An Expert System for ISO 9001 Certification Pre-Audit

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Abstract: - A high quality level in the processes and products implies prestige and competitive advantages for organizations in any domain. Thus, several quality models have been proposed for quality evaluation. One of these most important models is the standard ISO 9001. Usually, the ISO 9001 certification implies several pre-audits before the final certification audit. These audits are costly and it is therefore very important to pay only for the necessary ones. This paper proposes an expert system specifically oriented to software factories that helps to minimize the number of pre-audits. The expert system evaluates the software factory in the standard ISO 9001 and a pre-audit with a real audit team is only requested if the response of the system is positive. The design of this system is based on the CommonKADS methodology, and its implementation was carried out with the Clips tool.

Key-Words: - Audit, Clips, CommonKADS, Expert system, ISO 9001, Quality.

1 Introduction

In 1967, in the OTAN’s congress in Garmisch (Germany) the term “software crisis” was coined. To overcome this software crisis researches began to work in the different aspects of the software development (the 4 Ps): product, process, people, and problem [1]. Metrics, methodologies, etc. were developed for product. People capabilities are in continuous improvement through learning plans. Problem conceptualization is an important and prolific research issue. The remaining P—the process—is the relevant here. It is commonly accepted that it is necessary to improve the software process in order to obtain a good product (derived from a good process) [2]. With this aim, the software process (development and maintenance) must be monitored in order to control the quality of the final product and the development effort, time and cost. In this situation, several quality models and standards have been proposed with the aim of evaluate the quality of the processes in the organizations (e.g., TQM, CMMI, Bootstrap, and ISO 9000). One of the most important models is the standard ISO 9000 [3].

The standard ISO 9000 describes a quality management system (QMS) in a generic way and is intended to be applicable to all organizations, regardless of type, size and product provided. A QMS is defined as the organizational structure, responsibilities, procedures, processes and resources needed to implement quality management. Its aim is to help organizations in order to guarantee that their products and services comply with the customers specifications [1].

The ISO 9000 norms were firstly published in 1987. The protocol ISO establishes that every norm has to be revised almost every 5 years: ISO 9000:94 (in 1994), ISO 9000:2000 (in 2000), etc. Currently, the ISO 9000 family of standards is composed of [3]:
- UNE-EN ISO 9000. QMS fundamentals and vocabulary.
- UNE-EN ISO 9001. QMS requirements.
- UNE-EN ISO 9004. QMS guidelines for performance improvements.

This paper focuses on the UNE-EN ISO 9001, which is the standard used for process quality evaluation and certification.

The standard ISO 9001 specifies the QMS requirements. These are generic requirements applicable to all organizations and, for inclusion, to software factories. The standard is prescriptive; it says what to do but not how. The requirements are described in clauses 4 to 8 of the standard.

The first clauses are an introduction to the standard. A brief description of each clause is as follows:
- Clause 4. General requirements and documentation requirements. This clause focuses on the identification and management of the processes in the QMS
Clause 5. Management responsibility. Specifically identifies the responsibility of top management and the need for effective leadership.

Clause 6. Resource management. To ensure that the resources needed to both maintain and improve the QMS are available and also to carry out the work required in a manner that will satisfy customer requirements.

Clause 7. Product realization. Checklist that explains the processes involved in order to produce the product and the permissible exclusions to the norm.


Clause 7 contains most of the requirements. These requirements cover all the aspect of:
- Planning of product realisation.
- Customer related processes.
- Design and development.
- Purchasing.
- Control of production and service provision.
- Control of monitoring and measuring devices.

Two types of auditing are required to become registered to the standard:
- Pre-audit: It is a high level evaluation indicating where the company currently stands in compliance with ISO 9001. It reduces the risk of non-conformance during the actual audit. The early observations can be immediately implemented into the QMS, so it can benefit from the insights before the actual audit even starts.
- Audit: The audit team collects evidence that the organization has implemented a QMS in compliance with the ISO 9001 standard and the practices match the descriptions captured in the quality documentation. If all goes well, the organization will be recommended for certification and issued an ISO 9001 certificate. If non-conformances are identified, the audit team will confer with the organization management staff and agree upon the required follow-up actions.

Usually it is required more than one pre-audit. The pre-audit reviews the current business systems and documents and advises the organization what needs to be done to make the business ready for a full ISO 9001 certification audit. For businesses that are short and medium, this is usually needed one or more people on-site for one or more days, plus at least another day for the written report. Businesses that are large, or with multiple sites to be certified, will require additional time and perhaps even additional people. The pre-audit also provides opportunity to meet the persons most likely to do the final ISO 9001 certification audit and the subsequent 3-yearly re-certification audits, and begin an on-going relationship. The next step is to prepare the existing QMS as advised in the pre-audit report. The non-conformances observed are implemented into the QMS and a new pre-audit is necessary to check the improved organization practises. If new non-conformances arise a new pre-audit is required. The entire process may turn out to be very expensive. As an idea, an ISO 9001 consultant is charged-out at around 110 euro per hour. There is a 15% administration fee on any expenses we incur.

This paper proposes an expert system for the evaluation of an organization in ISO 9001. The application of this system will substantially reduce the need for expensive pre-audits because these will only take place after the system has issued a positive report.

The design of the proposed expert system is detailed in section 2 of this paper, section 3 shortly describes the system implementation, and section 4 sets out the conclusions.

### 2 Design of the proposed system

The quality of expert systems design depends on the programming skills of the knowledge engineers, and on their ability to devise, remember, and dynamically update a design specification. This is a difficult task for all but the smallest expert system.

Difficulties like these can be alleviated by producing representations of the experts’ knowledge and of the design specification in the shape of text or diagrams. The best known approach towards the production of such documents is the CommonKADS methodology [4, 5, 6, and 7] by which we elaborate a list of potential components of the model for the system, select the adequate template for the task, and construct the initial domain scheme. The last stage is a complete specification of the knowledge model. The following sections describe each of these activities.
2.1 List of potential model components

The task of the proposed expert system belongs to a highly specialized field (a concrete and classified theme within Quality Management). There are several organizations dedicated to ISO standards certification. In Spain, international norms are translated and published by AENOR [8]. AENOR and other companies as Lloyd's Register Quality Assurance (LRQA) and Bureau Veritas Quality International are authorized for ISO certification. Consequently, there are well known guides for ISO 9001 audits and the knowledge of the domain can be said to be formal.

On the one hand, there is evidence of the existence of a commonly accepted structure in the sphere of the standard ISO 9001—shown in Figure 1—that represents an initial candidate for the domain model. This structure reflects the existence of quality forms or questionnaires that helps to evaluate if the company currently stands in compliance with ISO 9001. Also, ISO 9001 requires compliance with a series of requirements [3], and each requirement specifies a series of activities that the organization must perform. Sets of questions have been designed to test how well the organizations perform these activities. Consequently, the compliance with these questions implies the compliance with the requirement, and the compliance with all the requirements is equal to the compliance with the standard ISO 9001.

![Fig. 1. Initial relationships structure](image)

On the other hand, it is necessary to store the pre-audits results (e.g. in a file or database). Therefore, before checking the compliance of the organization with the standard ISO 9001 through a pre-audit with this expert system, the system has to check if a pre-audit has been passed. In this case, it is required that the organization has not passed any pre-audit.

2.2 Selection of the task template

The final purpose of the proposed expert system is to provide an organization with the possibility to fill out a quality form for ISO 9001 and consult the system regarding the certification viability.

In this context, and from the point of view of the task, this is an activity that fits into the category of assessment. These activities are provided with various templates, from which we have selected the one mentioned in [5].

The main motive for this choice is that the associated inferential structure matches the purpose of the application. A good technique to establish this adequacy to the problem consists in building an annotated inferential structure in which the dynamic roles are annotated or made to correspond with specific elements of the domain. This inferential structure is shown in Figure 2.

![Fig. 2. Annotated inferential structure](image)

2.3 Construction of the initial domain scheme

As recommended in [5], this activity was carried out in parallel with the previous one. The result is a set of domain-specific conceptualisations—shown in Figure 3—and a set of method-specific conceptualisations—shown in Figure 4.
We have detected two main concepts in the problem domain: Quality Form, and Requirement. We also need some historical information, such as the results of the pre-audits. To this effect, we model a concept Record with one attribute that represent this information. The concepts Quality Form and Record constitute the initial reasoning case (concept Case). A Quality Form consists of a series of Requirements that each refer to an ISO 9001 requirement. This fact is reflected by modelling an aggregation relationship between the concepts Quality Form and Requirement. The concept Requirement presents four attributes: “name”, “total-questions”, “positives”, and “category”. The first refers to the name of the requirement—e.g. Purchasing—, the second indicates the total number of requirement-related questions, the third represents the total number of positively answered questions, and the last one refers to the level of compliance of the organization with the requirement.

The previously mentioned level of compliance is obtained in function of the attributes “total-questions” and “positives” as follows:
- If the positive answers (value of the attribute “positives”) represent less than 25% of the total (value of the attribute “total-questions”), the level of compliance is considered “none”. This means that the organization does not comply with the requirement.
- If the positive answers represent between 25-50% of the total, the level of compliance is considered “low”.
- If the positive answers represent between 50-75% of the total, the level of compliance is considered “medium”.
- If the positive answers represent between 75-100% of the total, the level of compliance is considered “high”.

In addition to the above, the notion of criterion plays an important role in the problem domain. In this case we can distinguish two types of criteria, each with a “truth-value” attribute that indicates whether it is true or false:
- Pre_audit_criterion: Was the organization successfully pre-audited?
- Requirement_level_criterion: Does the organization comply with the ISO 9001 requirements? If the organization wishes to be successfully evaluated in ISO 9001, it must meet its requirements at certain rates or levels (many possibilities are accepted).

Finally, we wish to emphasize that the system only offers a positive response if the first criterion has a false value and the second is true.

2.4 Complete specification of the knowledge model
As explained before, the activity to be modelled is an instance of the task type assessment. Also, the selected template shows an adequate inferential structure for the purpose of this expert system, in which the inferences present sufficient detail. It is for this reason that the construction process was executed by means of a “middle-out” approach [5].

Figure 5 shows the template that was chosen for the modelling and in which the global task is subdivided into two subtasks. As we can observe, the task method for the general task structures the reasoning process into two steps:
- Abstraction: the purpose of this step is for the organization to obtain the level of compliance for each requirement. As explained above, this level of compliance can be “none”, “low”, “medium” or “high”. The motive for this abstraction is the fact that what matters in a decision is not so much the number of positive answers by the user, but rather the meaning of this number. In other words, the reasoning of an expert auditor will be as follows: “The organization complies with the requirements at a medium level, but Planning is indispensable (must have a high level of compliance) and I therefore consider that there must be made improvements in that area ...”.
- Matching: the abstractions are matched in order to take the final decision on whether or not there is compliance with the established criteria.
On the other hand, and thanks to the “middle-out” reasoning process, we have obtained the final knowledge scheme that is shown in Figure 6.

Finally, we can observe that the final domain scheme incorporates three types of rules:
- “case-abstraction”: the abstractions that are required for calculating the compliance level with the requirements using the “total-questions” and “positives” attributes as previously mentioned.
- “form-requirement”: this type of rule aims at offering truth values to the norms “Pre_audit_criterion”, and “Requirements_level_criterion”. Their instances therefore indicate if the organization was pre-audited, and the acceptable compliance levels of the requirements in the quality form.
- “decision-rule”: we need some type of knowledge that refers to the final decision offered by the system to the user. This decision is represented by a “decision” concept with an attribute that indicates whether or not the organization has real possibilities of successfully passing an audit for ISO 9001. Also, the “decision-rule” expresses the relation between the different criteria and the final decision. In this case, “Pre_audit_criterion” must have the truth value true for the system to respond that the audit is possible.

3 System Implementation

The system was implemented according to the previously showed design and by means of the Clips tool [9]. In order to provide the application with modularity and to simplify the development and depuration processes, the following knowledge bases were defined:
- General: Contains all the definitions of classes, objects, and properties.
- Abstract: Contains the abstraction rules required for reaching the compliance level with each ISO 9001 requirement.
- Decision: The rules of this knowledge base refer to obtaining of the final decision, i.e. the compliance with the criterion “Requirements_level_criterion” and the non-compliance with the criterion “Pre_audit_criterion”.

The Clips inference engine is started, the corresponding knowledge bases are loaded and the inferential process begins. Figure 7 shows an execution example in which an organization lacks an acceptable level of compliance with the requirements. The requirements Purchasing and Customer Property have low and medium compliance levels respectively. However, a high compliance level is needed by the organization in order to pass the pre-audit.

4 Conclusion

In today’s competitive context, any software factory aims to provide excellent products in time and with the lowest costs. For this purpose, organizations need high quality processes. Several quality models and standards have been proposed with the aim of
evaluate the quality of the processes in the organizations. One of the most important standards is ISO 9001. Two types of auditing are required to become registered to the standard: pre-audit and the actual audit. Usually, several pre-audits are needed in order to improve the organization processes and ask for a certification audit. The entire process may turn out to be very expensive. This paper proposes an expert system that considerably reduces the number of pre-audits with a real audit team because they will only take place after a positive decision of the system.

Finally, the developed expert system is currently being installed and tested in a company at A Coruña, Spain, with which the authors have collaborated in previous occasions. The real case is too long to be included in this paper. However, the company did not pass the first pre-audit and the existing QMS is being prepared as advised in the pre-audit report in order to perform a new pre-audit using the expert system. When the organization passes the pre-audit using the expert system, an actual pre-audit will be required. The auditors’ response and reports will be compared with the system ones in order to continuously improve the expert system.

References:


