

Policy Title: Traceability and Uncertainty of Measurements

Policy: All measurements that have significant influence on interpretation and conclusions made during investigation and at autopsy, will be traceable. That is, all measurements will be related to a reference standard of measurement through a documented, unbroken chain of calibrations. These calibrations are used to determine the associated uncertainties of measurement. Any reference standards owned by the Medical Examiner's Office will be used for calibration only. This policy defines what articles of measurement are to be so calibrated, and establishes intervals and documentation of calibration.

Procedures and Practices Equipment Calibration:

Equipment Calibration: Equipment calibration must be performed on measuring equipment having a significant effect on the interpretations and conclusions made during death investigation and at autopsy. Measuring devices will be calibrated before being put into service and at intervals described below. The following measuring devices are subject to calibration in the Medical Examiner's Office:

1. Body scale
2. Pan scales for weighing organs
3. Digital scales for weighing infant organs
4. All rulers (those for body surface measurements, and injury measurement)
5. Digital thermometers for determination of core body temperature

(All of the devices above provide physical measurements.)

Note: Temperatures in the body storage refrigerator, and in all specimen storage freezer and refrigerators are monitored for quality improvement purposes, but those thermometers do not require traceability or determination of uncertainty of measurement. These temperatures allow for proper maintenance of samples but are not critical measurements in interpretation or conclusions.

Graduated metal cylinders and syringes are used for estimation of blood and body fluid volumes. The metal cylinders are graduated at 100 ml intervals. Body fluid volumes are estimated, because of the difficulty of extracting body fluids completely. For example, removing blood clot and liquid blood from the abdomen, in the case of hemoperitoneum, is practically difficult, and usually incomplete. Syringes are used to estimate things such as urine volume, but these measurements are considered estimates, and are not critical to autopsy interpretation.

Specifications for External Calibration Services: The body scale, pan scales, digital scales will be calibrated by an external calibration service (currently McCune's Instruments) accredited to ISO/IEC 17025:2005 by ILAC Mutual Recognition Arrangement. (McCune's is accredited by ANAB, the ANSI-ASQ National Accreditation Board, an ILAC signatory). The scope of accreditation of the external calibration service must be sufficient for calibration of the 5 items listed above.

Calibration of body scale, pan scales, and digital scales:

1. These scales will be calibrated by an accredited external calibration service once each year
2. The service will provide certification of traceability to the International System of Units (SI), which for mass is based on the kilogram.

3. This calibration will include measurement uncertainty using kilograms and grams for the pan scales and digital scales, and both kilograms and pounds for the body scale
4. The certificate of traceability will include the scale serial number, and will be placed in the measurement logbook section for that particular instrument (filed by function and serial number).
5. In case of malfunction or damage to any scale, the scales will be taken out of service, repaired, and will not be placed in service again, until recalibration. Any calibration after repair will be documented in the measurement logbook.

Performance Checks for Scales:

1. The Spokane County Medical Examiner's Office has NIST Traceable certified reference standards in 3 sizes: 5 pound, 2 grams, and 10 grams. These are reference standards and will be used for calibration only, and for no other purpose. The reference weights will be housed by themselves in a designated shelf in the facility between calibrations.
2. Once monthly the 5 pound reference standard will be used for a performance check of the body scale. The body scale result will be recorded in the measurement logbook section for that scale, with date, and initials of staff member performing the performance check. The acceptance criteria for the scale is plus or minus 3 pounds.
3. Once monthly the 2 gram reference weight will be used for a performance check of the digital scales, with result recorded the measurement logbook section for that scale's serial number. The date and initials of the staff member performing the check will also be recorded. The acceptance criteria is plus or minus 1 gram.
4. Similarly the 10 gram weight will be used as a performance check for the pan scales, and the result recorded in the measurement logbook section under the create scale serial number. The date and initials of the staff member performing the check will be recorded on the logsheet. The acceptance criteria is plus or minus 5 grams.
5. Any of the scales not meeting the acceptance criteria will be recalibrated.

Calibration of rulers:

1. Devices for measuring length include 6 inch, ABO (American Board of Odontology), and measuring tapes for body length. These shall be calibrated when brought into service then once per year
2. Calibration will be performed using the NIST traceable 6 inch and 48 inch steel rulers.
3. Calibration and equipment inspection will be documented in the measurement logbook by function and serial number, or by identifier placed on the ruler.

Calibration procedure for rulers

6. At six month intervals all rulers and measuring tapes will be inspected for wear, warping, rust, chipping of paint, tears, and defects. Any tape or ruler showing these or other signs of wear will be discarded.
7. The Medical Examiners Office owns 2 NIST traceable (certified) reference rulers, one 6 inch, the other 48 inches long, with corresponding centimeter increments. These are reference standards and will be used for calibration only, and for no other purpose. The reference rulers will be housed by themselves in a designated shelf in the facility between calibrations.

8. At the time of being brought into service, then yearly, the 6 inch rulers will be checked for performance. This will include checks for 4 inches, 4 centimeters, and total length. Results will be recorded in the measurement logbook corresponding to each ruler, with staff member initials and date. The ABFO rules will be similarly checked for performance, using 2 centimeter as the measurement check. The acceptance criteria is $\frac{1}{4}$ inch, 2 millimeters. Any ruler not meeting the acceptance criteria will be discarded.
9. When brought into service, then at yearly intervals the measuring tapes will be checked for performance using the 48 inch reference ruler. Measurements will be made from both ends of the tape measure, and at the 3 foot mark. Both inches and centimeters will be recorded in the corresponding section of the measurement logbook with date and staff member initials. The acceptance criteria is $\frac{1}{2}$ inch, 2 centimeter. Tape measures not meeting the acceptance criteria will be discarded.

Calibration of Digital Thermometers used for Core Body Temperature Determination:

1. Digital thermometers are purchased as traceable to NIST.
2. The original traceability document is filed in the measurement logbook by serial number and function.
3. An accredited external calibration service will re-calibrate the digital thermometers yearly, as suggested in the original traceability document.
4. Recalibration results are filed in the measurement logbook.
5. If any digital thermometer becomes damaged, it is discarded.

Measurement uncertainty:

For all scales: The accredited external calibration services provider provides measurement uncertainty for all scales, and uncertainty is reported in all investigative and autopsy reports as described below.

For rulers: The rulers, and tape measures are subject to performance checks. The reference standards used have uncertainty assigned on their calibration certificates. However; measurements on bodies are physically difficult, because of rigor mortis, uneven surfaces, curve of parts of the body, and practical matters positioning the body in various ways for measurement. The ruler's inherent calibration and accuracy, noted as measurement uncertainty, doesn't necessarily reflect actual uncertainty while performing autopsies. It is acceptable, to clearly state in the autopsy report that a measurement is estimated due to these practical considerations.

For digital thermometers used for core body temperature determination: Uncertainty of measurement is listed in the traceability certificate for the digital thermometer.

Overall Considerations: Measurement uncertainty for each scale, and digital thermometer is available in the measurement logbook. Calibration check results are similarly available for rules and scales. At the beginning of autopsy, the autopsy assistant will record the number of the scale used, and rulers used on the autopsy worksheet.

Digital thermometers are assigned to individuals, and these assignments are noted in the measurement logbook.

References:

1. ANAB: Guidance on Uncertainty and traceability for Forensic Agencies, 2016/07/01, Document number GD 3003
2. ANAB MA 3012
3. ASCLD/LAB Guidance on Measurement Traceability-Measurement Assurance, Approved May 22, 2013
4. ASCLD/LAB Policy on Measurement Traceability, 2013, Document Control Number AI-PD-3057 Ver 1.3
5. ASCLD/LAB Guidance on Measurement Traceability-Measurement Assurance, 2013, Document Control Number AL-PD-3059 Ver 1.0