Module P13: AOAC INTERNATIONAL
Conformity Assessment Programs – Reviewed and Recognized™ Program
About AOAC INTERNATIONAL

AOAC INTERNATIONAL brings together government, industry, and academia to establish standard methods of analysis that ensure the safety and integrity of foods and other products that impact public health around the world

- Leader of analytical excellence dedicated to developing and validating standards, methods and technologies, of global relevance to advance food safety, food integrity, and public health.

- AOAC INTERNATIONAL is a 501(c)(3), independent, third party, not-for-profit association and voluntary consensus standards developing organization.
Scientific Solutions

Scientific Standards: SMPRs

Conformity Assessment: OMA, PTM & R² Programs

Analytical Solutions Programs: SPADA, SPIFAN, FAF, CASP

Laboratory Proficiency Testing

Analytical Science Forum

Technical Divisions: TDRM, TDLM

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Reviewed and Recognized\textsuperscript{SM} (R\textsuperscript{2}) Program
Overview

The AOAC Research Institute (AOAC RI) is a division of AOAC INTERNATIONAL that promotes and conducts activities to help develop, improve, and validate proprietary testing methods.

• Incorporated in 1991 as a wholly-owned subsidiary of AOAC INTERNATIONAL
• Merged into AOAC INTERNATIONAL in 2019 as a division
• Administers the Performance Tested MethodsSM (PTM) Program
• Administers the Reviewed and RecognizedSM (R²) Program
• [https://www.aoac.org/scientific-solutions/research-institute-ptm/](https://www.aoac.org/scientific-solutions/research-institute-ptm/)
Overview

Reviewed and Recognized (R²) Program

• Helps companies and their customers safeguard their businesses, mitigate risk, and protect consumers through trusted, reliable testing methods and products.

• Provides independent third-party review and certification for equipment/component method performance.
  • Analogous to the PTM program, but for non-test kit methods.

• The certification mark assures users that an independent assessment found that method performance meets an appropriate standard for its intended use.

• Can be the first step toward Official Method℠ status
R² Process and Timeline

Consulting Service → R² Application → MD Studies → Report & AN Review → Certification → Renewal

IL Studies*

Typically 6-12 months

MD = Method Developer; IL = Independent Laboratory

*Traditional or On-Site Validation

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Consulting Service – Optional Fee for Service

Step 1: Application

• Includes method applicability statement (target analyte(s) and matrixes), method instructions, relevant method safety information, and whether harmonized with another program
• Applicant will be invoiced within 2-3 business days of submission

Step 2: Develop Validation Testing Protocol and Facilitate Review Process

• Validation outline designed to comply with current AOAC Guidelines and/or SMPRs
• Includes appropriate reference materials and methods
Consulting Service

Step 3: Expert Peer Review and Approval
- Technical consultants work with AOAC volunteer experts to ensure review and approval of testing protocols
- Statistical review (if applicable)

Step 4: Approved Testing Protocols and Plans
- AOAC approved testing protocols are valid for one year from the date of approval.
- Testing protocol for Method Developer and Independent Laboratory Studies
Data Requirements - Chemistry

Validation Studies

1. Calibration Model – typically carried out by MD, in some cases also the IL
2. Selectivity - can be carried out by MD or IL
3. Matrix Testing – MD and IL
   a. All matrixes tested by MD + 1/5 tested by IL
   b. All matrixes tested by IL
4. Robustness – can be carried out by MD or IL
5. Equipment/Component Consistency and Stability – MD; may be able to use QA data

See specific training modules for more details on the validation studies
Data Requirements - Microbiology

Validation Studies

1. Inclusivity/Exclusivity – can be carried out by MD or IL

2. Matrix Testing
   a. All matrixes tested by MD + 1/5 tested by IL
   b. All matrixes tested by IL

3. Robustness – can be carried out by MD or IL

4. Equipment/Component Consistency and Stability – typically carried out by MD; may be able to use QA data

See specific training modules for more details on the validation studies
Independent Laboratory Options

• Traditional Process
  • Equipment and components are shipped to the Independent Laboratory (IL)
  • MD provides training to IL on how to perform the method
  • IL performs study

• On-Site Process
  • MD is unable to ship large equipment or method is intended to be performed only by the MD (i.e., fee for service method)
  • IL prepares blinded validation samples and/or test portions
  • Analyst from IL performs study at MD site side by side with MD on blinded validation test portions with AOAC Technical Consultant present as observer
Various guidelines for microbiology and chemistry studies are available and can also be found as appendices in the AOAC Official Methods of Analysis of AOAC INTERNATIONAL: http://www.eoma.aoac.org/appendices.asp
Standard Method Performance Requirements

• Standard Method Performance Requirements (SMPRs®) are voluntary consensus standards, developed by stakeholders, that prescribe the minimum analytical performance requirements for classes of analytical methods.

• SMPRs are unique to AOAC’s processes and were introduced in recognition of the fact that acceptance criteria are critical to evaluating the suitability of any testing protocol for its intended use.

• Methods that meet the performance requirements can claim conformity to the SMPR.
Reference Methods

Must be applicable to the analyte/matrix and may include (but are not limited to):

FDA, FSIS, AOAC Official Methods of Analysis (OMA), ISO, EPA, Health Canada, American Public Health Compendium of Methods, validated methods from peer reviewed literature (chemistry)
Reference Materials and Reference Standards

Available at (but not limited to):

- National Institute of Standards and Technology (NIST)
- EPA
- National Research Council Canada (NRC)
- US Pharmacopeia (USP)
- Institute of Reference Materials and Measurements (IRMM)
- Chemical Suppliers
Statistical Tools

Excel Workbooks are available for analysis of qualitative and quantitative data for SLVs and MLVs.

An Excel Calculator is available for MPN determination.  
*(Note that the MPN calculator is not compatible with iMac.)*

Ask a Technical Consultant for the current versions.
Method Claims

Analyte

• The analyte(s) detected or determined by a method must be clearly stated in the intended use (applicability) statement of the method.
  • For example, metabolites or marker residues of pesticides and animal drugs.
  • *Listeria* spp. claims must specify which species are included in the claim. Recognized *Listeria* species include *L. grayi*, *L. innocua*, *L. ivanovii*, *L. marthii*, *L. monocytogenes*, *L. rocourtiae*, *L. seeligeri*, and *L. welshimeri*.
  • *Salmonella* claims must distinguish between *Salmonella enterica* and *Salmonella* spp. (*S. enterica* + *S. bongori*).

• Any limitations to the analyte claim must be clearly stated in the application note.
Method Claims

Matrix

• The matrix claim is the scope of matrixes included in the validation study and must be expressly stated in the intended use (applicability) statement of the method.

• The $R^2$ program allows certain general claim statements, but the list of specific matrixes from the validation study must also be included.

• The specific matrixes examined in the validation study are important for ISO 17025 certified laboratories to determine whether verification or validation studies are required when implementing the method for their matrixes.
Matrix Claim – General Claim Statements

<table>
<thead>
<tr>
<th>Claim</th>
<th>Number of Matrixes</th>
<th>Number of Categories</th>
</tr>
</thead>
<tbody>
<tr>
<td>Broad Range of Foods</td>
<td>15</td>
<td>5</td>
</tr>
<tr>
<td>Variety of Foods</td>
<td>10</td>
<td>5</td>
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<tr>
<td>Selected Foods</td>
<td>5</td>
<td>2</td>
</tr>
<tr>
<td>Food Category</td>
<td>5</td>
<td>1</td>
</tr>
<tr>
<td>Environmental Surfaces</td>
<td>7</td>
<td>NA</td>
</tr>
<tr>
<td>Selected Environmental Surfaces</td>
<td>1-6</td>
<td>NA</td>
</tr>
</tbody>
</table>

Acceptable food category sources include:
2. FDA 9-sector Food Triangle
R² Report

• Upon completion of a validation, method developers are required to prepare and submit a study report supporting the intended use claims of the method.

• The report is prepared following a standard template provided by the AOAC Research Institute. The template is intended to facilitate submission to the JAOAC.

• This report will include the results of both the Method Developer Validation Study and the Independent Validation Study, including all data generated during the studies.
R² Report

- Title
- Authors
- Abstract
- General information
- Principle of the method
- Definitions
- Safety precautions
- Method
  - Applicability Statement
  - Apparatus and Supplies
  - Reagents
  - Instructions
  - Results and Interpretation
- Validation Studies
  - MD and IL Studies
  - Methodology and results, including tables and figures
- Discussion
- Conclusion
- Acknowledgements
  - Submitting Company
  - Independent Laboratory
  - Reviewers
- References
The application note should include the following items, when applicable:

- **Intended User** - Specify the intended user
- **Environmental Factors** - Identify the environment that the test should be conducted
- **Applicability Statement** - Identify the analyte, mode of measurement and matrixes for which the kit has been validated
- **Limitations** – Disclose any known limitations or interferences of the method
- **System Suitability** – Requirements for determining valid equipment and component setup
- **Instructions** - Include complete instructions from sample preparation to data interpretation
- **Detection Limit and Limit of Quantitation** - Express in concentration (parts per million, percent, mg/kg, CFU/g, etc.) the limits of detection and quantitation
- **Precautions** - Provide warnings of safety concerns, disposal instructions, and potentially hazardous steps or components.
- **Technical Assistance** - Provide information (email, internet, telephone and FAX numbers) where the user can obtain technical assistance.
Example Applicability Statement:

Method X was certified by the AOAC Research Institute Reviewed and Recognized℠ Program for determination of glyphosate, N-acetylglyphosate, AMPA, and N-acetyl AMPA in a variety of matrixes including whole durum wheat, whole oats, groats, chickpeas, dried split green peas, infant cereal, infant formula, blueberries, apple juice, and soymilk.

Example of Method Claim Limitation:

Method not applicable to products with low pH (≤4).
Review

• One Volunteer Expert and 2 Expert Reviewers will review the $R^2$ Validation Study Report and Application Note to determine acceptability as a *Reviewed and Recognized* method.
• Reviewers will provide recommendations to the AOAC-RI Project Manager for awarding or denying $R^2$ status.
• Upon receipt, the Project Manager will compile each reviewer's recommendations and comments into a single form for the Method Developer. The Method Developer is responsible for responding to all comments and questions in writing.
• All responses and revised documents shall be submitted to the Project Manager, who will forward them to the AOAC Volunteer Expert and Expert Reviewers for additional comment or approval.
• The process continues until consensus is reached among the three reviewers for either approval or rejection.
A **Reviewed and Recognized** certificate is issued by the AOAC-RI to the Method Developer for each method granted R² status. The certificate carries a unique certification number and name of the approved test method. Certificates provide details about the method validation including:

- Overview of the method and validation
- Claimed matrixes
- Selectivity
- Results of method developer and independent laboratory matrix studies
Certification

$R^2$ certificates are made available to the public though the AOAC website. Certificates are searchable by:

- Analyte
- Matrix
- Manufacturer
- Method name
- License number
• Method Developers of approved methods are licensed to use the $R^2$ certification mark and $R^2$ certification number on their packaging, application notes, and promotional materials.

• Use of the certification mark and/or number is entirely optional but highly encouraged.

• Method Developers will receive a copy of the certification mark with a unique certification number as soon as the method is $R^2$ approved.
R² Modifications

• During the life cycle of a method, changes often occur
• As a validated method is modified, its certificate is no longer applicable, regardless of the size of the change
• The AOAC Research Institute (RI) has a process for method developers to modify their methods and maintain their certifications
• These modifications can be submitted to the AOAC RI at anytime during the year and must be reviewed before being implemented
R\textsuperscript{2} Modifications

- Modifications or changes to methods typically fall into one of three categories:
  - Changes to labeling
  - Changes to the components or reagents of the method
  - Changes to the manufacturing and/or quality process
  - Changes to the scope of the method

- When a modification to your method occurs, it is the method developer’s responsibility to notify AOAC RI.

Failure to notify AOAC RI of the changes may result in cancellation of your R\textsuperscript{2} Certificate.
Renewals

• An annual review is conducted on all approved Reviewed and Recognized SM methods.

• Method developers apply for recertification and indicate whether modifications have been made to the validated method or components.
  • Modifications will require additional review time and may require an additional fee.

• Certifications are reviewed and renewed on a yearly basis from June 01 to May 31.
AOAC created a non-voting membership category, Contributing Member, for the AOAC Research Institute. The AOAC Research Institute Advisory Council comprises representatives of the Contributing Member organizations in good standing.

Annual dues are $5,000.00 USD and benefits include:

• One seat on the RI Advisory Council
• $1,000.00 USD discount toward RI Consulting fees
• $6,000.00 USD discount toward R² Application fees
• Discounted Harmonized Consulting
• One complimentary individual AOAC INTERNATIONAL membership

• Join as a Contributing Member now
• For all questions, contact Nora Marshall at nmarshall@aoac.org
# R² Program Fees

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<th>AOAC RI Fees</th>
<th>Price(^c)</th>
<th>RICM Price(^c)</th>
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<td>Consulting – R²</td>
<td>$3000</td>
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<td>Consulting - Harmonized</td>
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<td>Application – R²</td>
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<td>Annual Renewal</td>
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\(^a\)A $500 discount applies if the Consulting Service was used  
\(^b\)If also an AOAC Organizational Member  
\(^c\)Discounted introductory pricing of $10,000 for the R² Application in effect through March 31, 2022.

The cost of the Independent Lab Study depends on the scope and nature of the matrix study and whether other studies (e.g., selectivity) are also included in the Independent Lab work. Your Technical Consultant can provide a nonbinding ballpark estimate for your situation.
# Method Conformity Assessment Programs

<table>
<thead>
<tr>
<th>Method Type(s)</th>
<th>Proprietary methods</th>
<th>Non-proprietary methods</th>
<th>Proprietary or non-proprietary methods</th>
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We’re here to help!