

OWM On-the-Job Training and Mentoring

Worksheet Form

Employee/Trainee Name:		
Trainer/Mentor Name:		
Topic/Procedure: SOP 8 Modified Substitution (plus: SOPs 2, 9, 29, 34, GMP 11 and GMP 13)		
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>8</u> Measurable Training/Learning Objectives	Trainee Initials and Date	Mentor Initials and Date
Section 1.1, Metrologist can: IDENTIFY and FIND the documentary standards (HB 105-1, ASTM E 617, OIML R111); LOOK UP tolerance limits for a sampling of nominal values; and DESCRIBE the purpose and application of weight classes in general - including the most likely procedure for each set of classes (See GMP 12).		
Section 1.2, After observing, reading, and performing this calibration procedure, the metrologist can: DESCRIBE and PERFORM the procedure in such a way that it would satisfy an internal auditor or accreditation auditor.		
Section 1.2, the metrologist can: IDENTIFY location of laboratory calibration certificates for working standards, laboratory traceability hierarchy, and status of calibration due dates; (ASSESSMENT of the laboratory traceability records is part of the LAP Problems). SELECT appropriate values and uncertainties from the calibration certificate for use - or verification of embedded values in laboratory software; DESCRIBE good weighing techniques based on reading GMP 10 and observing demonstrated SOP 8 calibration; 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); DISCUSS how staff members use check standards and control charts to monitor balance operation and DESCRIBE the maintenance service and/or calibration procedure for laboratory balances; VERIFY that standards to be calibrated have equilibrated the requisite amount of time (DESCRIBE Admin Procedure for Care and Handling of Submitted/Laboratory Standards).		
Section 2.3, NOTE: Option B will be expected for Seminar Preparation and normal use. The metrologist can: DEMONSTRATE SOP 8 with a full-electronic balance using Option B.		
Read SOP 34. Mentor to share practices in the laboratory for selection and use of sensitivity weights. Section 2.3.3 and SOP 34, the metrologist can: DESCRIBE laboratory practices for using sensitivity weights (ensuring it is consistent with SOP 34); and IDENTIFY and SELECT appropriate sensitivity weight consistent with SOP 34 and laboratory practices.		
Section 2.3, the metrologist can: IDENTIFY environmental equipment that is used in each area of the laboratory.		

<p>FIND and review calibration certificates, traceability hierarchy, and calibration intervals for equipment used to measure environmental conditions.</p> <p>REVIEW status of environmental equipment to ensure it has appropriate resolution and has suitable calibrations and uncertainties. (Related to Traceability Assessment for the LAP problems.)</p>		
<p>Section 2.6, Option B (Full Electronic Balance), the metrologist can:</p> <p>DESCRIBE the steps of the SOP 8 procedure, including evaluation of sensitivity and drift.</p> <p>PERFORM the steps of the SOP 8 procedure, following each step, using proper care and handling of mass standards, unknown standards, sensitivity weight, balances, and recording observations.</p> <p>DESCRIBE:</p> <ol style="list-style-type: none"> 1. which standards were used and why 2. how the sensitivity weight is selected and how sensitivity is assessed on the balance 3. how the weights are handled and placed on the balance 4. how the balance is zeroed/tared (depending on balance and approach) 5. what to watch for that might indicate problems with the balance during the procedure 6. how and when data is recorded 7. what values to expect for the check standard (awareness of appropriate limits) 8. how much drift is "acceptable" 		
<p>Section 2.6.8 (See also Section 3.4), the metrologist can:</p> <p>PERFORM calculations to determine the Conventional Mass Correction for the unknown weight.</p> <p>VERIFY that calculations are correct in laboratory software (values match)</p>		
<p>Section 2.8, the metrologist can:</p> <p>DESCRIBE what drift will look like in a series of observation and be able to IDENTIFY problematic data</p> <p>DESCRIBE the laboratory acceptable limits (5 %? 7 %? 10 %?)</p> <p>Uncertainties will be addressed later.</p>		
<p>Section 2.9, the metrologist can:</p> <p>For now - until Uncertainties are covered, the metrologist can:</p> <p>REVIEW "official laboratory uncertainties" and</p> <p>DETERMINE:</p> <ol style="list-style-type: none"> 1. Whether uncertainties are sufficiently small for applicable tolerances ($< 1/3$) per the documentary standards 2. Whether the absolute mass value plus the uncertainty is within the tolerance limits (be able to look up tolerances on a table and verify values if used in the laboratory spreadsheets). <p>DESCRIBE the official laboratory policy regarding adjustments and adjustment limits when standards are found out of tolerance.</p>		
<p>Section 3.2, the metrologist can:</p> <p>PERFORM calculation of sensitivity; verify errors are less than 2 % and ensure that this calculation is correct in the laboratory software.</p> <p>DESCRIBE the purpose of the sensitivity assessment.</p>		
<p>Section 3.3 and SOP 2, the metrologist can:</p> <p>DESCRIBE conventional mass corrections/errors, nominal mass, and LIST the reference conditions for Conventional Mass (Read SOP 2 and reference source of OIML D28 definition if applicable on certificates),</p> <p>Will be part of evaluating Mass Calibration Certificates on the LAP problems.</p>		
<p>Section 3.6</p> <p>TARE weights should not be needed for this preliminary orientation. BUT, laboratory practices should be discussed in the context of SOP 34 and potential need/applications that might be observed (e.g., if unequal nominal values are used such as with metric standards compared to avoirdupois unknowns or the use of summations of standards).</p>		
<p>Section 4, the metrologist can:</p> <p>IDENTIFY laboratory check standards that will be used and be able to FIND the applicable control chart for the check standards and balances that will be used;</p> <p>PERFORM the calibration of the check standard, calculate its conventional mass value, and enter the mass in the appropriate control chart</p>		

<p>and determine if the results are in/out of applicable statistical limits; DESCRIBE the laboratory control chart components based on the SOP 9 checklist (LAP Problems will also EVALUATE the control charts compared to the SOP 9 checklist); DESCRIBE what values are inside the warning and action limits and what the likely variation of values is for the balance and check standards being used. Mentor should provide insight of common problems that have been or might be observed for the standards and balance in question, what trends might be reviewed over time, and how data from the control chart is used to calculate and update the standard deviation of the measurement process, degrees of freedom, and uncertainties.</p>		
<p>Section 5 and SOP 29, 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 8. Step 1. SPECIFY - refers to SOP 8 and the measurement equations listed in the SOP (e.g., see Equation 2, section 2.6.8). 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 5.8, the metrologist can: EVALUTE the Uncertainty Statement on the calibration certificate (part of LAP problem evaluation of certificates).</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 8.</p> <p>LAP Problems include evaluation of laboratory templates against section 7.8 in ISO/IEC 17025 and SOP 1. Laboratory administrative procedures for calibration certificates to be reviewed and assessed for compliance as part of the LAP Problems as well.</p>		
<p>Section 6.2, the metrologist can: DESCRIBE the two requirements for conformity assessment that are listed in this section and assess the measurement results and uncertainties per section 2.9 for compliance with the applicable documentary standards.</p>		
<p>Appendix, the metrologist can: IDENTIFY applicable laboratory worksheets or spreadsheets used for modified substitutions and ensure that all applicable data is recorded/entered and maintained to demonstrate compliance with this SOP.</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 (Name, Date)

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):