

The ISO/IEC 17025:2017 standard includes the theme of Risk Management, that in a laboratory that has worked with the other versions of the standard, the theme could be related to the estimation of the uncertainty of the measurement.

The third edition of the standard states in the Introduction of the standard that the laboratory “requires to plan and implement actions to address risks and opportunities”, this for increasing the effectiveness of the management system, achieving improved results and preventing negative effects; besides, the standard mentions that the laboratory is responsible for deciding which risks and opportunities need to be addressed.

Some standards define risk as the effect of uncertainty on objectives and the standard clarify that the effect is a deviation from the expected. It can be positive, negative or both, and can address, create or result in opportunities and threats.

The requirement 4.1.4 in ISO/IEC 17025:2017 points out that the risks to be address include those from the activities of the laboratory and those from its relationships or from its relationships with the personnel.

The requirement 8.5.3 indicates that the actions taken to address risks and opportunities shall be proportional to the potential impact on the validity of the laboratory results.

Considering this approach in clause 8.5.3 the proposal in this paper is to assume that then the estimation of the uncertainty might be a starting point for addressing the risks in the laboratory. It means a starting point with a metrological character for the risk analysis.

This proposal is based considering that in other organizations the approaches on the Risk Management are directed to the fields of application of the organizations; one case to remark is the clinical laboratories where the theme of Risk Management, according to the bibliography, is understood as “the potential for harm to occur to a patient or the possibility of an error that can lead to patient harm. Risk can be estimated through a combination of the probability of harm and the severity of that harm.”

Since the calibration and testing laboratories approach of their activities is metrological, then risk would be defined as the possibility that the errors in measurements can lead to an impact in the measurement result.