Chapter X

AUDIT IN NORMALIZED MANAGEMENT SYSTEMS

1. Audit in Normalized Management Systems

An audit is a systematic independent and documented process of achieving the audit evidence and its objective evaluation in order to meet the given criteria [ISO 19011:2011 & ISO 9000:2005]. Internal audits amount to a necessary element of systematic quality management which protects its maintenance and development. An audit is also a fixed element of normalized management systems based on varied standards (e.g. ISO/ TS 16949, VDA 6.1, TE 9000, SA 8000, AQAP 110, ISO/ IEC 27001), environmental management systems (ISO 14001, EMAS), health and safety management systems (PN-N 18001, OHSAS 18001).

According to the typical classification [ISO 19011:2011], audits may be divided into internal (first party) and external, which can be divided into second and third party audits. A first party (internal) audit is most frequently realized by an internal team of auditors. This form of compliance evaluation is seen as the key element in the system [Urbaniak 2004]. Likewise, audit has gained recognition as an effective tool used as a method of qualification and constant supplier evaluation, in particular in reference to automotive, food and pharmaceutical industries. In practical terms this method is costly, but simultaneously effective, allowing not only the evaluation but also encouraging suppliers' self-development in the area of management.

Finally, we may enlist the certification audit – it is the final stage of implementing quality management systems, environmental management systems, health and safety management systems as well as information security systems, food safety systems (HACCP) and others.

Other types of audits should also be mentioned due to the fact that despite the management system audit we may also distinguish the product audit and production process audit. Table 1 presents differences in objectives and the object of the abovementioned audits.

Table 10. Object and objectives of audits

Types of audits	Object of the audit	Objective
Quality management system audit	quality management system (QMS)	compliance and effectiveness evaluation of systematic solutions
Production process audit	production process (mass production)	evaluation of quality ability for special products/groups of products and their process
Product audit	products and services	evaluation of meeting the requirements included in the specification in reference to the product

Source: On the basis of VDA 6.3 2010.

An audit is a particularly valuable tool at the stage of implementation as well as at the phase of developing the management system. Hence, it is extremely difficult to imagine proper maintenance and development of the system without the process of constantly improved internal auditing realized in the frames of the so-called audit program management. The necessity of changes which improve and increase the effectiveness is relevant to all element of the process – its planning, realization, documentation and post-audit actions. The particular role in this regard should be assigned to the competence of internal auditors. Audits amount to a mechanism of constant improvement of the system as they allow to confirm the conformity of solutions, but also indicate system mitigation (defining non-conformity and observation) and encourage the analysis of the reasons as well as taking corrective and preventive actions (if necessary).

Using the audit method allows the evaluation of the system [ISO 19011:2011] if it:
- meets planned assumptions (see 7.1: ISO 9001 and the point linked with planning), requirements of international standards (ISO 9001, ISO 14001, OHSAS 18001), and other requirements of quality, environmental or health and safety management system,
- is effectively implemented and maintained.

Furthermore, an audit allows defining the necessary directions of increasing the level of quality, development and broadening the quality/environmental management system. During the audit significant emphasis is put on the systematic solutions' compliance with the law, clients' requirements, normative basis of the system (e.g. ISO 9001, ISO 14001) and other internal regulations established by the organization.

In light of the abovementioned remarks, the internal audit system appears to be particularly essential as it is required by the quality management system. It is also a necessary element applied in other systems shaping the quality [ISO 19011:2011]. In order to fully benefit from the possibilities related to conducting an audit, it is crucial to know the basics of the method as well as the requirements of the standard, which amounts to a fundament for the system in a given organization (e.g. ISO 9001, ISO 14001), and the audit guidelines established in the standard – ISO 19011.

2. Essence of a Management System Audit

The definition of an audit depicted at the beginning of the present chapter appears to be the most comprehensive, however, in professional literature we may also come across other attitudes to this process [Kreier & Łuczak 2002]. The audit of environmental management system is a process of systematic, independent and documented gathering the audit evidence as well as its objective evaluation on the basis of which it is established whether the environmental management system in the given organization is in compliance with previously assumed criteria of the environmental management system audit [PN-EN ISO 14001:2005].

The health and safety management system audit [PN-N 18001:2004] is a systematic and independent examination whether the actions taken in the frames of the health and safety management system as well as the results of them reflect the planned assumptions, and whether the assumptions have been effectively implemented. The examination also aims at establishing whether the assumptions are appropriate in reference to realization of the health and safety policy as well as the objectives in this regard.

Each management system entails the risk of occurring non-conformity stemming from the imperfection of the system's assumptions, material defects and, finally, human imperfection. Thus, it appears to be legitimate to detect

the non-conformity in an intentional, regular and organized way in the frames of the conducted audit as well as to undertake systematic post-audit actions (focused not only on the results but also on the reasons of non-conformity). There are numerous terms related to the audit which are significant in the realization of the process.

As the most important terms in this context [ISO 19011:2011] we may enlist:
- audit criteria – a set of policies, procedures and requirements;
- audit evidence – records, statement of facts or other types of information relevant due to the audit criteria and possible verification;
- auditee – the organization which is audited;
- auditor – the person who is competent to conduct an audit;
- audit team – one or more auditors who conduct the audit, supported by technical experts (if required);
- audit program – a set of audits (one or more) planned in the established timeframes which has a particular objective.

Management system audit is conducted on a client's request. A client may be understood as:
- a customer – an enterprise which wants to realize the initial or periodical evaluation of the supplier with the use of an audit;
- a supplier – an organization which assumes that its quality management system will be audited internally;
- an independent body responsible for supervision over a product's or service's quality (e.g. responsible for supervision over given installations), i.e. a third party authorized to conduct the audit;
- a certification body selected to conduct the quality management system audit in order to certify the quality management system in a given organization, i.e. a body which conducts the certification audit.

An organization may order the audit to be conducted by e.g. a supplier of a different specialized organization. The reasons underlying such a decision may be:
- insufficient preparation of its own auditors;
- superior professionalism of external auditors in realizing the audit procedure;
- more importance attached to audits;
- eliminating bias in reference to the evaluation.

It is particularly significant in the case of an environmental management system, as we want to evaluate whether the supplier meets the requirements related to minimizing the influence on the environment. This way it is possible to have control over both the supplier's and contractor's activity, especially realizing some works on the organization's premises.

During an audit, the audit team verifies systematic solutions, assesses their compliance with the standards' requirements and other assumptions (so-called audit criteria), and emphasizes the effectiveness of actions taken. Each non-conformity detected is precisely defined and described with the indication of its basis.

First, the requirements in reference to which we conduct the audit should be established and known. They may be as follows:
- standards related to quality, environmental and safety systems;
- maintained and documented system of the supplier;
- legal requirements;
- realization of objectives and tasks related to the environment, health and safety;
- monitoring;
- contract with the client.

In the case of observing possible non-conformity it is necessary to relate it to a particular requirement as well as it is crucial to find the objective reason for it, which will confirm the observation. Having realized all the abovementioned actions we may state a non-conformity situation. If at least one of these elements does not occur, i.e. there is no basis for non-conformity, no observation has been made or no evidence has been found, it may not be regarded as a non-conformity occurrence.

3. Audit Objectives and Responsibility Scopes

On the basis of regulations included in the ISO standards from 9000 series as well as the ISO 14000 series it may be concluded that the executive personnel of an organization should ensure establishment of an effective and efficient internal audit process in order to evaluate the advantages and drawbacks of the management system. The following exemplary issues should be taken into account during an internal audit [ISO 9004:2009]:
- effectiveness of implementation processes;
- possibility of continuous improvement;
- process ability;
- effectiveness of the usage of statistical techniques;
- usage of information technologies;
- analysis of quality costs, environmental costs;
- effectiveness and efficiency of the usage of resources.

Audits are conducted by an audit team. Among auditors who participate in the audit it is necessary to select a lead auditor, even if the audit is conducted by one person. The lead auditor is responsible for conducting the audit.

An audit team frequently embraces:
- technical experts in a given area,
- auditors in training,
- observers.

The client and the lead auditor must be informed about the presence of these people. Moreover, this fact must be accepted by them.

Auditors should be free of bias and ought not to be influenced by any factors which may affect their objectivity.

The tasks and responsibilities of the following participants in the audit process are unequivocally defined:
- auditors,
- lead auditor,
- client,
- auditee.

The lead auditor bears the final responsibility for all the stages of audit. The lead auditor should be skilled and experienced in conducting audits as well as should be authorized to make final decisions related to all audit actions.

Among responsibilities and tasks of the lead auditor the following may be enlisted [ISO 19011:2011]:
- Defining the requirements and scope of the audit.
- Participation in selecting the remaining members of the audit team.
- Preparation of the audit plan, operational documentation and guidelines for auditors.
- Review of the quality management system documentation.
- Representing the audit team before the executive personnel of the auditee.
- Informing and removing obstacles come across during the audit.
- Preparation and presentation of the audit report.

4. Stages of Audit Actions

Acknowledging the significance and utility of the audit process, it is important to emphasize the need to recognize all of its stages presented in Figure 30.
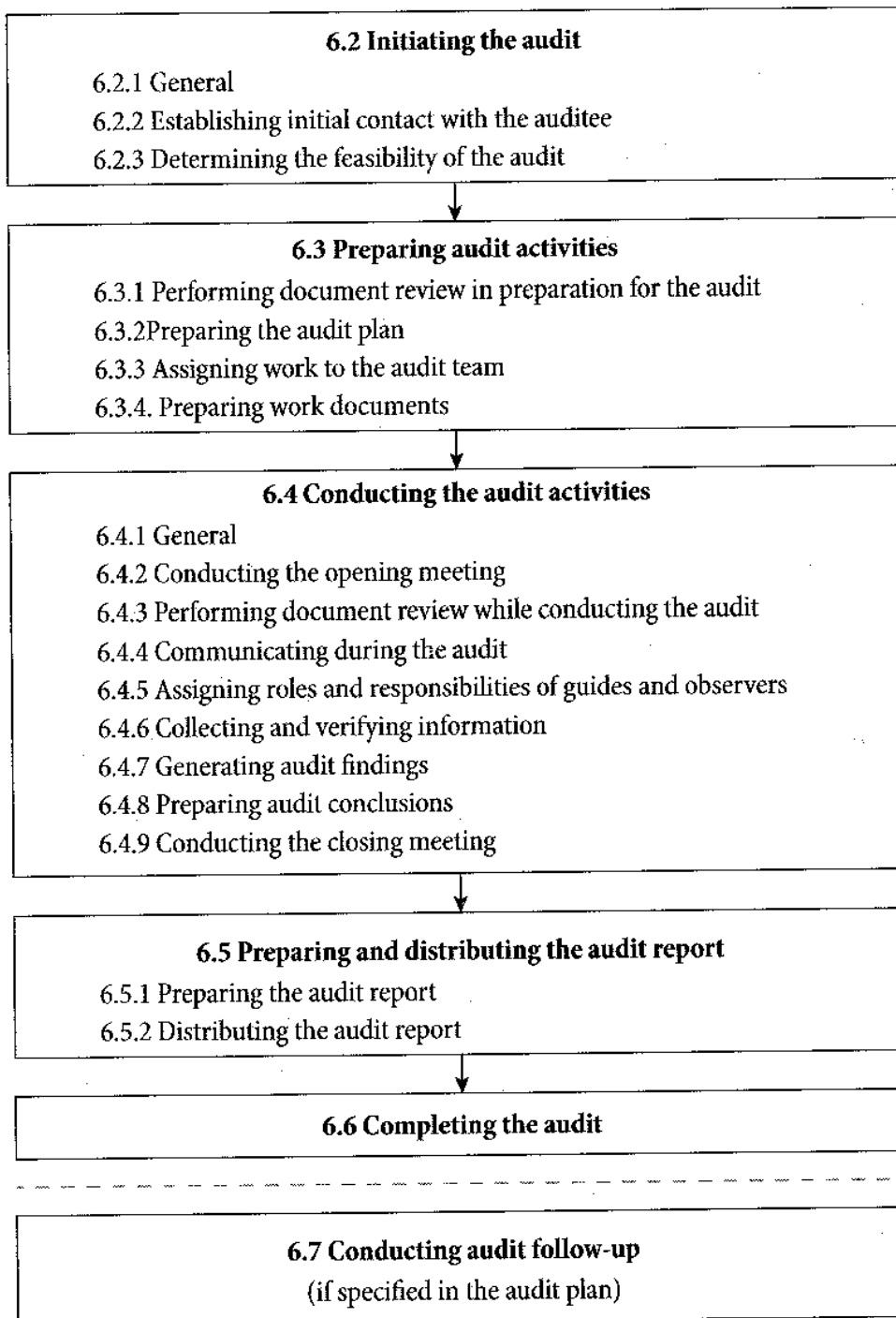

6.2 Initiating the audit

6.2.1 General

6.2.2 Establishing initial contact with the auditee

6.2.3 Determining the feasibility of the audit

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6.3 Preparing audit activities

6.3.1 Performing document review in preparation for the audit

6.3.2 Preparing the audit plan

6.3.3 Assigning work to the audit team

6.3.4. Preparing work documents

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6.4 Conducting the audit activities

6.4.1 General

6.4.2 Conducting the opening meeting

6.4.3 Performing document review while conducting the audit

6.4.4 Communicating during the audit

6.4.5 Assigning roles and responsibilities of guides and observers

6.4.6 Collecting and verifying information

6.4.7 Generating audit findings

6.4.8 Preparing audit conclusions

6.4.9 Conducting the closing meeting

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6.5 Preparing and distributing the audit report

6.5.1 Preparing the audit report

6.5.2 Distributing the audit report

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6.6 Completing the audit

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6.7 Conducting audit follow-up

(if specified in the audit plan)

Figure 30. Review of typical audit actions

Source: [On the basis of ISO 19011:2011]

Each of the elements of the audit process included in the ISO 19011 standard is crucial for attaining the audit objectives. Each of these elements is undoubtedly realized in the case of third party audit, but in reference to an internal audit some of them may be limited.

The basic stages of the audit actions may be as follows:
- initiation of the audit,
- document review,
- preparation of audit activities,
- realization of audit activities,
- documentation of audit results,
- audit completion,
- realizing post-audit actions.

The audit initiation includes selecting the lead auditor, defining the audit objectives, range and criteria as well as establishing the audit's feasibility and the first contact with the auditee. The standard recommends that people responsible for the audit program management select the lead auditor for the given audit.

In the case of joint audits it is important, prior to the audit, the auditing organizations reach an agreement in reference to their individual responsibilities, in particular linked with the lead auditor's authorities selected for the given audit.

In the frames of general objectives of the audit program it is recommended that individual audits be based on documented objectives, range and criteria.

The audit objectives define the anticipated results of the audit process. The objectives may embrace:
- defining the scope of compliance of the audit management system, or its part, from the audit criteria;
- evaluating the management system ability in order to ensure the compliance with legal and contract requirements;
- evaluating the management system effectiveness in attaining specific objectives;
- identifying the areas of potential improvement of the management system.

The range of the audit defines the area and borders of the audit, i.e. locations, organizational bodies, actions and processes which are to be audited as well as the timeframes of audits.

The audit criteria may include applicable policies, procedures, standards, regulations and the law, management system requirements, contract requirements or business activity codes.

It is necessary to define the essential resources associated with the audit process:
- audit objectives, scope, criteria and approximate duration;
- general authority of the audit team, essential for attaining the audit objectives;

- requirements of auditing and certification bodies (if applicable);
- need to assure independence of the audit team in reference to the actions to be audited in order to avoid the conflict of interests;
- ability of the audit team members to effectively cooperate with the auditee and with one another;
- language of the audit and understanding the social and cultural circumstances of the auditee with the use of the auditors' skills or the support/ help from a technical expert.

In the process of selecting the audit team members it is crucial to put strong emphasis on assuring proper knowledge and skills of the auditors in order to attain the audit objectives. The team needs to have full knowledge and skills related to the basis of the audit and the specificity of the auditee. If members of the audit team lack the necessary knowledge and competence, the team should be extended with technical experts. Their role is to verify the substantial questions and to support the system evaluation.

The auditee may apply to the certification body in order to change the members of the audit team by providing rational argumentation. It is recommended that this argumentation be informed to the lead auditor and auditors responsible for managing the audit in order to allow them to make the decision. It is a relatively rarely used right of the auditee, therefore, it should be remembered that there is such a possibility. The aforementioned rational argumentation may be linked with the conflict of interests, e.g. when the auditor used to be a consultant or employee of the auditee, which is against the rule of auditors' independence.

At the beginning of the audit we may observe:
- establishing the forms of communication;
- providing the information about the proposed timeframes and constitution of the audit team;
- request for assuring the access to relevant documents, including records;
- establishing the assumption related to the organization of the planned audit;
- agreement on the possibility of other people's participation in the audit team, e.g. guides.

The document review is most frequently conducted at the auditee's location and includes the determination of the system's compliance in a documented form as well as the audit criteria. The documentation may embrace relevant documents, management system, records and previous audit reports. During the review the following factors are taken into account: size, character and complexity of the organization, the audit objectives and scope. Occasionally

it is useful to pay a simultaneous visit to the auditee in order to confront the documentation adequacy and the specificity of the organization.

In the case of inadequacy of systematic documentation it is necessary to introduce proper corrections. The effectiveness of these actions determines the initiation of next audit stages.

The preparation of audit activities embraces: preparation of the audit plan, task assignment within the audit team and preparation of operational documents.

The lead auditor is responsible for the preparation of the audit plan in order to deliver crucial information to the audit team and the auditee. The comprehensiveness of the plan should reflect the scope and complexity of the audit. Plans may differ, e.g. for the certification audit and the following ones, for internal and external audits. It is necessary to ensure flexibility enabling changes, e.g. in the scope of the audit, which may be needed in the course of realizing the audit activities.

An audit plan should include:
- audit objectives;
- audit criteria and all reference documents;
- the scope along with identification of organizational and functional units as well as processes to be audited;
- dates and places where the audit activities are to be realized;
- anticipated duration of the audit actions along with meetings of the audit team and appointments with the executive personnel of the auditee;
- roles and responsibilities of the audit team members;
- assigning proper resources to critical areas of the audit.

Furthermore, the ISO 19011 standard indicates that an audit plan also embrace, if it is appropriate:
- identification of the auditee's representative for the purposes of the audit;
- language of the audit actions and reports, if it is different from the language of auditors and/or the auditee;
- main points of the audit report (including non-conformity gradation method), the form and structure, expected dates of publication and distribution;
- logistic solutions (trip, buildings at the location etc.);
- confidentiality issues.

An audit plan should be proposed to the client's consideration in order to conduct the audit with the highest efficiency possible. All remarks of the auditee should be discussed between the lead auditor and auditee.

The lead auditor in agreement with the remaining members of the audit team assigns auditors to monitor given processes of the management system, functions, locations, areas and activities.

During the assignment process it must be taken into account to respect the auditors' independence, competence and effective usage of available resources. Moreover, the roles and responsibilities of auditors-trainees and technical experts should not be neglected. In order to ensure attaining the audit objectives some changes in the task assignment may be introduced.

The audit team members are obliged to review the scope of the tasks assigned to them in the frames of the audit as well as to prepare necessary operational documents.

In order to conduct an audit in a professional manner, in particular with the view to document the results, appropriate operational documents should be created. They may include:
- list of control questions and plans of audit sampling;
- forms of recording information, e.g. supportive evidence, audit conclusions and records of meetings.

It is recommended not to limit the audit scope by the list of control questions and forms, as the scope may undergo changes in light of the information gathered in the course of the audit. Operational documents and records should be stored until the end of the audit. The documents containing confidential information as well as the documents protected by copyright should be secured in a special way.

Realization of the audit activities embraces: conducting the opening meeting, communication during the audit, guides' and observers' participation, gathering the audit evidence, developing the settlements of the audit, reaching conclusions and conducting the closing meeting.

This stage of an audit starts with an opening meeting of auditors and representatives of the auditee or personnel responsible for given functions and processes which are to be audited.

The aim of the opening meeting is:
- review of the audit plan,
- brief presentation of performed audit activities,
- confirmation of communication channels,
- to allow the auditee to ask questions.

The regular elements of the opening meeting are:
- presentation of participants along with their roles;
- confirmation of audit objectives, scope and criteria;
- confirmation of the audit timetable and other settlements related to the audited, e.g. date and time of the closing meeting, all meetings of the audit team and changes;

- methods and procedures applied in order to conduct the audit (including informing the auditee that the audit evidence is merely a sample of shared information and, thus, there is an element of uncertainty in auditing);
- confirmation of the formal way of communication between the audit team and auditee;
- confirmation of the language used during the audit;
- confirmation of the fact that during the audit the auditee will be informed on the progress;
- confirmation of the availability of resources and equipment necessary for the audit team;
- confirmation of confidentiality issues;
- confirmation of health and safety procedures, emergency procedures and security of the audit team;
- confirmation of guides , their availability and role;
- reporting method including gradation of non-conformity;
- information about conditions in which the audit completion may take place;
- information about the appeal system in reference to conducting the audit and its results.

It depends on the scope and complexity of the audit whether it is necessary to formally reach the settlement about the communication during the audit. In the course of realizing the audit activities the audit team exchanges information, evaluates the progress and modifies the auditors' tasks periodically up to several times.

The audit evidence or observations indicating non-conformity should be presented to the auditee without delay. If the initial evidence shows that the audit objectives are unattainable, it is recommended that the lead auditor present the auditee the reasons for taking given actions. These actions should include the confirmation of the audit plan alteration, the audit completion or modifying the audit objectives and scope.

Each modification of the audit plan which may occur during the realization of the audit activities should be looked into with the auditee and must be approved by them. Every issue related to a problem beyond the audit scope is noted and presented to the lead auditor in order to be transferred to the auditee.

Guides and observers may accompany the audit team, but are not its members. Therefore, they do not exert any influence or interrupt the realization of the audit.

They act the supervision of the lead auditor. Their duties include:
- establishing contact and time for the interviews,
- appointing visits at given locations,
- assuring that the audit team members are acquainted with the safety procedures and that they are followed.

Guides may also witness the audit on behalf of the auditee. On the auditor's request guides may provide explanations and help to gather correct information.

In the Figure 31 there is an overview of the audit process presented from collecting information to drawing audit conclusions.
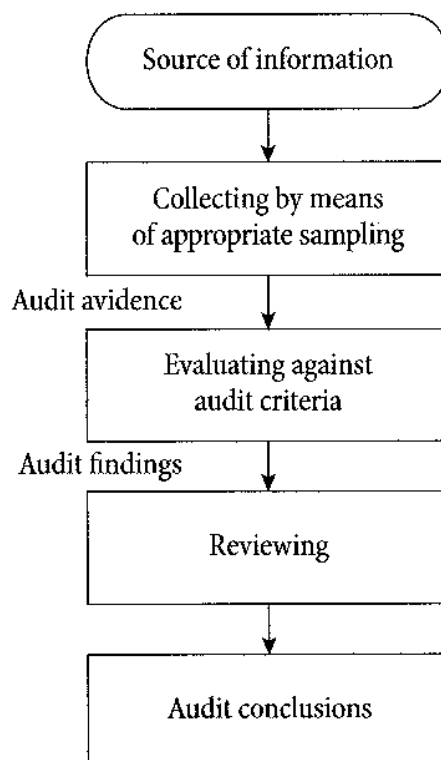
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                    ┌─────────────────────────┐
                   (    Source of information   )
                    └─────────────────────────┘
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                                 ▼
                    ┌─────────────────────────┐
                    │     Collecting by means  │
                    │  of appropriate sampling │
                    └─────────────────────────┘
     Audit avidence                │
                                   ▼
                    ┌─────────────────────────┐
                    │     Evaluating against   │
                    │       audit criteria     │
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     Audit findings                │
                                   ▼
                    ┌─────────────────────────┐
                    │                          │
                    │        Reviewing         │
                    │                          │
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                    ┌─────────────────────────┐
                    │                          │
                    │     Audit conclusions    │
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Figure 31. Audit process of a quality management system (from collecting information to drawing conclusions)

Source: On the basis of [ISO 19011:2011]

All information related to objectives, scope, criteria along with the data associated with interactions between functions, activities and processes is verified and collected by appropriate sampling during the audit. Only verified information may be treated as audit evidence. Audit evidence should be recorded.

Audit evidence is based on the sample of available information. Hence, there is an element of uncertainty in auditing. Consequently, the people taking actions on the basis of the audit conclusions should be aware of that fact.

It is recommended that information collecting methods embrace:
- interview;
- observation of activities;
- document review.

Selected sources of information may differ in the audit scope and complexity. They can include:
- interviews with employees and other people;
- observation of activities and surrounding conditions as well as environment;
- documents, e.g. policy, objectives, plans, procedures, instructions, licenses and permits, specifications and results of measurements;
- records, e.g. control records, meeting reports, audit reports, records related to monitoring programs and measurement results;
- summary of data, analysis and the rate of activity effectiveness;
- records related to the basis of sampling programs of the auditee and procedures assuring control over the quality of sampling and measurement processes;
- records of other sources, e.g. feedback from clients, external parties, and supplier rating;
- computer databases and websites.

Interviews amount to one of the most important ways of collecting information and it is recommended that they should be conducted in an appropriate manner in reference to the situation and people involved. Moreover, an auditor should take into consideration:
- conducting interviews with people of different ranks and functions who fulfill their tasks in the frames of the audit,
- conducting interviews with employees at their workplace during their working time,
- making an attempt to relax the interviewee before the interview,
- explaining the reason for conducting the interview and taking notes,
- beginning the interview with the request to describe the interviewee's work;
- avoiding biased questions (suggestive questions),
- summarizing and reviewing the interview results together with the interviewee,
- expressing gratefulness to the interviewee for their participation and co-operation.

Audit evidence must be evaluated in reference to audit criteria in order to prepare post-audit conclusions. Audit conclusions may indicate non-conformity with audit criteria or identify the capacity of development.

The audit team meets, if needed, in order to review the audit conclusions at given stages of the audit.

The non-conformity indicated in the course of the audit should be summarized in order to point out the location, function, processes and requirements to be audited.

Non-conformity and its evidence collected during the audit should be recorded. Non-conformity may be graded. It is recommended that it should be discussed with the auditee's representative in order to confirm that the audit is accurate and the non-conformity understood. It is also recommended to make every attempt to reconcile all differences related to the audit evidence and conclusions. The unsolved issues should be recorded.

Directly before the closing meeting auditors should reach a common position. Therefore, the following issues are analyzed:
- overview of audit conclusions and other relevant information collected in the course of the audit in regard to the audit objectives;
- reaching audit conclusions taking into consideration the uncertainty associated with auditing;
- preparation of recommendation if it has been included in the audit objectives;
- discussion about post-audit activities, if applicable.

The closing meeting is conducted in order to present the audit settlements and conclusions. It is important that the way of carrying out the meeting should allow understanding and confirmation of non-conformity by the auditee. During the meeting post-audit activities are also defined. The participants during the opening and closing ceremonies are most frequently the same.

In many cases, for example, of internal audits in small organizations the closing meeting may consist in presenting the audit settlements and conclusions. In other audit situations the meeting is formal and documented afterwards. The closing meeting with the executive personnel and relevant employees of the auditee is conducted by the lead auditor. One of the most important aims of the meeting is the analysis of discrepancies between the auditee's and audit team's settlements. All moot problems should be solved; in the case it has not been achieved the final discrepancy should be recorded.

Recommendations related to the development of the management system are optional.

Preparation of the audit report is a significant formal stage of an audit. It is also crucial to make the report available for the auditee. This stage consists of the following elements: preparation of the audit report, its confirmation and distribution.

The lead auditor is responsible for the preparation and content of the audit report. This document should include complete, thorough, brief and unambiguous audit records. The report should embrace, or at least refer to:
- audit objectives;
- audit scope, in particular identification of organizational and functional bodies as well as processes and their duration;
- identification of the audit's client;
- identification of the audit team members;
- dates and locations of audit activities;
- audit criteria;
- audit settlements;
- audit conclusions.

It is recommended that the audit report should include or refer to:
- audit plan;
- list of the auditee's representatives;
- audit process summary along with all encountered obstacles which may lower the credibility of the audit conclusions;
- confirmation that the audit objectives have been attained in the frames of the audit according to the audit plan;
- areas which have not been audited despite the fact that they belong to the audit scope;
- unsolved discrepancies between the auditors and auditee;
- recommendations related to improving the management system, if it has been included in the audit objectives;
- plan of post-audit activities;
- declaration of confidentiality of the audit content;
- distribution list for the audit report.

The lead auditor should make sure the audit report is published at the time agreed with the auditee. In the case of some certification bodies the report is delivered directly after the closing meeting.

The audit report belongs to the auditee. Therefore, it is necessary to respect the confidentiality and proper security by the audit team members as well as all recipients of the report.

Completion of the audit is divided into: retaining documents and formal completion of the audit.

It is recommended that the documents related to the audit should be retained or destroyed in agreement with the contract between the participating par-

ties, the audit program procedures as well as relevant acts of law and contract requirements.

The audit team is responsible for managing the audit process and must not reveal the content of documents or other information collected during the audit to any other party without the auditee's permission expressed in a direct way. The only exception is an accreditation body or other situations required by the law. If it is necessary to reveal the content of audit documents, it is recommended to inform the auditee about this fact without delay.

An audit may be acknowledged as completed if all the activities included in the plan are realized and the confirmed audit report is distributed.

Post-audit activities are subsequent and in all cases are related to conducting a non-conformity analysis, planning and carrying out corrective actions. These activities should be conducted at agreed time. Then the final verification of post-audit activities' effectiveness is performed.

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