

OWM On-the-Job Training and Mentoring Worksheet Form		
Employee/Trainee Name:		
Trainer/Mentor Name:		
Topic/Procedure: SOP 19 Standard Operating Procedure for Calibration of Graduated Neck-Type Metal Provers (Volume Transfer Method) (Plus GMP 3, GLP 10, SOP 17, 20, 29)		
GENERAL Measurable Training/Learning Objectives Applicable for all SOPs	Trainee Initials and Date	Mentor Initials and Date
DESCRIBE (and FOLLOW/USE) applicable safety and protective equipment requirements for this SOP		
DESCRIBE (and PERFORM) laboratory process for receipt, handling, storage, and return of related customer standards (noting issues unique to this SOP)		
DESCRIBE (and FOLLOW) laboratory process for preparing calibration certificates (and amendments)		
DESCRIBE (and FOLLOW) laboratory process for documenting non-conformities to laboratory procedures and/or ISO/IEC 17025		
PERFORM this SOP while DESCRIBING steps as if for an assessor		
SOP <u>19</u> Measurable Training/Learning Objectives	Trainee Initials and Date	Mentor Initials and Date
Section 1, metrologist can: LOCATE applicable documentary standards (e.g., HB 105-3, OIML R 1200 in the laboratory; LOOK UP or CALCULATE tolerance values for unknown standards; IDENTIFY and DESCRIBE non-compliance of submitted standards (for both 1) specifications and 2) tolerances - use the checklists in 105-3!).		
Section 1.3, the metrologist can: DESCRIBE the submission requirements, care, and handling of unknown standards submitted for calibration and whether there is a laboratory policy, cleanliness/condition standard practice, and where the unknown items will be placed and logged in prior to calibration.		
Section 1.3, the metrologist can: IDENTIFY and SELECT applicable working standards for calibration of unknown test items; FIND, DESCRIBE, and EVALUATE the applicable calibration certificates, traceability hierarchy, calibration intervals, and current status of laboratory working standards (Part of LAP Problem evaluations). SELECT appropriate values and uncertainties from the calibration certificate for use - or verify embedded values in laboratory software; DESCRIBE meniscus observations based on reading GMP 3, observing demonstrated meniscus readings, and practice reading sample meniscus demonstrations; IDENTIFY and VERIFY that laboratory facility is operating within limits and DESCRIBE what happens if environmental limits are not met (non-conformity; should be an Admin Procedure and Action Item Forms); DESCRIBE laboratory water source, water quality, and how GLP 10 is met; DISCUSS how staff members use check standards and/or repeatability assessments in control charts and/or standard deviation charts to monitor measurement operations; VERIFY that standards to be calibrated are clean and have equilibrated if applicable (DESCRIBE Admin Procedure for Care and Handling of Submitted/Laboratory Standards).		
Section 1.4 This section is NOT covered as a part of NIST training and should be "rare". Laboratories that do not comply with facility requirements will have to address this		

<p>section and the new metrologist can DESCRIBE what and how measurement validity is ensured.</p>		
<p>Section 2.3, the metrologist can: IDENTIFY and FOLLOW safety considerations in the laboratory (especially with wet floors, use of stairs/ladders, lifting). IDENTIFY, SELECT, SET UP, and PROPERLY use: Standards, Equipment, Meniscus Readers, Thermometers, Timing Devices, Hoses, (everything listed in this section if/as applicable) Etc.... IDENTIFY and SELECT proper calibration and uncertainty values for laboratory standards and environmental standards. DESCRIBE good "<i>mise en place</i>" for a volume transfer calibration.</p>		
<p>Section 2.4.1, the metrologist can: DESCRIBE the application of cleanliness evaluations within the laboratory. (In OWM seminars, there are no "dirty" or contaminated standards used.)</p>		
<p>Section 2.4.2, the metrologist can: DESCRIBE the laboratory practice for conformity assessments and ensuring unknown standards comply with documentary standards (E.g., 105-3) and if/when neck scale calibrations are performed. DESCRIBE the steps of SOP 31 and its purpose. NOTE: Laboratory supplement may be needed to describe laboratory policy regarding SOP 31 and its implementation. During training this is likely presented as a requirement for conformity assessment and meeting requirements of the documentary standards. If NOT performed, notations are needed in that section of a calibration certificate and uncertainties need to address the values (or lack) for it.</p>		
<p>Section 2.4.3, the metrologist can: DESCRIBE the process/steps of the procedure based on reading SOP 18 and SOP 19, observing the SOP 18/19 video, and observing a demonstration of the SOP in the laboratory. PERFORM a calibration following each step of the procedure, including: Measurement of standard temperature(s); Setting the meniscus or slicker plate on the standard; Delivery of volume from the standard; Proper pour/drain cessation/timing; Reading the meniscus in the unknown test measure or prover; Measurement of temperature(s) in the unknown test measure or prover; Emptying the unknown following the appropriate process for the wet down and for each run; Repeating steps when multiple deliveries from the standard are required (up to how many??); and Complete all applicable runs for the calibration (minimum of two).</p>		
<p>Section 3, the metrologist can: Review Appendix A against the laboratory data sheet/spreadsheet and the calculations in this section to ensure that 1) all data is recorded for calculations what will be performed and 2) all information is recorded that will be needed for the calibration certificate.</p>		
<p>Section 3.1, Note: A simple calibration with a SINGLE DELIVERY will be used for the orientation webinars. The Volume Seminar provides opportunities for multiple delivery practice and calculations; Mentors may cover multiple deliveries after covering a single delivery process and ensuring new metrologist can meet all the learning objectives. The metrologist can: DESCRIBE each variable in the V-60 equation (from Table 2) and IDENTIFY the source and appropriate values for the equation; CALCULATE the volume of the unknown based on a reference temperature of 60 °F; DESCRIBE what is meant by a volume at a reference temperature and why that is important. VERIFY calculations against official laboratory spreadsheets as appropriate.</p>		
<p>Section 3.3., OWM recommends the volume be included on the calibration certificates. IF/WHEN the laboratory is evaluating tolerance,</p>		

<p>the error/correction must also be determined to perform conformity assessment (even if errors/corrections are not reported). the metrologist can: CALCULATE the Prover (or Test Measure) Error and DETERMINE compliance with applicable tolerances in the documentary standards (Decision rules have two components: 1) uncertainty must be less than the tolerance and 2) value and uncertainty must be within limits to state compliance.) DESCRIBE laboratory adjustment policies and practices to ensure test measures and provers (values and uncertainties) are within tolerance.</p>		
<p>Section 3.5, the metrologist can: CALCULATE the standard deviation of the two runs performed (and VERIFY laboratory software if the calculation is usually automatic). DETERMINE if the repeatability is within acceptable laboratory limits (See Measurement Assurance).</p>		
<p>Section 3.7, Note: The average of the V-60 volumes is calculated and reported (not each individual or one of the runs). This section just specifies that the mean is used. For the orientation webinars, the mean of the calculated values from 3.1 is to be used. Hopefully, if the metrologist can calculate the value in 3.1, they can also calculate an average value.... Mentor/Instructors to verify this is followed and true....</p>		
<p>Section 4, the metrologist can: FIND and DESCRIBE the overall measurement assurance practices used in the laboratory for volume calibrations. FIND applicable laboratory control charts and standard deviation charts and applicable limits for this procedure. EVALUATE laboratory control charts for compliance with SOP 9 checklist. presence of values outside limits, and/or obvious trends; IDENTIFY mean values, suitable repeatability for the process, and what values are transferred to the uncertainty calculations. For any item that says "May" for measurement assurance, the metrologist will need to be able to DESCRIBE the laboratory process/policies for incorporating and reviewing that item (e.g., check standards, t-test, F-test). Note: For SOP 20 and volume procedures OWM recommends "standard deviation charts" instead of "range" charts. One or the other is needed. Standard deviation of check standards is "better" and usually a larger standard deviation, but repeatability estimates are needed to ensure a process and the unknowns are in control and repeating properly and for later extrapolation and evaluation of repeatability for larger provers.</p>		
<p>Section 4.2, the metrologist can: DESCRIBE and ASSESS a process with repeatability failures. Note: Instructors and Mentors will describe examples of what/when a process might not repeat in addition to what is stated in the SOP based on their experience and knowledge of this measurement process.</p>		
<p>Section 5, the metrologist can: Read SOP 29 and be able to LIST and DESCRIBE the 8 steps in the uncertainty process in the context of SOP 19. Step 1. SPECIFY - refers to SOP 19 and the measurement equations listed in the SOP (e.g., see Equation 3.1). Step 2. Metrologist should be able to IDENTIFY, DESCRIBE, SELECT, QUANTIFY, CONVERT all sources/components from Table 5 to: CALCULATE the COMBINED uncertainty using a root sum square method. COMPARE and EVALUATE - this section and TABLE 5 with the official laboratory uncertainties. (Part of the LAP Problems). VERIFY calculations in the laboratory spreadsheets for uncertainty using this SOP.</p>		
<p>Section 6.1, the metrologist can: CREATE a calibration certificate that COMPLIES with SOP 1 and items that must be included per SOP 19, Section 6.1. Note: LAP Problems include evaluation of laboratory templates against section 7.8 in ISO/IEC 17025 and SOP 1. Laboratory administrative procedures for calibration</p>		

Trainee Final Observations/Assessments Summary:

Describe how confident you are with finding all the files and resources in your laboratory that are needed to perform this calibration, prepare a certificate, and return items to customers? What additional training do you think you need to improve? How much additional time performing this calibration do you think you need to feel confident? What additional questions do you have or follow up would you like to see?

Trainer Observations/Assessments Summary:

Describe in your own words: How closely did the trainee follow the SOP? How many times and what nominal values/standards/equipment were used when you demonstrated the procedure AND when you observed the trainee performing the procedure? How did your measurement results agree? How did their values look on the laboratory control chart(s)? Were they able to describe the procedure to your satisfaction? Were gaps observed? Is additional follow up needed? What additional assessments did you observe that help to ensure that learning objectives were met?

Objective Evidence Assessed by Trainer/Mentor (maintenance of electronic records is encouraged):

- Reading Outline (completed by trainee, reviewed by trainer/mentor, discussed)
- Video of Demonstration/Performance (optional, recommended)
- Data Sheet(s) of completed measurements
- Traceability Assessment of Laboratory Standards Used completed by trainee (Using GMP 13 forms, with list of laboratory files/locations)
- Calculations for the SOP with work shown by hand or in Excel with Validation Notes
- Spreadsheet File(s) PDF print-out of data entry of completed measurements
- Control Chart record showing trainer/mentor data and trainee data and evaluation of control charts with SOP 9 checklist evaluation
- Independent Uncertainty analysis following applicable SOP and SOP 29, comparison with official laboratory uncertainties
- Calibration Certificate for calibrations performed by trainee
- Calibration Certificate marked up as reviewed for compliance with SOP 1 and applicable SOP
- List of laboratory files reviewed by trainee:
 - Template Spreadsheet File:
 - Completed Spreadsheet File(s):

Applicable Proficiency Test(s):	Date of Calibration:	PT Evaluation Report <i>(Name, Date)</i>

Employee/Trainee Signature:	Trainer/Mentor Signature:
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Recommended for Approved Signatory Status (Name, Title, Signature):

Approved for signatory status by NIST Office of Weights and Measures (name & date);