

# **Specifications, Measurement Uncertainty and OOT Impact Analysis; a Practical Approach**

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## **Abstract**

Accredited labs dread the thought of finding one of their measuring instruments out-of-tolerance during re-calibration. According to ISO17025:2005, a possible “non-conforming work” condition has occurred, requiring the lab to first define "non-conforming work" as it relates to their work and then to evaluate if this event caused any previous work to be "non-conforming work".

While non-conforming work can have many causes, the instrument accuracy specification is often the dominant contributor in the measurement uncertainty, having a significant affect on the measurement quality. Although in some cases, the instrument specification is barely significant in the combined uncertainty and the device could be out-of-tolerance and have little to no discerning affect on the prior measurements made.

Dealing with this issue is an important decision on the labs part and is open for assessment by the accrediting body. The process is to include an impact analysis and identification of all affected measurement work. The lab is to notify all affected customers.

These requirements have presented many questions, such as;

What is non-conforming work and where should we draw the line between conforming and non-conforming in our labs measurement work?

How do we determine if the instrument out-of-tolerance condition caused “non-conforming work” to occur?

How can the lab easily determine the impact and what measurements were affected?

This paper presents logical answers along with practical solutions to dealing with these related issues.

Sample policies and procedures will be presented, examined, and discussed.