

INTERNAL AUDIT AND MANAGEMENT REVIEW IN ISO 9001:2015

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Purpose: The aim of the paper is to analyze the problems connected with internal audit and management review within the organization in the ISO 9001:2015 implementation process.

Design/methodology/approach: Critical literature analysis. Analysis of international literature from main databases and polish literature and legal acts connecting with researched topic.

Findings: To achieve good functioning level of Quality management system we need to do periodically the internal audits and management reviews. Audit is the examination or inspection of various books of accounts by an auditor followed by physical checking of inventory to make sure that all departments are following documented system of recording transactions. Audits are very useful tool to analyses the organization functioning and improve it's performance. On the basis of the conducted analysis we can say that the main activities needed in the internal audit process are: interview personnel, observe operations, review documents and records and examine records. In the audit process is especially important for auditor to have appropriate qualities. They should be according to ISO 19011 requirements. The best solution for the analysis of the performance of ISO 9001 system can be done when we not only use internal audits but also management reviews in our managerial practice.

Originality/value: Detailed analysis of all subjects related to internal audits and management reviews in ISO 9001:2015.

Keywords: quality management, ISO 9001:2015, ISO 9001, audit, management review.

Category of the paper: literature review.

1. Introduction

To achieve good functioning level of Quality management system we need to do periodically the internal audits and management reviews. Audit is the examination or inspection of various books of accounts by an auditor followed by physical checking of inventory to make sure that all departments are following documented system of recording transactions (Horodecka, and Wolniak, 2015; Pacana, 2014; Pacana et al., 2014, 2017; Pacana, and Stadnicka, 2006, 2017; Wolniak, 2011; Wolniak, and Sułkowski, 2015, 2016; Wolniak et al.,

2019; Wolniak, and Skotnicka-Zasadzień, 2008, 2011, 2019; Novakova et al., 2016; Stawiarska et al., 2020). It is done to ascertain the accuracy of financial statements provided by the organization (Hillson, 2001; Gębczyńska, and Wolniak, 2018; Juszczak-Wiśniewska, and Ligarski, 2015, 2016; Łuczak, and Wolniak, 2016; Sułkowski and Wolniak, 2016, 2018; Szczucka-Lasota, and Wolniak, 2018). Audit can be done internally by employees or heads of a particular department and externally by an outside firm or an independent auditor. The idea is to check and verify the accounts by an independent authority to ensure that all books of accounts are done in a fair manner and there is no misrepresentation or fraud that is being conducted (ISO 9001:2015; Chen et al., 2016; Cholewicka-Goździk, 2016; Łagowski and Żuchowski, 2016; Wolniak, and Hąbek, 2015; Wolniak, and Skonicka-Zasadzień, 2010; Wolniak, and Sułkowski, 2015; Wolniak, 2020).

The aim of the paper is to analyze the problems connected with the audit and management review within the organization in the ISO 9001:2015 implementation process.

2. Internal audit

To assess the functioning of the implemented quality management system organization should conduct internal audits at planed intervals to provide information on whether the quality management system (ISO 9001:2015, Egonsson et al., 2013):

- conforms to:
 - the organization's own requirements for its quality management system;
 - the requirements of this International Standard;
- is effectively implemented and maintained.

Internal audit is a very strong tool by which an organization can make substantial improvement in its systems and performance. The sincerity of the management and staff in religiously following the process of internal quality audit is the key factor for getting the full advantage of the system (Purushothama, 2015). Basic definitions connected with auditing quality management system are in the table 1.

Table 1.*Terms connected with auditing quality management systems*

Term	Definition
Audit	Systematic, independent and documented process for obtaining audit evidence and evaluating it objectively to determine the extent to which the audit criteria are fulfilled Internal audits, sometimes called first party audits, are conducted by the organization itself, or on its behalf, for management review and other internal purposes (e.g. to confirm the effectiveness of the management system or to obtain information for the improvement of the management system). Internal audits can form the basis for an organization's self-declaration of conformity. In many cases, particularly in small organizations, independence can be demonstrated by the freedom from responsibility for the activity being audited or freedom from bias and conflict of interest. External audits include second and third party audits. Second party audits are conducted by parties having an interest in the organization, such as customers, or by other persons on their behalf. Third party audits are conducted by independent auditing organizations, such as regulators or those providing certification.
Audit criteria	Criteria set of policies, procedures or requirements used as a reference against which audit evidence (3.3) is compared.
Audit evidence	Records, statements of fact or other information which are relevant to the audit criteria and verifiable.
Audit findings	Results of the evaluation of the collected audit evidence against audit criteria.
Audit conclusion	Outcome of an audit, after consideration of the audit objectives and all audit findings.
Audit client	Organization or person requesting an audit.
Auditee	Organization being audited.
Auditor	Person who conducts an audit.
Audit team	One or more auditors conducting an audit, supported if needed by technical experts.
Technical expert	Person who provides specific knowledge or expertise to the audit team.
Observer	Person who accompanies the audit team but does not audit.
Audit plan	Description of the activities and arrangements for an audit.

Source: own work on basis: (ISO 19011:2011. Guidelines for auditing management system, Hoyle, 2009; Locher, 2008).

The internal audit has four primary objectives (Philips, 2015; Misztal, 2013):

- To verify conformance to applicable standards.
- To verify conformance to documented processes and procedures.
- To verify effectiveness of business processes.
- To identify opportunities to improve the quality management system.

The objectives of audit can be based on (ISO 19011:2011; Mitra, 2016):

- management priorities;
- commercial and other business intentions;
- characteristics of processes, products and projects, and any changes to them;
- management system requirements;
- legal and contractual requirements and other requirements to which the organization is committed;
- need for supplier evaluation;
- needs and expectations of interested parties, including customers;
- auditee's level of performance, as reflected in the occurrence of failures or incidents or customer complaints;
- risks to the auditee;

- results of previous audits;
- level of maturity of the management system being audited.

In this case organization should (ISO 9001:2015; Natarjan, 2017; Novakova et al., 2016):

- plan, establish, implement and maintain an audit programme(s) including the frequency, methods,
- responsibilities, planning requirements and reporting, which shall take into consideration the importance of the processes concerned, changes affecting the organization, and the results of previous audits;
- define the audit criteria and scope for each audit;
- select auditors and conduct audits to ensure objectivity and the impartiality of the audit process;
- ensure that the results of the audits are reported to relevant management;
- take appropriate correction and corrective actions without undue delay;
- retain documented information as evidence of the implementation of the audit programme and the audit results.

The audit programme should include information and resources necessary to organize and conduct its audits effectively and efficiently within the specified time frames and can also include the following points (ISO 19011:2011; Pokosińska et al., 2002):

- objectives for the audit programme and individual audits;
- extent/number/types/duration/locations/schedule of the audits;
- audit programme procedures;
- audit criteria;
- audit methods;
- selection of audit teams;
- necessary resources, including travel and accommodation;
- processes for handling confidentiality, information security, health and safety, and other similar matters.

Internal auditors often only rely upon documents and records as evidence of process conformity and don't adequately interview personnel and observe operations (Szkiel, 2016). To change this and attain conformity internal auditors should use four activities described in the table 2.

There is no perfect number of auditors an organization must have to perform effective internal audits (Vogt, 2010). Some organizations, particularly those in the medical and aerospace industries are fortunate enough to have full-time internal auditors. most, however, call on employees who are already fully utilized in other roles. The number of auditors the organizations should to use depend on several facts (Philips, 2015):

- The size of the organization.
- The type of product or service produced.

How you define the scope of each audit. Auditors and the person managing audit programme should (ISO 19011:2011):

- perform their work with honesty, diligence, and responsibility;
- observe and comply with any applicable legal requirements;
- demonstrate their competence while performing their work;
- perform their work in an impartial manner, i.e. remain fair and unbiased in all their dealings;
- be sensitive to any influences that may be exerted on their judgement while carrying out an audit.

Table 2.

Activities in audit to ensure conformity

Activity	Characteristic
Interview personnel	Based on your audit planning and checklist questions, ask employees about their jobs. Listen to what they tell you and see if their explanations match the defined process. Use open-ended questions to elicit more complete responses. Do not be afraid to challenge and probe or follow an audit trail to see where it leads you. Talking to people is the best possible way to test their understanding and knowledge about the processes and sub-processes in which they are involved.
Observe operations	Aid your own understanding of the process by watching it being performed. See if the observed practices comply with requirements. You will discover the persons being interviewed are more relaxed when you allow them to demonstrate their jobs. In addition, internal audits will be less disruptive since work is actually being completed.
Review documents and records	Ask the persons being interviewed what documents and records are used in their work. You may find documents, records and forms beyond those identified in your audit planning. See if the documents are adequately controlled and available for use. Refer to the documents and records to help you follow the work being shown. Verify the records described in the documents are being properly collected and controlled. Also challenge the need for documentation and always try to find better and more effective ways of managing and controlling the processes being audited.
Examine records	Auditors cannot interview every person, observe every activity, look at every document, and evaluate every record. You should strive for representative samples that allow you to make informed judgements. Since audits are limited due to sampling, non-conformities may continue to exist in the system beyond those identified and reported. However, with time and well planned audits you can feel confident that you have thoroughly reviewed your system and its performance.

Source: own work on basis: (ISO 9001, 2020).

The ISO 19011 standard specifies the required auditors qualities (ISO 19011:2011):

- **Ethics:** An auditor will possess personal characteristics like credibility, integrity, and honesty and provide reliable information and results regarding the unit the auditor is auditing.
- **Open-minded:** An auditor will be willing to listen, learn, and accept new ideas and to reflect them on the situations or requirements. Sometimes auditor may encounter new approaches or opinions. An auditor must have the ability to assess and accept different points of view as long as they achieve the requirements.
- **Diplomatic:** An auditor will be polite and well-mannered; an auditor serves as the representative of the top management.

- Observer: An auditor will have the ability to recognize and evaluate what he or she sees and to understand and interpret events without deep interrogation.
- Perspective: An auditor will have the ability to evaluate situations beyond the person's appearance, with a systematic view of things, and will have the ability to understand the organizational consequences of the evidence he or she finds.
- Versatile: An auditor will have the ability to mobilize from one situation to another without losing direction. One moment the auditor may audit one field; the next moment it may be another. An auditor must be able to stay focused.
- Structured: An auditor will advance and progress the audit according to a defined method or plan and within the boundaries of the scope.
- Persistence: An auditor must be persistent with their objectives, so that when they ask a question, they must receive an answer to it and not be diverted by interferences or disturbances.
- Independent: An auditor shall have their own opinions on things, will not be influenced by the environment, and will be free from conflict of interest.
- Decisive: An auditor must be ready to make decisions even when they are hard or will not satisfy the auditee.

Any findings during the audit shall be indicated with one of the following classifications (Abuhay, 2017):

- Conformity – the process or product sampled was in accordance with the relevant requirements and criteria.
- Opportunity for improvement – in the auditor's opinion, an improvement can be applied to the matter, and the organization may or may not adopt this opportunity and submit it to the control of opportunities as required in clause —Actions to address risks and opportunities.
- Nonconformity – the process sampled was not according to the requirements and the audit criteria.
- If the organization feels the need to add another classification suitable to its nature or processes, it may do that.

3. Management review

Next method of assessment quality's management system functioning is management review. In this case top management should to review the organization's quality management system, at planned intervals, to ensure its continuing stability, adequacy, effectiveness and alignment with the strategic direction of the organization (Ząbek, 2016; Żemigła, 2017).

The management review shall be planned and carried out taking into consideration following points (ISO 9001:2015):

- the status of actions from previous management reviews;
- changes in external and internal issues that are relevant to the quality management system;
- information on the performance and effectiveness of the quality management system, including trends in:
 - customer satisfaction and feedback from relevant interested parties;
 - the extent to which quality objectives have been met;
 - process performance and conformity of products and services;
 - nonconformities and corrective actions;
 - monitoring and measurement results;
 - audit results;
 - the performance of external providers;
- the adequacy of resources;
- the effectiveness of actions taken to address risks and opportunities;
- opportunities for improvement.

The outputs of the management review shall include decisions and actions related to¹:

- opportunities for improvement;
- any need for changes to the quality management system;
- resource needs.

The main inputs to analyze in the management review were characterized in the table 3.

Table 3.
Management review inputs

Input	Characteristic
Actions from Previous Reviews	The outputs of management review are mostly in the form of action points, assigned to relevant process owners with time schedule for completion. The status of the action points of the previous management reviews is discussed until they are closed. Evidences for the implementation of the action points are maintained.
Changes in External and Internal Issues	Monitoring the changes in external and internal issues that are relevant to organization is assigned to appropriate process owners during management reviews. The results of monitoring the issues are presented by the process owners during the reviews. The results are discussed and appropriate actions are decided for improving the quality management systems of organization.

¹ ISO 9001:2015. Quality management systems – Requirements.

Cont. table 3.

Results of Performance Evaluation	<p>Information on the performance and effectiveness of the quality management systems is discussed in management review. The sources of information are the outputs of monitoring, measurement, analysis and evaluation, customer satisfaction and internal and external audits.</p> <p>Monitoring the needs and requirements of external providers is assigned to appropriate process owners during management reviews. Feedback from external providers is presented by the process owners:</p> <ul style="list-style-type: none"> • Quality objectives, process performance, conformity of products and services and performance of external providers with monitoring and measurement results. • Internal audit results and external audit reports • Performance of external providers.
Other Inputs	<p>The additional requirements for people, infrastructure, operating environment and enhancing organizational knowledge and competence of personnel are presented by process owners for the implementation of the quality management systems. The effectiveness of the action taken to address risks and opportunities are also presented by relevant process owners. The inputs from process owners are reviewed. New opportunities for improving the quality management systems are identified during the review.</p>

Source: own work on basis: (Natarajan, 2017).

4. Conclusion

Audits are very useful tool to analyses the organization functioning and improve it's performance. On the basis of the conducted analysis we can say that the main activities needed in the internal audit process are: interview personnel, observe operations, review documents and records and examine records. In the audit process is especially important for auditor to have appropriate qualities. They should be according to ISO 19011 requirements. The best solution for the analysis of the performance of ISO 9001 system can be done when we not only use internal audits but also management reviews in our managerial practice.

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