3M EHS Laboratory

Standard Operating Procedure

Reference Materials

SOP Number: ETS-4-042.2

Adoption Date: 11/30/18

Approved By:

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Quality Assurance

1 Scope and Application

To describe the procedure used to monitor and verify the availability of certified reference materials to be used as standards from an ISO 17034 Reference Material Producer (RMP). This procedure also describes the procedures to be used when certified reference materials are not available. This SOP does not describe standard preparation, see ETS-4-013 and ETS-8-196.

2 Definitions

2.1 Certified Reference Material (CRM)

Reference material characterized by a metrologically valid procedure for one or more specified properties, accompanied by a reference material certificate that provides the value of the specified property, its associated uncertainty, and a statement of metrological traceability.

2.2 Certified Value

Value assigned to a property of a reference material that is accompanied by an uncertainty statement and a statement of metrological traceability, identified as such in the reference material certificate.

2.3 Reference Material

A Material, sufficiently homogeneous and stable with respect to one or more specified properties which has been established to be fit for its intended use in a measurement process.

2.4 Metrological Traceability

An unbroken chain of calibrations, each contributing to the measurement uncertainty, linking them to the SI unit.

3 Precautions

None.

4 Responsibility

Anyone who orders reference materials to be used for methods on our ISO/IEC 17025 scope of accreditation is responsible for ordering reference materials from approved vendors that hold the required accreditations.

5 Supplies and Materials

NA

6 Equipment

Computer with network, LIMS and internet access.

7 Procedures

It is recognized that there will be times when a CRM is not used for accredited work. Some examples of times when CRMs would not be used are as follows:

- A CRM is not available (this is a common occurrence with the physical/chemical property testing methods)
- The only CRMs available are in an incompatible matrix
- Use of the CRMs available as standards is not financially practicable
- Replacing the stable standards already in house with CRMs is an environmental stewardship concern
- A CRM is available, however cannot be obtained before the start of a project.

In these and other similar cases there is a hierarchy that should be followed for determining the best course of action.

1. Use CRMs as standards
2. Purchase CRMs and make a direct comparison of reference standard being used to the CRM (see ETS-8-084)
3. Purchase a reference material that is manufactured to published standard or by an authoritative source (e.g. USP, IRMM, BCR, etc.)
4. Determine the purity/concentration (or other needed property) per in-house SOPs (see ETS-4-043)
5. Use 3M NMR lab to generate a CoA

In all instances the reference materials being used as standards must be fit for their intended use.

Before ordering a standard to be used in methods on our ISO/IEC 17025 scope of accreditation it must first be determined if a CRM is available. Additionally, the purchase must come from an approved vendor (per ETS-1-011). If a CRM is available and if it is ordered, no further documentation on Attachments A or B is needed. If a CRM is not available, document CRM search results in Attachment A. Attachment A will be attached to the purchase order in the Lotus Notes Order Processing database. When the standard is received, the completed Attachment A form will be attached to the substance in LIMS.

If a CRM is available but is not purchased or if a CRM is not available, complete both Attachments A and B. Document CRM search results in Attachment A. Attachment A will be attached to the purchase order in the Lotus Notes Order Processing database. When the standard is received, the completed Attachment A form will be attached to the substance in LIMS. Once complete Attachment B will also be attached to the substance in LIMS.

Use Attachment B to record the results of the validation of the purity/concentration (or other needed property) using methods 2-4 above. If using a CRM as a standard, use of Attachments A and B will not be necessary.

Attachments A and B must be completed for all non-CRM standards being used in accredited work. Once Attachments A and B are filled out completely, attach the signed and dated forms to the substance in LIMS.

Please note that it is expected that the certificate of analysis accompanying a CRM will have the manufacturer's accreditation symbol with their accreditation number, indicate which property is certified (if more than one property is listed), the uncertainty associated and a statement of metrological traceability for the certified value.

If a CRM is available but cannot be obtained before the start of a project, the project cannot be performed under the lab's scope of accreditation, this must be reflected in the project GPO. If however the CRM can be obtained before the end of the project, and the direct comparison can be made per ETS-8-084 prior to the end of the study, the project can be performed under the lab's scope of accreditation.

The use of CRMs is not required for process controls. Process controls serve as a reproducibility standard and are not used as a reference material or standard. When internal standards and surrogates are used as process controls, they do not fall under this procedure and they do not need to be a CRM.

8 Records

Attachments A and B will be attached to LIMS for all non-CRM standards used in accredited work.

9 Attachments

Attachment A: Reference Material Source Review Form

Attachment B: Reference Material Validation Results Form

10 References

ETS-1-011 Purchasing of Supplies and Services

ETS-4-013, Determination of Solutions and Standards Preparation

ETS-4-043 Determining Purity/Concentration (or Other Appropriate Property Value) of Reference Materials

ETS-8-084 Comparison of Non-Certified Reference Materials to Certified Reference Materials, and Determination of Suitability for Use in ISO/IEC 17025 Accredited Methods

ETS-8-196, Gas Standard Preparation

11 Revisions

Revision Number	Summary of Changes
1	Item number 3 in section 7. Included information on process controls in section 7. Attachment A is no longer needed when a CRM is purchased. Updated Attachments A and B to reflect this change along with some direction as to when to use them and where to store them once complete.
2	Added second bullet point in section 7. Other minor updates made. Removed section 11, affected documents.

Reference Material Source Review Form

Reference Material Name:	
CAS #:	
Is the reference material a certified reference material (CRM, ISO 17034 or Guide 34)? If the answer is "Yes" this form does not need to be used.	Yes:☐ No:☐
Is a certified reference material (CRM, ISO 17034 or Guide 34) available for this substance? If the answer is "Yes" Attachment B must also be completed.	Yes:☐ No:☐
If "No", which sources (vendors, websites, etc.) were checked:	
Date sources were checked:	

Substance Review submitted by:

Reference Material Validation Results Form

Reference Material Name:	
CAS #:	
TCR or TN number:	
Is a certified reference material (CRM, ISO 17034 or Guide 34) available for this substance?	Yes:☐ No:☐
If “No” the reference material is not a CRM and “Yes” a CRM is available, provide a reason for not using the CRM for calibration standards and the results for the direct comparison to a CRM (along with the project number).	Reason:
	The direct comparison CRM project ID:
	Results (project number, date tested, result, uncertainty):
If “No” the reference material is not a CRM and “No” a CRM is not available, describe how the measurement results are “fit for their intended use and ensured by suitable comparison”.	In house SOP ID used to determine concentration/purity (or other required property), project ID, date tested, result, uncertainty:
	3M NMR lab generated CoA (concentration/purity, project ID, date tested):

Substance Review submitted by: