3M EHS Laboratory

Standard Operating Procedure

Determining Purity/Concentration (or Other Appropriate Property Value) of Reference Materials

SOP Number: ETS-4-043.0

Adoption Date: Upon Signing

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Quality Assurance

1 Scope and Application

To describe how the laboratory will determine the purity/concentration (or other appropriate property value) of a reference material to be used as a standard when certified reference materials are not available for use in ISO/IEC 17025 accredited methods.

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

The person ordering a reference material to be used as a standard in ISO/IEC 17025 accredited work that is not a CRM is responsible for making sure the purity/concentration (or other property value) has been determined per ETS-4-042 or ETS-4-043 before it is used.

5 Supplies and Materials

NA

6 Equipment

Computer with network, LIMS and internet access.

7 Procedures

One or more methods will be used to determine the purity/concentration (or other property value), the method(s) to be used will be determined by the project lead and documented in a project plan per ETS-1-009.

Whatever method is used to determine a property value, it is important to be sure that metrological traceability of the measurement results is maintained by means of a documented unbroken chain of calibrations, each contributing to the measurement uncertainty, linking them to SI.

7.1 Reference Materials with Vender Assigned Purity/Concentration (or Other Property Value)

In instances where a reference material is purchased from a vender and comes with an assigned purity/concentration (or other property value) but these values are not certified values, the laboratory will verify these values using an appropriate in-house method. If the value generated by the laboratory is within 5% RPD of the vender value, the vender value will be used. If the value obtained by the laboratory is greater than 5% of the vender value, discuss with management to determine a course of action. Document the action plan with in the project data.

7.2 Uncertainty Determinations

The uncertainty associated with the measurements used to determine the purity/concentration (or other property value). Please refer to ETS-12-012 for calculating uncertainty.

7.3 Applying Uncertainty

The uncertainty determined for each reference material will be combined with the individual method uncertainty determined with each use. Please refer to ETS-12-012 for combining and applying uncertainty.

7.4 Frequency of Purity/Concentration (or Other Property Value)

The frequency at which a purity/concentration (or other property value) must be determined will be evaluated on a case by case basis. The frequency will be dictated by an expiration date assigned by the laboratory based on known stability information regarding the chemical or material in question. If a reference material was purchased from a vendor and had a vender assigned expiration date and purity/concentration (or other property value), the vender assigned expiration will be used. Document the information used in determining the expiration date assigned with the project data. See ETS-4-027 for expiration date assignment procedures.

7.5 Purity/Concentration (or other Property Value) Determination Methods

Please refer to individual methods for purity/concentration (or other property value) determinations.

8 Records

Results will be documented in the relevant ETS-4-042 attachments and attached to LIMS

Data and reports generated will be archived under the project number

9 Attachments

None

10 References

ETS-1-009 General Project Outline (GPO)

ETS-4-027 Assignment of Purity and Expiration Dates of Laboratory Chemicals

ETS-4-042 Reference Materials

ETS-12-012 Estimation of Uncertainty of Measurements

11 Revisions

Revision Number	Summary of Changes
	List the history of revisions including reason for change, starting with revision 1.