Risk analysis during method validation

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INTRODUCTION

During the transition towards compliance with the new version of ISO / IEC 17025, laboratories need to perform the risk analysis throughout the entire test process. This paper presents the methodology applied for risk analysis in the validation or confirmation stage of test methods to verify the adequacy and improve the available control actions (portfolio) defined into the laboratory.

EXPERIMENTAL METHODS

The tool requires, in the first instance, the identification of the process stages to be evaluated (selection or design of the method, method validation/confirmation and use of the method in routine analysis). In a second stage, requirements to be met must be identified, those related with ISO / IEC 17025: 2017 standard, analytical, legal and customer requirements and those related with the laboratory management system. Risks related with non-fulfillment of these requirements, that could affect the quality in the result or service are identified. Based on the portfolio of actions, the probability and magnitude of the risks is evaluated. The risk significance is based on the parametric of the following table:

Usually					
Probable					
Possible					
Unlikely					
Rare					
Probability / Consequencce	Insignificant	Minor	Moderate	Significant	Mayor

Significance	Actions to avoid / minimize risk
Extreme risk	Monitor and take immediate action to change current controls / actions
High risk	Monitor and change controls / current actions
Moderate risk	Monitor and evaluate if change of controls / current actions is necessary
Low risk	Control measures / current actions are sufficient

Based on the expected test quality result, the portfolio of action stablished into the laboratory and the risk level to be assumed, action plans are defined for monitoring and improvement.

RESULTS AND DISCUSSION

Identification of stages: although the tool is applicable in all stages for the analysis process, for this paper we consider exclusively the method validation requirements.

Identification of requirements: some of the validation stage requirements include documentation, personnel competence, statistical criteria / parameters / sources of
influence, traceability of measurements, equipment / supplies / conditions / information, among others.

Identification of risks: some of the risks identified in the validation stage are, refer to a method not documented /
updated / adequate, studies influenced by the results obtained, incomplete data or statistical significance not adequate / representative of the scope of the method in range , matrices and analytes, not considering all sources of influence to assess the need for control, interferences not identified in routine matrices, unknowledge of the analytical-client-legal and possible uses of the test result requirements, not clear responsibilities, use of not fit for purpose equipment, personnel not competent in the method and use of the result, environmental conditions not defined / under control.

Portfolio of actions: some of the actions to be taken to minimize the risks can be: have an updated database of methods and regulations applicable to client requests. Agree with the client in the contract review an evaluation of uncertainty and applicable regulations. Have competent personnel in the specific area. Have a validation plan that includes studies to be carried out and criteria to assure objective evaluations. Have an updated database of reference material and proficiency test providers that includes an assessment based on compliance with technical requirements and applicable reference standards. Control of uncertainty sources considering the validation data. Database that allows an overall controls evaluation (including at least, equipment controls, internal and proficiency testing quality controls, use of reference materials) to evaluate and prevent that changes in the quality and/or frequency of controls do not affect the confidence level of the result.

Evaluation of significance: the significance levels varies between laboratories, depending on the result and quality expected service. The evaluation of risks significance depends on the test type, the impact of the test result (health, environment, etc.) and risk frequency. The risks can be evaluated from low to extreme significance.

Decision and action plan: each laboratory define the risk levels to be assumed and managed, as well as the controls to be taken to reduce the frequency of occurrence and / or minimize the consequences thereof. Actions can vary from monitoring, changes in sample flow, improvement of staff competence, new control strategies, etc.

REFERENCES

ISO/IEC 17025:2017 General requirements for the competence of testing and calibration laboratories
ISO 31000:2018 Risk management – Guidelines

KEYWORDS

Risk, validation, uncertainty, ISO/IEC 17025, controls