ISO/TS 20914:2019, *Medical laboratories — Practical guidance for the estimation of measurement uncertainty*, provides a practical approach for medical laboratories to estimate and express **measurement uncertainty (MU)**.

1. Measurement uncertainty (MU): MU describes the **range of doubt associated with a measurement result**. It recognizes that a reported laboratory result is an estimate and may vary due to factors affecting the measurement process.

2. Why MU is important: MU helps laboratories:

- Assess whether a result is fit for its intended medical use
- Support interpretation of results near medical decision limits
- Compare results with allowable analytical performance
- Identify opportunities to improve analytical performance
- Better understand the reliability and limitations of measurement results.

3. Scope: The guidance applies to:

- **Quantitative laboratory tests**
- **Point-of-care testing (POCT)**, especially results near medical decision thresholds
- **Qualitative/nominal methods** that include a measurement step.

4. Define the measurand clearly - The laboratory should clearly identify **what is being measured** and under what conditions. A clear measurand definition is the starting point for a meaningful MU estimate.

5. Main sources of uncertainty- Important contributors can include:

- Measurement precision (imprecision)
- Calibrator uncertainty
- Bias and its uncertainty
- Reagent and calibration changes
- Lot-to-lot variation
- Instrument or measuring-system differences
- Other relevant steps in the measurement process.

6. Use available laboratory data: The standard promotes a practical, laboratory-focused approach that uses:

- Internal quality control (IQC) data
- Manufacturer information
- Calibration and traceability information
- Other relevant analytical performance data.

7. Estimate and combine uncertainty: Individual relevant uncertainty components are identified, quantified and combined to obtain the overall measurement uncertainty. The MU may be expressed as:

- Standard measurement uncertainty
- Combined standard uncertainty
- Expanded uncertainty, usually using a coverage factor.

8. Consider medical decision limits: MU is especially important when a patient result is close to a **clinical decision threshold**, because uncertainty may influence how confidently the result can be interpreted.

9. Reporting MU: The standard states that MU **does not normally need to be routinely reported with every patient result**, but the information should be **available on request**.

SUMMARY

ISO/TS 20914:2019 helps medical laboratories systematically estimate how much confidence can be placed in a numerical measurement result. The emphasis is on a **practical, clinically relevant estimation of uncertainty**, rather than unnecessary mathematical complexity.

For a laboratory, the core workflow can be summarized as:

Define the measurand → Identify significant uncertainty sources → Collect suitable data → Estimate and combine uncertainty → Express MU → Review its clinical significance → Update when the measurement process changes.