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Quality management system auditing and ISO 19011: Fundamentals for future standardization of the method

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Abstract: Auditing is used to assess whether the requirements laid down in standards are being met. This paper studies the process of auditing quality management systems (QMS) to enhance our understanding of the process and develop a systematic approach. We focus on the information gathering and judgement parts of it. We compare the scarce literature about QMS auditing with the management system auditing standards ISO 19011 and ISO/IEC 17021-1. We incorporate insights from philosophical literature to develop a process model regarding the main steps of reliable auditing: observing reality; recalling memory and understanding the observed reality; contemplating and understanding abstract objects; expressing what is understood; judging: comparing what is understood and concluding about fulfilment of a requirement; and expressing the judgement. The methods described in these two standards are insufficient. Future researchers can use our model in developing theory on conformity assessment. The International Organization for Standardization (ISO) may use it to improve its conformity assessment standards.

Keywords: Auditing, Audit method, Quality management system, QMS, ISO 19011.

Highlights:

1. Despite its business relevance there is a lack of theory on quality management system (QMS) auditing.
2. The current standards for quality management auditing provide insufficient guidance for QMS auditing.
3. We present a philosophy-based process model for QMS auditing.
4. The model can be used for future QMS audit method research.
5. Our model can form the basis for the standardisation of the QMS audit method.

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1 Introduction

In many cases the implementation of standards for management systems is followed by auditing and certification. Quality management system (QMS) audits have become more prominent since the 80s of the last century (Karapetrovic & Willborn, 2000). QMS auditing serves companies' internal assurance and vendor appraisals, and is essential for its contribution to QMS certification (ISO 19011:2018, p. vi, Table 1; ISO/IEC 17021-1:2015). Quality management system auditing and certification is used at more than one million organisations all over the world (ISO, 2021). QMS certification signals that the quality management system (QMS) meets criteria laid down in the applicable standards, e.g. ISO 9001. However, there are doubts about the quality and value of the certificates: are these really reliable (Kuceja, 2017; Manders, 2015; Heras-Saizarbitoria & Boiral, 2012)? Are the costs for QMS certification worth the investment? This raises questions not only on the decisions to grant certificates but especially on the quality of the audits on which the certifications are based. What do these auditors actually do? In current literature this auditing process is to a large extent a black box.

This paper evaluates to evaluate the auditing method clauses in present QMS auditing standards, in particular on the information gathering part of it, and the insights in scientific literature, and aims to develop a more systematic approach to QMS auditing. We reveal the fundamental steps that constitute the core of this auditing process, with a focus on information gathering and judgements.

Section 2 describes the outcome of our literature review. Section 3 describes the research approach, and Section 4 develops a proposal for the a general process using a philosophical angle. Section 5 discusses the relevance of this process model for QMS auditing, and Section 6 compares our model with texts of the standards for QMS auditing, ISO 19011:2018, and for certifying QMSs, ISO/IEC 17021-1:2015, and discusses consequences for auditing QMSs. In Section 7, we discuss the implications of our findings, draw conclusions, and suggest avenues for further research.

2 Literature review

2.1 Introduction

Abuazza, Labib et. al. (2019), Kuceja (2017), Manders, (2015), Heras-Saizarbitoria and Boiral (2012), Biazzo (2005), Beckmerhagen, Berg et. al. (2004), Pivka (2004), and Karapetrovic and Willborn (2000) raise doubts about the reliability of QMS certification and the effectiveness of QMS auditing. We conducted a literature review to gain more insight in these doubts. QMS auditing is shaped by standards and therefore we start the literature review with the relevant standards. These standards are: ISO/IEC 17000:2020 'Conformity assessment – Vocabulary and general principles', and the standards about (Q)MS auditing, ISO 19011:2018 'Guidelines for auditing management systems' and ISO/IEC 17021-1:2015 'Conformity assessment – Requirements for bodies providing audit and certification of management systems – Part 1: Requirements'. The review is meant to investigate whether the standards and literature on QMS auditing provide information on the QMS audit method, and if so, to extract that information. This paper focuses on the information gathering process as part of the entire QMS audit. The review questions are: how is the information gathering process described, and what methods are addressed in the standards and literature? The standards are reviewed in section 2.2, the literature in 2.3. This literature includes literature on basic measurement principles, and QMS auditing and financial auditing. Section 2.4 presents the review conclusions.

2.2 Standards

ISO/IEC 17000:2020 ‘Conformity assessment – Vocabulary and general principles’ presents the basic concept of conformity assessment. Quality management system (QMS) auditing is a basis for QMSs conformity assessment (ISO/IEC 17000:2020). Conformity assessment includes five phases: (1) selection; (2) determination; (3) review; (4) decision making and (5) attestation (ISO/IEC 17000:2020, Annex A, A.1.1). The selection phase includes preparing the QMS audit, selecting the audit team members, calculating audit time, drawing up the audit plan, and determinating the audit objectives, scope, and criteria (ISO 19011:2018; ISO/IEC 17021-1:2015). The organisation’s QMS is the object of the audit. The second phase is the determination phase. Although all phases are important in the conformity assessment process, the determination is the most important. It includes investigating the object and receiving information regarding the fulfilment of requirements by the (selected) object of the conformity assessment (ISO/IEC 17000:2020, Annex A, A.3.1). At the premises of the auditee, the actual onsite audit starts with an opening meeting and concludes with a closing meeting. In between, information is gathered about the functioning of the QMS compared with the audit criteria (ISO 19011:2018; ISO/IEC 17021-1:2015). Next, the overall review of the selection and determination activities takes place leading to a conclusion about the suitability, adequacy and effectiveness of the selection and determination activities and the information provided by these activities, especially regarding the fulfilment of requirements (ISO/IEC 17000:2020, 7.1, and Annex A, A.4.1). This study focuses on the information gathering process and the judgement

The audit report is the final output of the auditing process. Based on this report, the company may have to take corrective actions. After implementation of these, a new assessment may be needed: “The completion and effectiveness of these actions should be verified. This verification may be part of a subsequent audit” (ISO 19011:2018 Clause 6.7). Also, ISO/IEC 17021-1 (9.4.10) requires an additional audit or document verification: “The client shall be informed if an additional full audit, an additional limited audit, or documented evidence (to be confirmed during future audits) will be needed to verify effective correction and corrective actions”.

A decision regarding fulfilment of requirements is made based on the final audit conclusion (ISO/IEC 17000:2020, 7.2). If this fulfilment of requirements is demonstrated, an attest is granted (ISO/IEC 17000:2020, 7.3 and Annex A.4.3).

QMS certification demonstrates that the QMS has fulfilled its requirements (ISO/IEC 17000:2020). The final activities in the process of QMS certification include a review and a decision based on a QMS audit (ISO/IEC 17000:2020; ISO/IEC 17021-1:2015, section 9.5). Proper reviews and decisions rely on the quality of auditing. The QMS standard ISO 9001 is well-known. The standards for auditing QMSs, ISO 19011 and ISO/IEC 17021-1 are less will-known and less transparent (Carnerud, 2018; Lenning, 2018). ISO 19011 provides methods for organising and performing QMS audits. Information gathering is the core process of the QMS audit. ISO 19011:2018 specifies:

> “6.4.7 Collecting and verifying information
>
> During the audit, information relevant to the audit objectives, scope and criteria, including information relating to interfaces between functions, activities and processes should be collected by means of appropriate sampling and should be verified, as far as practical.
>
> Only information that can be subject to some degree of verification should be accepted as audit evidence. Where the degree of verification is low the auditor should use their professional judgment to determine the degree of reliance that can be placed on it as evidence. Audit evidence leading to audit findings should be recorded. If, during the

collection of objective evidence, the audit team becomes aware of any new or changed circumstances, risks or opportunities, these should be addressed by the team accordingly.

Methods to collect information include, but are not limited to the following:

a) interviews;

b) observations;

c) review of documented information".

The following diagram provides an overview of a typical auditing process:

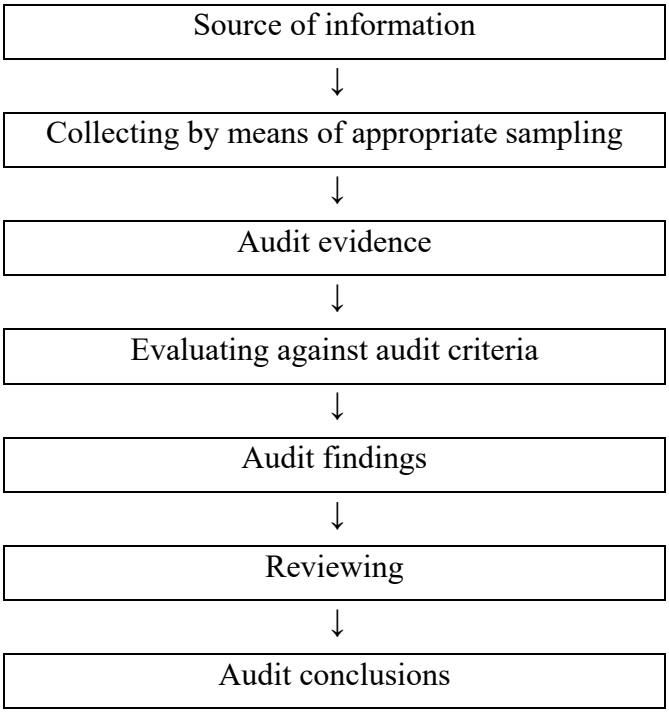

Figure 1: Overview of a typical process, from collecting information to reaching audit conclusions.

In ISO/IEC 17021-1:2015, this guidance is formulated as a requirement:

"9.4.4 Collecting and verifying information

9.4.4.1 During the audit, information relevant to the audit objectives, scope and criteria (including information relevant to interfaces between functions, activities and processes) shall be collected by appropriate sampling and verified to become audit evidence.

9.4.4.2 Methods to collect information shall include, but are not limited to:

a) interviews;

b) observation of processes and activities;

c) review of documentation and records".

This is remarkably brief. Numerous international standards for testing specify test methods in detail, but ISO 19011 and ISO/IEC 17021-1 do not specify an audit method. Only annexes of ISO 19011:2018 present some information about sampling and interviewing without describing how these methods can be or should be used during the information gathering process and the subsequent judgement process. The expression 'relevant information' is vague. What is relevant? What would be the necessary minimum? How should this information be collected?

Next, the words ‘methods (…) are not limited to’ lead to the obvious question: What other methods can there be? And for the three methods mentioned, the standard does not specify which techniques should be used. This lack of clarity about the processes complicates discussions about the validity of new auditing techniques, such as remote auditing techniques (ISO/IEC DTS 17012:2024). These provide new opportunities but also have inherent limitations. However, their validity cannot be determined properly without a better understanding of the fundamentals of auditing.

The main conclusions of this review are:

1. In the case of a QMS audit and subsequent certification, the QMS of the organisation is the object of the conformity assessment.
2. The QMS audit consists of the selection and determination activities to provide information about the QMS’s fulfilment of requirements.
3. The methods for the information gathering and judgement processes include interviewing, observing and verifying. The application of these methods is focused on ‘observable’ parts of reality: persons, activities, and documents. A direct relationship between these parts of reality and the QMS is essential.
4. Standards do not clarify how these methods i.e. interviewing people, observing activities, and verifying documents should be applied
   to provide suitable, adequate and effective information on the QMS’s fulfilment of requirements.
5. However, apparently, these methods can all be considered as kinds of observing particular parts of the reality.

The overall conclusion is that the standards ISO/IEC 17000:2020, ISO 19011:2018 and ISO/IEC 17021-1:2015 lack a comprehensive method for observing activities, interviewing persons and verifying documents for QMS auditing. The fundamental question is: how do we observe reality?

2.3 Scientific literature

2.3.1 Introduction

In 1997, Forstén expressed the need for developing a method for conformity assessment. In conformity assessment, observations lead to facts which need to be compared with requirements by professional judgments, leading to conformity statements (Forstén, 1997). “All efforts to clarify the concept [of fact-finding and making judgements] are certainly welcomed” (Forstén, 1998). Unfortunately, his plea did not lead to a prominent place for the audit method on the scientific agenda (concluded from Carnerud, 2018). This is surprising because there can be doubts about its credibility (Biazzo, 2005).

2.3.2 Measurement theory

As a determination activity QMS auditing can be considered as a kind of measurement (Karapetrovic & Willborn, 2001; Pivka, 2004). It is a kind of nonquantitative measurement leading to nominal information (ISO/IEC 17021-1:2015, 9.4.8; Churchman, 1959; Giordani & Mari, 2012; Gutierrez Alcantara, 2013; Menger, 1959; Orth, 1974; Pfanzagl, 1971). Measurement includes the measurement operation, involving an operator connecting symbols to encounters with reality (Caws, 1959; Pfanzagl, 1971).

Measurement operations have three main aspects. First, the need for the existence of an entity having properties to be measured (Churchman, 1959; Giordani & Mari, 2019; Mari & Giordani, 2012; Mari et al., 2018). Separate of the existence of the objects to be measured, one first has to have some concepts of these entities and the measurement operation (Caws, 1959). In social

reality this means that conceptual models of social entities need to be developed including causal relations between constructs (Chang & Cartwright, 2010; Portides, 2010). This is not easy because, in social reality measurement faces the challenge to determine an adequate representation of social entities, together with the empirical operation to measure such entities (Chang & Cartwright, 2010). In order to audit a QMS it needs to be implemented, and a measurement operation needs to be developed.

The second main aspect of measurement is the ability to operate measurement and to provide facts (Churchman, 1959; Giordani & Mari, 2012; Mari, 2005). The measurement operation method must be standardised for repeatedly using that operation and for the use of the measurement outcome. Standardisation is essential to ensure the uniformity of the circumstances and conditions, the method, and precision of measurement operations, and the measurement outcomes (Churchman, 1959). Standardisation includes how the empirical operation and the "mensuration" of information are connected to reality (Menger, 1959). For nonquantitative nominal measurement in social reality it is the observer's perception and mensuration that constitute the measurement operation and outcome (see Coombs, 1959; Menger, 1959). However, standardising the measurement of social entities is not easy (Annett, 2002). In QMS auditing the difficulty is that the mensuration is the auditor's subjective understanding of the functioning of a particular QMS. The accuracy and control of measurement operations to achieve accuracy of the measurement outcome is the third main aspect of measurement, and a further argument for standardization (Churchman, 1959; Menger, 1959).

Accuracy concerns the degree to which a measurement outcome deviates from reality (Churchman, 1959). In a perfect operation, accuracy will lead to an error-free factfinding where the results correspond with the facts and reality (Giordani & Mari, 2012; Mari, Maul, et. al., 2013); Kuselman et al., 2016; Mari, Carbone, et al., 2017; Stallard et al., 2018). The results are truth-bearers conveying true statements (Mari, 2003; Mari, 2005; Giordani & Mari, 2012; Mari, Maul, et al., 2013; Prenesti & Gosmaro, 2015). The control of the measurement operation concerns the extent to which this operation is performed suitably and adequately in order to be sure about the outcome (Churchman, 1959). Social sciences tend to question whether there is an objective social reality that can be measured with an accurate and precise outcome (Pendrill, 2018; Cano, et al, 2016). Investigations of social reality through human observations and understanding, satisfying metrological concepts, is still in its infancy (Pendrill & Fisher Jr., 2013). In QMS auditing, it is important that the auditor achieves precision and accuracy in the audit results. This is a common issue in measurement theory.

Solutions to ensure the precision and accuracy of audit results seem far away. Recently, Mari, Wilson and Maul (2023) published a study on measurement across several sciences. However, the authors didn't provide an elaborated method for measuring QMSs (nor have they provided any information on QMS auditing).

2.3.3 QMS audit theory

The literature on QMS auditing pays some attention to the ISO 19011 standard. Beckmerhagen, Berg and Karapetrovic (2004) and Karapetrovic and Willborn (2001) acknowledge the lack of adequate QMS audit methods. Adherence to the standard for (Q)MS auditing, ISO 19011 'Guidelines for auditing management systems', does not contribute to the effectiveness of a QMS audit (Beckmerhagen et al., 2004). Unfortunately, they fail to explain the reasons for their conclusions.

The onsite QMS audit process starts with an opening meeting after which the collection and verification of information begins (Beckmerhagen, 2004; Pivka, 2004; Karapetrovic & Willborn, 2001; Gutierrez Alcantara, 2013). The audit team verifies the effective

implementation of the quality management system by identifying and analysing the organisation's processes (Gutierrez Alcantara, 2013). The collected information is evaluated in order to become audit evidence (Karapetrovic & Willborn, 2001; Pivka, 2004; Gutierrez Alcantara, 2013). This evidence is subsequently compared with the audit criteria to form audit findings, by weighing the value of the collected information into a categories of a nominal classification system (Karapetrovic & Willborn, 2001; Goldberg & Shmilovici, 2005; Gutierrez Alcantara, 2013). They are then classified into conformities, non-conformities, observations and opportunities for improvement (Gutierrez Alcantara, 2013). The audit findings are recorded and overall audit conclusions are drawn up (Karapetrovic & Willborn, 2001; Beckmerhagen et al., 2004). The audit findings and conclusions are communicated to the auditee in a closing meeting (Beckmerhagen et al., 2004).

To establish reliable audit evidence, and to achieve precise and accurate audit findings, an appropriate and sound method and valid related auditing techniques should be developed (Willborn, 1989; 1990; Karapetrovic & Willborn, 2000; 2001; Beckmerhagen et al., 2004; Pivka, 2004). These methods and techniques include:

- Observing operations;
- Interviewing people;
- Examining documents and records;
- Using standardised checklists;
- Measuring selected system characteristics;
- Implementing performance measurement tools;
- Conducting statistical sampling;
- Employing computer-added auditing techniques;
- Computing;
- Conducting forward/backward/cross analysis;
- Using flowcharts.

QMS audits need to produce reliable audit results to be effective (Karapetrovic & Willborn, 2001; Beckmerhagen et al., 2004). Therefore, an audit must be carried out error-free (Karapetrovic & Willborn, 2000). However, there are doubts about whether this level of effectiveness can be achieved. QMS audit errors and inconsistencies can and do happen (Karapetrovic & Willborn, 2000). QMS auditors face the risk of creating incorrect, incomplete, and misleading findings due to incorrect sampling methods, mistakes in the collection of evidence, and misjudgements by incorrectly comparing evidence with the audit criteria (Karapetrovic & Willborn, 2000; Karapetrovic & Willborn, 2001; Beckmerhagen et al., 2004). Karapetrovic and Willborn (2000) do not answer the question of how a QMS auditor ensures error-free QMS auditing. To handle these risks, the need for a 'sound' QMS audit method is obvious (Karapetrovic & Willborn, 2000).

There have been a few attempts to develop QMS auditing methods (e.g. Fahmy Salama et al., 2009; Gutierrez Alcantara, 2013; Biazzo, 2005; Nivolianitou & Papazoglou, 1998). However, these attempts focus on other issues than the information gathering process. Other authors (e.g. Gale et al., 1997; Conti, 2002; Pivka, 2004; Lenning, 2018; Refaat & El Henawy, 2019) who have discussed auditing methods have failed to present auditing methods. To conclude: the literature does not describe a complete QMS auditing method. How is QMS auditing performed in practice? Kuceja (2017) conducted case study research on (QMS) auditing. He studied five cases and found that QMS auditors did not always refer to the QMS standard ISO 9001 when concluding about conformity of (elements of) the QMS or methodically verify evidence before accepting that evidence (Kuceja, 2017). Kuceja suggests that auditors should collect complete information and should critically analyze it. He concludes that he did not have a QMS audit

method as a benchmark for his research. Such a QMS audit method for scientific research is needed as a basis for investigating the practice of QMS auditing.

2.3.4 Financial audit theory

Following the suggestion of Karapetrovic and Willborn (2000; 2001) we reviewed literature on financial auditing. They have the perception that in the discipline of financial auditing theories, concepts, and methods already have been developed that could be used for improving QMS auditing theory (Karapetrovic & Willborn, 2000). However, at that time, these have not been done yet, nor did they do this themselves (Karapetrovic & Willborn, 2000; Karapetrovic & Willborn, 2001). However, it seems that they were too optimistic. The literature on financial auditing has paid little attention to the auditing method, nor does itt provide an accurate theory for it (Solomon & Trotman, 2003; Trotman et al., 2011; Mactavish, McCracken & Schmidt, 2018; Simnett & Trotman, 2018). The accuracy of audit judgements has only rarely been researched because of the prejudicial point of view that an accuracy measure is normally not available in audit situations (Trotman et al., 2011). This suggests that scientists in the discipline of financial auditing have accepted that circumstance as an unsolvable issue, and that they have given up hope for improvement on this aspect. Searching for a developed financial audit theory and method will be in vain, as such a theory has not yet been developed, and as it is very difficult to do so (Dennis, 2015; see also Hay, 2020; Hay, et al, 2014). This issue still needs to be addressed.

2.3.5 Conclusions from the literature

The literature addresses the need for reliable and effective QMS auditing by employing a sound method, including sampling, performance measurement, observing activities, conducting interviews, verifying documents, and employing performance measurement tools. The literature also explicitly mentions doubts and open issues regarding QMS auditing, such as the risks that a QMS audit outcome may contain errors and that the sampling method may not be applied in a sound way. The literature provides some ideas for improvement, but has not proposed a reliable and effective QMS audit method, or new conceptual models. Unexpectedly, the field of financial auditing has not been able to help either.

2.4 Review conclusions and research topics

The reviews of standards and scientific literature show that some general basic ideas have been expressed. ISO/IEC 17000:2020 categorises a QMS audit as a kind of determination activity, meaning that it actually assesses whether a QMS fulfils specified requirements, or not. Forstén (1997; 1998) mentions some general steps for such a process. The literature on QMS auditing shows unelaborated aspects, such as observing activities, interviewing persons, verifying documents, and sampling. However, the literature provides some directions for improvement.

The main basic aspects of measurement provide the basis for a framework for improvement, which is necessary because the review of standards and scientific literature also reveals a lack of a QMS audit method. First, there needs to be something to be audited: the functioning of an organisation's QMS. A QMS needs to exist and to be implemented, and must somehow relate to the material reality. However, determining the existence of a QMS has not been studied in the literature. Apparently, this is considered as self-evident.

Second, there needs to be a valid method to conduct a QMS audit as a nominal non-quantitative measurement operation. Such a method has neither been presented in the standards nor in the literature. Nevertheless, some activities, for example, observing activities, interviewing persons and verifying documents, have been mentioned. Regarding these activities, both the standards and literature on QMS auditing are confusing. The differences and relations concerning QMS

auditing and observing activities, interviewing persons and verifying documents require clarification. The QMS audit can include these activities, but if these activities are three separate methods, how can they be integrated in a QMS audit?

Third, a new approach to the concept of mensuration as a measurement operation of a QMS as social entity is needed. The way of mensuration by human thinking for the – mainly – nominal nonquantitative measurement of an organization's QMS needs to be developed.

Fourth, the literature review shows that QMS auditing itself as a kind of determination activity needs to be performed error-free in order to be effective, and to produce error-free true results in order to be effective. The need to achieve this has been addressed in the scientific literature, but there is no (Q)MS audit method available.

Fifth, although the need for standardization of the QMS audit operation is mentioned, such an elaborated standardized QMS audit method is not provided in the standards on QMS auditing, and the scientific literature does not provide any guidance for it.

There appears to be a need for a sound QMS auditing method for a reliable and effective QMS audit process to ensure the accuracy and precision of a true and relevant QMS audit outcome. The question of whether this can be achieved and how to achieve it has been raised in the literature, but has not been answered. However, the scientific literature has provided directions for research as a basis for solutions: consultation of philosophical views and insights. There is not a total lack of ideas, but the QMS audit method on how to perform a QMS audit is still a black box. These omissions cannot all be addressed within the scope of this study. The aim of this paper is to analyse and conceptualise some fundamental ideas for QMS auditing. For a contribution to a solution of the issues, we focus on exploring the philosophical literature regarding the fundamentals of observing and mensuration as a measurement operation. So, we will not be able to close this wide gap, but we expect to contribute towards a first step for the grounding of the theory for an audit method.

Dennis (2015) and Mari (2003; 2005) suggest using philosophical views and insights for developing audit theory. Especially metaphysical and epistemological views might be used as a basis for conceptualisation. In this paper, we follow this suggestion, resulting in three research questions: (1) To what extent can philosophical insights be used for developing audit theory? (2) Is it possible to create a process model for auditing? (3) Can this model be used to improve the current standards on (Q)MS auditing?

3 Research approach

Our research consists of two major steps: (1) developing and establishing a descriptive model for the process from observing reality up to making judgements as the basis for an auditing theory, and (2) comparing it with existing models defined in standards. We intend to study QMS auditing in a systematic way at a conceptual level. In doing so, we build on scientific sources. At this stage, we do not conduct new empirical research but search for a normative QMS auditing method. In the presumption that creating a process sequence based on philosophical views is possible, we create a model that forms the basics of the process of actual QMS auditing as a determination activity: the process of observing (a part of) reality and making and expressing a judgement. We prefer to provide a sound basis for future research, and create a basic theory for the actual auditing process, which can form the basis for the development of practical audit methods and standardization of those methods as well.

For the conceptualization we followed suggestions and used insights from philosophy to better understand the process steps of auditing. We consulted two sources in which such insights can

be found in a condensed form: the Encyclopedia of Philosophy (Edwards, (Chief Ed.), 1972), and the Routledge Companion to Metaphysics (LePoidvin et al., 2012). Additionally we used other philosophical sources for specific topics (Fish, 2010, Fleck, 1983; Hartmann, 1938; Hartmann, 1962; Moser, Mulder & Trout, 1998; Von Wright, 1977).

In order to understand what is needed for coming to judgements on the basis of observing reality several philosophical views are connected. Philosophers call this method an '*ars combinaria*', a way to connect relatively simple individual concepts into one overall conceptual model (Brody, 1972). By connecting views about propositions, judgements, facts, perceiving, observing, and the material reality and social entities, we have connected metaphysical aspects in order to find an answer to the sequence of observing the material reality up to making a judgment. We keep away from philosophical discussions, but focus on (to a certain extent) agreed-upon elementsto find fundamentals for possible solutions.

We position our research and process model within the broader framework of conformity assessment because QMS auditing is part of that. The process model to be created preferably needs to fit into the concept of conformity assessment as presented in the standard on conformity assessment principles, ISO/IEC 17000:2020, Annex A.

4 The process from observing reality towards judgments

The process of conformity assessment has five phases: (1) selection as preconditional phase prior to determination, (2) determination of conformity with requirements, followed by (3) review, (4) decision and (5) attestation (ISO/IEC 17000:2020, Annex A) We focus on the second phase. Within determination, the information gathering process is the main activity. Following ISO/IEC 17000:2020, the determination activity can be separated into several steps for establishing facts, comparing results, and making judgements, see above in Figure 1.

As mentioned above, the standards do not indicate *how* to obtain informationor *how* to evaluate the functioning of a QMS. Descriptions such as: 'only information that can be subject to *some* degree of verification should be accepted as audit evidence', and 'where the degree of verification is *low* the auditor should use his or her professional judgement to determine the degree of reliance' raise questions. What constitutes *some* and what is *low* in these cases (ISO 19011:2018, 6.4.7)? It is clear that these (mental) activities need to be carried out, but unclear which method(s) should be used to do this. The texts show serious omissions of the requirements and guidelines regarding the determination of conformity with the requirements. Scientific research is necessary for grounding a theory for a method of the information gathering process, as the main part of the determination activity.

The ultimate aim of theory is to gain a better understanding of reality. It should be informative for practical use. That practice demands valid QMS audit results based on correct judgements. These judgements need to be based on observing reality (see Forstén, 1997; 1998). How can we come to correct judgements? When the reviewed literature does not provide answers, we need to turn to philosophical views and combine them to conceptualise the process from observing and perceiving reality to making judgements (Dennis, (2015); Mari (2003). Thereafter, we can add some specific aspects concerning conformity assessment in general and QMS auditing in particular: a judgement about the fulfilment of requirements and expressing the judgement into a conformity statement.

Regarding that determination process, the baseline of the actual information gathering process is as follows. The start of the process isan encounter with reality by the (human) senses, mostlyvisual and aural observing (see below Figure 2). Next, mental activities are needed in order to understand what has been observed (Hirst, 1972a; 1972b; 1972d; 1972e). This

understanding leads to establishing facts (based on Dodd, 2012). Facts can be compared by our minds, to come to judgements whether they match or not. And these judgements can be expressed so that we inform others about our judgements (based on Gale, 1972). For recognising something, this mental activity is important, and all previous stages are necessary for achieving the result. This seems to be a simple straightforward process, but only this description is simple; in reality this process is much more complex (based on Hirst, 1972d; 1972e).

4.1 Observing reality

Visual and aural observing and perceiving a part of the reality includes sending and receiving. At the receiving side it first involves the sensational (physiological) activity of observing parts of the reality. Observing is an activity by which human senses are focused on a part of the reality in order to receive impressions of that reality. Most commonly, we observe with our eyes and ears, sometimes we also smell, taste, or touch. Using our eyes, the impressions of reality, provides us humans with images about parts of reality (Hirst, 1972b; 1972d; Fish, 2010). We observe things such as trees, flowers, tables and chairs, and also complex human-made constructions such as buildings and bridges (Mari, 2005).

Material objects have substance, and each substance has properties such as colour, length and hardness (O'Connor, 1972). At each moment of time, a material object has one quality of a property for each property (e.g. an object with the length of 1 meter): a property-quality-combination (based on the famous remark by W.V. Quine: 'to be (…) is to be reckoned as a value of a variable', Quine, 2012, p. 12). These property-quality-combinations might change in the course of time. Many of those properties are stimuli which can be received by human senses. Presumably other properties are not stimuli for the human senses but can be made visible by instruments (like radioactive radiation). Properties, such as mass or shape, are intrinsic to the object (Cameron, 2012). Other properties are external; these exist in relation to other things (e.g. speed as a relation between distance and time) (Ellis, 1972; Jammer, 1972; Hirst, 1972c; 1972d; 1972e; O'Connor, 1972; Woozley, 1972; Cameron, 2012). The world is full of material objects (O'Connor, 1972). Motion can also be observed. Objects can change in the course of time; they can change mutual positions and by motion they form events (Jammer, 1972; Dodd, 2012). Because of motion of material objects, these events can be observed. Observation makes humans aware of these objects and (some) of their properties (based on Cameron, 2012).

Next to material objects, non-material objects are considered to exist. These objects are considered to be, at least partially, mind-dependent (Hirst, 1972d; O'Connor, 1972; Thomasson, 2012; Searle, 1995). In general, these non-material objects somehow have a relation to material objects. Non-material objects include social entities and relate to interpersonal phenomena which "would not exist without human behavior, customs and agreements", but which are beyond the control of a (every) person individually (Thomasson, 2012). They cannot be observed, but someone can be aware of them by what people consider as a social entity and by the awareness of mutual agreements of acceptance of behaviors, customs and agreements.

In summary, the world consists of material and non-material objects, relationships and events. Material objects and events can be observed by human senses. Non-material objects have a relation with the material world and are considered to exist in the world. Social entities, such as management systems, are non-material objects. Requirements are also non-material objects, and are expressed as commands or prohibitions.

4.2 Recalling memory and understanding what has been observed

Now, we come to the second part of the process from observing towards a judgement: mental activities. These mental activities include recalling memories, contemplating and comparing. Observation, e.g., by eyes, is a matter of looking at something material. By recalling memory, a person can understand what she observes (Shoemaker, 1972). This presupposes that there must be something in a memory before it can be recalled. It is common sense that humans fill their brains with memories via experiences and education. By recalling memories after observing something material, a human can understand what something is. That is to say, if the person is not mistaken: only correct recognition by correctly recalling memory leads to understanding that something is what it is. Any form of illusion or mistake will lead to incorrect understanding (misunderstanding) (Hirst, 1972a; Fish, 2010). So, the observation should not be disturbed. To avoid mistakes, the observing and perceiving need to be carried out correctly in the sense that the consequential activity follows the preceding activity logically, e.g. if we observe 'A', we understand 'A', and we express 'A' (Hirst, 1972b; Aune, 1972). In order to correctly understand what something is, a person needs to be an expert in that matter. In many cases, especially in daily life situations, all humans are experts, simply because they have shared equivalent experiences or received equivalent education. In other areas, specialised experts have the specific memory to be recalled. All persons can look at something, but only the expert can really see and understand (Fleck, 1983). A correct understanding by correctly recalling memory leads to understanding correctly that something is what it is. In this way we (humans) establish a fact.

On the other hand, we cannot observe what is missing or absent. The determination that something is missing or absent is a conclusion based on observing reality. Such conclusions are also facts. Thus, we can consider a fact as a correct understanding that something is what it is, or as a correct conclusion that something is absent (based on Prior, 1972a; Prior, 1972b; Aune, 1972; Dodd, 2012).

4.3 Contemplating, understanding and expressing understanding objects

These activities, observing and perceiving, are applicable to property-qualitycombinations of material objects. What about understanding non-material objects? Unfortunately, they cannot be observed and perceived in the same way as material objects. To understand a non-material object, such as a social entity, something material must be observed and understood (by recall of memory), followed by the mental activity of contemplation to understand what the non-material object is (Hirst, 1972b; 1972c; 1972d; Aune, 1972; Woozley, 1972). The outcome of this contemplation can be considered as a fact (based on Dodd, 2012).

After observing and understanding what a material or non-material object is, the mind can also conclude that it is not anything else. A correct conclusion about what something is not, following accurate observation and correct understanding, leads to a fact about what it is not (based on Prior, 1972a; 1972b; Aune, 1972; Dodd, 2012). An established fact may concern three different mental situations (Dodd, 2012):

1. A correct understanding of what something is after correctly observing a property-quality-combination of a material object;
2. A correct contemplation – after a correct understanding after correctly observing a property-quality-combination of a material object – about a property-quality-combination of a non-material object;
3. A correct conclusion what something is not, after the correct understanding after correctly observing a property of a material object, or after a correct contemplation – after a correct understanding after correctly observing a property-quality-combination of a material object – about a property-quality-combination of a non-material object.

In addition to observing a part of reality to understanding that part of reality, this implicit knowledge can be made explicit by writing it down (Nonaka, 1990; Freyer, 1966). This may take the form of a proposition. If correctly expressed, a correct fact is expressed as either a true affirmative proposition about what is so and so, or as a true negative proposition about what is not so and so. On the other hand, if something went wrong in the entire series of activities from observing and contemplating up to understanding the expressions are not true but false. A false affirmative proposition conveys what is supposed to be so, while it is not. A false negative proposition conveys what is supposed not to be so and so, but it actually is (Prior, 1972b; Gale, 1972; Moser, Mulder & Trout, 1998).

4.4 Judging: comparing what is understood, concluding about the comparison, and expressing the juidgement

The next mental activities are (1) making a judgement by comparing facts, and thereafter (2) expressing the judgement in a proposition. Of course, the comparison, judgement and expression all need to be carried out correctly, otherwise the expressed judgement is incorrect (based on: Hirst, 1972b; Aune, 1972; Gale, 1972).

If the outcome of the contemplation is correctly expressed, this judgement is correct. A judgement is either a true affirmative proposition or a true negative proposition if this mental process is carried out correctly, or a false affirmative proposition or a false negative proposition if this mental process is carried out incorrectly (see Prior, 1972a; Gale, 1972; Aune, 1972). The expression in a proposition of the judgment is thus the end of the process from observing to making a judgement.

4.5 Summary

The entire process, from observing a part of reality up to expressing a judgement comprises several steps. Observing the property-quality-combination of a material object forms the start of this process. Thereafter, several mental steps are necessary to come to a judgement. Part of these steps is the contemplation of non-material objects, respectively, the conclusion of the absence of an object or a property. All steps in the process can be considered as separate activities with their own outcomes, and the output of a step is the input of the next step, resulting in a process model (see Figure 2).

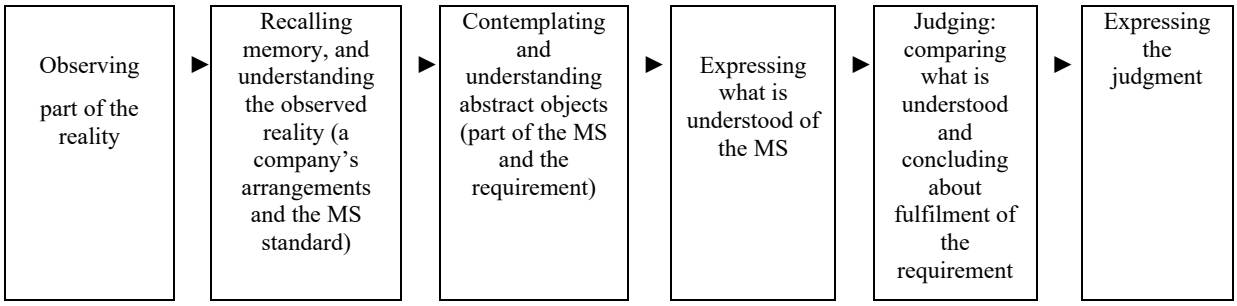

Figure 2: Determination and judgement process flow

Each activity in this series of consequential activities has to be carried out correctly in order to achieve a correct judgement as the final result.

5 Consequences for QMS auditing

The description of the model presented in Section 4 of this paper can be compared with the present QMS auditing theory as reviewed in Section 2 of this paper. This literature does not question QMSs as such. It seems that it is taken for granted that any QMS exists and can be audited. However, it is unclear what exactly a QMS is, because the QMS audit theory does not indicate which "system characteristics" (Pivka, 2004) exist, nor how they can be observed, perceived and assessed.

According to scientific literature on QMS auditing (Karapetrovic & Willborn, 2001; Pivka, 2004; Beckmerhagen et al., 2004; Goldberg & Shmilovici, 2005; Gutierrez Alcantara, 2013), an auditor needs to collect information by investigating processes, by analysing "elements, activities, tasks, inputs and outputs". The collected information is evaluated in order to become audit. Thereafter audit findings are established by weighing the value of the collected information into categories of a nominal classification system. Audit findings are classified into conformities, non-conformities, observations and opportunities for improvement. The audit findings are recorded and overall audit conclusions are drawn up. To do and achieve this the auditor needs to use proper audit methods and techniques. These parts of the audit method and the related techniques are summarised in ISO 19011:2018. According to that standard, an auditor should collect evidence by interviews, document reviews, and observations, based on sampling (ISO 19011:2018, 6.4.7).

When we compare our analysis of philosophical literature with the literature on QMS auditing, the conclusion is not surprising. All these activities need to be carried out correctly. All analyses of processes, all interviews, all document reviews, all observations, and all conclusions need to be carried out correctly. Any inconsistencies and deviations in these activities can (and almost surely will) lead to incorrect findings and conclusions, resulting in incorrect 'conformity' and incorrect 'nonconformity'. Comparing the literature on QMS auditing with our analysis of philosophical literature leads to the conclusion that for every activity, whether interviewing, document reviewing, or observing activities, the process model we have created is applicable. The main activity is observing a part of the material reality. In principle this material reality consists of material objects, some of which can be in motion (forming events). For example, in the agricultural industry such objects can be plants, animals and (bio-based) products. The events can include production processes or service delivery processes. Some properties of products and the materials they are made of, and also some processes (events), can be observed. The audit methods which are typically considered in the literature, such as sampling, interviewing, verifying documents, and observing activities, focus on the material reality and the property-quality-combinations of material objects.

Besides material objects, non-material social entities somehow exist. QMSs are such non-material social entities. Requirements expressed in symbols and visualised in written tokens (or spoken words), are also social entities. Although they cannot be observed directly, they have a relation with the real world (based on Thomasson, 2012 and Searle, 1995). A requirement is not a description of the existing reality but a normative expression of a reality that has to be: An imagined property of an object or an imagined event is required (see Hartmann, 1938; 1962; Mulligan, 2012). Requirements are expressed as commands (what needs to be achieved) or as prohibitions (what is not allowed) (based on ISO/IEC 17021-1:2015).

Thereafter, the mental processes of understanding that part of the material reality and comprehending non-material objects and social entities (e.g., quality management systems and requirements) and making a judgment on fulfilment or non-fulfilment of a part of the QMS with one requirement seem to be complicated. An auditor needs to do this for all audit criteria. In particular, regarding the method and techniques for observing activities, the auditor needs to operate the process as described in the process model regarding observation of material objects and events.

The information gathering activities start with observing reality. When carried out correctly, observing it should lead to a correct understanding of and conclusions about that reality. For all audit criteria, the auditor needs to engage in that mental process again and again. An auditor can draw the final audit conclusion on fulfilment of all the audit criteria. How (s)he must carry out this process is the black box in the current audit theory. In this respect it does not help that the context of QMS auditing is complicated. Auditing a QMS focuses on social entities such as organizations and their QMSs. These social entities are difficult to understand from the social sciences' ontological point of view (see Thomasson, 2012; Cano, et al, 2016; Searle, 1995). To conclude, QMS auditing is challenging, both in terms of context and process steps.

6 Comparing the process model with auditing standards

We apply the insights from Section 4 to the standards for QMS auditing. QMS auditing includes (1) obtaining information and (2) evaluating this information to determine the extent to which specified requirements are fulfilled (ISO/IEC 17021-1:2015, 9.4; see also ISO 17000:2020, 6.4), followed by a statement of conformity or nonconformity (ISO 19011:2018, 6.4.8; ISO/IEC 17021-1:2015, 9.4.5.3 & 9.4.8.3.a). It is a process of observing a part of the reality, understanding the observed and making judgments whether a requirement is met or not (ISO 17000:2020). We discuss these three subsequent steps in the next three sections. We start each section by quoting some core clauses in the standards ISO/IEC 17021-1:2015 and ISO 19011:2018. These will be compared with the general process descriptions in Section 4 of this paper.

6.1 Obtaining information

ISO/IEC 17021-1:2015 requires:

- 9.4.4.1 During the audit, information (...) shall be obtained (…).
- 9.4.4.2 Methods to obtain information shall include (…) interviews; observation of processes and activities; review of documentation and records.
- 9.3.1.3 The purpose of (...) [an audit] is to evaluate the implementation, including effectiveness, of the client's [Q]MS.

ISO 19011:2018 advises:

- 6.4.7 During the audit, information relevant to the audit objectives, scope and criteria, including information relating to interfaces between functions, activities and processes should be collected by means of appropriate sampling and should be verified, as far as practical.
- Only information that can be subject to some degree of verification should be accepted as audit evidence. Where the degree of verification is low the auditor should use their professional judgment to determine the degree of reliance that can be placed on it as evidence. Audit evidence leading to audit findings should be recorded (...).
- Methods to collect information include, but are not limited to the following:
  a) interviews;

  b) observations;

  c) review of documented information.

The wording 'obtaining information' can be understood as: observing; understanding the observed; comparing and understanding an abstract object (the part of the QMS); expressing what is understood (the part of the QMS).

The object of a QMS audit is a QMS. Being a non-material object, the QMS is supposed to exist, somehow with connections to material objects. A QMS is an interpersonal phenomenon which would not exist without human behavior, customs and agreements. It is considered to have properties, which are assigned to that QMS (based on ISO 9000:2015, 3.10.2, Note 2). ISO/IEC 17021-1:2015 indicates the QMS's connection with the material world: "The purpose of [a QMS audit] is to evaluate the implementation, including the effectiveness, of the [organization's] management system" (ISO/IEC 17021-1:2015, 9.3.1.3). This is a *conditio sine qua non*: if a QMS is not implemented, it does not exist, and if it does not exist, it cannot be audited. In the standard, the focus of the information gathering process, is on operational control, internal evaluations, internal audits and management review (see ISO/IEC 17021-1:2015, 9.2.3.3, 9.3.1.3, 9.6.2.2, 9.6.3.2.1). These are all social entities (non-material objects). The connection with the material world is expressed in clause 9.4.4.2 of that standard: methods shall include interviewing persons, observing processes and activities, and assessing documents and registrations. People can be considered (not very politely formulated) as material objects; processes and activities are events in reality, and documents and registrations consist of symbols written or expressed on material objects (data carriers) such as paper or IT systems. ISO 19011:2018 Clause 6.4.7 mentions interviews, observations, and review of documented information. This can be seen as a connection to the material world, but the connection itself remains unclear. It is also unclear how the audit methods contribute to understanding the functioning of a QMS. It remains vague what a auditors observe and understand when interviewing persons, observing activities, and verifying registrations. A QMS is a set of coordinated activities to direct and control the organisation (see ISO 9000:2015). However, the method of observing and understanding such activities has not been described in ISO 19011 and ISO/IEC 17021-1. Interviewing persons, observing activities and verifying documented information are complex mental activities. To use the combination of these audit activities is even more complex. Standards do not describe how an auditor should use and verify the interview and observation outcomes, or how to contemplate all these outcomes in order to understand the management system. This constitutes a first difficulty for any QMS auditor.

Next, how does one operate regarding the absence of a part of the management system? Absence as such cannot be observed, but a person can observe what is there and thereafter conclude what is absent. A conclusion of the absence of a part of the management system can be a fact after observation and understanding. An auditor is expected to discover any absence of any part of a management system (see ISO/IEC 17021-1:2015, 9.2.3.3). This discovery needs to be based on interviewing, observing and verifying and on the mental activities of contemplating and concluding. For error-free auditing and not missing one case, this means that an exhaustive investigation needs to be carried out, in order to trace all missing elements.

An auditor has to understand the requirement(s) in the applicable QMS standards. These requirements are specified (see ISO/IEC 17000:2020, 4.1 & 5.1): they are written down in tokens and symbols. Each requirement can be read. The auditor can observe the tokens and symbols, and understand their meaning. The reading of the symbols must be carried out correctly, and the recall of memory must be performed correctly to understand what is required correctly. If not, the outcome of this process leads to a misunderstanding about what is required.

Next to obtaining information about the existence of the QMS, the auditor has to obtain information about its effective functioning. Surprisingly, effective functioning of the QMS is not literally required in ISO 9001:2015, but ISO/IEC 17021-1:2015 prescribes it (ISO/IEC 17021-1:2015, 9.2.3.3; 9.3.1.3).

Auditing is a process of observing and perceiving parts of reality and contemplating and concluding regarding the understanding of the functioning of a part of a QMS and the applicable requirement(s) (see ISO/IEC 17000:2020). Comparing the understanding of that part of the MS

and the understanding of that requirement leads to a conclusion on whether that specified requirement is fulfilled. The auditor has to understand a part of the QMS by interviewing one or more persons and/or observing one or more activities and/or verifying one or more documents. This is the consequence when QMS auditing is considered as a kind of conformity assessment (see ISO/IEC 17000:2020, 4.1, 6.4 and Annex A; ISO/IEC 17021-1:2015).

6.2 Determination of conformity or nonconformity

ISO/IEC 17021-1:2015 requires:

- 9.4.5.1 Audit findings summarizing conformity and detailing nonconformity shall be identified, classified and recorded (…).
- 9.4.5.3 A finding of nonconformity shall be recorded against a specific requirement (…) identifying in detail the objective evidence on which the nonconformity is based.

ISO 19011:2018 advises:

- 6.4.8 Audit evidence should be evaluated against the audit criteria in order to determine audit findings. Audit findings can indicate conformity or nonconformity with audit criteria. (…) Nonconformities can be graded depending on the context if the organization and its risk. This grading can be quantitative (e.g. 1 to 5) and qualitative (e.g. minor, major). (For definitions of a major and minor nonconformity, see ISO/IEC 17021-1:2015, 3.12 and 3.13.)

The wording ‘determination of conformity or nonconformity’ can be understood as judging and comparing what is understood, and then concluding about the fulfilment of the requirement. The expressions seem to indicate that there are two categories of audit findings: conformity and nonconformity with a specified requirement. A finding is thus a conclusion resulting from comparing two facts. The first is understanding something in reality (the value of one property of a material object or a conclusion about a non-material object or an event, or the conclusion about the absence of a property). The second is related to understanding the specified requirement. Conformity with a requirement is the conclusion that these match, after comparing the two understandings; nonconformity results from a mismatch. The contemplation leading to the conclusion of either conformity or nonconformity must be carried out correctly, based on correct understandings, in order to have a correct judgement about whether or not something in reality fulfills the the applicable requirement. This may seem simple: the auditor just has to summarize conformity and provide more details about any nonconformity (ISO/IEC 17021-1:2015, 9.4.5). Section 4 shows that this is a complicated mental process. A disturbance can (and presumably in many occasions will) lead to an incorrect understanding and a misunderstanding of the functioning of the QMS. Any misunderstanding will lead to an incorrect audit finding regarding either conformity or nonconformity.

6.3 Conformity statement

ISO/IEC 17021-1:2015 requires:

- 9.4.5.3 A finding of nonconformity shall be recorded against a specific requirement, and shall contain a clear statement of nonconformity (…);
- 9.4.8.3.a The [audit] report shall also contain: a statement on the conformity and the effectiveness of the management system (…). (By the way, in Subsection 8.2.2 of that standard there is no requirement that a statement of conformity has to be expressed on certification documents.).

ISO 19011:2018 advises:

- 6.5.1 The audit report (…) should include or refer to the following: (…) a statement on the degree to which audit criteria have been fulfilled (…).

The wording ‘conformity statement’ can be understood as: expressing the judgment. A statement of conformity is an expression of the judgment of conformity regarding one requirement. If all these statements on all requirements are similarly affirmative, an overall concluding statement expressing conformity (fulfillment) with all requirements can be expressed. A statement is correct if it correctly expresses the judgement, and also if the judgement itself is properly based on the correct performance of all previous activities up to the observation. If all these activities – observing, recalling memory, understanding, comparing, concluding, and expressing – are carried out correctly for each requirement, then a statement can be expressed correctly for each requirement. Then the conformity statement is true. In the event of any incorrectness the conformity statement is false. It is self-evident that for thoe who rely on a QMS certificate, true conformity statements are valuable in the market and false are not. QMS certificates might be granted even when it not all minor nonconformities have been solved yet (see ISO/IEC 17021:2015, 9.5.2.c). ISO/IEC 17021-1:2015 does not mention corrective actions to be verified prior to the certification decision. In principle nonconforming situationscan continue to exist, despite a certificate being granted. ISO/IEC 17021-1:2015 does not require the withdrawal of a statement of nonconformity after the confirming verification of corrective action(s).

7 Conclusions, discussion, and suggestions for further research and for practices

7.1 Discussion

The wide-spread doubts about the reliability of QMS certification also raise concerns about the QMS auditing process. In this paper we evaluated the information gathering and judgement aspects of QMS auditing, as described in the applicable standards, ISO 19011:2018 and ISO/IEC 17021-1:2015, and the scientific literature. These standards mention observing, interviewing people and verifying documents as the means to gather information, but do not prescribe how to perform these activities. In the scarce literature, the QMS auditing method, particularly the information gathering method, is an almost neglected topic. At the time that the first edition of ISO 19011 was developed, some studies were carried out, but thereafter, research on this topic was almost absent, despite its relevance for business and society. The main insight from the literature is that a QMS audit should be conducted by observing activities, conducting interviews and verifying documents, based on sampling. Also, in the field of financial auditing theory, information gathering methods are hardly available, but the suggestion is made to use philosophical insights as a basis for further research. With no other support from literature than just a few relevant publications, we used an uncommon approach for setting the next step in research. We analyzed philosophical insights to develop a very basic process model for gathering information about parts of reality. This process model is our main addition to the current body of knowledge, and can serve as a foundation and guidance to further develop a QMS auditing method.

We realise that our model is not a complete solution to the lack of QMS audit methods in the standards and literature. First, our model covers only the basics of the information gathering process, but does not address other phases of the QMS audit process, such as drawing up the QMS audit plan, the QMS audit objectives, the scope and criteria, and the selection of the audit team members. Second, although we made choices in the selection of the philosophical insights, when creating our model, we kept away from fundamental discussions within the field of

philosophy on observing and perceiving reality, and subsequent judgement. We trust that this model can contribute to further develop the QMS audit method.

Some specific issues for discussion can be identified. First, the information gathering and judgement processes are only two parts of the entire QMS audit. To determine the conformity of a QMS with requirements the former is *the* activity through which information about the QMS's functioning is provided. However, it is not the only key factor for an effective audit. The activities during the selection phase are preconditions for effective QMS auditing. Without adequate preparations effective QMS auditing cannot be guaranteed. Next to these preparations, there are other fundamental preconditional aspects. First, interviewing people presupposes that interviewees answer the interview questions truthfully. If not, it is doubtful whether their i replies contribute to an effective QMS audit. Is it possible to distinguish between true answers and errors or lies? How can a QMS audit method address this fundamental issue? Second, an organisation's documentation creates the same problem. Does a documented registration always provide the evidence needed to determine the functioning of an organisation's QMS, and how can we distinguish correct registrations from incorrect ones? Third, the literature suggests that an effective QMS audit should be error-free. Can this be achieved? The QMS audit literature and the financial audit literature do not answer this question, nor do they develop a valid solution. The measurement theory could provide insights for theorising on this theme, but a recent publication shows that there are inherent difficulties concerning error-free measurement (Mari, Wilson & Maul, 2023). Is the aim of error-free QMS auditing realistic, or should this aim be reevaluated? Consequently, is it necessary to reevaluate the claims of QMS certification? A QMS certificate cannot claim more than it can prove, and the audit on which it is based needs to provide evidence for what it claims. A fourth specific discussion issue is the integration of observing activities, interviewing persons and verifying documents into one information gathering process. How should this be achieved? Another issue for discussion is the way social entities are materialised. The materialisation of money by coins and banknotes (Searle's example) is easy to understand, but what about a QMS of an organisation? How do activities, documentation, and the staff affect a QMS? We briefly touched on the existence of QMSs, but we have not fully addressed this issue. The intentionality and material dimension of QMSs make them observable and perceivable, but their functioning deserves more attention. Insights from social sciences, in particular philosophy on the social ontology, might provide solutions for conceptualising a QMS.

Finally, we focused on QMS auditing, but our model can likely be used as the basis for developing an audit method for other types of management systems, financial auditing, or other kinds of conformity assessments, such as inspection, as well. Undoubtedly a QMS has similarities with other types of MSs. Also our model has such a general character that it could perhaps be used for developing a general audit or a general conformity assessment method.

7.2 Suggestions for future research

QMS auditing is essential for modern business and trade as it provides confidence in a company's performance. It had notably been neglected on the scientific agenda. Our study makes a start in increasing knowledge about QMS auditing by providing a model that can serve as a starting point for developing better methods. We focused on the information gathering and judgement processes. We carried out desk research by reviewing standards and literature, and analyzing philosophical insights. Future research could further analyse philosophical insights on observing and perceiving aspects of reality, including an understanding of how social entities function. Additionally, insights from hermeneutics for analyzing and understanding documents can be useful. Empirical and experimental research, including the involvement of experts in this field, can contribute to developing and validating QMS audit methods.

The focus of further research should not be limited to information gathering alone. Other aspects of the QMS audits are also relevant subjects for research. Additionally, other elements such as the integration of interviewing people, observing activities, assessing and verifying documents, determining the correctness of responses on interview questions, and verifying the truthfulness of documents as evidence for the functioning of a QMS are important topics for future research. Our focus was on QMS auditing, but we expect our model can be applied in auditing of other management systems. This can be investigated in future research. The same can be done for other forms of conformity assessment, such as the auditing of other types of MSs and inspection.

7.3 Practical implications

Reliable QMS auditing is a prerequisite for reliable QMS certification. QMS auditing is based on the ISO 19011:2018 and ISO/IEC 17021-1:2015 standards. Our study reveals that these standards provide insufficient guidance on the auditing method. Concerns about the effectiveness of QMS auditing relate to this. Our findings show that better auditing methods are indeed needed. These standards need to be improved by providing additional guidance and requirements for the auditing method. Our study provides the basis for this. Based on our process model, valid methods can be developed that demonstrate how a QMS should be audited. These methods should include measurement of the QMS elements and their functioning by human observation, and should be supported and framed by techniques and tools.

One of the issues will be balancing the three forms of information gathering: documentation, interviews and observations. In his seminal paper on ISO 9001 implementation, Boiral (2007) distinguishes between ceremonial integrators, quality enthusiasts, and dissidents. The first group, ceremonial integrators, is probably the biggest; they have the documentation in place but lack a well-functioning QMS. During the audit, they put up a façade but manage to obtain the certificate. Apparently, the signalling effect of the certificate is more important than the added value of the QMS itself (Manders, 2015). It might well be that this widespread practice is possible if auditors rely mainly on documentation, less on interviews, and hardly on observations of business practices. This is food for thought for individual auditors, certification bodies, companies that seek certification for their QMS, and other organisations that rely on certification. More in general, until a valid QMS audit method has been developed, auditors can use our findings to reflect on the work they are doing, and organisations relying on auditing and auditing results should be aware of its current limitations.

7.4 Conclusions

In this paper, we have studied QMS auditing, focusing on the information gathering and judgment processes, in order to develop a systematic approach. The standards and the literature on QMS auditing have failed to address several important aspects of the audit method. The literature is scarce, and after some publications at the beginning of this century, scientific research on this topic stopped. QMS audit standards need to mature in their information gathering and judgment processes. This paper has created a process model as a primary grounding to fill in this omission. However, the result of our study is not the solution to the entire problem. It is merely a first step into the direction of more attention and research on this topic. We followed the advice of Dennis (2015) and Mari (2003; 2005) to use philosophical views and insights. Philosophers have thought about observing and understanding a part of reality, up to making a judgment based on the comparison of understanding that part of reality with the understanding of a requirement. Based on this, we created a process model as a primary grounding to fill in the black box of the information gathering and judgments. Our model is

general and has not been elaborated or adapted for a QMS auditing method. Nevertheless, we compared our process model with the present standards on (Q)MS auditing and discovered that many aspects had not been addressed. This can stimulate future research on this topic. Our model can be used to improve the current auditing standards. This, in turn, may reshape QMS auditing practices, both internal auditing and auditing by third parties. The latter may lead to more reliable certification.

Epilogue

This article is a summary of parts of the first author's future PhD thesis. This thesis will present further grounding for the research approach and for the development of the model. This PhD research will also address some issues which were mentioned as suggestions for future research in Section 8.2 of this paper. We invite readers of this paper to provide more suggestions to improve QMS auditing as a means to create confidence among market parties.

Contributor Statement

Author 1: Conceptualization; Writing – Original Draft
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There is no conflict of interest.

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Standards

ISO 9000:2015 Quality management systems – Fundamentals and vocabulary.
ISO 9001:2015 Quality management systems – Requirements.
ISO/IEC 17000:2020 Conformity assessment — Vocabulary and general principles.
ISO/IEC DTS 17012:2024 Guidelines for the use of remote auditing methods in auditing management systems
ISO/IEC 17021:2006 Conformity assessment — Requirements for bodies providing audit and certification of management systems
ISO/IEC 17021-1:2015 Conformity assessment — Requirements for bodies providing audit and certification of management systems — Part 1: Requirements.
ISO 19011:2018 Guidelines for auditing management systems.