

AOAC Analytical Communities and Official Methods Board

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AOAC Methods Development & Method Approval Processes

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Goals and Objectives

- To understand the concept of community and its components
- To understand the difference between AOAC standard setting and conformity assessment activities
- To understand that OMB involvement in AOAC standard setting and conformity assessment activities
- To explain how to get started and get involved

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AOAC Process Overview

Community Analytical Needs



CONSENSUS STANDARDS DEVELOPMENT

Stakeholder panel
(- Working Groups) $\xrightarrow[\text{on}]{\text{Reaches consensus}}$ Performance Requirements
(including panels & selection criteria)



Expert Review Panels $\xrightarrow[\text{on}]{\text{Reaches consensus}}$ Candidate Methods



CONFORMITY ASSESSMENT

Method Committee
(- and Advisors) $\xrightarrow[\text{approves}]{\text{Reviews \&}}$ Validation Protocols
(with Acceptance Criteria)
and
Validation Manuscripts

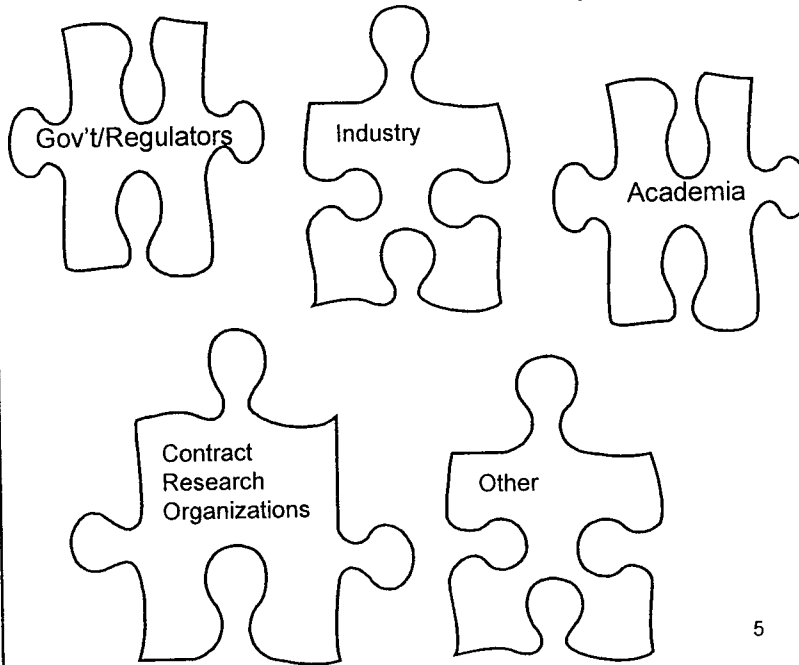
OMB as the Firewall

- OMB has OMB liaisons to the communities
- OMB vets and approve chair & voting members of stakeholder panels
- OMB vets and approves chair and voting members of Expert Review Panels
- OMB approves and trains method volunteers and appoint method committees
- OMB makes decisions regarding Final Action status

Community

- **Community**

Interest in an scientific or analytical area



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Community Infrastructure

- **Develop a Terms of Reference Document**
 - Reviewed and considered by the AOAC Board of Directors
- **Meet at the AOAC Annual Meeting and as needed through the year**
- **Guidelines for the Analytical Communities document**

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OMB Liaison

- Provides guidance and assistance on analytical issues
- Keep OMB apprised of community efforts or issues

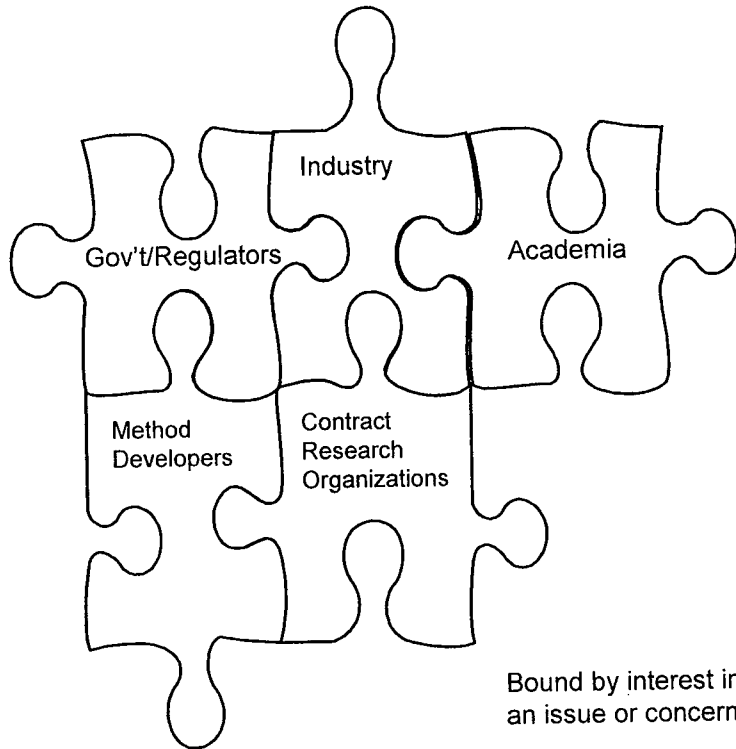
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When a Community has an Issue

- AOAC can work with the community to identify and bring together the appropriate balanced consensus group
 - Scientific & Technical Experts
 - Government Agencies & Regulators
 - Method Developers & Technology Providers
 - Contract Research Organizations
 - Universities
 - Other
- AOAC provides documentation

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Consensus Groups



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Types of Consensus Groups

- Stakeholder Panels
- Working Groups
- Expert Review Panels
- Task Forces, Task Groups, etc...

***MEMBERS OF THESE GROUPS
ARE FROM THE COMMUNITY***

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Consensus Group Infrastructure

- AOAC Consensus Groups are funded
- Formed in accordance with
 - Office of Management & Budget (the other OMB) Circular A-119
 - National Technology Transfer Advancement Act (Public Law 104-113)
- AOAC OMB approves appointments of Chair and voting members
 - Ensures balance and consistency

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Consensus Group Work

- Discuss and reach consensus on
 - Fitness-for-purpose statement
 - Method performance standards
 - Additional validation parameters
 - Candidate Methods

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Question and Answer 1

- Can a community operate as a consensus body regarding an issue?

– Absolutely!

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Question and Answer 2

- Must a community be *funded* to operate as a “community”?

– No.

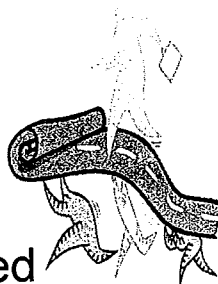
However, there are fees associated with AOAC establishing the consensus groups (stakeholder, working groups, ERPs, etc...) and for method validation.

The Community finds the
Fund.

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Key Participants and Programs

- Consensus Group
- AOAC Method Volunteers
- AOAC Staff & Technical Consultants

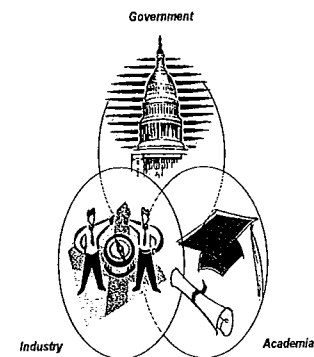


- Performance Tested Methods Program
- Official Methods Program

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Stakeholder Panels

- What are these?
 - Based on engagement of and are represented by
 - Government
 - Industry
 - Academia
 - Common interests in standards and analytical methods
 - Arrange funding for a validation project
 - Make recommendations to AOAC on method performance characteristics and potential validation study design parameters

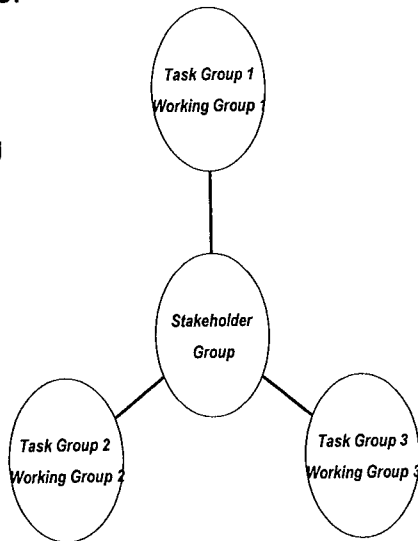


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Stakeholder Panels (con't)

- Stakeholder Panel

- Can be an
 - AOAC Community
 - AOAC Working Group
 - AOAC Task Force
 - Other
- Subdivide into Task Groups or Working Groups
 - To effectively work on the components required to complete the mission of the Stakeholder group



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Task Groups/Working Groups

- WHO IS THIS GROUP?

- Members appointed to group from and report to the stakeholder group or community
- Consist of voting members and non voting members
- Four Main Areas have included, but not all inclusive:
 - Method Specifications
 - Materials/ Panels
 - Ingredient Ranking
 - Laboratory Selection
 - Expertise

- DUTIES OF GROUP

- Reach consensus on
 - **Method Performance Requirements**
 - **Fitness for Purpose**
 - **Selection Criteria**
 - **There can be other depending upon the goal of the stakeholder panel**

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PHASE 1 – TASK/WORKING GROUP & STAKEHOLDER GROUP RECOMMENDATIONS

- Task or Working Groups make recommendations to the stakeholder group based on their assignments
- Stakeholder panel reach consensus on the recommendation of the task or working group
 - Method Performance Requirements & Validation Acceptance Criteria
 - Experts to be engaged throughout project
- AOAC maintains official documentation of stakeholder proceedings and working group minutes

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PHASE 2 – FROM STAKEHOLDER TO EXPERT REVIEW PANEL

- OMB established a process for codifying method performance standards
- Stakeholder consensus on method performance standards should be fit-for-purpose and contain acceptance criteria that should be incorporated into study designs and validation protocols.
- Note: Stakeholder panels are a great resource for potential Experts and AOAC topic advisors.

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Expert Review Panel

- A specialized version of a working group or task group
 - Experts review and select candidate method(s)
- Can recommend to AOAC or to the community or consensus bodies.

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How are methods chosen for Submission?

- According to AOAC policy for Expert Review Panels (ERP)
 - AOAC issues
 - a Call for Methods
 - a Call for Experts
 - OMB approves ERP chair and voting members
 - AOAC distributes methods that may meet the fitness for purpose and/or method performance requirements

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ERPs

- AOAC Chief Scientific Officer(s)
 - Work with ERP Chair to arrange meeting of ERP and draft report after the meeting
 - ERP members review methods
 - ERP members meet to discuss methods and reach consensus on a method or a composite method, also known as candidate method(s)

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Candidate Methods

- OMB codifies candidate methods and ERP reports
- ERP chosen to undergo validation
 - Single Laboratory Validation (SLV)
 - Performance Tested Methods
 - Collaborative Study (OMA)
 - ERPs can be assembled to review validation data after SLV

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Method Volunteer Input

- Topic Advisors, Study Directors, Laboratories, Method Committee members all can be recruited from the communities, stakeholder panels, working groups, etc...
- Method volunteers can be appointed at any point along the way to participate and provide guidance to the consensus groups.

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Study Designs & Protocols

- Candidate methods require validation protocols that are based upon AOAC's expectations and demonstrate the communities method needs
- AOAC can work with study directors and volunteers to establish study designs and protocols

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OMB Requirements

- NEW!** • Method Committee will be appointed at the submission of a collaborative study protocol proposal
- NEW!** • SLV report must accompany **all** Collaborative study protocol submission
 - SLV / PTM report serves to provide evidence that the method has a high probability of successful collaborative study.
- NEW!** • OMB reviews and delegates **all** Official Methods submissions
 - Include new submissions and modification/matrix extensions

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General Roles - AOAC Method Committee Members

– WHO IS THIS GROUP?

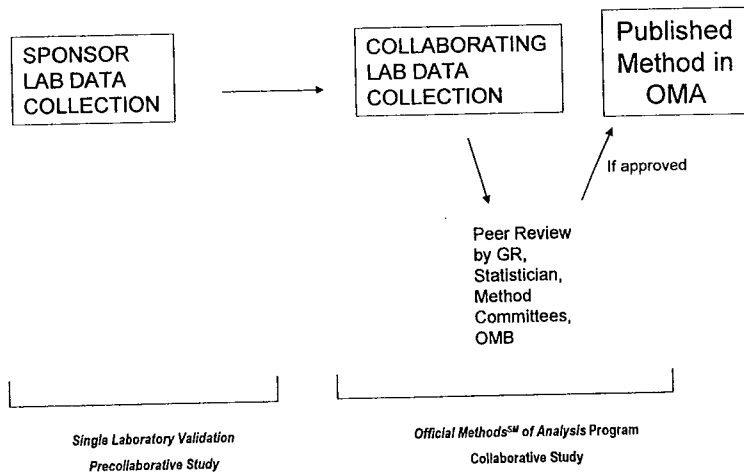
DUTIES OF GROUP

- Formed by the OMB to address methods under development or validation
- Trained AOAC Volunteers from the community and stakeholder group with expertise in Committee method areas and AOAC Validation Processes
- May not serve as a Voting Member of the AOAC consensus body (stakeholder panel, working group, task group, expert review panel, etc...) from which the method(s) may be submitted to AOAC
- Participate in method development activities.
- Participate on stakeholder task groups by providing and oversight as it pertains to specific requirements for method validation.
- Consider advice from General Referee, Topic Advisors, Statistician and Safety Advisors.
- Review and Approve Recommended Collaborative Study Designs and Manuscripts
- Approve peer reviewed methods as Official First Action

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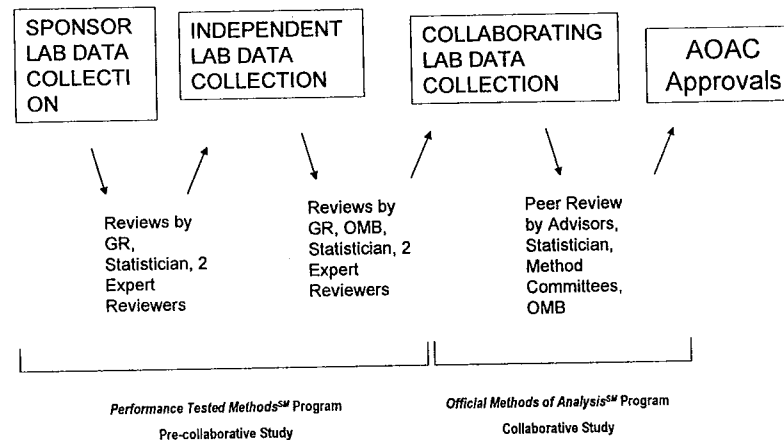
PHASE 3 - AOAC VALIDATION SCHEME OVERVIEW

Official MethodsSM of Analysis (OMA)



AOAC HARMONIZED VALIDATION SCHEME OVERVIEW

Performance Tested MethodsSM - Official Methods of AnalysisSM (PTM-OMA)



Question and Answer 3

- I heard that Methods Committees are going away.
 - The OMB adopted a more flexible, method-centric, community-based method committee structure.
 - Method Committees will be formed out of the communities and stakeholder groups as needed, last as long as is needed and will retire when its work is completed.

Method Submission

- Through the Communities
- Through an ERP
- Through a stakeholder group
- Through an individual method sponsor
- Through harmonized PTM-OMA program
- Through a contract agreement

Pool of Experts

- Communities are sources of:
 - Members for method committees
 - Members for Committee on Statistics
 - Members for Committee on Safety
 - Potential Topic Advisors
 - Potential General Referees or Process Experts
 - Potential candidates for Official Methods Board

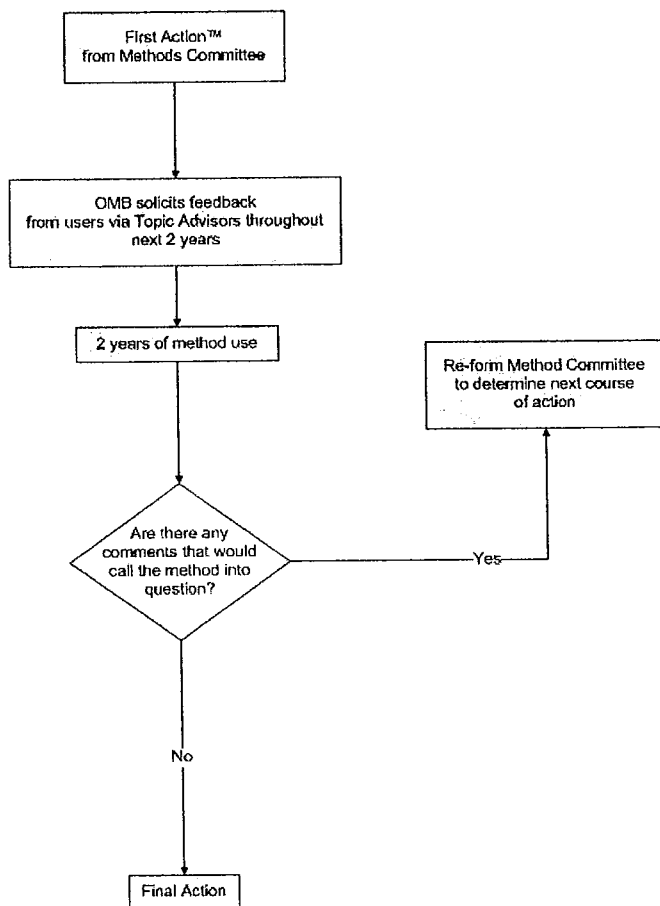
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First to Final Action

- Topic Advisors follow a First Action method collecting feedback on the method
 - Topic Advisors collect comments on first action methods for two years and presents comments to OMB
- Topic advisor will go to the users of the First Action method, the community members, to obtain feedback.

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OMB Overview of Feedback Process



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Documentation and Outcomes

- Stakeholder Panel Proceedings
- Fit-for-Purpose Statement(s)
- Performance Criteria/Standards
- Candidate Methods
- ERP Reports
- Validation Guidelines & Protocols
- Validation Manuscripts
- First Action Methods
- Method Committee Reports
- Topic Advisor Reports
- Final Action Methods

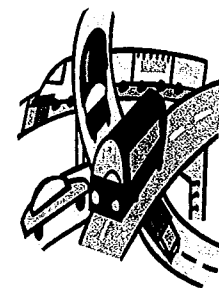
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Getting Started - Getting Involved

- If you are interested in getting involved or starting an AOAC analytical community
 - Please see Guidelines for Analytical Communities (available at community meetings)
- If you want to become a method volunteer and the roles available
 - Please see *Method Volunteer Appointment Process* (in your folder)
- If you are interested in submitting a method of analysis to the Official Method Program
 - Please see *Method Submission Process*
- If you are interested in more information about Single Laboratory Validation and/or Performance Tested Methods validation studies
 - Please see the Professional Development Course listing and other resources (in your folder)
- If you are interested in participating or starting a consensus body
 - Please contact AOAC Executive Office

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**Getting started is just a
click away....**



Thank
You

www.aoac.org

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