ISO 17034:2016 General requirements for the competence of reference material producers

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PJLA Testing Program Manager
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Webinar Overview

- Review of the standard requirements for Reference Material Producers
- The various processes involved with reference material production to educate
  - RMP(S)
  - Labs
- Opportunity for Questions

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Webinar Housekeeping

- This webinar is being recorded
- All PJLA webinar recordings and slides are available for download from the Past Webinars section of our website
  - https://www.pjlabs.com/training/pjla-webinars
- All attendees are muted. However, feel free to utilize the questions tab and they will be answered at the end of the session.

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Welcome and Introductions

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PJLA –Tracy Szerszen
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Presenter:
Doug Berg
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Douglas Berg has 45+ years' experience in testing, calibration, laboratory operations, engineering, and management. He has worked for the US EPA and GM and, since retiring, has worked with accreditation organizations as an assessor and program manager. He's currently the Testing Program Manager for PJLA, an ILAC MRA signatory. As program manager, he is responsible for the programs for testing, environmental field sampling, reference materials, and proficiency testing. He is also a peer evaluator for other accreditation bodies in the Asia Pacific Accreditation Cooperation (APAC)

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ISO 17034:2016 General requirements for the competence of reference material producers

This webinar will provide an overview of the ISO 17034:2016 standard as the basis of accreditation of reference material producers. This will emphasize the various critical components of reference material production such as requirements and limitations on subcontracting , production planning, homogeneity, stability, property values and their uncertainties, documents and labeling and distribution. This webinar will be educational for currently accredited reference material providers, those seeking this accreditation or to laboratories interested in what reference material producers are required to have in place to meet the requirements.

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ISO 17034:2016 General requirements for the competence of reference material producers

- ***One*** requirements document (normative)
  - **ISO 17034:2016 General requirements for the competence of reference material producers**
- ***Three*** Guides (informative)
  - **ISO Guide 30:2015 Reference materials – selected terms and definitions**
  - **ISO Guide 31: 2015 Reference materials – Contents of certificates, labels and accompanying documentation**
  - **ISO Guide 35:Reference materials – General and statistical principles for certification**

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ISO/IEC 17025:2017 General requirements for the competence of testing and calibration laboratories

6.5.2 The laboratory shall ensure that measurement results are traceable to the International System of Units (SI) through one of the following:

b) *certified values* of *certified reference materials* provided by a *competent producer* with stated metrological traceability to the SI

Note 2 Reference material producers fulfilling the requirements of ISO 17034 are considered to be *competent*

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ISO/IEC 17025:2017 General requirements for the competence of testing and calibration laboratories

6.5.3 When metrological traceability to the SI units is not technically possible , the laboratory shall demonstrate metrological traceability to an appropriate reference, e.g.

a) *certified values* of *certified reference materials* provided by a competent provider

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3.1 reference material producer (RMP)

body (organization or company, public or private) that is fully responsible for project planning and management; assignment of, and decision on property values and relevant uncertainties; authorization of property values, and issuance of a reference material certificate or other statements for the reference material it produces.
[Source: ISO Guide 30:2015, 2.3.5]

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3.3 reference material (RM)

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

Note 1 to entry: Reference material is a generic term

Note 2 to entry: Properties can be quantitative or qualitative. e.g. identity of substances or species

Note 3 to entry: Uses may include the calibration of a measurement system, assessment of a measurement procedure, assigning values to other materials and quality control

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3.3 certified reference material (CRM)
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 associate uncertainty and a statement of metrological traceability.

Note 1 to entry: The concept of value includes a nominal property or a qualitative attribute such as identity or sequence. Uncertainties for such attributes may be expressed as probabilities or levels of confidence.

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3.3 certified reference material (CRM) (cont'd)

Note 2 to entry: Metrologically valid procedures for the production and certification of reference materials are given in, among others, ISO Guide 35.

Note 3 to entry: ISO Guide 31 gives guidance on the contents of reference material certificates.

Note 4 to entry: ISO/IEC Guide 99:2007 has an analogous definition.

[Source: ISO Guide 30:2015, 2.1.2 modified – Reference to ISO Guide 34 has been removed from the Note 2 to entry]

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ISO Guide 30:2015 - Definitions

2.2.12 homogeneity

Uniformity of a specified property value throughout a defined portion of the reference material (RM)

Note 1 to entry: Tests for homogeneity are described in ISO Guide 35

Note 2 to entry: The defined portion may be, for example, and RM batch or single unit within the batch

Note 3 to entry: See also IUPAC Compendium of Analytical Nomenclature

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ISO Guide 30:2015 - Definitions

2.2.13 between-unit homogeneity
Uniformity of a specified property value among units of a reference material

Note 1 to entry: It is understood that the term “between unit homogeneity” applies to any type of package (e.g. vial) and other physical shapes and test pieces

2.2.14 within-unit homogeneity
Uniformity of a specified property value within each unit of a reference material

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ISO Guide 30:2015 - Definitions

2.2.15 stability

Characteristic of a reference material when stored under specified conditions, to maintain a specified property value within specified limits for a specified period of time.

Note 1 to entry: See also IUPAC Compendium of Analytical Nomenclature

2.2.16 transportation stability

Stability of a reference material (RM) property for the time period and condition encountered in transportation to the user of the RM.

Note 1 to entry: Transportation stability has often been referred to as "short term stability"

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ISO Guide 30:2015 - Definitions

2.2.17 long term stability

Stability of a reference material property over an extended period of time

2.2.18 lifetime

Time interval during which RM properties retain their assigned values within their associated uncertainties

Note 1 to entry: The lifetime is often determined retrospectively, i.e. after RM properties no longer retain assigned values or attributes.

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ISO Guide 30:2015 - Definitions

2.2.19 period of validity

Time interval during which the producer of the RM warrants it stability

Note 1 to entry: The period of validity may be expressed as a specific date or otherwise defined period of time.

2.2.20 commutability

Property of a reference material (RM), demonstrated by the equivalence of the mathematical relationships among the results of different measurement procedures for an RM and for representative sample of the type intended to be measured.

Note 1 to entry: See also ISO/IEC Guide 99:2007, ISO 17511:2003

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ISO 9000:2015 - Definitions

3.4.1 process

set of interrelated or interacting activities that use inputs to deliver an intended result

Note 1 to entry: Whether the "intended result" of a process is called *output* (3.7.5), *product* (3.7.6) or *service* (3.7.7) depends on the context of the reference

Note 2 to entry: Inputs to a process are generally the outputs of other processes and outputs of a process are generally the inputs to other processes.

Note 3 to entry: Two or more interrelated and interacting processes in a series can also be referred as a process.

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3.4.1 process (cont'd)

Note 4 to entry: Processes in an *organization* (3.2.1) are generally planned and carried out under controlled conditions to add value

Note 5 to entry: A process where the conformity (3.6.11) of the resulting output cannot be readily or economically validated is frequently referred to as a "*special process*"

Note 6 to entry: This constitutes one of the common terms and core definitions for ISO management system standards given in Annex SL of the Consolidated ISO Supplement to the ISO/IEC Directive, Part 1. The original definition has been modified to prevent circularity between process and output and Notes 1 to 5 to entry have been added.

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ISO 9000:2015 - Definitions

3.4.5 procedure

specified way to carry out an activity or a *process* (3.4.1)

Note 1 to entry: ***Procedures can be documented or not.***

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ISO 9000:2015 - Definitions

3.7.9 risk

effect of uncertainty

Note 1 to entry: An effect is a deviation from the expected - positive or negative

Note 2 to entry: Uncertainty is the state, even partial, of deficiency of information (3.8.2) related to, understanding or knowledge of, an event, its consequence, or likelihood.

Note 3 to entry: Risk is often characterized by reference to potential events (as defined in ISO Guide 73:2009, 3.5.1.3) and consequences (as defined in ISO Guide 73:2009, 3.6.1.3), or a combination of these.

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ISO 9000:2015 - Definitions

3.8.6 documented information

information 3.8.2 required to be controlled and maintained by an *organization* (3.2.1) and the medium on which is it contained.

Note 1 to entry: Documented information can be in any format and media and from any source

Note 2 to entry: Documented information can refer to:
- the *management system* (3.5.3) , including related *processes* (3.4.1)
- information created in order of the organization to operate (documentation)
- evidence of results achieved (*records* (3.8.10))

Note 3 to entry: This constitutes one of the common terms and core definitions for ISO management system standards given in Annex SL of the Consolidated ISO Supplement to the ISO.IEC Directives, Part 1

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ISO 9000:2015 - Definitions

3.8.10 record

document (3.8.5) stating results achieved or providing evidence of activities performed

Note 1 to entry: Records can be used, for example, to formalize *traceability* (3.6.13) and to provide evidence of *verification* (3.8.12), *preventive action* (3.12.1) and *corrective action* (3.12.2)

Note 2 to entry: Generally records need not be under revision control.

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ISO 17034:2016

- **Scope**
  - General requirements – competence and consistent operation of RMPs.
  - Production of all reference materials including certified reference materials
- **Normative references**
  - ISO/IEC 17025, “General requirements for the competence of testing and calibration laboratories” – ***latest edition***

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ISO 17034:2016

- **General requirements**
  - Contractual matters
  - Impartiality
  - Confidentiality
- **Structural requirements**
  - Legal entity
  - Organizational
  - Responsibilities, authorities – all personnel affecting the RMs produced
  - Managerial, technical management
  - Authority for ISO 17034 – direct access to highest level making decisions on RM policy and production

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ISO 17034:2016

- **Resource requirements**
  - Personnel
  - Subcontracting
  - Equipment, services, suppliers
  - Facilities and environmental conditions

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ISO 17034:2016

- **Technical and production requirements**
  - General requirements
  - Production planning
  - Production control
  - Material handling and storage
  - Material processing
  - Measurement procedures
  - Measuring equipment
  - Data integrity & evaluation
  - Metrological traceability of certified values
  - Assessment of homogeneity

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ISO 17034:2016

- **Technical and production requirements**
  - Assessment & monitoring of stability
  - Characterization
  - Assignment of property values & their uncertainties
  - RM documents and labels
  - Distribution service
  - Control of quality and technical records
  - Management of non-conforming work
  - Complaints

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ISO 17034:2016

- **Management system requirements**
  - Options – Option A, Option B (requirements of ISO 9001)
  - Option A
    - Quality policy
    - General management system documentation
    - Control of management system documentation
    - Control of records
    - Management review
    - Internal audit
    - Actions to address risks & opportunities
    - Corrective actions
    - Improvement
    - Feedback from customers

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ISO 17034:2016 – 6.2 Subcontracting

RMP ***shall not:***

- Subcontract the following processes:
  - ***Production planning***
  - ***Selection of subcontractors***
  - ***Assignment of property values and their uncertainties***
  - ***Authorization of property values and their uncertainties***
  - ***Authorization of RM documents.***

RMP shall:

- Establish and maintain procedures to assess that all tasks subcontractors perform comply with the requirements set by the RMP and relevant clauses of ISO 17034
- Establish and maintain records of subcontractor competence including evaluations and any audits conducted

  Note: Examples of evidence - assessments, PT participation, certificates/accreditations, other materials similar to the RMs

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Steps at the Core of RMP

- Production planning/control
- Material handling/storage
- Material processing
- Measurement procedures/equipment
- Certified values – metrological traceability
- Assessment of homogeneity
- Assessment of stability
- Characterization – planning etc.

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Steps at the Core of RMP

- Assignment of property values and uncertainties
- RM documents and labels
- Distribution and service

Check the processes, documents and records

For each type of RM/CRM – but accounting for similar materials, etc. and previous data on previous materials ….

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Examples of RMs/CRMs

This is a calibration gas produced by Linde Gas and Equipment (ne' Praxair) – Portagas in Pasadena TX – PJLA Accredited for Testing, Calibration and RMP. Another Linde location in Los Angeles CA makes EPA Protocol Gases and NIST NTRMs

These are used not only in the USA but are exported to countries around the world

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Examples of RMs/CRMs

This is a specialty gas produced by ILMO Products Co – PJLA Accredited for Testing, Calibration and RMP

This cylinder is an internal standard used to analyze smaller, mailable units that are filled, distributed and used to calibrate breath alcohol analyzers. Note the certificate and body label. They also make NIST Research Gas Materials (RGM) for ETOH blends

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Examples of RMs/CRMs

This is an ampoule of a CRM from Chem Service PJLA accredited for testing and RMP. Note the label. These are distributed widely in the USA, Europe and elsewhere.

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Examples of RMs/CRMs

This is a container of a “neat” CRM from Chem Service PJLA accredited for testing and RMP. Note the label and seal. These are widely distributed. widely in the USA, Europe and elsewhere.

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Examples of RMs/CRMs

These are ampoules of a CRM from Lab Instruments s.r.l. (Italy) PJLA accredited for Testing and RMP

These are exported around the world.

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Examples of RMs/CRMs

These are vials of a CRM from Lab Instruments s.r.l. (Italy), PJLA accredited for Testing and RMP

These are exported around the world.

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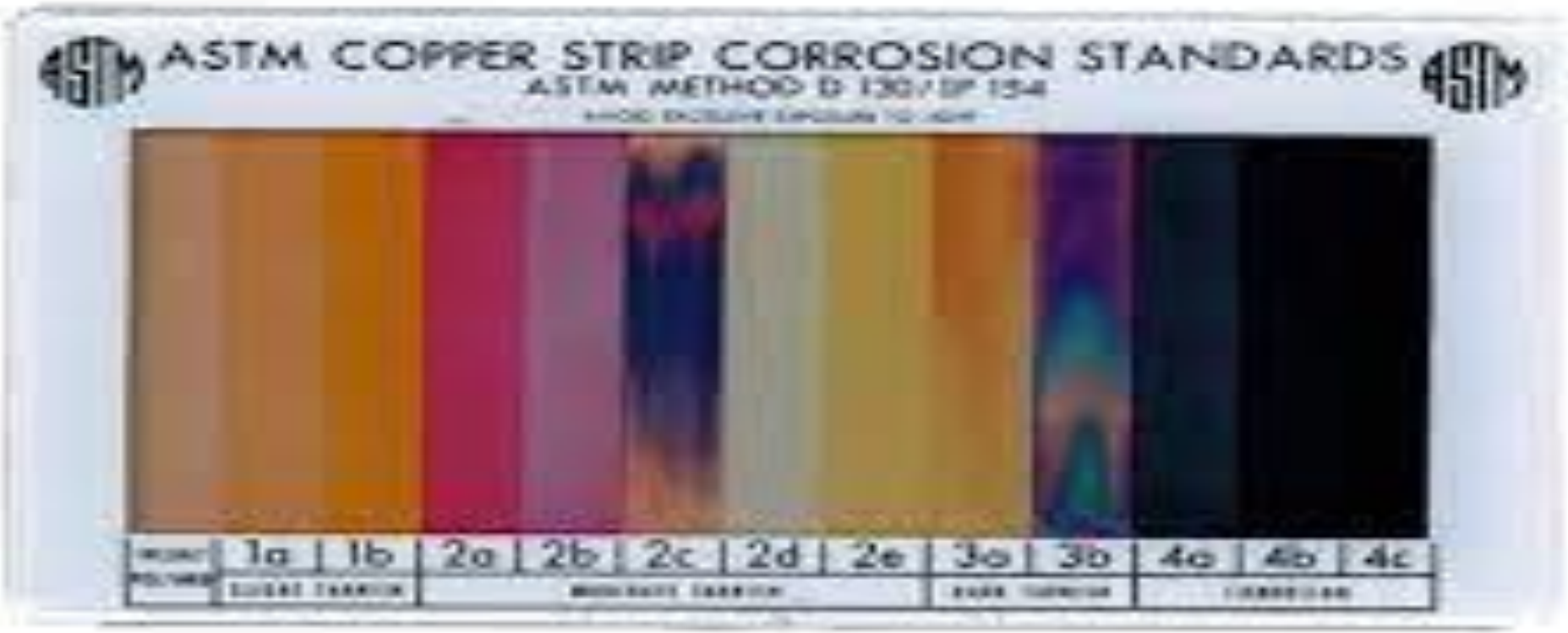
Reference Materials …. What About?



Reference Materials – What About?

AATCC Fade Scale - Used to estimate/describe the degree of "fade" in textiles, also finishes etc.

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Reference Material – What About?

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Reference Material – What About?

Indium

(99.99%)

TG

standards

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Reference Material – What About?

Indium

(99.995%)

TG

Standard

Material

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Thank You

This time is allocated for questions. You should have a space provided for submitting questions.

If a question is not answered, please submit directly to webinar@pjlabs.com

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Save the Date

Monday, November 22, 2021

1:00 pm EST

A Look at ISO/IEC 17025:2017: Section 7.10" Nonconforming Work" & Section 8.6 "Improvement"

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Contact Information

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