that a broader application approach of ISO 10009:2024 quality tools towards more integration, a data-driven and sustainability-oriented framework needs evolution. The tools themselves are still valid, but their relevance depends on how they can benefit from real-time data and digital technologies applied to modern industrial environments. Focus on reframing traditional tools and digitizing them. Such as, VSM can be turned out into Digital VSM [32]; poka yoke can be converted to digital poka yoke by embedding IoT sensors there [16], which enable features on real-time data capture of energy consumption, machine utilization and emissions for gear. Another example where you can add value is upgrading Statistical Process Control (SPC) to real-time SPC dashboards, allowing automated monitoring and response in a timely manner if there are deviations from the process. Cost of Quality (CoQ) can turn into Cost of Poor Sustainability (CoPS), tracing using digital databanks. Secondly, the combination of IoT and advanced analytics moves organizations from reactive to predictive and prescriptive quality management. They can be leveraged for predictive upkeep, fault forecasting and anomaly spotting, making traditional approaches like FMEA and control mapping far more scalable with the help of machine learning models. This reliance on robots helps to enhance process adherence and reduce human error in repetitive quality activities through Robotic Process Automation (RPA). On top of that organizations should use sustainability and digital performance measures in their management systems, enabled through data collection and visualization platforms. Important sustainability tools to be proposed include the Sustainable Value Stream Mapping (SVSM) [33] and Life Cycle Assessment (LCA) [34]. Thirdly, integrating ISO 10009, as well as digital ecosystems and standards, including but not limited to ISO 14001 and Industry 4.0 frameworks, will support organizations in creating smart, sustainable resilience operations. This change positions quality tools as more than just analysis methods; they are now part of an intelligent, connected, future-ready quality management system.

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