Sections Included in this Document and Document History

1. Purpose

This procedure describes how the laboratory achieves measurement traceability for its measuring and testing equipment, as well as for its physical standards and media.

2. Scope

This procedure addresses the traceability of Office of Regulatory Affairs (ORA) Laboratory instruments used for measuring and testing. It also addresses equipment used for the direct measurement of fundamental properties, such as balance masses and thermometers.

3. Responsibilities

ORA laboratories are responsible for maintaining records of measurement traceability. These records include certificates for the calibration of the balance masses and. Thermometers. They also include the certificates for reference materials used to calibrate or standardize laboratory equipment and for reference cultures.

4. Background

None

5. References

ISO/IEC 17025. *General requirements for the competence of testing and calibration laboratories* (5.6 Measurement Traceability). Geneva, Switzerland: The International Organization for Standardization and the International Electrotechnical Commission.

Taylor, J. K. (1993). *Handbook for SRM users* (NBS Special Publication No. 260-100). Gaithersburg, MD: National Institute for Standards and Technology.

6. Procedure

A. Measurement Traceability

1. Reference balance masses, thermometers and thermocouples are traceable to international standard (SI) units of measurement.

2. Laboratory measuring equipment is calibrated or standardized using materials of known and acceptable purity (i.e. neat compounds, or reference materials of know composition traceable to national, international or equivalent standards).

3. Media are verified against national or international standards (i.e. reference cultures or certified reference cultures).

4. The traceability to SI units is achieved by reference to national measurement standards that are primary realizations of the SI units or agreed representations of SI units. SI units are based on fundamental physical constants of mass, distance, and time.

5. Traceability may also be established through secondary standards that are calibrated by a national metrology institute such as the National Institute for Standards and Technology (NIST).

B. Traceability Alternatives to SI Units

1. Where calibrations cannot provide measurement traceability to SI units, confidence in measurements is established with traceability to measurement standards such as:

   - certified reference materials provided by a competent supplier to give a reliable physical or chemical characterization of a material, and

   - the use of specified methods and consensus standards that are clearly described and agreed by the parties concerned.

2. Where traceability of measurements to SI units is not possible or not needed, the same requirements for traceability, for example, certified reference materials, agreed methods or consensus standards, are needed.

3. For some analyses certified reference materials are not readily found. In this case, a material with similar properties and stability is selected.

The properties of interest in this material is characterized by repeat testing, preferably by more than one laboratory and using a variety of methods.

4. Where national or international standards are not found for the verification of the performance of microbiology procedures, the laboratory documents recovery by either participating in a program of interlaboratory comparison or proficiency testing, use of reference cultures or certified reference cultures, or by a mutual agreement with client on expectations.

C. Calibration and Calibration Services for Physical Standards

1. Calibration is conducted for the physical standards used by the laboratory by an accredited calibration laboratory who provide the laboratory with certificates of calibration linking the calibrations to measurements made by NIST or some equivalent. The identity of the calibration laboratory is included on the certificate as well as the methods and standards primary to the process.

2. Traceable thermometers are calibrated annually, thermocouples every year, and masses are calibrated every five years. These reference standards are used for calibration checks only and not as working standards.

3. A calibration certificate bearing an accreditation body logo from a calibration laboratory accredited to the International Organization for Standardization and the International Electrotechnical Commission (ISO/IEC) 17025 standard for the calibration concerned is sufficient evidence of traceability of the calibration data reported.

4. The date of calibration and the date of the next calibration that is due is included for the reference standard in the calibration certificates.

5. These reference standards are stored in a secured area to prevent any damage that would invalidate their use.

6. Servicing is requested from the calibration laboratory when data acceptance criteria for verification are not met and the analyst is unable to effect a corrective action.

D. Calibration of Laboratory Measuring Instruments

1. Calibration or standardization of laboratory instruments is conducted according to the test method employed. The uncertainty contributions are addressed in ORA Laboratory Manual, Volume II, Section 2, ORA-LAB.5.4.6. Estimation of Uncertainty of Measurement.

2. Instruments identified in the test methods which call for calibrations as part of their normal operation are calibrated by laboratory personnel who conduct these operations using reference materials.

3. Reference materials, where possible, are to be traceable to SI units of measurement, to standard reference materials (SRMs), certified reference materials (CRMs), or certified reference cultures (CRCs).

4. Certificates of Analysis from the manufacturer for reference materials used are maintained.

5. A listing of reference materials in use in the laboratory is maintained. This listing will contain, as a minimum, the chemical name or description, source, manufacturer's lot number, laboratory number (if lot number not used), date of receipt, and expiration date, if present.

6. Reference materials are labeled with date of receipt and initials, date opened and initials, and expiration date.

7. Analyst's records include the identity of and the measurement values for standards or reference materials used in the routine analyses. This information is to have record traceability to the measurements for batches of samples measured sequentially to the standard or reference material. This information is recorded in the analytical worksheets, instrument logbooks or incorporated in the instrument print out for the analyses.

8. Calibration is verified during the performance of analyses. The frequency of calibration is identified in the test method or per laboratory instrument procedure.

9. The safe handling, transport, storage, and use of laboratory reference materials are conducted according to the manufacturer's instructions in order to prevent contamination, deterioration, and to protect their integrity.

10. Reference materials are not stored with samples.

E. Reagents, solvents, gases, and media

1. For most analyses, analytical reagent grade is satisfactory. Trace analyses frequently call for special *ultra* pure reagents, solvent and gases.

2. Reagent grade chemicals should be ordered in quantities such that the supply will be consumed within the manufacturer's expiration date or five years, whichever is first.

3. All reagents, solutions and media are labeled with date of receipt and initials, date opened and initials, and expiration date.

4. Reagents, solvents, gases, and media are stored according to the manufacturer's direction and are not be kept longer than recommended by the manufacturer or the method. Reagents are checked for signs of deterioration. Reagents that have deteriorated are not used and are discarded in accordance with a Laboratory's Safety and Hazardous Waste procedures.

5. Media purchased or prepared are evaluated for suitability.

F. Disposal

Reference materials, reagents, solvents, gases, and media are disposed of according to federal, state and local regulations. The laboratory has procedures for the proper disposal.

7. Definitions

Calibration – A calibration is the set of operations which establish, under specified conditions, the relationship between values indicated by a measuring instrument or measuring system, or values represented by a material measure, and the corresponding known values of a known values of a measurand.

Calibration laboratory - a calibration laboratory provides calibration services as its principal activity. This type of laboratory is also referenced as a metrology laboratory.

Certified reference cultures (CRC) – These are cultures traceable to

nationally or internationally recognized type culture collection (i.e. American Type Culture Collection).

Certified reference material (CRM) – A certified reference material is one or more of whose property values are certified by a technical valid procedure, accompanied by or traceable to a certificate or other documentation which is issued by a certifying body.

International standard – These are standards from an international repository that fulfill the properties of primary standards for the realization of SI units. Measurand – A measurand is a particular quantity subject to measurement.

Measuring and testing equipment – These are devices used by the laboratory for testing and measurement. Equipment, instruments, and instrumentation are terms used synonymously with measuring and testing equipment.

National Standard – These standards are from a national repository that fulfill the properties of primary standards for the realization of SI units.

Reference material (RM) - A reference material is one or more of whose property values are sufficiently well established to be used for calibration or standardization of an apparatus, the assessment of a measurement method, or for assigned values to materials.

Reference standard – This is a standard generally of the highest metrological quality found at a given location, from which measurements made at that location are derived.

Standard reference material (SRM**)** - a certified reference material produced by the National Institute for Standards and Technology or a certified reference material whose metrological values are approved by a nationally recognized measurement body. The National Institute for Standards and Technology is the United States nationally recognized measurement body.

Standardization – This is the assignment of a compositional value to one standard (measurand) based upon another standard.

Traceability – Traceability is an unbroken chain of calibrations or comparisons to identified primary standards of the SI units of measurement.

Verification – Verification is confirmation by examination and provision of evidence that specified requirements have been met.

8. Records

List of standards used by the laboratory
Reference materials certificates
Physical standards certificates of traceability
Media suitability records

9. Supporting Documents

ORA lab manual of quality policies and procedure, Volume II, Section 2
ORA-LAB.5.5 Equipment
Laboratory Hazardous Waste Management Plan
Laboratory Chemical Management Plan
Microbiology Laboratory media procedure for preparation, labeling and quality control

10. Attachments

None

Document History					
Version No.	**Status** (I, R, C)	**Date Approved**	**Location of Change History**	**Name & Title**	
				Author	**Approving Official**
1.2	R	11/16/05	In Document	LMEB	LMEB
1.3	R	12/06/06	In Document	LMEB	LMEB

Approving Official's signature: _____ Date: _____