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WELCOME!

You are welcome to subscribe our free Newsletter, dedicated to laboratory personnel, which carries articles and information related to application of statistical tools in chemical and microbiological analyses in plain language. Topical subjects on MU evaluation now covering both sampling and analytical uncertainties, risk-based assessment techniques and decision rules will be regularly featured. Click Follow me



Precision and accuracy are the norm

OUR MISSION

Help test laboratories in our region to build up confidence in statistical applications and meet ISO/IEC 17025:2017 quality requirements.

OUR VISION

Be proud to produce consistent quality test data to the valued clients

What are the major changes in the new ISO standards?



- Retaining all elements of the 2005 version but preventive action, which has been replaced by risk-based thinking
- Sampling has been added as a new laboratory activity
- Sampling uncertainty is now part of measurement uncertainty evaluation
- Combining requirements of suppliers, service providers and subcontractors into one clause under Clause 6.6: "Externally provided products and services"
- "Personnel" covers all personnel of the laboratory, either internal or external, who could influence the laboratory activities
- New standard stresses the legal implications of "impartiality"
- Choice of Options A and B for Management System requirements

Decision Rule – a not so new concept

When we come to make a statement of conformance on a product specification or of compliance to a regulatory limit, the old ISO's 2005 version clause 5.10.3.1 has stated "*c*) *where applicable, a statement on the*

estimated uncertainty of measurement; information on uncertainty is needed in test reports when, or when the uncertainty affects compliance to a specification limit;".

Now, the new ISO standard defines **Decision Rule** as : "*rule that describes how measurement uncertainty is accounted for when stating conformity with a specified requirement.*" In sub-clauses of clause 7 on **conformance testing**, the decision rule provides a prescription for the acceptance or rejection of a product based on the measurement result, its uncertainty associated, and the specification limit or limits.

In fact, the subject of decision rule is not really a totally new concept because it has been highlighted in the previous ISO version subtly. Now, where product testing and calibration provide for reporting a statement of conformity or compliance on measured values, levels of measurement decision risk acceptable to both the customer and supplier must be prepared by the laboratory concerned. In other words, it must weigh and decide on the level of risk (5%, 2% or whatever percentage) it can comfortably take in making such a statement of conformance or compliance in its test report issued, as its reported data carry a certain degree of measurement uncertainty.

Read more of our article: <u>https://consultglp.com/2017/11/12/isoiec-170252017-and-decision-rule/</u> and subsequent series on decision risk: <u>https://consultglp.com/2018/01/08/decision-risks-in-conformance-testing-part-i/</u>

An example of "conservative" or "safer" manner of decision rule which can be chosen to safe guard the laboratory interest is as shown in the following figure. The guard bands can be the +/- uncertainty interval of the measurement.



Why do we always talk about 95% confidence or 5% probability in presenting our test results?

Actually no one will stop you from using any level of confidence. But, practically all of us are following the advice of Sir Ronald Fisher. Here is the quote from Fisher, who is famously known for his *F*-statistic test on hypothesis (significance) testing and ANOVA (Analysis of Variance):

If one in twenty does not seem high enough odds, we may, if we prefer it, draw the line at one in fifty (the 2 per cent. point), or one in a hundred (the 1 per cent. point). Personally, the writer prefers to set a low standard of significance at the 5 per cent. point, and ignore entirely all results which fail to reach this level. A scientific fact should be regarded as experimentally established only if a properly designed experiment rarely fails to give this level of significance.



Today, data analysis getting easier

Contact Us

GLP Consulting

35 Kallang Pudding Road #05-14 Tong Lee Building, Singapore 349314 Telephone: +65 96799313 Email: guanhuah.yeoh@consultglp.com

Website: <u>https://consultglp.com</u>

PUBLIC SHORT TRAINING WORKSHOPS IN THE PLAN

Although GLP Consulting promotes in-house training with many added values such as deliberating worked examples directly related to the client's routine analytical works, discussing unique issues of the client concerned, and more cost effective, 2-day public short courses can be offered if there are enough interest in the topics of measurement uncertainty covering both sampling and analytical uncertainties, and risk, opportunity & decision rule.

Do drop me a note at <u>guanhuah.yeoh@consultglp.com</u> or

<u>guanhuah.yeoh@yahoo.com.sg</u> to express your wish. We shall offer a 15% discount on the training fees to our readers subscribing to this Newsletter.

DO YOU HAVE SOMETHING TO SAY?

Indeed, this Newsletter is for you.

If you have any interesting article, review or worked example in relation to laboratory data analysis to share, I shall be very pleased to publish it on our website <u>https://consultglp.com</u> as a Guest Contribution. Today, this website is attracting more than 4000 views monthly.