Appendix G: Procedures and Guidelines for the Use of AOAC Voluntary Consensus Standards to Evaluate Characteristics of a Method of Analysis

General Comments:

AOAC can't seem to decide what to do with the Communities and the language in this draft document is further reduction of their impact. The whole point of creating the Task Forces/Communities was to ensure the right methods are validated and that the validation is done properly and reviewed by appropriate experts. Both co-chairs of the Marine and Freshwater Toxins Community, Drs. James Hungerford and Ana Gago-Martinez, agree on the above feedback

CHAIR: Text added to include communities in ERP FORMATION section

Official Methods Board,

COMMENT (Line 4): The abbreviation OMB should be added

CHAIR: Abbreviation in text below not in heading (no change to document)

Expert Review Panels,

COMMENT (Line 5): The abbreviation ERP should be added

CHAIR: Abbreviation in text below not in heading (no change to document)

First and Final Action *Official Methods*℠

Since 2011, Expert Review Panels (ERPs) have been used to assess methods against Standard Method Performance Requirements (SMPR®). In 2021, after a decade of successful adoption of over one hundred Official Methods, the Official Methods Board (OMB) undertook a review to integrate and clarify the standards process, to ensure continued best practice, while recognizing and embracing flexibility to meet each community's needs as part of the Official Methods Program.

Definitions

Call for Methods: public announcement inviting method submissions for a given analyte and/or matrix.

Candidate Method: a method accepted into the Official Methods Program for possible adoption as First Action.

Evaluation Period: interval between adoption as First Action and consideration as Final Action during which further method validation or information gathering is undertaken.

First Action: AOAC First Action *Official Methods*.

Final Action: AOAC Final Action *Official Methods*.

Lead Reviewer: an ERP Voting Member charged with presenting in depth method reviews and making initial recommendations to the ERP.

Non-voting Observer: a contributing expert to scientific deliberations of ERP, however, is ineligible to vote during an ERP meeting.

Method Author: method developer or developer's representative who serves as primary contact throughout Official Method development.

Voting Member: scientific expert vetted by the OMB and selected to vote on motions as part of an ERP meeting.

COMMENT (Definitions): In "definitions" section should "ERP", "SMPR"," stakeholders", "non-voting observers", "evaluation period" and "method author" also be defined?

CHAIR: Some of these have been defined. Addition of Stakeholder in DEFINITIONS sections

OMB Oversight

The OMB serves the Association in a scientific and advisory capacity, including on the process

COMMENT (Line 31): Replace "on the process" with "the process"

CHAIR: Sentence edited in OMB OVERSIGHT section

of method adoption. As such the OMB is responsible for oversight of the Official Methods Program and ensures compliance to policies and procedures in the development of voluntary consensus standards.

COMMENT (Line 32): Insert a comma after "as such"
CHAIR: Done, see OMB OVERSIGHT section

See Figure 1 for process flowchart.

ERP Formation

An ERP is authorized to adopt candidate methods as First Action and to recommend subsequent adoption for Final Action status. Scientists are recruited to serve as ERP members or as ERP Chair through a public call or by recommendation by members of AOAC. Interested scientists are invited to submit their curriculum vitae (CV) for initial assessment by the AOAC Science Team, who then forward to the OMB evaluations and recommendations for formal review. Both the Science Team and OMB strive to ensure that the composition of a proposed ERP is both qualified and equitably representative of stakeholder groups. The OMB-approved ERP candidates are reviewed and appointed as ERP Members by the AOAC President.

COMMENT (Line 38-44): No mention of a Community role in recruitment of ERP members in the above text.
CHAIR: Add text on recommendations from relevant communities, see ERP FORMATION section

The Chair of an ERP serves as moderator for discussions, ensuring all relevant topics of a method are adequately discussed prior to a call for a vote.

ERP Requirements

(1) When established, an ERP shall consist of a minimum of 7 Voting Members representing a balance of stakeholders.
(2) A quorum is established by the presence of 7 Voting Members or 2/3 of total Voting Members, whichever is greater.
(3) The ERP must hold transparent public meetings.

Method Submission

Methods may be submitted by the Method Author at any time, although typically during the Call for Methods period. All submitted methods must be accompanied by validation data upon which the ERP can undertake a comprehensive review. Various method performance parameters may be required or expected by different ERPs depending upon the nature of the analytes, matrices, and techniques pertinent to the method.

COMMENT (Line 54): Insert "although typically they are inserted" during the....
CHAIR: The word “inserted” deemed in appropriate (no change to document)

Each community will assess the necessary forms that this validation may include, such as:

- range of matrices tested
- repeatability
- reproducibility
- other inter-laboratory precision
- recovery
- comparison to reference material
- comparison to reference method
- ruggedness/robustness
- specificity/selectivity

- linearity and/or analytical range
- limits of detection and/or quantitation ?
- stability
- inclusivity/exclusivity
- uncertainty
- probability of detection.

COMMENT (Line 59-74): This is the only text in the document that mentions Community input, namely specifying what parameters are required in a Method Submission. Communities need to have a larger role in methods approval than this

CHAIR: Text added to include communities in ERP FORMATION section. No other change made.

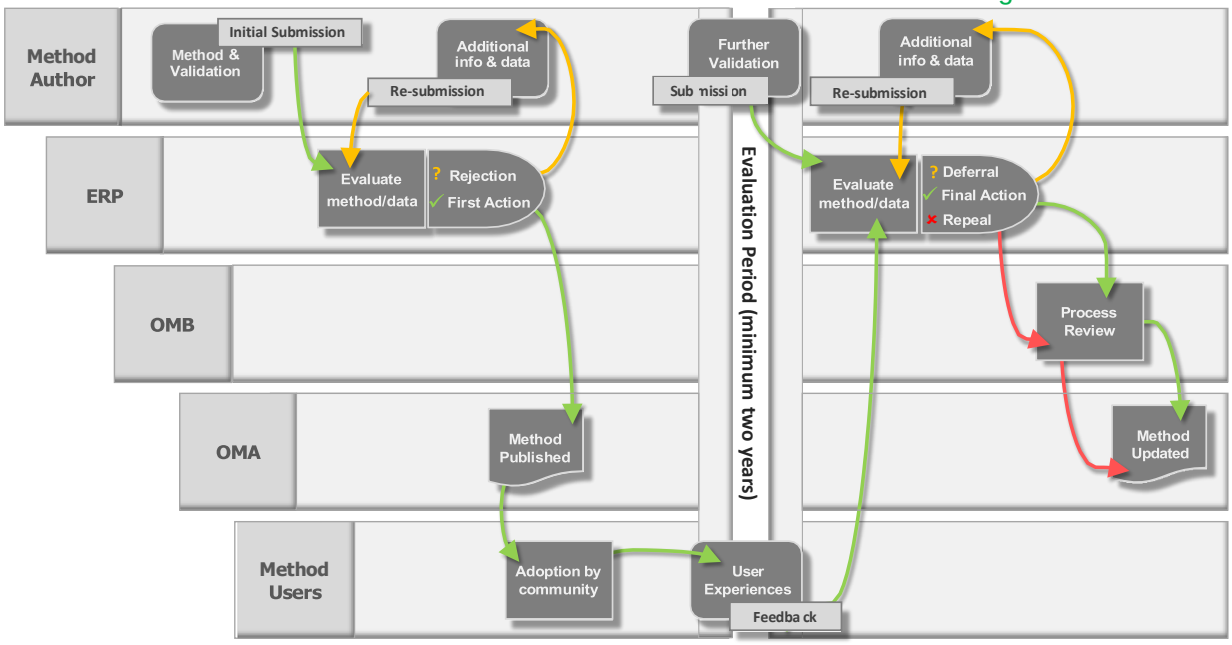

Figure 1. Process for development of voluntary consensus standards for methods of analysis within the AOAC Official Methods Program

COMMENT (Line 76): Very helpful visiual which shows each step of the process method developer/author to final acceptance and publication, plus a 2 year review period.

CHAIR: Okay.Note the text on figure for evaluation period "(minimum two years)" has been removed.

The minimum necessary parameters may be specified by the relevant community as part of SMPR development (*Official Methods of Analysis*, Appendix F: Guidelines for Standard Method Performance Requirements). Acceptable experimental designs used to collect this data may vary with the method protocol and the intended use of the method.

ERP Voting

Votes shall be cast by show of hands at in-person meetings and by roll call at virtual/remote meetings.

Abstentions

At the beginning of an ERP meeting when the agenda is confirmed, Voting Members shall declare any perceived or actual conflicts of interest to any agenda items on which a vote will be called. Such a declaration need not preclude a Voting Member from voting, and at that time, the ERP Chair will rule whether any Voting Member must abstain from voting on that particular agenda item based upon this declaration. All Voting Members and Non-voting Observers, whether they have a declared conflict or not, are freely able to share their expertise during the discussion period prior to the First Ballot.

Voting Members may need to abstain on motions pertaining to: (i) methods they have

authored or co-authored; (ii) methods from entities with which they are affiliated; or (iii) methods from other entities in which a conflict of interest has been identified.

Abstentions are not counted as a “yes” or “no” vote, but instead are a non-vote and contribute only toward establishing a quorum.

Duty to Vote

Unless required by the Chair to abstain, as experts Voting Members are expected to vote on

COMMENT (Line 99): Should say "Unless required by the Chair to Abstain, all expert voting members .....
CHAIR: Change made as suggested, see DUTY TO VOTE section

all motions. Any Voting Member who abstains on grounds other than a declared conflict of interest should delineate reasons. Where the number of abstentions exceeds 1/3 of the Voting Members present, the vote is declared invalid and must be retaken at a later date.

COMMENT (Line 99): "Any Voting Member who abstains on grounds other than a declared conflict of interest should delineate reasons." Can there be any grounds for abstaining (on either First or Second Ballot) other than conflicts of interest specified in Lines 93-95? If not, this clause allowing abstention should be removed.
CHAIR: Ultimately can’t stop members from abstaining for any reason. But being asked for their expert opinion reasonable to expect up or down vote but right to abstain s still afforded to members. The word “scientific” removed however, see FIRST BALLOT section.

First Ballot

(1) A motion shall pass the First Ballot only by unanimous affirmative vote of the ERP.
(2) A motion shall fail if negative votes exceed 1/3 of the vote.
(3) If neither (1) or (2) is achieved, scientific reasons must be delineated for negative votes. Following further discussion, a second ballot is taken.

COMMENT (Line 104): Optional wording:
(1) A unanimous affirmative vote of the ERP is required for a method to pass the First Ballot
(2) A motion fails if negative votes exceed 1/3 of the vote
CHAIR: Consistent wording between two clauses desired, no change made.

Second Ballot

After further discussion and consideration, and the motion shall pass in a Second Ballot by 2/3 or greater affirmative vote.

CHAIR: Text change by Methods Working Group for clarity.

Review of Methods for First Action

Methods submitted to AOAC are collected and compiled by the Science Team and are categorized as Candidate Methods and assigned a unique identifier.

An ERP meeting, open to all interested parties, is convened to review Candidate Method(s). Two (or more) ERP members may be assigned by the ERP Chair as Lead Reviewers to provide in depth, written reviews and to make a recommendation for First Action adoption, as appropriate. The merits and deficiencies of the Candidate Method are reviewed and discussed by the ERP, using the relevant SMPR (where applicable) as a guide.

COMMENT (Review of methods for first action): Does it need to indicate that the review info will be shared electronically as appropriate?
CHAIR: Details on mechanism of sharing information is not relevant to policy document, but may be necessary in future guidance document. No change made to document.

Down-selection

If the stakeholders have designated in the SMPR the need for a dispute resolution method, the ERP may identify a single candidate method as dispute resolution method.

COMMENT (Down selection): Where and when do stakeholders decide if a dispute resolution method is

needed – I thought this was the aim for all e.g., SIFAN methods so in that case is this not discussed? Should this be made clear?
CHAIR: Details on mechanism on how stakeholders/communities make this decision is not relevant to policy document, but may be necessary in future guidance document. No change made to document.

Requirements/Recommendations for Final Action

After First Action adoption, the ERP may choose to make specific requirements or recommendations to the Method Author. This information should be clearly delineated and approved by the ERP as official recommendations and/or requirements, to be revisited upon consideration for Final Action.

Candidate Method Resubmission

When a Candidate Method is not adopted as First Action, the ERP shall document its concerns with the methodology and/or associated validation data, the reasons for this decision, and any expected remedies necessary as part of resubmission of the method. This information should be clearly delineated and approved by the ERP as official recommendations and/or requirements.

COMMENT (Line 130): This information should be clearly delineated and approved by the ERP as official recommendations and/or requirements.
This information must ....
CHAIR: The words "should" or "shall" changed to "must" for clarity in CANDIDATE METHOD RESUBMISSION section and elsewhere in document.

Upon subsequent review(s), the ERP should focus on whether the Method Author has complied with the documented concerns from the initial ERP review. However, the ERP reserves the right to raise any issue at any time that may materially impact upon method fitness-for-purpose and/or ability to meet the requirements as defined in the applicable SMPR(s), regardless of whether this was raised in a previous review.

Publication of First Action Methods

Candidate Methods are not required to be submitted for ERP review in AOAC Official Methods format. However, subsequent to First Action adoption, AOAC Staff will support the Method Author in ensuring proper formatting of the method for publication in *Official Methods of Analysis*.

(1) A Candidate Method becomes First Action on the date when the ERP motion is passed.
(2) Methods must be drafted into AOAC format by the Method Author in collaboration with AOAC staff.

COMMENT (Line144): It is not clear whether each First/Final Action method needs to have precision data (RSDs) listed in OMA to avoid users from needing access to other documents.
CHAIR: The issue of what is to be included into the OMA method document is important and goes beyond just precision. However, this is outside scope of this policy document on Official Method development process. No change made.
COMMENT (Line 104): Methods must be drafted into AOAC format by the Method Author in collaboration with AOAC staff.
Does this mean it must be in AOAC format, or it must be in AOAC format only if drafted in collaboration with AOAC staff?
CHAIR: Text "in collaboration with AOAC staff" removed.

(3) The Official Method status decision is reported concurrently with the method in traditional AOAC publication venues.

As part of First Action publication in the *Official Methods of Analysis*, the method authors must have an accepted manuscript or published paper in a reputable scientific journal,

preferably the *Journal of AOAC INTERNATIONAL*, containing relevant validation data.

Evaluation Period

Methods remain as First Action for a minimum period of two years. During this Evaluation Period, the method undergoes further evaluation and validation studies. Users of First Action

COMMENT (Line 153): How is the information gathered? The first action review should also include grammatical, and other errors in the method that may be in conflict with approved AOAC style or requirements for VCSB methods

CHAIR: Text "Methods remain as First Action for a minimum period of two years. During this Evaluation Period, the method undergoes further evaluation and validation studies." Removed and substituted with "A First Action method undergoes additional evaluation and validation studies to be considered for Final Action status. The ERP will meet to consider the status of a First Action method following an evaluation period of two years, or earlier at the Method Authors' request."

methods are asked to provide feedback to AOAC or the Method Author on the performance of the method during the Evaluation Period, to include positive and negative feedback, as well as specific feedback about ruggedness. This feedback, as well as an assessment of future availability of vital equipment, reference materials, and supplies should be documented in a report by the Method Author for consideration by the ERP.

COMMENT (Line 157): Instead of "should" the information "must" be documented. The use of must would also apply to line 161

CHAIR: The words "should" or "shall" changed to "must" for clarity in EVALUATION PERIOD section and elsewhere in document.

Any additional validation data obtained during this period is to be collated by the Method Author and submitted to the ERP for review. Additionally, responses to requirements or recommendations made by the ERP at the time of First Action adoption should be submitted to the ERP for consideration.

For quantitative methods, data demonstrating reproducibility and uncertainty must be present for Final Action consideration. Experimental designs to collect this data may vary with the method protocol, available laboratories, and the intended use of the method (i.e., collaborative studies, proficiency testing, etc.). The ERP may consider other forms of information in lieu of the traditional collaborative study to demonstrate method reproducibility.

For qualitative methods, data demonstrating the probability of detection at specified concentration levels as applicable must be present for Final Action consideration. Experimental designs to collect this data may vary with the method protocol, available laboratories, and the intended use of the method.

COMMENT (Evaluation period): What happens to first action methods that do not progress after 2 years?

CHAIR: The fate of any methods introduced through this pathway is the responsibility of that ERP. Method submissions may be deferred or repealed. See DEFERRAL section. Text removed: "Subsequent reviews of a deferred First Action Method by the ERP must occur within two years." Text added: "Subsequent deferrals of a First Action Method by the ERP must be justified to OMB for continued retention of First Action status."

COMMENT (Evaluation period): The ERP may consider other forms of information in lieu of the traditional collaborative study to demonstrate method reproducibility." Give examples?

CHAIR: Text added: "such as proficiency data" added.

Review of Methods for Final Action

At the conclusion of the Evaluation Period, an ERP meeting is convened. Lead Reviewers will report to the ERP on assigned First Action methods and should assess any additional validation data or information provided during the Evaluation Period and make a

recommendation for deferral, repeal of First Action status, or adoption as Final Action.

Deferral

If, at the end of the Evaluation Period, the feedback from method users or additional validation data supplied by Method Author at the end of the Evaluation Period is deemed

COMMENT (Line 180): The phrase "at the end of the evaluation period" is repetitive.
CHAIR: Text: ”by Method Author at the end of the Evaluation Period” deleted.

inadequate or inconclusive, the ERP may choose to retain First Action status to allow time for further information or validation data to be acquired. The ERP should discuss strategies to obtain additional information to make an appropriate Final Action decision. Subsequent reviews of a deferred First Action Method by the ERP must occur within two years.

Repeal

At the end of the Evaluation Period, if the feedback from method users indicates that the performance of a First Action method in other laboratories is unacceptable; or if no further validation data is obtained, the ERP may vote to repeal the First Action status of a method.

Final Action

A recommendation for a method as Final Action is forwarded to the OMB and the method process undergoes a full procedural review and OMB approval.

OMB Review

The OMB will review all recommendations for Final Action adoption, deferral, or repeal by the ERP using applicable factors in their decision:

Procedural

- ERP recommendations and improvements completed
- Draft Final Action method reviewed by ERP
- Reference materials used
- Verify Community validation protocols followed
- Verify SMPR criteria met
- Feedback from users of method considered
- Statistics Committee review
- Safety and Security Committee review

Documentation

- Validation data
- Statistics Committee report
- Safety and Security Committee report
- User feedback
- External status
- ERP Report
- Impact statement from author
- Method in OMA format
- Manuscript(s) published or in press

The OMB may ask ERPs for further information on any potential points of concern.

Publication of Final Action Methods

As part of Final Action adoption, method authors must have an accepted manuscript or

published paper in a reputable scientific journal, preferably the *Journal of AOAC INTERNATIONAL*, containing relevant validation data.

Extensions of Scope

For methods which have attained Official Method status for an analyte or analytes in one or more matrices, an extension of scope may be sought such that the method would be considered as an Official Method for additional matrices or additional analytes. The validation required for an extension of method scope would typically be, as a minimum, the same as that required by the ERP for a method to obtain First Action status. However, the ERP may recommend alternative validation data to demonstrate that the extended method performs in the same manner as the method under its original scope. Each ERP should develop method extension guidelines to suit its needs.

Method Modifications

Modification to an Official Method may be editorial, minor, or major. Upon submission of a method modification application, AOAC staff identify editorial modifications and process changes through AOAC publications. The classification of minor and major modifications is made by the ERP following a public comment period.

Minor changes should not be expected to affect the current validated performance nor significantly affect measured results. Supporting information to justify the proposed modification must accompany a request for ERP review of a minor modification to an Official Method and equivalency data may be required to justify a method change.

Major modifications to a method will likely impact measured results or change method performance. This level of modification will result in the creation of a new method, with a new method number, and will follow the Official Methods Program guidance for voluntary consensus standards in same manner as any other new method.

Conclusion

This universal pathway to Official Methods is deliberately designed to avoid creation of elaborate review systems applicable only to each particular community within AOAC. The

COMMENT (Line 38-44): This reviewer is not aware of "…elaborate review systems applicable only to each particular community"
What is being referred to here?
CHAIR: Text modified to “This universal pathway to Official Methods has been designed to simplify and harmonize the method review process within AOAC”

intent of this universal pathway is to provide a single framework for experts in analytical sciences to apply their scientific knowledge, experience, and judgment in an evidenced-based manner to identify, review, and adopt the best methods currently available to meet the analytical needs of each community within AOAC INTERNATIONAL.

This guidance document was approved by the AOAC Board of Directors on MMM DD, YYYY