Frequency of review of Measurement Uncertainty for ISO15189 applicant and accredited laboratories

April 2015.

1.Introduction

ISO 15 189 (Cl 5.5.1.4) states that 'The laboratory shall define the performance requirements for the measurement uncertainty of each measurement procedure and regularly review estimates of measurement uncertainty'.

This note is to clarify the INAB expectations on what 'regularly review' means for the applicant and accredited medical laboratories, to allow for a consistent implementation of requirements for all medical laboratories.

2. Review period for measurement uncertainty calculations

It is a requirement that measurement uncertainty is calculated/estimated when a new method is introduced. This would also include each 'measured step' in cases where examination does not report a quantitative result.

The intention of the regular review stipulated in the standard, is to ensure that results produced for users of the laboratory are valid for the current measurement system and are not based on an historical measurement uncertainty calculation.

It is expected that the laboratory shall review and re-calculate measurement uncertainty, at minimum, once per year.

A more frequent review and re-calculation of the uncertainty should also be completed if significant changes occur within the measurement system. Examples include, but are not limited to, change of equipment, upgrade of equipment, SOP / test method change, staff changes and other changes that may be noted from trends in the laboratory's own internal controls etc.

This regular review will enable the laboratory to give *current* information to its users regarding the uncertainty of each measurement reported.

Please also refer to INAB document DC1, ILAC/EA websites for other related mandatory documents.

If you require any further information, please contact your INAB officer.