DIAGNOSTIC ACCREDITATION PROGRAM
College of Physicians and Surgeons of British Columbia
300–669 Howe Street
Vancouver BC V6C 0B4
www.dap.org
Telephone: 604-733-7758 ext. 2635
Toll Free: 1-800-461-3008 (in BC)
Fax: 604-733-3503

A Guide to Fulfillment of DAP Measurement Uncertainty Standards at a Regional or Organizational Level

This document from the Diagnostic Accreditation Program (DAP) provides guidance for organizations on fulfilling the 2015 Laboratory Medicine Accreditation Standards.

If you have questions about items in the standards please email them to:
laboratorymedicine@cpsbc.ca

Introduction

Incorporation of ISO 15189 into the 2015 laboratory medicine standards requires health authorities and organizations to address measurement uncertainty (MU) for quantitative laboratory examinations. To assist laboratories with the regional requirements for measurement uncertainty, the DAP held a multidisciplinary meeting with representation from various health authorities and the private laboratory sector to discuss models that will fulfill the criteria. The general and discipline-specific information from this meeting was used to create the following guidance on measurement uncertainty for laboratories in British Columbia.

Comparability requirements

There are six criteria used to evaluate the laboratory's verification of the comparability of patient results within the region or organization. They are as follows:

EXA3.2.1 **M** The laboratory determines measurement uncertainty for each quantitative measurement procedure.

EXA3.2.2 **M** The performance requirements for measurement uncertainty for each quantitative measurement procedure are defined.

EXA3.2.3 **M** Estimation of measurement uncertainty is reviewed at a defined frequency. This is documented. *Guidance: Estimation of measurement uncertainty does not require reassessment unless the original conditions of estimation have changed.*

EXA3.2.4 **M** Measurement uncertainty is considered when interpreting measured quantitative values.

EXA3.2.5 **M** Measurement uncertainty is provided to users upon request.

EXA3.2.6 Where examinations include a measurement step but do not report a quantitative value, the laboratory calculates the measurement uncertainty where it has value in assessing the reliability of the examination procedure or has influence of the reported result (e.g. serology testing for immune status).

Assessment

During the regional assessment, regional personnel:

- will be asked about quantitative examinations where MU has been calculated
- will provide and discuss the procedures used to calculate MU and any associated performance requirements
- will discuss when MU is reviewed and how this is documented
- will discuss how MU is considered in the interpretation of measured values and how MU is provided to user upon request
- will discuss if MU is calculated for examinations that include a measurement step but where no quantitative value is reported

Guidance on examinations that require calculation of MU

- All examinations that report a quantitative value must have measurement uncertainty calculated.
- It is preferable, but not mandatory to calculate MU on examinations that include a measurement step but do not report a quantitative value.

Guidance on calculation of MU

Laboratories may use the following determinations of MU:

- a bottom-up approach as per GUM principles
- a top-down approach using examination performance information
- other approaches using a combination or modifications of the above

Alternately, laboratories may use the "Uncertainty Calculator" which is available through a link for the Gamma Dynacare Measure Uncertainty (MU) Calculator: https://www.dynacare.ca/healthcare-providers-and-hospitals/continuing-medical-education/publications.aspx. Scroll down the page to the bottom and then click on "Uncertainty of Measurement in the Canadian Laboratory." This will bring up the licence agreement that must be sent into uofmcalculator@gamma-dynacare.com along with your contact information. It will take a couple of weeks for the tool to be sent via email.

Guidance on performance requirements for MU

Laboratories should establish performance requirements for MU. These may include internationally accepted performance goals, establishing analytical goals for imprecision based on intra-individual biological variation or defining upper limits as a proportion of the intra-individual biological variation of the measurand. Examples of performance requirements for MU include:

- the analytical goal for precision of an examination method should remain below half the intra-individual biological variation
- collective uncertainty should not exceed 25% of the maximum calculated standard deviation for an examination

Guidance on the review of MU

If the laboratory has defined a timeframe for the review of MU, the assessors will require evidence that this has been done. Estimation of MU does not require review unless the original conditions of estimation have changed.

References

For further information consult the following documents:

- Clinical and Laboratory Standards Institute. Expression of measurements uncertainty in laboratory medicine. Wayne, PA: Clinical and Laboratory Standards Institute; 2012. 72 p. CLSI document: EP29-A.
- Allen L, Crawford L. Guidance on measurement uncertainty for medical laboratories, December 2014, version 1.0 [Internet]. Toronto: Institute for Quality Management in Healthcare; 2014. [cited 2016 Oct 25]. 21 p. Available from: https://iqmh.org/Portals/0/Docs/Resources/IQMH%20Guidance%20on%20Measurement%20Uncertainty%20for%20Medical%20Laboratories%20-%202014.pdf
- Ricos C, Alvarez V, Cava F, Garcia-Lario JV, Hernandez A, Jimenez CV, Minchinela J, Perich C, Simon M. Current databases on biologic variation: pros, cons and progress. Scand J Clin Lab Invest 1999;59:491-500.
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