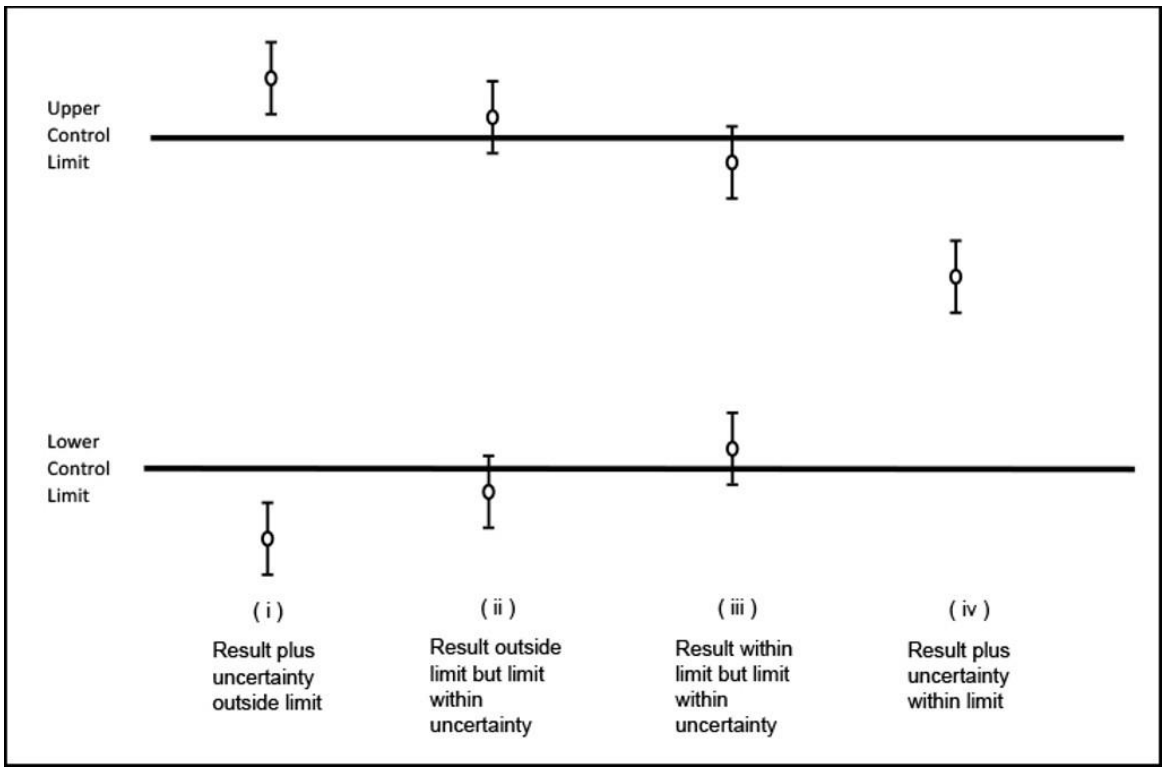
QM - GCN

Decision Rule of Compliance with specification

Rules of compliance

Assuming that limits were set with no allowance for uncertainty, four situations are apparent for the case of compliance with an upper limit (see below pic):



Four situations are apparent for the case of compliance with an upper limit

Case (i), the result exceeds the limit value plus the expanded uncertainty.

- This case is normally interpreted as demonstrating clear non-compliance (FAIL) and reported as "Non-compliance" or "Non-compliance – The measurement result is outside (or above) the specification limit when the measurement uncertainty is taken into account". For reporting of overall evaluation of non-compliance, it can be stated as "Some/All of the measured values do not comply with specifications" or "The item/sample does not comply with the requirements".

Case (ii), the result exceeds the limiting value by less than the expanded uncertainty.

Case (iii), the result is below the limiting value by less than the expanded uncertainty.

- It is not possible to confirm either compliance or non-compliance at the stated confidence level for case (ii) and case (iii). It will normally require individual consideration in the light of any agreements with the user of the data. In case (ii), where the result of a measurement is above the limit set in the specification or standard, even if the lower limit of uncertainty is below the limit set in the standard or specification, the result shall be declared as "It is not possible to state compliance" (FAIL). For reporting of overall evaluation result for both case (ii) and (ii) as non-compliance (FAIL), it can be stated as "For some/all of the measured values it is not possible to make a statement of compliance with specification". For Case (iii), in

some testing lab, the test is required to be repeated when possible, employing a system with a better uncertainty. If, after all reasonable attempts to reduce the total uncertainty have been made, the re-measurement again results in the same situation, it is possible to indicate the measurement is below the limit (PASS), with the statement "It is not possible to state compliance using a 95% coverage probability for the expanded uncertainty although the measurement result is below the limit". When shorter statements are reported, it should not give the impression that the result complies with specification or standard. For reporting of overall evaluation of compliance, it can be stated as "The statement(s) of compliance with specification (or requirement) is based on a 95% coverage probability for the expanded uncertainty of the measurement results on which the decision of compliance is based".

Case (iv), the result is less than the limiting value minus the expanded uncertainty.

- It is normally interpreted as demonstrating compliance (PASS) and reported as "Compliance" or "Compliance – The measurement result is within (or below) the specification limit when the measurement uncertainty is taken into account". For reporting of overall evaluation of compliance, it can be stated as "All measured values comply with the specification limit(s)" or "The item/sample complies with the requirements". Analogous arguments apply in the case of compliance with a lower limit. In case any deviation to this document was existed and agreed with customer, detail of the altered decision rule shall be properly remarked and recorded in the conformity assessment report. Customer can request that questionable results are declared FAIL.

iii) Additional reference documents

- ILAC-G8:03/2009 Guidelines on the Reporting of Compliance with Specification