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Guidance on:

Auditing a Quality Management System that uses Artificial Intelligence (AI) systems

Contents

INTRODUCTION

Artificial intelligence systems (AI systems) are increasingly being integrated into quality management systems (QMS) processes such as design and development, supplier evaluations, customer interactions, predictive maintenance, quality control, and process optimization. While these integrations are an opportunity to improve efficiency, consistency, and decision-making, they have the potential of introducing risks and complexities that may affect process performance and the organization's ability to consistently provide conforming products and services.

While AI systems require auditors to acquire new knowledge and to further develop their competence, they do not require new auditing methods, nor a change in the audit objectives. AI systems are essentially advanced tools with high potential for both improvement and abuse.

This paper illustrates the challenges and considerations that should be incorporated into our existing auditing practices, providing guidance for auditors conducting ISO 9001 audits in organizations that use AI system(s).

1. AI SYSTEM USE IN QMS PROCESSES

Auditors should be alert to areas where AI systems can be embedded in QMS processes. Examples include:

- **Design and Development**: AI models generating product designs, optimizing parameters, and enhancing prototypes through predictive analytics.
- **Supplier Evaluation:** AI tools scoring or ranking supplier performance using large datasets and predictive models.
- **Customer Interaction:** Chatbots, automated response systems, or recommendation engines.
- **Predictive Maintenance:** AI monitoring equipment conditions and scheduling interventions.
- **Quality Control:** Defect detection using computer vision and machine learning, providing greater speed, efficiency, and consistency than manual inspection.
- **Production automation**: Enabling monitoring of equipment to make real-time adjustments to decrease product and process variability
- **Process Optimization:** Algorithms optimizing production sequences, resource utilization, and minimizing waste.

— **Inventory and Supply Chain:** AI-enabled tools forecasting demand, optimizing inventory levels, and monitoring supplier risks.
— **Training and Development:** AI-personalized learning paths supporting skills development and continual professional growth for operational staff.
— **Compliance and Risk Management**: AI monitoring regulatory compliance and providing real-time alerts on potential nonconformities.

2. SPECIAL ATTENTION AREAS FOR AUDITORS

An artificial intelligence (AI) system is '*an engineered system that generates outputs such as content, forecasts, recommendations, or decisions for a given set of human-defined objectives*[1]. There are many types of AI systems, e.g., natural language processing (NLP), machine learning (ML), computer vision, or generative AI (GenAI).

For auditing purposes, it is helpful to recognize that an AI system typically consists of several interrelated components. These may include:

- One or more AI models (e.g., machine learning or rule-based models),
- Data used for training and operation,
- Supporting infrastructure (hardware, software platforms, data storage, and monitoring tools), and
- A user interface through which personnel interact with the system and interpret its outputs.

Understanding these components can help auditors determine where risks and opportunities may arise and how the AI system influences QMS processes. These components often evolve over time and may interact in non-linear ways, which differentiates AI systems from conventional software tools.

AI presents unique challenges such as unpredictability, reliance on data quality and integrity, ethical considerations, security, and privacy concerns. Unlike traditional technologies, AI systems may require continuous monitoring, validation, and governance to ensure they remain reliable, unbiased, and aligned with QMS objectives. Their non-deterministic nature and potential to evolve over time mean that conventional quality controls may not be sufficient on their own to avoid unintended consequences.

[1] ISO/IEC 22989:2022 Information technology – Artificial intelligence – AI concepts and terminology

The need for additional measures addressing risks and opportunities, transparency, explainability, and accountability depends on the specific use case. Likewise, the extent to which an AI system influences the overall effectiveness of the QMS and supports the achievement of its objectives is also determined by the use case. For example,

1. The use of an AI system that predicts sales will affect planning and the disposition of resources.
2. The use of a chatbot for customer interaction can have a direct impact on customer satisfaction.

When preparing the audit, the auditor should:

- Identify whether the organization uses any AI system type for any of its processes within the scope of the QMS.
- Determine the specific function(s) of these processes within the QMS, and
- Recognize assigned responsibilities in relation to these processes.

During the audit, the auditor should

- evaluate how AI system(s) are integrated into and influence the operation of these processes, and
- obtain evidence that the organization can demonstrate that the use of AI system(s) within these processes does not adversely affect conformity, process control, or achievement of the QMS objectives.
- Obtain evidence that intellectual property rights are respected, including, but not limited to, the assurance that ISO standards and other copyrighted materials are not uploaded to AI systems, as required by ISO.

3. CLAUSE-BY-CLAUSE CONSIDERATIONS

The following clause-by-clause considerations are intended to support auditors in evaluating how the use of AI system(s) influences the effectiveness of the organization's QMS. The list is not exhaustive, and its applicability will depend on the specific AI use case, the role of the affected process, and the potential impact on meeting customer, statutory, and regulatory requirements. These considerations are meant to provide practical guidance to auditors as they plan, conduct, and report audit activities where AI system(s) are integrated into QMS processes.

Clause 4: Context of the Organization

- Has the organization considered the implications of the use of AI system(s) when determining its internal and external issues? E.g., technological complexity,

dependence on external AI providers, availability and competence of personnel necessary to ensure effective oversight of AI system(s).

- Has the organization identified customer requirements in relation to the use of AI systems? E.g., specific considerations for transparency and explainability, expectations regarding accuracy of AI-generated outputs, contractual clauses regarding human oversight, and restricting automated decision-making.
- Has the organization identified statutory and regulatory requirements in relation to the use of AI systems, such as those related to data privacy and information security? E.g., sector-specific AI regulations, cybersecurity, and data protection regulations.
- Have interested parties affected by AI-driven decisions been identified, and are their needs and expectations understood? E.g., personnel subject to AI-supported performance evaluation, suppliers evaluated through AI-based scoring systems, and customers interacting with chatbots.

Clause 5: Leadership

- Are appropriate resources available to ensure the controlled use of the AI system(s) in a manner that supports conformity of products and services and the achievement of QMS objectives?
- When promoting ethical behaviour, does top management ensure that ethical issues related to the use of AI are addressed and that a culture of responsible use of AI is promoted, e.g., respect for intellectual property rights and confidentiality?
- Does top management take accountability for ensuring that the AI system(s) within the QMS support its effectiveness and achievement of intended results?
- Have appropriate roles and responsibilities been defined and assigned for the activities related to the AI system(s) lifecycle, including
    - ownership of data inputs,
    - activities related to the design, operation, updating, maintaining and decommissioning of AI system(s), as applicable,
    - operational controls,
    - performance monitoring,
    - interpretation of AI outputs.

Clause 6: Planning

- Has the organization determined and addressed risks and opportunities related to the use of AI system(s)? E.g., risks of biased or inaccurate outputs, overreliance on automated decisions, and opportunities for enhanced customer experience.
- Are AI-related risks such as algorithmic bias, data quality issues, unintended outcomes, or model drift identified, evaluated, and addressed?
- Has the organization planned appropriate controls for the use of AI system(s), including human oversight, validation, and safeguards for unintended outcomes where needed?
- Has the organization established contingency plans for AI system failures or degradation in performance, including how such events will be detected and managed?
- Where AI system(s) influence QMS processes, are relevant quality objectives and planning arrangements reviewed to ensure continued alignment with the organization's strategic direction?
- Where AI system(s) rely on data inputs that may affect process performance or conformity, has the organization considered the adequacy of data quality controls as part of its risk-based planning?

Clause 7: Support

- Are adequate resources available to maintain and update AI system(s), including access to technical expertise, data quality management, and cybersecurity support
- Have infrastructure needs been determined, and is adequate infrastructure available to ensure consistent, reliable, and secure operation of the AI system(s), including hardware, software, data storage, and monitoring tools?
- Is the organization able to demonstrate that personnel who use, manage, or oversee AI system(s) meet the determined competence requirements?
- Are appropriate communication channels in place to ensure that relevant personnel understand the purpose, limitations, risks, and opportunities, and expected use of the AI system(s)?
- Is documented information established and controlled, and where traceability is necessary to ensure conformity or meet applicable requirements, does it address aspects such as data lineage, model version control, modifications or retraining, and AI-generated outputs used in decision-making?

Clause 8: Operation

- Where AI system(s) are used within operational processes, has the organization ensured that their use supports the achievement of intended results and does not introduce unintended risks affecting conformity of products and services?
- Are such processes monitored, and are changes related to the use of AI system(s) controlled?
- Does the use of AI system(s) affect customer experiences, and how does the organization address AI system-related customer concerns?
- Where AI system(s) are used to support design and development activities, how does the organization ensure that appropriate verification and validation activities are performed prior to implementation or release?
- Where AI-generated outputs support design specifications, analyses, simulations, calculations, or technical decisions, how does the organization confirm that such outputs are suitable for their intended use and do not introduce unintended risks affecting product or service conformity, safety, or regulatory compliance?
- How does AI impact supplier relations, interactions and supply chain management?
- If the AI system is externally sourced or maintained, how were the provider and the technology itself evaluated?
- Where AI-generated outputs are used in processes affecting conformity or regulatory compliance, has the organization determined whether human review or oversight is necessary based on risk, complexity, or applicable requirements? For example, where AI outputs influence product release decisions, safety-related determinations, or regulatory reporting.
- Where traceability is necessary to ensure conformity of products and services or meet applicable requirements, is traceability maintained for decisions influenced by AI outputs?
- How does the organization ensure the consistency, correctness, and reliability of AI outputs?
- If the AI system is developed by the organization itself:
    - Are processes defined for data acquisition, validation, and protection (quality and integrity of training data)?
    - Has the AI system been determined to be capable of meeting the required outcomes?
    - How was the dataset assembled for training the AI model (natural, semi-synthetic, or synthetic)?
    - Are training and update activities defined and controlled?

- Is the performance of the AI system evaluated to confirm that it supports effective process operation?

- Are changes to AI system(s) controlled to prevent unintended changes to process performance or product/service conformity?

Clause 9: Performance Evaluation

- Are monitoring and evaluation mechanisms in place to evaluate AI system performance (e.g., accuracy, relevance, consistency)?
- Are customer satisfaction trends evaluated for potential impacts arising from AI-enabled processes or interactions?
- Is internal auditing addressing the effectiveness of AI-influenced processes?
- Is information related to the performance and effectiveness of AI systems an input into management review?

Clause 10: Improvement

- Is continual improvement applied to both the AI systems and the processes they support?
- Has the organization evaluated opportunities to improve the reliability, transparency, and responsible use of AI system(s)?
- Are nonconformities or complaints involving AI system outputs recorded, analyzed, and addressed?

4. COMPETENCE REQUIREMENTS FOR AUDITORS

The integration of AI systems into QMS processes introduces additional considerations related to data, technology, risks, opportunities, and ethical implications. Auditors need an understanding of how AI systems operate, how they influence process controls, how they may affect conformity, performance, and decision-making across the QMS.

To effectively audit an organization that uses AI system(s), auditors should have competence in the following areas:

- Understanding of AI Concepts: Basic knowledge of how AI systems function, including machine learning, predictive analytics, natural language processing, and automation tools commonly used in operational and administrative processes.

- Risk Awareness: Ability to identify and evaluate risks introduced by AI, such as model drift, bias, lack of transparency in decision-making, cybersecurity vulnerabilities, and ethical concerns.

- Digital Systems and Data Literacy: Familiarity with how data is collected, prepared, used, and monitored in AI system(s), and how data quality, integrity, and governance influence AI performance and QMS outputs.

- Process Impact Evaluation: Capability to evaluate how AI modifies process controls, roles, responsibilities, validation activities, and monitoring requirements.

- Ethical and Legal Considerations: Awareness of emerging legal and ethical issues relevant to the use of AI system(s), including privacy, security, transparency, accountability, and potential impact on customer and other interested parties.

- AI Tools Landscape: Familiarity with common categories of AI tools and applications, such as predictive maintenance systems, computer vision for inspection, supply chain optimization applications, digital twins, and personalized training solutions.

Auditors are encouraged to engage in continual professional development related to digital technologies and AI management systems.

CONCLUSIONS

Auditing a management system in an organization that uses AI system(s) requires targeted evaluation of how these technologies influence processes, risks, opportunities, performance, and decision-making. The use of AI introduces new considerations, and auditors need to develop the competencies to reach valid audit conclusions that support continued conformity and effectiveness of the QMS.

AI systems bring opportunities for improved quality, consistency, and efficiency, but they also require new forms of governance and oversight to prevent unintended outcomes. In this context, the audit process plays a crucial role in independently evaluating how AI systems affect process controls, customer satisfaction, and conformity with requirements, potentially contributing to greater organizational awareness of such impacts.

Note: Further reading may include ISO/IEC 23894 (AI risk management), ISO/IEC 22989 (AI concepts and terminology), and THE APG paper on Auditing Digital Processes

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ISO 9001 APG paper on Auditing digital processes

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