THE ISO/IEC 17025 REVISION PROCESS

María del Rosario Rodríguez Báez y Carlos Antonio Rivera Orozco
Bufete de ingenieros industriales, S.C.
Francisco Pimentel 4104 B Col. Las Granjas. Chihuahua Chih., C.P. 31100
614 - 419 3700; info@bii.com.mx

Abstract: ISO/IEC 17025:2005 is nowadays in a revision process that started in 2014. This paper is intended to display the information about the revision process itself, the changes of the standard, the actors involved in the revision process, and the complexity of the revision related to the different approaches within ISO/IEC 17025. Besides the ILAC and ISO/CASCO newsletters about the changes of the standard, other sources of data were consulted from legal, scientific and industrial metrology organizations; finding clear information about the change in the structure of the standard, and some ideas of the particular changes in the ISO/IEC 17025 requirements.

1. INTRODUCTION

The use of ISO/IEC 17025 for granting accreditation as a laboratory with technical competence started in 1999 with the first edition of the standard; in 2005 the standard was revised mainly for paring it with the principles of ISO 9001, and in 2010 the review resulted in no modifications at all.

As said by ILAC on April 2014 [1], ISO/IEC 17025 *General requirements for the competence of testing and calibration laboratories* was due for review in 2015 and remarked that "The Accreditation Committee has set up a working group to address areas for improvement of the standard which really has not been significantly changed since 1999."

2. THE ISO/IEC 17025:2005 REVISION PROCESS

The search of what the focus of the change process would be directed started since the announcement of the revision of the ISO/IEC17025:2005. At the beginning following the process through the ISO/CASCO and ILAC newsletters, then reviewing the information (points of view) of the legal, scientific and industrial metrology organizations on the matter. In Mexico the Mexican accreditation body started a group representing the CASCO committee in the revision process, and at an international level a working group (WG44) initiated the gathering and analysis of the comments worldwide.

The following is the timeline of the revision process according to the ILAC and ISO/CASCO newsletters.

- April 2014, ILAC proposes the revision of the standard [1].
- July 2014, CASCO joins the ILAC revision proposal [2].
- November 2014 CASCO working group WG44 is assigned for the revision of ISO/IEC 17025 [3].
- February 2015, CASCO WG44 with more than 60 experts holds a meeting to launch the revision [4].
- April 2015, ISO/CASCO informs the modification of the standard structure and the consultation period for the change [5].
- August 2015, ISO/CASCO reports that WG44 has two consultations among the experts to identify the gaps in the current version [6].
- September 2015, ISO/CASCO writes that WG44 started the vote on the Committee Draft (CD) ISO/IEC 17025, setting the competence requirements for testing and calibration laboratories [7].
- December 2015, ISO/CASCO announces that the vote on the Committee Draft (CD) ISO/IEC 17025 closed and that the WG44 will meet again to decide whether to progress the document to the next stage or organize a second CD ballot due to the number of comments received [8].

With no more information available from ILAC or ISO/CASCO related to the revision process the following citation is included as part of the timeline.

- March 2016, CALA remarks that "given the number of important comments received and the changes made to the CD at this 4th meeting, it was decided not to proceed to Draft International Standard but to launch a second CD for a period of 2 months." [9]

It is important to note that the revision process must be completed in three years, so the new edition should be public in 2017 [10].

3. ACCOUNTABILITY OF THE CHANGES OF THE ISO/IEC 17025 REVISION PROCESS

The only change that may be considered official up to date is the new structure of the document to comply with the ISO/CASCO standards format. The other changes remained closed for the public; nevertheless some organizations in the legal, industrial and scientific metrology have openly been discussing some of the possible ones.

3.1. New structure of the standard

The proposed structure is process based and converges with the other 17000 series standards.

3.2. Changes in the requirements

The changes mentioned by some of the metrological organizations such as NCSL [11], BIPM [12], French Agency for Food, Environmental and Occupational Health & Safety (ANSES) [13], PTB [14], NATA [15], EUROLAB [16] among others, are focused in the following topics:

- Sampling and sub-sampling.
- Top management, management systems and management systems function, documentation.
- ISO/IEC 17025 approach, notes, scope, pre/post analysis, bio-security/safety, ISO/IEC 17000, national regulations, product certification.
- Metrological traceability, reference materials, metrological inter-comparison, calibration and uncertainty.
- Vocabulary and terminology, International vocabulary of Metrology (VIM), and bibliography.
- Impartiality, confidentiality, claims, preventive action, outsourced processes, subcontracting.
- Risk, tests and calibrations.
- Information technologies, technology, control data, and information management, computer systems, electronic records/report issue, remote issue of results/reports, software validation, records.
- Personnel competence, quality assurance.

4. DISCUSSION

The uncertainty of the ISO/IEC 17025:2005 revision process, with more than 200 comments worldwide, might be high considering that the previous revisions of the standard did not consider the changes the world was experiencing in the organizations in matters like management systems with system, process and lean approaches, the electronic documentation (Internet) with different means of communication, and the software development with its impact in the Metrology practice; and therefore the changes in Metrology worldwide, for example the third edition of the International Vocabulary of Metrology.

One possibility for minimizing the uncertainty mentioned above is that ISO/CASCO and ILAC initiate continuous updates possibly similar to the ones in the software management, where antiviruses for example send daily revisions of the antivirus status and the software versions changes according to the actual so fast changing world and the communication means.

5. CONCLUSIONS

The main question relies on whether the ad hoc laboratories competence requirements would be fulfill in the third edition of the standard, on the state of the art management systems, metrology, technology and information technology because of the revision process times and the process itself.

REFERENCES

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