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| **OWM On-the-Job Training and Mentoring** **Worksheet Form**  |
| **Employee/Trainee Name:** |
| **Trainer/Mentor Name:** |
| **Topic/Procedure:** SOP 14Standard Operating Procedure for Gravimetric Calibration of Volumetric Standards Using an Electronic Balance (Plus GMP 3, GLP 10, SOP 2, 4, 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 14 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 (Note: tolerances are not evaluated in SOP 14 at this laboratory);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 mass standards and transfer vessel 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.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 (for graduated neck-type provers and glassware only);IDENTIFY and VERIFY that laboratory facility is operating within limits andDESCRIBE 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 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 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 "*mise en place*" for a gravimetric volume calibration. |  |  |
| 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.) |  |  |
| Sections 2.8 (Flasks – To Deliver), 2.10 (Slicker-Plate Type Standards), 2.11 (Hand-held Graduated Neck Type Provers), 2.12 (Large Volume Graduated Neck Type Provers) the metrologist can:DESCRIBE the process/steps of the procedure based on reading SOP 14 and observing a demonstration of the SOP in the laboratory.PERFORM a calibration following each step of the procedure, including:Placing mass standards on the balance slightly larger than mass of drained vessel (if applicable) after zeroing;Placing empty transfer vessel on the balance after zeroing;Measurement of unknown temperature(s);Setting the meniscus or slicker plate on the standard;Delivery of volume from the standard;Proper pour/drain cessation/timing;Placing mass standards on the balance slightly larger than mass of filled vessel (if applicable) after zeroing;Placing full transfer vessel on the balance after zeroing;Measurement of temperature(s) in the transfer vessel;Complete all applicable runs for the calibration. |  |  |
| Section 3, the metrologist can:Review Appendix A and B 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. |  |  |
| Section 3.1 – 3.4, the metrologist can:DESCRIBE each variable in the equations (from Table 2) and IDENTIFY the source and appropriate values for the equation;DESCRIBE what is meant by a volume at a reference temperature and why that is important.CALCULATE the volume of the unknown based on the applicable reference temperature;VERIFY calculations against official laboratory spreadsheets as appropriate. |  |  |
| Section 3.8, 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).Enter the within process standard deviation into the standard deviation chart that is linked to the gravimetric volume spreadsheet |  |  |
| Section 3.9, the metrologist can:CALCULATE the F statistic to compare the observed within process standard deviation to the accepted (pooled) standard deviation from the standard deviation chart.VERIFY calculations against official laboratory spreadsheets as appropriate. |  |  |
| Section 3.11, Note: The average of the V-ref volumes is calculated and reported (not each individual or one of the runs). CALCULATE the average of the two runs performed (and VERIFY laboratory software if the calculation is usually automatic) |  |  |
| Section 4, the metrologist can:FIND and DESCRIBE the overall measurement assurance practices used in the laboratory for gravimetric volume calibrations. FIND applicable laboratory standard deviation charts and applicable limits for this procedure.EVALUATE laboratory standard deviation charts for compliance with SOP 9 checklist, presence of values outside limits, and/or obvious trends;IDENTIFY accepted (pooled) standard deviations, suitable repeatability for the process, and what values are transferred to the uncertainty calculations.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. |  |  |
| 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. |  |  |
| 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 14 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 4 to:CALCULATE the COMBINED uncertainty using a root sum square method.COMPARE and EVALUATE - this section and TABLE 4 with the official laboratory uncertainties. VERIFY calculations in the laboratory spreadsheets for uncertainty using this SOP. |  |  |
| Section 6.1, the metrologist can:CREATE a calibration certificate that COMPLIES with SOP 1 and items that must be included per SOP 14, Section 6.1. |  |  |
| Section 6.2, the metrologist can:DESCRIBE the two requirements for conformity assessment and assess the measurement results and uncertainties for compliance with the applicable documentary standards.Note: tolerances are not evaluated in SOP 14 at this laboratory The metrologist can:DESCRIBE the laboratory practices related to conformity assessment; and ASSESS the calibration certificate for compliance. |  |  |
| Appendix A and B, the metrologist can:ASSESS the data sheet compared to the laboratory methods for recording data to ensure that all data that needs to be recorded is documented and maintained for calculations and creation of the calibration certificate. |  |  |

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| **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):
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| **Applicable Proficiency Test(s):** | **Date of Calibration:** | **PT Evaluation Report** (*Name, Date*) |
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| **Employee/Trainee Signature:** | **Trainer/Mentor Signature:** |
| **Recommended for Approved Signatory Status (Name, Title, Signature):** |
| **Approved for signatory status by NIST Office of Weights and Measures (name & date);** |