Approaches to Improving and Demonstrating Method and Laboratory Performance

- Analytical quality assurance
- Method validation
- Proficiency testing
- Certified reference materials
What is Reference Material?

2.1

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 RM is a generic term.

NOTE 2 Properties can be quantitative or qualitative, e.g. identity of substances or species.

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

NOTE 4 A single RM cannot be used for both calibration and validation of results in the same measurement procedure.

NOTE 5 VIM has an analogous definition (ISO/IEC Guide 99:2007, 5.13), but restricts the term “measurement” to apply to quantitative values and not to qualitative properties. However, Note 3 of ISO/IEC Guide 99:2007, 5.13, specifically includes the concept of qualitative attributes, called “nominal properties”.

ISO Guide 30 Amendment 1 2008
What is a CRM?

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

NOTE 1 The concept of value includes qualitative attributes such as identity or sequence. Uncertainties for such attributes may be expressed as probabilities.

NOTE 2 Metrologically valid procedures for the production and certification of reference materials are given in, among others, ISO Guides 34 and 35.

NOTE 3 ISO Guide 31 gives guidance on the contents of certificates.

AOCS Certified Reference Materials

- AOCS has been assisting the Life Sciences Industry meet regulatory requirements for international registration of their products since March 2004.

- AOCS CRMs:
  - ISO Guide 34:2009 accredited by A2LA since 2013
  - intended for use as quality control material or calibrant in methods for the detection, identification, and/or quantification of biotechnology-derived events.
  - were prepared in accordance with ISO Guide 34:2000 before accreditation.
Questions to be Asked and Answered by Biotechnology Provider and AOCS

- Type of material needed?
  - Seed? Powder? Genomic DNA? Plasmid?
    - Qualitative?
    - Quantitative?
    - Semi-quantitative?
- How many samples?
- Sample size?
- What laboratory is licensed to use the validated method?
Current AOCS Offerings

• Canola (11)
  o Bayer
  o Monsanto
• Corn (13)
  o Bayer
  o Monsanto
  o Syngenta
• Cotton (8)
  o Bayer
  o Monsanto
• Potato (2)*
  o BASF
• Rice (2)
  o Bayer
• Soybean (14)
  o BASF
  o Bayer
  o Monsanto
• Sugarbeet (2)*
  o KWS - Monsanto
# Certified Reference Materials (CRM)

This program is A2LA accredited to ISO Guide 34. These CRMs are intended for use as quality control material or calibrant in methods for the detection, identification, and/or quantification of biotechnology-derived events.

The tariff code for Certified Reference Materials is 3822.00.6000.

Purchase CRMs in our online Store.

To minimized delays, seizure, clearance, and third party intervention, please include all necessary government paperwork (i.e. Import Permits or Phytosanitary Certificates) with your order to AOCs. Any additional charges incurred from these requirements will be borne by the recipient.

**Additional Resources:**
- Center for Environmental Risk Assessment
- The CropLife International Detection Methods Database
- Council for Biotechnology Information

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<thead>
<tr>
<th>Canola</th>
<th>Company</th>
<th>Event</th>
<th>Product Code</th>
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<tbody>
<tr>
<td>Leaf Tissue DNA 10 μg</td>
<td>Bayer CropScience</td>
<td>Ms1</td>
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<tr>
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<td>Rf1</td>
<td>0711-B2</td>
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<tr>
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<td>0208-A5</td>
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<td>0306-F5</td>
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<td>Whole Seed 100g</td>
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<td>0304-A</td>
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Accredited Reference Material Producer

A2LA has accredited

AOCS
Urbana, IL

This accreditation covers the specific materials listed on the agreed upon Scope of Accreditation. This producer meets the requirements of ISO Guide 34:2009 General Requirements for the Competence of Reference Material Producers, in combination with the relevant requirements of ISO/IEC 17025:2005 General Requirements for the Competence of Testing and Calibration Laboratories. This accreditation demonstrates technical competence for a defined scope and the operation of a quality management system.

Presented this 16th day of September 2015.

President & CEO
For the Accreditation Council
Certificate Number 3438.01
Valid to May 31, 2017

For reference materials to which this accreditation applies, please refer to the reference material producer’s Scope of Accreditation.
SCHEME OF ACCREDITATION TO ISO-IEC GUIDE 34-2009

AOCS
2710 S. Boulder Drive
Urbana, IL 61802-7190
Dr. Richard Churnin Phone: 217 693 4830

REFERENCE MATERIALS PRODUCER.

Valid To: May 31, 2017
Certificate Number: 3438.01

In recognition of the successful completion of the A2LA evaluation process, accreditation is granted to this Reference Material Producer for the production of certified reference materials and reference materials of the following categories:

<table>
<thead>
<tr>
<th>Category of Reference Material</th>
<th>Certified Reference Material</th>
<th>Test Analysis Measurement</th>
<th>Measurement Technique</th>
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<td>Powder</td>
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<td>Topaz 19/2 Canola</td>
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Maize Monsanto Company Event MON87427 Powder 0512-A

AOCS 0512-A was prepared from MON87427 maize provided by Monsanto Company. AOCS 0512-A is available in 10 g of powder, packaged in 27-mL glass headspace vials.

Additional Details: 0512A Certificate | 0512A Report | A2LA Scope

Purchasing: If you require a PROFORMA invoice or an invoice that includes a true value for Customs, please contact orders@aocs.org. Any additional charges incurred from these requirements will be borne by the recipient. All sales are final and cannot be returned.

Shipping: The tariff code for Certified Reference Materials is 3822.00.6000. To minimize delays, seizure, clearance, and third party intervention, please include all necessary government paperwork (i.e. Import Permits or Phytosanitary Certificate requests) with your order to AOCS. Any additional charges incurred from these requirements will be borne by the recipient.

Item Details:

Intended Use: These products are intended for use as quality control material or a calibrant in methods for the detection, identification, and/or quantification of biotechnology-derived events.

This program is A2LA accredited to ISO Guide 34:2009.
Why does AOCS provide “0” and “100” instead of levels?

- Cost prohibitive as AOCS hires the analysis
  - IRMM have an ISO 17025:2005 accredited laboratory on-site
- Globally, there are too many “levels” to consider
- Sample sizes are large enough for creating personalized calibration curves or levels of material
What is proficiency testing?

- One of several quality assurance measures available to laboratories
- Regular distribution of test samples to participating laboratories for independent analysis
- Results are returned to the organizer for statistical analysis
- Collated results are distributed to the participants for internal assessment
Objectives

- Regular, objective, independent assessment of laboratory’s analytics for routine test samples
- Promotes improvements in the accuracy of routine analytical data
Benefits of participation

- Regular, external, and independent check on data quality
- Assistance in demonstrating quality and commitment to quality issues
- Motivation to improve performance
- Support for accreditation/certification to quality standards

- Comparison of performance with that of peers
- Assistance in the identification of measurement problems
- Feedback and technical advice from the organizers
- Assistance in the evaluation of methods and instrumentation
AOCS Laboratory Proficiency Program
Celebrating 100 years!

- Formerly the Smalley Check Sample Program
  - More than 500 chemists participate annually to verify their lab’s quality control
  - 2015-2016 Program offers 43 different series

- Participants use AOCS or similar methods for sample analysis and then compare their results with a large cross-section of other laboratories using the same methods and samples

- Participating in LPP may be sufficient for national and professional accreditation requirements
Most series are offered 4 x per year with 2 samples each round.

There are suggested methods listed for most series, though some indicate that the user should identify the method utilized.

Occasionally, results are method-dependent and there is a need to separate statistical analysis based on method applied.
o Though AOCS recommends a test method for each parameter, it does not mean that all reported results are generated by the stated method

o However, one of the reasons for participating in PT is to see if your internal method compares to industry methods...
AOCS requests results in singlet
  - This does not support traditional method validation (r and R)

- Though it does allow participants to see if their method compares to industry
To Calculate a Z Score we need:

- A lab result to test ($X_{LAB}$).
- An Assigned Value ($X_a$) to test against.
- A SD for Proficiency Testing ($\sigma_p$) that is a measure of the anticipated data spread.

$$Z = \frac{X_{LAB} - X_a}{\sigma_p}$$
- AOCS uses the consensus mean after outlier removal to generate the Assigned Value

- SD is generally the consensus after outlier removal, though it can also be assigned if the true value of the sample is known
In a series of less than 30 participants outliers are indicated when a result is greater than 2.5 standard deviations from the mean.

In series of 30 participants or more outliers are indicated when a result is greater than 3.0 standard deviations from the mean.

In determining outliers, they are identified and removed from the calculation, then the process is repeated with the remaining results.
LPP is administered and operated in accordance to ISO 17043

AOCS will apply for accreditation to ISO 17043 in 2015

AOCS is working with QuoData to improve the online reporting and statistical analysis for LPP
Thank you!

Questions?
Gina.Clapper@aocs.org