"PROCESS APPROACH" BASED ISO/IEC 17025 TRAINING

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Abstract

Ce document recommande l'utilisation de l'approche processus pour aligner la norme ISO / CEI 17025 à l'ISO 9001 dans les laboratoires d'enseignement de la théorie du système de gestion pour le personnel chargé de l'accréditation des méthodes dans le laboratoire. Alors que les laboratoires de formation et lors de l'établissement de la relation, il est demandé pourquoi les normes ne sont pas semblables dans leur arrangement; quelqu'un avec expérience dans la norme ISO 14001 pour les regarder à travers la relation des systèmes de gestion des modèles. ISO 10012 [1] modèle est approprié pour l'aménagement des éléments [2]. Les stagiaires comprennent - à cette pratique - la logique suivie pour respecter la norme en évitant la duplicité des activités au sein de leurs opérations.

This paper recommends using the processes approach for aligning ISO/IEC 17025 to ISO 9001 in teaching laboratories the management system theory to personnel responsible for accreditation of the methods in the laboratory. While training laboratories and when establishing the relationship, it is questioned why the standards are not alike in their arrangement; someone with experience in ISO 14001 look for the relationship throughout the management systems models. ISO 10012 [1] model is appropriate when arranging the elements [2]. Trainees understand - with this practice - the logic followed to comply the standard avoiding duplicity of activities within their operations.

INTRODUCTION

The latest revision of the ISO/IEC 17025 standard shows deviations to the ISO 9001 quality principles [3], situation that has practical consequences in the study, design, implementation, and operation of the laboratories management systems.

The *Joint IAF-ILAC-ISO Communiqué on the Management Systems Requirements of ISO/IEC 17025:2005, General requirements for the competence of testing and calibration Laboratories* [4] points out that "A laboratory's fulfillment of the requirements of ISO/IEC 17025:2005 means the laboratory meets both the technical competence requirements and management system requirements that are necessary for it to consistently deliver technically valid test results and calibrations. The management system requirements in ISO/IEC 17025:2005 (Section 4) are written in language relevant to laboratory operations and meet the principles of ISO 9001:2008 Quality Management Systems — Requirements and are aligned with its pertinent requirements". Nevertheless, such statement is incongruent due to the structure of the ISO/IEC 17025 document itself.

The ISO/IEC 17025 standard lacks of the elements to complying plentifully the eight quality principles stated in ISO 9001[5], in particular the "process, and system approaches" to management.

The standard seems deficient in the "process approach", since the clauses are classified by a general affinity of the requirements; instead of being presented by sequence of the required activities, or clustered [6]. As a result, the standard appears as if divided in two different parts: one section for the Technical Competence Requirements, and another one for the Management System Requirements.

There is an evident risk in not understanding the elements of the standard as a whole, and even more its corresponding application in the laboratory as a whole organization.

The standard is also deficient in the management "system approach", because the array isolates each one of the requirements from the rest; avoiding explicit interactions among them.

Reading the standard alone reduces the possibility of using the Shewhart Cycle (Plan-Do-Study-Act) [7] in establishing the logic for the activities required by the standard. Furthermore, the possibility of finding out the latter is almost zero, due to the lack of a diagram that represents the model of a management system as the ones shown within the ISO 9001 or ISO 10012 standards.

The previous scenario impacts adversely the effectiveness of the ISO/IEC 17025 training sessions; unless the deficiencies in the ISO/IEC 17025 standard [8] are corrected in the training program, when modifying the structure of the requirements in the standard, remodeling the practices for the trainees, and modernizing the role of the instructors.

This paper presents the methodology being used for applying the "process approach" in ISO/IEC 17025 training courses. Title sections presented in this paper are aligned to the process ideas and to the Shewhart cycle, originated by Dr W Edwards Deming: inputs – [plan – do – study – act] – outputs. The sections for the discussion and conclusions are presented out of this scheme sharing the experiences of using this training method for laboratories, regulatory authorities and accreditation bodies in Mexico.

INPUTS

Input elements. - Specified requirements, including resources [6].

The ISO/IEC 17025 standard preferably printed in paper or as an electronic document. It is the main training material; nevertheless, the training program is completed when including the «Measurement management system model» from ISO 10012 Figure 1.

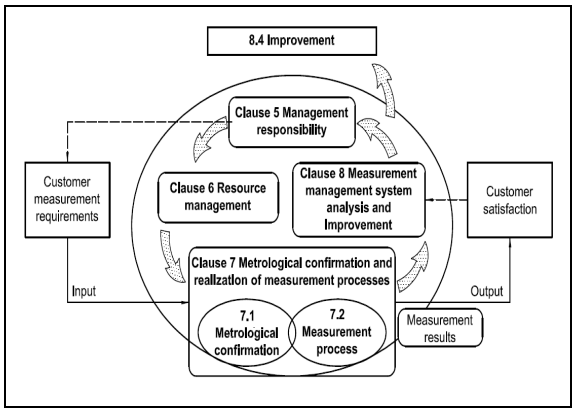

Figure 1. Measurement management system model

Trainees receive a standard and the diagram of the Measurement management system from ISO 10012. Meanwhile the instructor explains the taxonomy of the management systems that is shown in ISO/IEC 17025:2005 Annex A, where provides nominal cross-references between the standard and ISO 9001.

To make evident to the trainees the quality and metrology profiles, an explanation is given; based on Clauses 2 and 3 in the standard and, about the terms and definitions of Quality found in ISO 9000 [9] and to the ones in the International Vocabulary of Metrology VIM [10].

Then, the Bibliography in the ISO/IEC 17025 standard is introduced as a part of the related references on subjects included within the standard; finding ISO 10012 as one of them. Figure 2 classifies the references in ISO/IEC 17025 considering what Annex B establishes for specific fields as for industrial or scientific information.

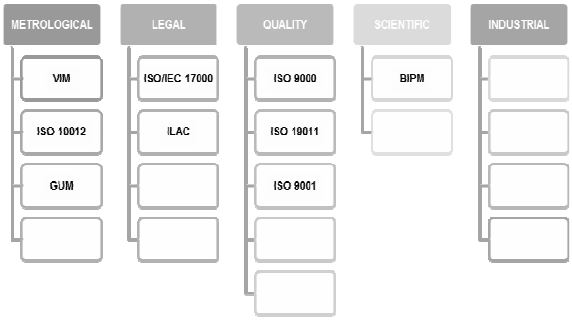

Figure 2. Taxonomy of the references in ISO/IEC 17025

Afterwards, the model in ISO 10012 is used as a format to group the clauses in ISO/IEC 17025 and map the main processes in the laboratory. As an example, the process for clause 5 in ISO 10012 «Management responsibility» is associated to 4.1/4.2/4.3/4.13 and 4.15 in ISO/IEC 17025.

PLAN (First step)

The conceptual framework received by trainees is the input for the activity of planning; in this stage the instructor guides participants to work in teams with one requirement, or a set of requirements from the ISO/IEC 17025 standard; like subclauses 4.9/ 4.11/ 4.12/ 4.14 and 5.9. The team analyzes the logics of the requirements in the subclauses, organizes the processes sequence, and places the results within a diagram following the Shewhart cycle steps. As part of the profound knowledge process, proposed by Dr W. Edwards Deming [7], it is preferably that teams cooperate in conforming all of the requirements flow charts; reason why each team works with the particular subclauses assigned.

DO (Second step)

In this stage the instructor assigns the time for the practice, pointing out the importance of concentrating their ideas in what the standard really expresses; and emphasizing that the subclauses are the inputs for the processes they are mapping, as well as the need of knowing the results they are expecting. The instructor also recommends to the teams that they "shall maintain the work free of what their fellows already have, or had done in their laboratories before."

The activities for the teams include: reading carefully the assigned subclauses; discussing the meaning of each one of the requirements; essaying the reorder of the activities stated in the subclauses; agreeing on the sequence of the steps as a process; and modeling their conclusions in the Shewhart cycle.

With this methodology, teammates work together playing four roles: (1) coordinator, the one that monitors the work progress; (2) analyst, the one that presents the elements of the requirements; (3) moderator, the one that suggests conclusions to the discussion; (4) draftsperson, the one that translates the results of the group in processes charts. On the other hand, the instructor represents the role of a guide in the application principles [11]. The stage concludes when the teams provide the diagrams to the instructor; so she, or he, digitalizes them to project them on the electronic screen. Annex A and B show examples of diagrams drawn during training sessions in Mexico.

STUDY (third step)

The instructor starts this stage asking the speaker of each team to explain their developed flow chart to the rest of the group, indicating the steps of planning-doing-studying-acting for the operations within the laboratory to comply the standard requirements. During the

explanation everyone reviews the clauses explained in the map and collaborates in clarifying doubts derived from the application or, in confirming criteria that might result more complex.

As mentioned in the planning stage, only the team that is explaining their results had the time to study those clauses during the practice; this motivates the cooperation in the group because there is no direct competence among the applications, on the contrary the work is improved by the whole group. The instructor moderates the explanation in a professional frame of work, at the same time, redirects the correct understanding of the requirements and process approach and brings the particular references as needed. This stage is over when all the teams explain their diagrams.

ACT (Fourth step)

This stage initiates when the instructor links the charts as a network to consolidate the system approach; this means the flow of operations in the laboratory as a whole to comply ISO/IEC 17025. Denoting that the applications are linked to consolidate the "process and system approaches". The instructor now, sets each team flow chart within the systems context shown in Figure 4.

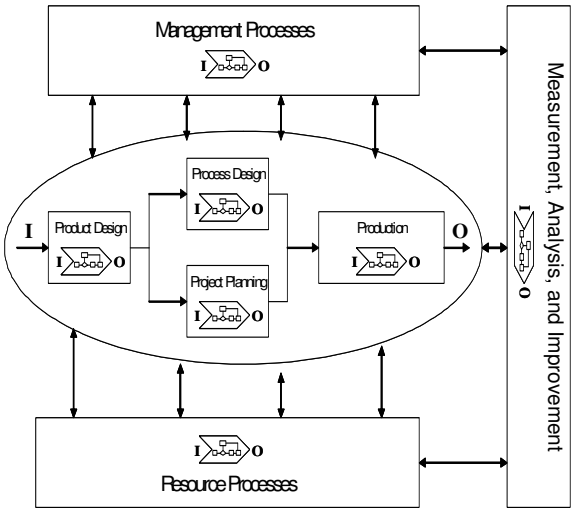

Figure 4. Process sequence and its interactions [6]

OUTPUTS

This methodology of training conducts the group to rethinking the structure of the standard in such a way that the requirements are regrouped according to a management system model based on processes as shown in Figure 5.

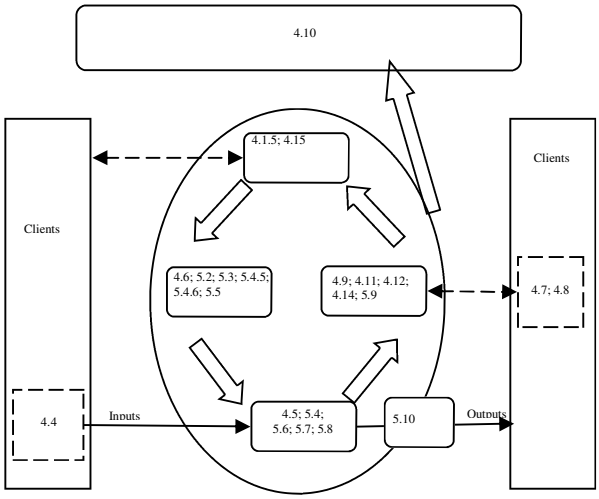

Figure 5. Management system model proposed for ISO/IEC 17025

Discussion

Traditional training programs about management systems standards are based on the platform of the structure of the standard itself; such is the case of ISO/IEC 17025 training courses where linear reading of the clauses nullifies the systems approach, since the requirements are not grouped; as in the case of the Resources Process where it is necessary to link the requirements 4.6; 5.2; 5.3; 5.4.5; 5.4.6; and 5.5.

Therefore, when laboratories try to start working according to the standard, they tend to have a "system of documents" instead of a "documented management system"; opposite to the idea of ISO 9001:2008 to allow organizations to develop the minimum quantity of documentation needed to demonstrate the effective planning, operation, and control of their processes [12].

The ISO/IEC 17025 standard should include Figure 6 to help users to understand that the requirements within the standard should be connected to propose the laboratory operations structure, and therefore its corresponding documentation [13]; the revision and structure based on process approach will be an improvement in the right direction; the idea is not new, ISO 9001, ISO 14001 [14], ISO 19011 [15], or OHSAS 18001 [16] include these approaches.

This training program has been developed and applied by the authors since 2006; comments from the trainees have allowed inferring that the methodology consolidates the process approach and preparing them for integrating systems with other standards. It is important to highlight that the process of knowledge has modify the role of the instructor because it situates the instructor as an integrator of knowledge in metrology, quality, and theory of systems, Besides, it has been needed to form the instructor to manage people. The latter has increase the complexity of the instructor training for this kind of programmes.

Conclusion

The ISO/IEC 17025 standard appears deficient in the process and system approaches. Nowadays, the instructor must correct the structure of the standard for the better understanding of it; at least until the standard is comprehensively revised and updated [17].

The methodology proposed demands that participants play an active role as a group of discussion and analyses. At the same time, cooperation among the teams is evident for the success of the training.

The training needs of the instructor acquires a new complexity since the instructor plays at least two new roles: first, input information facilitator so the teams analyze and discuss the data; second, as integrator of knowledge to organize the teams work within the management system model.

Such condition is extended to the laboratory accreditation process, and to the actual need in conformity assessment: reliable laboratory operations.

"Not just focusing in the measurement method, but in the laboratory as a whole system, is how ISO/IEC 17025 accreditation will assure safety in products and services."

References

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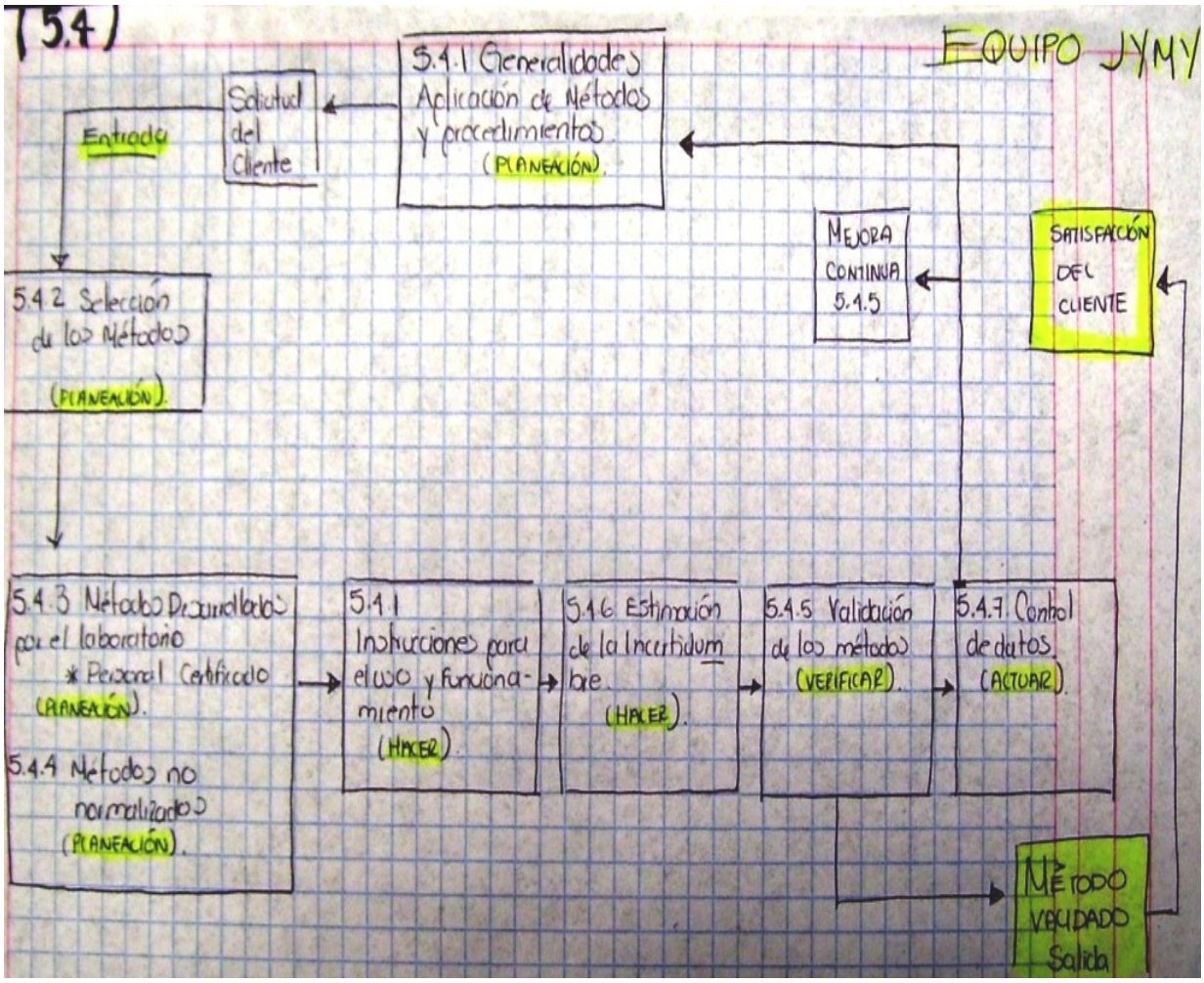

Figure A. Teamwork practice on drawing the process approach diagram for subclause 5.4

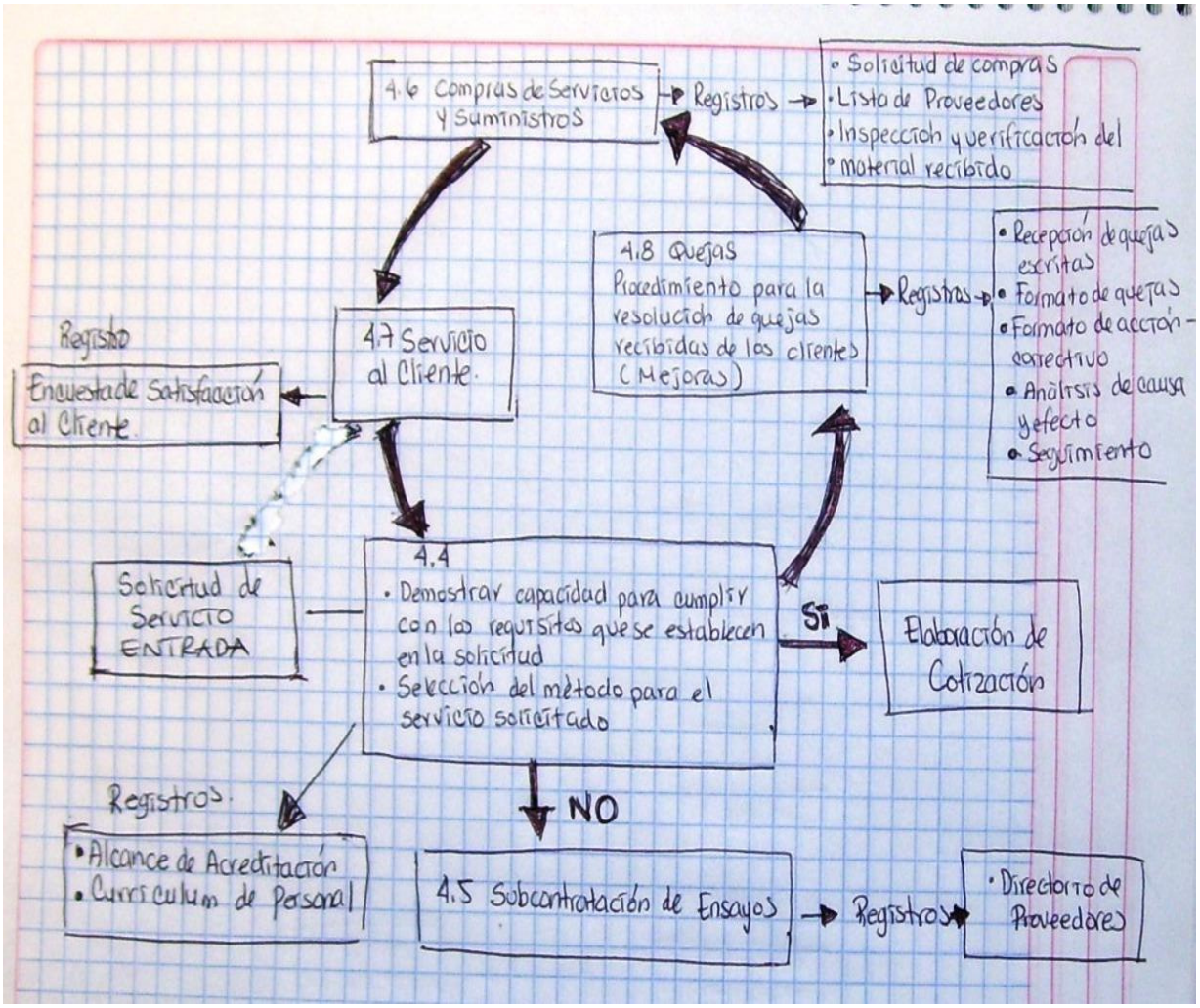

Figure B. Teamwork practice on drawing the process approach diagram for subclauses 4.4/4.5/4.6 and 4.7