AOAC Official Methods Board
February 10-11, 2016
Teleconference

AOAC INTERNATIONAL
2275 Research Blvd, Suite 300
Rockville, MD 20850
1.301.924.7077

CONFERENCE CALL INFORMATION:
Dial in: 1-877-647-3411 (US/Canada)
Pass code: 373 523 5702 #

OFFICIAL METHODS BOARD MEETING

Wednesday & Thursday, February 10-11, 2016

9:00am – 5:00pm ET (Day One)
8:30am – 4:00pm (Day Two)

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AOAC BOARD OF DIRECTORS MEETING
March 14, 2016

AOAC SPSFAM MEETING
March 14, 2016

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March 15, 2016

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March 15, 2016

AOAC RI BOARD OF DIRECTORS MEETING
AOAC SPIFAN ERP
March 16, 2016

AOAC ERP FOR SPIFAN NUTRIENTS
March 16, 2016

AOAC ERP FOR MICROBIOLOGY METHODS
March 16, 2016

AOAC SPDS MEETING
March 17, 2016

AOAC SPDS WORKING GROUP MEETINGS FOR ALOE VERA, PROTEIN, & VITAMIN B_{12}
March 18, 2016

Calls for Methods
SPDS – Cinnamon, Aloin, Tea, Vitamin D

AOAC INTERNATIONAL
OFFICIAL METHODS BOARD

2015 – 2016

Chair	**Shauna Roman** Reckitt Benckiser, Inc. Shauna.Roman@reckittbenckiser.com Term 3: August 29, 2013 – September 21, 2016	*Member*	**Joe Boison** Canadian Food Inspection Agency Joe.Boison@inspection.gc.ca Term 1: August 29, 2013 – September 21, 2016
Member	**Doug Abbott** Independent Consultant douglas.abbott@gmail.com Term 2: September 11, 2014 - September 27, 2017	*Member*	**Don Gilliland** Abbott Nutrition don.gilliland@abbott.com Term 1: October 1, 2015 - September 29, 2018
Member	**Sneh Bhandari** Silliker, Inc. Sneh.Bhandari@Silliker.com Term 2: August 29, 2013 – September 21, 2016	*Member*	**Katerina Mastovska** Covance Laboratories Katerina.Mastovska@covance.com Term 1: October 1, 2015 - September 29, 2018
Member	**Jo Marie Cook** Florida Department of Agriculture and Consumer Services JoMarie.Cook@freshfromflorida.com Term 2: August 29, 2013 – September 21, 2016	*Member*	**Tom Phillips** Maryland Department of Agriculture phillitd@mda.state.md.us Term 2: August 29, 2013 – September 21, 2016
Member	**Erin Sutphin Crowley** Q Laboratories, Inc. ecrowley@qlaboratories.com Term 2: October 1, 2015 - September 29, 2018	*Member*	**Bradley Stawick** Microbac Laboratories, Inc. brad.stawick@microbac.com Term 2: October 1, 2015 - September 29, 2018
Member	**Qian Graves,** US FDA *AOAC Committee on Statistics, Chair* Qian.graves@fda.hhs.gov Term 2: August 29, 2013 – September 21, 2016	*Member*	**Yvonne Salfinger,** Independent Consultant *AOAC Committee on Safety, co-Chair* Yhale@aol.com Term 1: August 29, 2013 – September 21, 2016
Past Chair (Ex-officio Member)	**John Szpylka** Silliker, Inc. John.Szpylka@Silliker.com Term 4: August 29, 2013 – September 21, 2016		

AOAC Staff Liaisons

Deborah McKenzie Sr. Director- Standards Development Sr. Director- AOAC Research Institute dmckenzie@aoac.org	Delia Boyd Program Manager – Standards Development dboyd@aoac.org

AOAC INTENATIONAL Terms begin following the AOAC Business Meeting. Terms expire at the AOAC Business Meeting. Version 2

AOAC INTERNATIONAL
The Scientific Association Dedicated to Analytical Excellence®

MEMORANDUM

Date: **February 10, 2016**

To: **AOAC INTERNATIONAL Official Methods Board**

From: **Deborah McKenzie, Staff Liaison – AOAC Official Methods Board**

Subject: **Item I.b. Call to Order/Introductions/Announcements**
Item I.c. Review of Policy Documents/Terms of Reference

Shauna Roman will call the meeting to order, initiate introductions, make any announcements and bring the group's attention to the AOAC Policies and Procedures by which the meeting will be conducted.

Enclosed: AOAC Policy Documents and AOAC OMB Terms of Reference

AOAC INTERNATIONAL
BYLAWS

As Amended September 26, 2010

ARTICLE I
Name

The name by which this Association shall be known is "AOAC INTERNATIONAL" (hereinafter referred to as the "Association").[1]

ARTICLE II
Purpose

The primary purpose of the Association is to promote methods validation and quality measurements in the analytical sciences.

ARTICLE III
Membership

Section 1. Types of Membership

There shall be three (3) types of membership in the Association: Individual Members, Sustaining Member Organizations, and Organizational Affiliates.

A. Individual Members

There shall be four (4) categories of Individual Members in the Association: Members, Retired Members, Student Members, and Honorary Members.

B. Sustaining Member Organizations

There shall be one (1) category of Sustaining Member Organizations.

C. Organizational Affiliate

There shall be one (1) category of Organizational Affiliate.

Section 2. Qualifications for Membership

A. Individual Members

[1] Members

Qualifications for Members shall be a degree in science, or equivalent as approved by the Board of Directors, and interest in supporting and furthering the purpose and goals of the Association. Such scientists shall be eligible for membership provided they are engaged, or have been engaged, directly or indirectly, in a field relevant to the purpose of the Association.

[2] Retired Members

[1] AOAC INTERNATIONAL was incorporated in the District of Columbia on January 20, 1932, as the Association of Official Agricultural Chemists. On November 10, 1965, the name of the corporation was changed to the Association of Official Analytical Chemists, and on September 12, 1991, the current name was adopted.

A current Member who is no longer actively engaged, directly or indirectly, in a field relevant to the purpose of the Association but who has served the Association as a Member for at least ten (10) years shall be eligible for Retired Member status upon written request and payment of the annual Retired Member dues. Any special benefits accorded Retired Members shall be determined by the Executive Director.

[3] Student Members

Any full-time student working toward an undergraduate or graduate degree in the areas of chemistry, microbiology, food science or other related science shall be eligible for Student Membership in AOAC INTERNATIONAL.

[4] Honorary Members

Honorary Members shall be persons recognized for their substantial contribution toward the achievement of the objectives of the Association. They shall be nominated by the Board of Directors and may be elected by a two-thirds vote of the Individual Members voting.

B. Sustaining Member Organizations

A Sustaining Member Organization shall be any agency of a local, state, provincial, national, or international government; a university, college, or academic department; or any firm, business, or organization with an interest in supporting and furthering the purpose of the Association. Every Sustaining Member Organization must have a designated representative(s). All such Sustaining Member Organization representatives must meet the qualifications for Members and become Individual Members with all the rights and privileges thereof.

C. Organizational Affiliate

An Organizational Affiliate Organization shall be any agency of a local, state, provincial, national, or international government; a university, college, or academic department; or any firm, business, or organization with an interest in supporting and furthering the purpose of the Association. Every Organizational Affiliate must have a designated representative(s). All such Organizational Affiliate representatives must meet the qualifications for Members and become Individual Members with all the rights and privileges thereof.

Section 3. Application for Membership

Applications or requests for membership shall be submitted to the Association's headquarters office. Membership shall become effective upon approval of the application or request, payment of any required membership dues, entry on the membership rolls, and assignment of a member number.

Section 4. Expulsion

The Board of Directors, at any duly called meeting of the Board, by a two-thirds vote of those holding office, may terminate the membership of any member who in its judgment has violated the Bylaws or has been guilty of conduct detrimental to the best interests of the Association. Any member convicted of a felony is subject to immediate expulsion from the Association. Expulsion of a member by the Board of Directors shall be final and shall cancel all rights, interest, or privileges of such member in the services or resources of the Association. Any member, for whom expulsion is proposed, for reasons other than conviction of a felony, shall be entitled to not less than 60 days advance notice of the charges, the date upon which a hearing will be scheduled, and the right to present evidence in defense. The date and place of any such hearing, if held other than at the headquarters or annual meeting site of the Association, must be reasonable with respect to the location of any individual so charged.

Section 5. Dues, Membership Year, and Waivers

A. Annual dues for membership in the Association shall be fixed by the Board of Directors, subject to approval by the majority of the Individual Members voting by ballot by any of the following means (whichever is deemed appropriate by the Board at the time): mail, telephone call, telegram, cablegram, electronic mail or other means of electronic or telephonic transmission.

B. Honorary Members of the Association shall be exempt from payment of dues and annual meeting registration fees.

C. The membership year and the delinquency date shall be determined by the Board of Directors.

D. The authority to grant waivers of membership dues rests with Executive Director.

E. Student Member dues shall be one-third of regular Member dues, rounded up to the nearest $5.00 increment.

Section 6. Members in Good Standing; Rights and Privileges

All Individual Members who maintain their membership by payment of dues as required under these Bylaws and who otherwise qualify shall be considered in good standing and entitled to full privileges of membership.

ARTICLE IV
Officers

Section 1. Elected Officers

The elected officers of the Association shall be Individual Members and shall consist of a President, President-Elect, Secretary, Treasurer, and Immediate Past President.

A. President

The President shall be the principal elected officer of the Association, shall preside at meetings of the Association and of the Board of Directors and of the Executive Committee, and shall be a member ex-officio, with right to vote, of all committees except the Nominating Committee. He or she shall also, at the annual meeting of the Association and at such other times as he or she shall deem proper, communicate to the Association or the Board of Directors such matters and make such suggestions as may in his or her opinion tend to promote the welfare and further the purpose of the Association and shall perform such other

duties as are necessarily incident to the office of President or as may be prescribed by the Board of Directors.

B. President-Elect

In the absence of the President, or in the event of the President's inability or refusal to act, the President-Elect shall perform the duties of the President, and, when so acting, shall have all the powers of and be subject to all the restrictions upon the President. The President-Elect shall perform such other duties as from time to time may be assigned to him or her by the President or by the Board of Directors.

C. Secretary

The Secretary shall give notice of all meetings of the Association, keep a record of all proceedings, attest documents, and, in general, perform such other duties as are usual of the office of Secretary and such other duties as may be assigned by the President or by the Board of Directors.

D. Treasurer

The Treasurer shall be responsible for the funds and securities of the Association; serve as financial officer of the organization and as Chairperson of the Finance Committee; manage the Board of Director's review of and action related to the Board of Director's financial responsibilities; serve as the chief Board liaison in overseeing and reviewing the annual audit, and in general, perform such other duties as are usual of the office of Treasurer and such other duties as may be assigned by the President or by the Board of Directors.

E. Immediate Past President

The Immediate Past President shall serve as advisor to the President and Directors and perform such other duties as may be assigned from time to time by the President or by the Board of Directors.

Section 2. Appointed Officers

The appointed officers shall include the Executive Director and such other appointed officers as may be designated by the Board of Directors from time to time.

A. Executive Director

The day-to-day administration and management of the Association's offices shall be vested in a salaried manager employed or appointed by, and directly responsible to, the Board of Directors. This manager shall have the title of Executive Director with responsibility for the management and direction of all operations, programs, activities, and affairs of the Association, as approved or delegated by the Board of Directors. The Executive Director shall have direct responsibility for employment and termination of employment and the determination of compensation for staff members within the budgetary framework determined by the Board of Directors. The Executive Director functions as the chief operating officer of the Association within the guidelines established by the policies and procedures of the Board of Directors and, as necessary, with the concurrence of the President. The Executive Director shall have such other duties as may be prescribed by the Board.

B. Other Appointed Officers

Other appointed officers shall have such duties as may be prescribed by the Board.

ARTICLE V
Nominations, Elections, Terms, and Appointments to the Board of Directors

Section 1. Nominating Committee

The Nominating Committee shall annually recommend to the Board of Directors a slate of Individual Members as potential nominees for the elected positions where vacancies will occur. The Nominating Committee shall consist of five (5) members who shall be three (3) immediate Past Presidents, as available, and two (2) Individual Members-at-Large of the Association. If three Past Presidents are not available to serve, other Individual Members-at-Large shall be appointed by the President to the extent necessary to form the five (5)-member committee.

Section 2. Elections and Terms of Office

The President-Elect, the Secretary, Treasurer, and the Directors of the Board of Directors shall be elected by a majority of Individual Members voting, from a slate of nominees recommended annually by the Board of Directors.

Terms of office for all Officers and Directors shall begin with the adjournment of the annual meeting following their election and shall end with the adjournment of the annual meeting occurring nearest the expiration of their term. The six (6) Directors shall be elected to staggered three-year terms with two Directors elected to full three-year terms each year, but not to more than two (2), consecutive, three-year terms. Appointment or election to fill an unexpired term shall not affect the eligibility of a person to subsequently be elected to two (2) full terms. The Secretary shall be elected to a one-year term and may be re-elected to successive one-year terms. The Treasurer shall be elected for a one-year term and may be re-elected to successive one-year terms. The President-Elect shall be elected to a one-year term; whereupon the current President-Elect shall become President and the current President shall become the Immediate Past President, each serving a one-year term.

Section 3. Appointments

Directors-at-Large are appointed by the Board in accordance with Article VI, Section 2. Directors-at-Large are appointed for one (1) year terms, renewable at the discretion of the elected Board.

ARTICLE VI
Board of Directors

Section 1. Composition

The Board of Directors shall consist of eleven (11) elected members to include the President, President-Elect, Secretary, Treasurer, Immediate Past President, six (6) Directors, and up to three (3) appointed Directors-at-Large, all of whom shall be Individual Members of the Association. The elected Board shall reflect the makeup of the Association membership and shall not be dominated by any single interest.

Section 2. Powers and Duties

The Board of Directors shall provide supervision, control, and direction of the affairs of the Association, shall determine the Association's policies or changes therein within the limits of the Bylaws, shall actively prosecute

its purpose, and shall have discretion in the disbursement of its funds. It may adopt such rules and procedures for the conduct of its business as shall be deemed advisable, and may, in the execution of the powers granted, appoint such agents as it may consider necessary. The Board of Directors may appoint up to three (3) Directors-at-Large, if, in their opinion, such appointments advance the purpose of the Association. Directors-at-Large shall be accorded the same voting privileges as elected Directors.

Section 3. Meetings

Except that the Board shall have a regular meeting at the time and place of the annual meeting, the Board shall meet, in person or via telephone conference call, upon call of the President at such times and places as he or she may designate within the policies adopted by the Board, and shall be called to meet upon demand of a majority of its members. Notice of all meetings of the Board of Directors shall be sent by any of the following means (whichever is deemed appropriate by the President at the time): mail, telephone call, telegram, cablegram, electronic mail or other means of electronic or telephonic transmission to each member of the Board at his or her last recorded address or number at least fourteen (14) days in advance of in-person meetings or forty-eight (48) hours in advance of conference call meetings.

Section 4. Quorum

A quorum for any meeting of the Board is six (6) Board members elected in accordance with Article V (1). Any less number may: (1) set a time to adjourn, (2) adjourn, (3) recess, or (4) take measures to obtain a quorum.

Section 5. Absence

Any member of the Board of Directors unable to attend a meeting of the Board shall notify the President and state the reason for his or her absence. If a member of the Board is absent from two (2) consecutive meetings, he or she may be removed by a two-thirds vote of the Board Members then in office.

Section 6. Compensation

Members of the Board of Directors, as such, shall not receive any compensation for their services as Board members, but the Board may, by resolution under policies it may adopt, authorize reimbursement of expenses incurred in the performance of members' duties. Such authorization may prescribe conditions and procedures for approval and payment of such expenses. Nothing herein shall preclude a Board member from serving the Association in any other capacity and receiving compensation for such services, if compensation is customarily paid for such services.

Section 7. Resignation or Removal

Any member of the Board may resign at any time by giving written notice to the President, Secretary, Treasurer, or to the Board of Directors. Such resignation shall take effect at the time specified therein, or, if no time is specified, at the time of acceptance thereof as determined by the President or the Board.

Any member of the Board may be removed by a three-fourths vote of the Board members then in office and present at any regular or special meeting of the Board.

Section 8. Vacancies: Members of the Board

If a vacancy should occur in the membership of the elected Board of Directors, any Past President may be appointed by action of the remaining members of the Board to temporarily fill such vacancy until the next

regularly scheduled election. At the next regularly scheduled election nominations will be presented to fill the vacancy for the unexpired portion of the term remaining.

Section 9. Vacancies: President and Other Officers

If the office of the President shall become vacant, the President-Elect shall thereupon become President of the Association for the unexpired term, followed by his or her duly elected term. In the event the office of President becomes vacant at a time when the office of President-Elect is also vacant, the Presidency shall be filled for the remainder of the term by the action of the Board of Directors. If any other officer position shall become vacant, the office may be filled for the remainder of the term by action of the Board.

ARTICLE VII
Committees

Section 1. Committee Formation

The Board of Directors shall form and adopt terms of reference for such standing or special boards, committees, subcommittees, task forces, or task groups as may be required by these Bylaws or as the Board may determine necessary to carry out the affairs of the Association.

Section 2. Committee Appointments

Subject to the requirements of these Bylaws and the specific terms of reference adopted by the Board, the President shall make the appointments to fill the vacancies occurring in the Association's standing or special boards, committees, subcommittees, task forces, or task groups.

ARTICLE VIII
Official Methods of Analysis

The Board of Directors (BoD) is empowered to develop written policies and procedures for the study, adoption, and change in status of the Official Methods of Analysis of AOAC INTERNATIONAL. Implementation of the policies and procedures shall be delegated to an Official Methods Board (OMB).

Section 1. Composition of the Official Methods Board

The Official Methods Board shall consist of a chair and a vice chair, and members who are recommended by the chair. The chair, vice chair and members are appointed by the President of AOAC INTERNATIONAL. The OMB shall be composed of members representing a balance of government, industry, and academia as appropriate to the scope of the group and shall not be dominated by any single interest.

Section 2. Purpose of the Official Methods Board

The OMB shall serve the Association in a scientific and advisory capacity on methods and the process of their adoption. The OMB shall be responsible for implementation of procedures adopted by the BoD, according to the principles in section 3 below.

Section 3. Principles of the Official Methods Program

A. Adequate records of technical data, discussions, and decisions on the study, adoption, and change of status of Official Methods of Analysis shall be maintained for a reasonable time.

B. Timely notice of proposed method studies, adoption, or change in status shall be published in an Association publication that is circulated to the members.

C. Opportunity shall be provided for materially interested parties to submit input during method study and adoption procedures and to submit comments on the adoption, use of, or change in status of specific methods.

D. Methods submitted to the OMB for inclusion in the OMA shall be thoroughly studied, scientifically reviewed, and available in published form prior to adoption as Final Action by the OMB.

E. The OMB shall adopt methods as Final Action.

ARTICLE IX
Meetings

Section 1. Annual Meeting

The annual business meeting of the Association shall be held at the time and place decided by the Board of Directors. A special meeting of the entire Association may be called by the Board of Directors; announcement thereof shall be made at least thirty (30) days prior to the time of said meeting.

Section 2. Quorum

One hundred Individual Members who are present in person or by proxy and entitled to vote shall constitute a quorum at any meeting of the Association which is duly called pursuant to the provisions of these Bylaws.

ARTICLE X
Voting

Section 1. Voting by Ballot

By direction of the Board of Directors, unless otherwise required by these Bylaws or conducted under alternative procedures established under these Bylaws, voting on any matter, including the election of officers and directors, the election of Honorary Members, amendment of the Bylaws, and the approval of dues, may be conducted by ballot of the voting membership by any of the following means (whichever is deemed appropriate at the time): mail, telephone call, telegram, cablegram, electronic mail or other means of electronic or telephonic transmission, and the question(s) thus presented shall be determined according to the votes received, provided in each case votes of at least five (5) percent of the voting membership shall be received. Any and all action taken in pursuance of a vote by any of the means indicated above (whichever the Board deemed appropriate at the time)

in each case shall be binding upon the Association in the same manner as would be action taken at a duly called meeting and shall become effective, unless otherwise provided for in these Bylaws or otherwise stated in the ballot, on the day following certification of the vote.

Section 2. Voting by Proxy

At any duly called meeting of Individual Members, a member-of-record, as determined thirty (30) days prior to any meeting and who is entitled to vote, may vote by proxy executed in writing by the Individual Member or his or her duly authorized attorney-in-fact. No proxy shall be valid for more than eleven (11) months after the date of its execution unless otherwise provided in the proxy.

ARTICLE XI
Earnings and Assets

Section 1. Non-Profit Status

A. Regardless of any provision of the Bylaws which may be construed otherwise:

[1] No part of the net earnings of the Association shall under any circumstances inure to the benefit of any member or individual.

[2] The Association shall not be operated for a private profit.

B. On lawful dissolution of the Association and after settlement of all just obligations of the Association, the Board of Directors shall distribute all remaining assets of the Association to one (1) or more organizations selected by the Board of Directors which have been held exempt from Federal Income Tax as organizations described in section 501(c)(3) of the Internal Revenue Code of 1954.

Section 2. Political Activities

A. No substantial part of the Association's activities shall consist of carrying on propaganda or otherwise attempting to influence local, state, or national legislation. All activities of the Association shall be determined by the Board of Directors.

B. The Association shall not participate or intervene in any manner in any campaign on behalf of any candidate for a political office.

ARTICLE XII
Sections

Section 1. Sections

The Board of Directors shall set geographic limits and grant authority to groups of Individual Members of the Association residing or working in the same geographical areas for the establishment of Sections.

Section 2. Purpose of Sections

The purpose of Sections shall be to promote and further the purpose of the Association.

Section 3. Membership in Sections

Individuals interested in the purpose of the Section shall be eligible for Section membership. Only Individual Members of the Association shall be eligible for election to the Executive Committee of the Section.

Section 4. Bylaws of Sections

Subject to approval of the Board of Directors, each Section shall adopt, for its own governance, bylaws not inconsistent with these Bylaws.

Section 5. Dissolution of Sections

When any Section shall cease to function as a Section for a period of more than one year, or if its membership shall be less than ten (10) Individual Members of the Association for a period of one (1) year, the Board of Directors may terminate the existence of such Section.

Section 6. Actions of Sections

No act of a Section or its members shall be considered an act of the Association unless expressly authorized, ratified, or affirmed by the Board of Directors.

ARTICLE XIII
Technical Divisions

Section 1. Purpose

Technical Divisions shall represent communities of interest within the Association which have the purpose of furthering the purpose of the Association through the development of the analytical sciences either in a commodity-based or scientific discipline-based field. Their activities shall not duplicate the organizational structure nor conflict with the policies or procedures for the adoption of official methods of analysis by the Association.

Section 2. Creation, Combination, Discontinuance, or Change

Technical Divisions may be created, existing Technical Divisions may be combined or discontinued, or the name of a Technical Division may be changed under policies and procedures adopted by the Board of Directors. Each Technical Division shall adopt bylaws not inconsistent with these Bylaws. The jurisdiction of each Technical Division shall be described in its bylaws. No act of any Technical Division or its members shall be considered an act of the Association unless expressly authorized, ratified, or affirmed by the Board of Directors.

ARTICLE XIV
Indemnification

The Association shall have the power to pay, by indemnity, reimbursement, or otherwise, to or for the use of any person designated by resolution of the Board of Directors who was or is a party or is threatened to be made a party to any threatened, pending, or completed action, suit, or proceeding, whether civil, criminal, administrative, or investigative (other than an action by or on behalf of the Association), by reason of the fact he or she is or was a director, officer, committee member, employee or agent of the Association, or was serving as such for another at the request of the Association, against expenses (including legal, accounting, witness and other), judgments, fines, and amounts paid in settlement so long as such person was not found by a court of competent jurisdiction to have been willfully negligent of the interests of the Association or such person had reasonable cause to believe that his or her conduct was lawful.

ARTICLE XV
Parliamentary Authority

The rules contained in the current edition of *Robert's Rules of Order Newly Revised* shall govern the Association in all cases in which they are applicable and in which they are not inconsistent with these Bylaws or any special rules of order the Association may adopt.

ARTICLE XVI
Amendments to the Bylaws

These Bylaws may be amended, repealed, or altered, in whole or in part, by a three-fourths vote: (a) of the Individual Members at any annual business or duly called special meeting of the Association, provided notice of any amendment proposed for consideration shall be sent by any of the following means (whichever may be deemed appropriate at the time): mail, telephone call, telegram, cablegram, electronic mail or other means of electronic or telephonic transmission to the last recorded address or number of each Individual Member at least thirty (30) days prior to the date of the meeting; or (b) by approval of the Individual Members through ballot sent by any means indicated above in accordance with the provisions of Article X, Voting.

All proposed amendments of these Bylaws shall be presented in writing to the Board of Directors. The Board shall present the proposals to the Association membership, with recommendations. All amendments to the Bylaws, unless otherwise stated, will become effective at the adjournment of the meeting where action is taken or on the day following the certification of a vote by mail ballot.

AOAC INTERNATIONAL
POLICY ON THE USE OF THE
ASSOCIATION NAME, INITIALS,
IDENTIFYING INSIGNIA, LETTERHEAD, AND BUSINESS CARDS

Introduction

The following policy and guidelines for the use of the name, initials, and other identifying insignia of AOAC INTERNATIONAL have been developed in order to protect the reputation, image, legal integrity and property of the Association.

The name of the Association, as stated in its bylaws, is "AOAC INTERNATIONAL". The Association is also known by its initials, AOAC, and by its logo, illustrated below, which incorporates the Association name and a representation of a microscope, book, and flask. The AOAC logo is owned by the Association and is registered with the U.S. Patent and Trademark Office.

AOAC INTERNATIONAL

The full Association insignia, illustrated below, is comprised of the logo and the tagline, "The Scientific Association Dedicated to Analytical Excellence," shown below. The typeface used is Largo. The AOAC tagline is owned by the Association and is registered with the U.S. Patent and Trademark office.

AOAC INTERNATIONAL

The Scientific Association Dedicated to Analytical Excellence®

Policy

Policy on the use of the Association's name and logo is established by the AOAC Board of Directors as follows:

> "The Board approves and encourages reference to the Association by name, either as AOAC INTERNATIONAL or as AOAC; or reference to our registered trademark, AOAC®, in appropriate settings to describe our programs, products, etc., in scientific literature and other instances so long as the reference is fair, accurate, complete and truthful and does not indicate or imply unauthorized endorsement of any kind.
>
> The insignia (logo) of AOAC INTERNATIONAL is a registered trade and service mark and shall not be reproduced or used by any person or organization other than the Association, its elected and appointed officers, sections, or committees, without the prior written permission of the Association. Those authorized to use the AOAC INTERNATIONAL insignia shall use it only for the purposes for which permission has been specifically granted.
>
> The name and insignia of the Association shall not be used by any person or organization in any way which indicates, tends to indicate, or implies AOAC official endorsement of any product, service, program, company, organization, event or person, endorsement of which, has not been authorized by the Association, or which suggests that membership in the Association is available to any organization."

The Executive Director, in accordance with the above stated policy, is authorized to process, approve, fix rules, and make available materials containing the Association name and insignia.

It should be noted that neither the Association's name nor its insignia nor part of its insignia may be incorporated into any personal, company, organization, or any other stationery other than that of the Association; nor may any statement be included in the printed portion of such stationery which states or implies that an individual, company, or other organization is a Member of the Association.

Instructions

1. Reproduction or use of the Association name or insignia requires prior approval by the Executive Director or his designate.

2. Association insignia should not be altered in any manner without approval of the Executive Director or his designate, except to be enlarged or reduced in their entirety.

3. Artwork for reproducing the Association name or insignia, including those incorporating approved alterations, will be provided on request to those authorized to use them (make such requests to the AOAC Marketing Department). Examples of the types of alterations that would be approved are inclusion of a section name in or the addition of an officer's name and address to the letterhead insignia.

4. When the Association name is used without other text as a heading, it should, when possible, be set in the Largo typeface.

5. Although other colors may be used, AOAC blue, PMS 287, is the preferred color when printing the AOAC insignia, especially in formal and official documents. It is, of course, often necessary and acceptable to reproduce the insignia in black.

6. Do not print one part of the logo or insignia in one color and other parts in another color.

7. The letterhead of AOAC INTERNATIONAL shall not be used by any person or organization other than the Association, its elected and appointed officers, staff, sections, or committees; except by special permission.

   Correspondence of AOAC official business should be conducted using AOAC letterhead. However, those authorized to use AOAC letterhead shall use it for official AOAC business only.

   Copies of all correspondence using AOAC letterhead or conducting AOAC official business, whether on AOAC letterhead or not, must be sent to the appropriate office at AOAC headquarters.

8. AOAC INTERNATIONAL business cards shall not be used by any person or organization other than the Association, its staff, and elected officials, except by special permission.

   Those authorized to use AOAC business cards shall use them for official AOAC business only and shall not represent themselves as having authority to bind the Association beyond that authorized.

Sanctions

1. Upon learning of any violation of the above policy, the Executive Director or a designate will notify the individual or organization that they are in violation of AOAC policy and will ask them to refrain from further misuse of the AOAC name or insignia.

2. If the misuse is by an Individual Member or Sustaining Member of the Association, and the misuse continues after notification, the Board of Directors will take appropriate action.

3. If continued misuse is by a nonmember of the Association or if a member continues misuse in spite of notification and Board action, ultimately, the Association will take legal action to protect its property, legal integrity, reputation, and image.

* * * * * *

Adopted by the AOAC Board of Directors: September 24, 1989
Revised: June 13, 1991; February 26, 1992; March 21, 1995; October 1996

AOAC INTERNATIONAL
ANTITRUST POLICY
STATEMENT AND GUIDELINES

Introduction

It is the policy of AOAC INTERNATIONAL (AOAC) and its members to comply strictly with all laws applicable to AOAC activities. Because AOAC activities frequently involve cooperative undertakings and meetings where competitors may be present, it is important to emphasize the on_going commitment of our members and the Association to full compliance with national and other antitrust laws. This statement is a reminder of that commitment and should be used as a general guide for AOAC and related individual activities and meetings.

Responsibility for Antitrust Compliance

The Association's structure is fashioned and its programs are carried out in conformance with antitrust standards. However, an equal responsibility for antitrust compliance __ which includes avoidance of even an appearance of improper activity __ belongs to the individual. Even the appearance of improper activity must be avoided because the courts have taken the position that actual proof of misconduct is not required under the law. All that is required is whether misconduct can be inferred from the individual's activities.

Employers and AOAC depend on individual good judgment to avoid all discussions and activities which may involve improper subject matter and improper procedures. AOAC staff members work conscientiously to avoid subject matter or discussion which may have unintended implications, and counsel for the Association can provide guidance with regard to these matters. It is important for the individual to realize, however, that the competitive significance of a particular conduct or communication probably is evident only to the individual who is directly involved in such matters.

Antitrust Guidelines

In general, the U.S. antitrust laws seek to preserve a free, competitive economy and trade in the United States and in commerce with foreign countries. Laws in other countries have similar objectives. Competitors (including individuals) may not restrain competition among themselves with reference to the price, quality, or distribution of their products, and they may not act in concert to restrict the competitive capabilities or opportunities of competitors, suppliers, or customers.

Although the Justice Department and Federal Trade Commission generally enforce the U.S. antitrust laws, private parties can bring their own lawsuits.

Penalties for violating the U.S. and other antitrust laws are severe: corporations are subject to heavy fines and injunctive decrees, and may have to pay substantial damage judgments to injured competitors, suppliers, or customers. Individuals are subject to criminal prosecution, and will be punished by fines and imprisonment.
Under current U.S. federal sentencing guidelines, individuals found guilty of bid rigging, price fixing, or market allocation must be sent to jail for at least 4 to 10 months and must pay substantial minimum fines.

Since the individual has an important responsibility in ensuring antitrust compliance in AOAC activities, everyone should read and heed the following guidelines.

1. Don't make any effort to bring about or prevent the standardization of any method or product for the purpose or intent of preventing the manufacture or sale of any method or product not conforming to a specified standard.

2. Don't discuss with competitors your own or the competitors' prices, or anything that might affect prices such as costs, discounts, terms of sale, distribution, volume of production, profit margins, territories, or customers.

3. Don't make announcements or statements at AOAC functions, outside leased exhibit space, about your own prices or those of competitors.

4. Don't disclose to others at meetings or otherwise any competitively sensitive information.

5. Don't attempt to use the Association to restrict the economic activities of any firm or any individual.

6. Don't stay at a meeting where any such price or anti_competitive talk occurs.

7. Do conduct all AOAC business meetings in accordance with AOAC rules. These rules require that an AOAC staff member be present or available, the meeting be conducted by a knowledgeable chair, the agenda be followed, and minutes be kept.

8. Do confer with counsel before raising any topic or making any statement with competitive ramifications.

9. Do send copies of meeting minutes and all AOAC_related correspondence to the staff member involved in the activity.

10. Do alert the AOAC staff to any inaccuracies in proposed or existing methods and statements issued, or to be issued, by AOAC and to any conduct not in conformance with these guidelines.

Conclusion

Compliance with these guidelines involves not only avoidance of antitrust violations, but avoidance of any behavior which might be so construed. Bear in mind, however, that the above antitrust laws are stated in general terms, and that this statement is not a summary of applicable laws. It is intended only to highlight and emphasize the principal antitrust standards which are relevant to AOAC programs. You must, therefore, seek the guidance of either AOAC counsel or your own counsel if antitrust questions arise.

* * * * *

Adopted by the AOAC Board of Directors: September 24, 1989
Revised: March 11, 1991
Revised October 1996

AOAC INTERNATIONAL

POLICY AND PROCEDURES ON

VOLUNTEER CONFLICT OF INTEREST

Statement of Policy

While it is not the intention of AOAC INTERNATIONAL (AOAC) to restrict the personal, professional, or proprietary activities of AOAC members nor to preclude or restrict participation in Association affairs solely by reason of such activities, it is the sense of AOAC that conflicts of interest or even the appearance of conflicts of interest on the part of AOAC volunteers should be avoided. Where this is not possible or practical under the circumstances, there shall be written disclosure by the volunteers of actual or potential conflicts of interest in order to ensure the credibility and integrity of AOAC. Such written disclosure shall be made to any individual or group within the Association which is reviewing a recommendation which the volunteer had a part in formulating and in which the volunteer has a material interest causing an actual or potential conflict of interest.

AOAC requires disclosure of actual or potential conflicts of interest as a condition of active participation in the business of the Association. The burden of disclosure of conflicts of interest or the appearance of conflicts of interest falls upon the volunteer.

A disclosed conflict of interest will not in itself bar an AOAC member from participation in Association activities, but a three-fourths majority of the AOAC group reviewing the issue presenting the conflict must concur by secret ballot that the volunteer's continued participation is necessary and will not unreasonably jeopardize the integrity of the decision-making process.

Employees of AOAC are governed by the provision of the AOAC policy on conflict of interest by staff. If that policy is in disagreement with or mute on matters covered by this policy, the provisions of this policy shall prevail and apply to staff as well.

Illustrations of Conflicts of Interest

1. A volunteer who is serving as a committee member or referee engaged in the evaluation of a method or device; who is also an employee of or receiving a fee from the firm which is manufacturing or distributing the method or device or is an employee of or receiving a fee from a competing firm.

2. A volunteer who is requested to evaluate a proposed method or a related collaborative study in which data are presented that appear detrimental (or favorable) to a product distributed or a position supported by the volunteer's employer.

3. A referee who is conducting a study and evaluating the results of an instrument, a kit, or a piece of equipment which will be provided gratis by the manufacturer or distributor to one or more of the participating laboratories, including his or her own laboratory, at the conclusion of the study.

4. Sponsorship of a collaborative study by an interest (which may include the referee) which stands to profit from the results; such sponsorship usually involving the privilege granted by the investigator to permit the sponsor to review and comment upon the results prior to AOAC evaluation.

5. A volunteer asked to review a manuscript submitted for publication when the manuscript contains information which is critical of a proprietary or other interest of the reviewer.

The foregoing are intended as illustrative and should not be interpreted to be all-inclusive examples of conflicts of interest AOAC volunteers may find themselves involved in.

Do's and Don'ts

Do avoid the appearance as well as the fact of a conflict of interest.

Do make written disclosure of any material interest which may constitute a conflict of interest or the appearance of a conflict of interest.

Do not accept payment or gifts for services rendered as a volunteer of the Association without disclosing such payment or gifts.

Do not vote on any issue before an AOAC decision-making body where you have the appearance of or an actual conflict of interest regarding the recommendation or decision before that body.

Do not participate in an AOAC decision-making body without written disclosure of actual or potential conflicts of interest in the issues before that body.

Do not accept a position of responsibility as an AOAC volunteer, without disclosure, where the discharge of the accepted responsibility will be or may appear to be influenced by proprietary or other conflicting interests.

Procedures

Each volunteer elected or appointed to an AOAC position of responsibility shall be sent, at the time of election or appointment, a copy of this policy and shall be advised of the requirement to adhere to the provisions herein as a condition for active participation in the business of the Association. Each volunteer, at the time of his or her election or appointment, shall indicate, in writing, on a form provided for this purpose by AOAC, that he or she has read and accepts this policy.

Each year, at the spring meeting of the AOAC Board of Directors, the Executive Director shall submit a report certifying the requirements of this policy have been met; including the names and positions of any elected or appointed volunteers who have not at that time indicated in writing that they have accepted the policy.

Anyone with knowledge of specific instances in which the provisions of this policy have not been complied with shall report these instances to the Board of Directors, via the Office of the Executive Director, as soon as discovered.

* * * * * *

Adopted: March 2, 1989
Revised: March 28, 1990
Revised: October 1996

AOAC INTERNATIONAL

TERMS OF REFERENCE

I. NAME:

OFFICIAL METHODS BOARD (OMB)

II. MISSION:

To serve the Association in a scientific and advisory capacity on standards and methods with ethical, timely, open and independent scientific oversight for the implementation of standards development and conformity assessment policies and procedures of AOAC INTERNATIONAL.

III. RESPONSIBILITIES:

To provide ethical, timely, open and independent scientific oversight for the policies and procedures of AOAC INTERNATIONAL.

To approve "Final Action" status for First Action Methods (new and revised) following a proactive review;

To repeal methods, if necessary, in accordance with established policies and procedures;

To participate in addressing appeals and requests for action or guidance, and in resolving disputes;

To endorse and monitor all voluntary consensus panels for appropriate representation and balance of stakeholders' perspectives;

To endorse and monitor all volunteer subject matter experts for volunteer conformity assessment activities;

To adopt and monitor scientific and technical guidance and references;

To acknowledge outstanding scientific and technical volunteer activity and achievement within AOAC;

To actively participate in AOAC standards development activities and maintain and communicate explicit knowledge of AOAC standards development and conformity assessment;

IV. COMPOSITION AND ORGANIZATION:

The Official Methods Board shall consist of up to 13 voting members including a Chair, a Vice-chair, the Chair of the Committee on Safety and the Chair of the Committee on Statistics. The Committee on Safety and the Committee on Statistics may contain co-chairs. The co-chairs for these committees represent one vote on the OMB. Members of the OMB may serve in multiple volunteer roles for the benefit of the Association. The Chair of the Official Methods Board shall have previously served as a member of the Official Methods Board. The Chair, Vice-chair, and members of the Official Methods Board including the chairs of standing committees shall be appointed for a term of three years. A member of the OMB may be reappointed upon the recommendation of the Chair of the Official Methods Board with a maximum term of service of six (6) years. Exceptions may be made at the discretion of the President. The Chair of the Official Methods Board is eligible to serve an additional post chair term of up to three (3) years as an *ex-officio* member. Members of the Official Methods Board must be members of AOAC.

All members of the Official Methods Board are recommended by the Chair and appointed by the President. All Official Methods Board members serve at the pleasure of the President.

The Official Methods Board represents the membership of AOAC INTERNATIONAL. It shall be composed of members representing a balance of scientific expertise, government, industry, and academia as appropriate to the scope of the Board. Every effort should be made to include international representation on the Board.

Additional working groups, task forces, and other appropriate subgroups shall be appointed as needs arise by the Chair of the Official Methods Board.

V. STAFF LIAISON:

The Executive Director shall assign a member of the staff to serve as staff liaison.

VI. REVIEW SCHEDULE:

Every three years.

VII. DATE ESTABLISHED:

Renamed in 1981

VIII. DATES REVIEWED

01/08,

IX. DATES REVISED:

9/89; 5/90; 1/91; 8/06;
02/07; 07/07; 2/08; 4/13; 8/13

AOAC INTERNATIONAL
The Scientific Association Dedicated to Analytical Excellence®

MEMORANDUM

Date: **February 10, 2016**

To: **AOAC INTERNATIONAL Official Methods Board**

From: **Deborah McKenzie, Staff Liaison – AOAC Official Methods Board**

Subject: **Item I.d. Review of Draft Agenda**

Shauna Roman will invite OMB members to review the draft meeting agenda, entertaining any revisions and motion to approve the agenda.

RECOMMENDATION: OMB to approve draft agenda following review and any revisions.

ENCLOSURES: AOAC OMB Meeting Draft Agenda

OFFICIAL METHODS BOARD TELECONFERENCE

Wednesday and Thursday, February 10-11, 2016

9:00am – 5:00pm ET (Day One)
8:30am – 4:00pm ET (Day Two)

DRAFT MEETING AGENDA

I. PRELIMINARY ITEMS

a. Welcome *(Bradford)*
b. Call to Order /Introductions/Announcements *(Roman)*
c. Review of Policy Documents/Terms of Reference *(Roman)*
d. Review of Draft Agenda* *(Roman)*
e. Review of November 12, 2015 OMB Meeting Minutes* *(Roman)*
f. Update on OMB Report to the AOAC Board of Directors *(Roman)*
g. December Board of Directors Meeting Update *(Bradford/Sullivan)*
h. AOAC Final Action Methods and Road in Codex *(Sullivan)*

II. OFFICIAL METHODS OF ANALYSIS

a. Recommendation to Revise Method Format* *(Coates)* **Wed. 11am ET**
b. Recommendation to Revise to Appendix F* *(Coates)*
c. New in the 20th Edition of OMA
d. Sole Source Modification of *Official Methods*
    i. Sole Source Official Methods Modification Working Group Summary
    ii. Recommendation on Sole Source Modification of *Official Methods*^{SM}*

III. EXPERT REVIEW PANELS

a. First Action to Final Action Guidance to ERPs *(Roman)* **Wed 1pm ET**
    i. First to Final Action Working Group Summary
    ii. Role of OMB Liaisons*
    iii. Recommendation to Revise Appendix G*
    iv. Revision to OMB First to Final Action Presentation*
b. Expert Review Panel Recommendations for Final Action
    i. Expert Review Panel for Microbiology Methods* **Thursday 1pm ET**
    ii. Expert Review Panel for Veterinary Drug Residue Methods*
c. Process for ERP Review of Methods for First Action & Final Action status *(McKenzie)*
d. Modifications to ERPs *(Roman/McKenzie/Boyd)*
    i. ERP for Dietary Supplements – Ashwagandha, Folin C, & Kratom
    ii. ERP for SPSFAM Heavy Metal Methods
    iii. ERP for SPIFAN Nutrient Methods

IV. STAKEHOLDER PANELS

a. AOAC Mid-Year Meetings and OMB Liaisons *(Roman & McKenzie)*
b. Proposal for Vetting a Stakeholder Panel Vice Chair* *(McKenzie)*

**** Items that require or may require a vote***

Upcoming Mid-Year Meetings in Gaithersburg, MD

AOAC BOARD OF DIRECTORS MEETING
March 14, 2016

AOAC SPSFAM MEETING
March 14, 2016

AOAC SPIFAN MEETING
March 15, 2016

AOAC ISPAM MEETING
March 15, 2016

AOAC RI BOARD OF DIRECTORS MEETING
AOAC SPIFAN ERP
March 16, 2016

AOAC ERP FOR SPIFAN NUTRIENTS
March 16, 2016

AOAC ERP FOR MICROBIOLOGY METHODS
March 16, 2016

AOAC SPDS MEETING
March 17, 2016

AOAC SPDS WORKING GROUP MEETINGS FOR ALOE VERA, PROTEIN, & VITAMIN B_{12}
March 18, 2016

Calls for Methods
SPDS – Cinnamon, Aloin, Tea, Vitamin D

V. AOAC OFFICIAL METHODS BOARD MAINTENANCE

a. Documentation
   i. OMB Terms of Reference
   ii. OMB New Member Selection
   iii. OMB Vice Chair Selection
   iv. OMB Vetting of Stakeholder Panel Voting Members
   v. OMB Vetting of ERPs
   vi. Committee on Statistics TOR
   vii. Committee on Safety TOR
b. Awards Update
   i. Process
   ii. OMB Review
c. OMB New Member Selection Working Group Update *(Crowley)*
d. OMB - Next Teleconference

VI. ADJOURNMENT

**** Items that require or may require a vote***

AOAC INTERNATIONAL
The Scientific Association Dedicated to Analytical Excellence®

MEMORANDUM

Date: **February 10, 2016**

To: **AOAC INTERNATIONAL Official Methods Board**

From: **Deborah McKenzie, Staff Liaison – AOAC Official Methods Board**

Subject: **Item I.e. Review of November 12, 2015 OMB Meeting Minutes**

Shauna Roman will invite OMB members to review the draft meeting minutes, entertaining any revisions and motion to approve the minutes.

RECOMMENDATION: OMB to approve draft meeting minutes following review and any revisions.

ENCLOSURES: AOAC OMB Meeting Draft Minutes from November 12, 2015 OMB Teleconference.

AOAC OFFICIAL METHODS BOARD
Teleconference
November 12, 2015
1:00pm ET – 2:30pm ET

DRAFT MEETING MINUTES

OMB MEMBERS *(present during all or part of the meeting)*

Shauna Roman	Reckitt Benckiser	Chair
Erin Crowley	Q Laboratories	Vice Chair
Douglas Abbott	Independent Consultant	Member
Sneh Bhandari	Mérieux NutriSciences	Member
Joe Boison (proxy)	Canadian Food Inspection Agency	Member
Jo Marie Cook (proxy)	Florida Dept. of Agriculture and Consumer Services	Member
Don Gilliland	Abbott Nutrition	Member
Qian Graves	US FDA	Member
Katerina Mastovska	Covance	Member
Tom Phillips	Maryland State Dept. of Agriculture	Member
Yvonne Salfinger (proxy)	Independent Consultant	Member
Brad Stawick	Microbac	Member
John Szpylka	Mérieux NutriSciences	Past Chair-Ex-Officio

BOARD OF DIRECTORS AND OBSERVERS *(present during all or part of the meeting)*

Darryl Sullivan	Covance	Secretary, Board of Directors

AOAC STAFF ***(present during all or part of the meeting)***

Delia Boyd
Scott Coates
Deborah McKenzie

I. INTRODUCTORY ITEMS

a. Call to Order/Introductions/Announcements
Roman called the meeting to order at 1:06pm ET.
ACTION: OMB members to review their information on the roster and to send an email to Boyd and McKenzie if information requires revisions.

b. Roman called OMB's attention to the AOAC policy documents and reminded all attendees to review the documents and that the meeting will be held according to these policies.

c. Review and Approval of Draft Meeting Agenda
MOTION: For OMB to approve the agenda as amended.
Bhandari moved and Abbott seconded. Consensus: passed.

d. OMB reviewed the October 1, 2015 OMB teleconference minutes.
MOTION: For OMB to approve the minutes as presented.
Crowley moved and Mastovska seconded. Consensus: Passed; 2 abstentions.

II. EXPERT REVIEW PANELS

a. McKenzie provided an overview of the proposal for the forming an ERP for Dietary Supplements – Ashwagandha, Folin C, Kratom. OMB discussed that since the Ashwagandha ERP members have only one method for which Balasuramanian is the author that he should not serve as an ERP member.

MOTION: For OMB to approve the slate of ERP members as recommended for Folin C and Kratom and for Ashwagandha with the exception of M. Balasuramanian.
Crowley moved and Gilliland seconded. Consensus: passed; 1 abstention.
ACTION: Staff to forward approved members to President for appointment

III. ERP RECOMMENDATIONS

a. McKenzie and Crowley provided an overview of the potential changes to Appendix J based on the ERP's recommendations.

ACTIONS: Staff to provide OMB with the language for how Appendix J is to be revised with the Definition of Broad Range of Foods, Variety of Foods, Select Foods and the reference to ISO 16140-2 Annex A Food Categories tables.

VI. OMB DOCUMENTATION

a. OMB Terms of Reference
b. OMB New Member Selection
c. OMB Vice Chair Selection
d. OMB Vetting of Stakeholder Panel Voting Members
e. OMB Vetting of ERPs

ACTIONS: Staff to add this agenda item to next OMB teleconference agenda.

VII. UPDATES

a. Sole Source Method Modification Working Group *(Roman/McKenzie)*
b. First to Final Action Working Group (Roman/McKenzie)
c. OMB New Member Selection Working Group *(Szpylka/Roman/McKenzie)*
d. Update on AOAC Final Action Methods and Road to Codex *(Sullivan)*

ACTIONS: Staff to add this agenda item to next OMB teleconference agenda.

VIII. STAKEHOLDER PANELS

a. Proposal for Vetting a Stakeholder Panel Vice Chair *(McKenzie)*

ACTIONS: Staff to add this agenda item to next OMB teleconference agenda.

IX. OFFICIAL METHODS BOARD FUTURE MEETINGS

a. December Teleconference

ACTIONS: Staff to survey OMB members and reschedule December OMB teleconference agenda.

b. Winter Meeting Dates

ACTIONS: Staff to add this agenda item to next OMB teleconference agenda.

X. ADJOURNMENT

a. **Motion:** To adjourn the meeting.
Bhandari moved and Cook seconded. Consensus was unanimously in favor. Meeting adjourned at 2:32pm ET.

AOAC INTERNATIONAL

The Scientific Association Dedicated to Analytical Excellence®

MEMORANDUM

Date: **February 10, 2016**

To: **AOAC INTERNATIONAL Official Methods Board**

From: **Deborah McKenzie, Staff Liaison – AOAC Official Methods Board**

Subject: **Item I.f. Update on OMB Report to the AOAC Board of Directors**

Shauna Roman will share with OMB members her report to the AOAC INTERNATIONAL Board of Directors during their December 9-10, 2015 meeting.

RECOMMENDATION: None.

ENCLOSURES: AOAC OMB Report to the AOAC Board of Directors

MEMORANDUM

Date: **8 December 2015**
To: **AOAC INTERNATIONAL Board of Directors**
From: **Shauna Roman – Chair, Official Methods Board**
Subject: **AOAC Official Methods Board Update**

STANDARDS DEVELOPMENT AND CONFORMITY ASSESSMENT

OMB Participation in Standards Development (2015 Summary)

- Vetted 10 sets of stakeholder panel voting members
- At least one OMB member has participated in stakeholder panel meetings and affiliated working groups, totalling 18 in 2015.
    - Twelve (12) working groups for which SMPRs were approved, and
    - Six (6) working groups for which SMPRs are in development

OMB Participation in Expert Review Panels and *Official Methods of Analysis* (2015 Summary)

- Vetted thirteen (13) AOAC Expert Review Panels
- At least one OMB member has participated on AOAC Expert Review Panels which will have totalled 18 by end of 2015.
    - Fourteen (14) methods adopted as First Action OMAs
    - Two (2) ERPs recommended a total of nine (9) First Action methods for Final Action status
- Accepted the recommendations of the ERP for SPIFAN Nutrient Methods and moved two (2) First Action methods to Final Action status. ERP Recommendation Report is in development for the other seven (7) methods recommended.

OTHER DECISIONS AND ACTIONS OF THE AOAC OMB

Official Methods Pathway

- November 12, 2015- OMB vetted AOAC ERP for Dietary Supplements- Ashwagandha, Folic C, Kratom

OMB Meetings and Teleconferences

- October 1, 2015- Face-to-Face at the AOAC annual meeting (Los Angeles)
- November 12, 2015- Teleconference
- The next in-person OMB meeting will be January or February 2016 at AOAC Headquarters (exact date TBD)

AOAC INTERNATIONAL
The Scientific Association Dedicated to Analytical Excellence®

MEMORANDUM

Date: **February 10, 2016**

To: **AOAC INTERNATIONAL Official Methods Board**

From: **Deborah McKenzie, Staff Liaison – AOAC Official Methods Board**

Subject: **Item I.g. December AOAC Board of Directors Meeting Update**

Dr. Bradford will give an update to the OMB on the AOAC INTERNATIONAL Board of Directors from their December 9-10, 2015 meeting.

RECOMMENDATION: None.

ENCLOSURES: None.

AOAC INTERNATIONAL
The Scientific Association Dedicated to Analytical Excellence®

MEMORANDUM

Date: **February 10, 2016**

To: **AOAC INTERNATIONAL Official Methods Board**

From: **Deborah McKenzie, Staff Liaison – AOAC Official Methods Board**

Subject: **Item I.h. December AOAC Final Action Methods and Road in Codex**

ISO published the following AOAC Final Action Methods as ISO and/or ISO/IDF standards

Pantothenic acid	AOAC 2012.16	ISO 20639
Myo-inositol	AOAC 2011.18	ISO 20637
Vitamin B12	AOAC 2011.10	ISO 20634
Nucleotides	AOAC 2011.20	ISO 20638
Vitamins A & E	AOAC 2012.10	ISO 20633
Fatty acid profile	AOAC 2012.13	ISO 16958 IDF 231
Cr, Mo, Se	AOAC 2011.19	ISO 20649 IDF 235
Iodine	AOAC 2012.15	ISO 20647 IDF 234

Darryl Sullivan attended the FAO/WHO Codex Committed on Nutrition and Foods for Special Dietary Uses (CCNFSDU) on November 23-27, 2015, Germany. The CCNFSDU moved the methods to CCMAS.

President Hill re-appointed Darryl Sullivan as the AOAC representative to the FAO/WHO Codex Committee on Methods of Analysis which will meet on February 22-26, 2016 in Budapest, Hungary.

RECOMMENDATION: None.

ENCLOSURES: Criteria document and Conference Room Document

TO: INTERAGENCY MEETING (IAM) 20 FEBRUARY 2016

FROM: AOAC INTERANTAIONAL
INTERNATIONAL DAIRY FEDERATION (IDF)

SUBJECT: **PROPOSAL TO ADD LANGUAGE TO THE CODEX PROCEDURAL MANUAL – RE: CRITERIA APPROACH**

DATE: FEBRUARY 4, 2016

Need for compliance methods with more strict precision compared to what is required according to the Horwitz/Thompson equation in the "Criteria Approach".

Introduction
At the 26th meeting of International Organizations working in the field of methods of analysis and sampling (Inter-Agency Meeting on February 20, 2015) the use of Standard Method Performance Requirements (SMPR) in AOAC was discussed. From an example it became clear that the allowed precision for a method based on the Codex Criteria approach can be much higher compared to the needed precision to verify certain regulatory requirements.

The basis for the criteria approach in Codex is the Horwitz/Thompson equation, derived from performance characteristics of methods used in the past. These criteria are not suitable for compliance verification of current regulations, particularly at low concentration analytes.
IAM members were invited to work on a revised text of the Procedural Manual to indicate that in some situations it is not appropriate to use the criteria approach to establish suitable precision requirements.

Examples where the Codex Criteria approach based precision cannot be used to verify compliance
Two examples of situations where analytical methods with a low precision are not fit for purpose to verify compliance to regulations are explained below.

1. Many countries have specific regulations including accepted tolerances for label declarations. An example is a minimum tolerance of 20% from the label declaration for low level nutrients in infant formulas.
2. New European draft regulation on specific compositional and information requirements for infant formula and follow-on formula (EU No 609/2013 (June 2015)) stipulates new ranges for fortification of nutrients. The allowed fortification range for e.g. vitamin A is between 70 and 114 µg-RE/100kcal. The relative difference between the levels is 39%.

Assuming a fortification level of 70 µg-RE/100kcal which is equivalent with 0.49 mg vitamin A/kg Ready To Feed (RTF) infant formula. The Codex criteria approach as described in the Procedural Manual, allows a $PRSD_R$ and a maximum RSD_R of 18% and 36% respectively.

It can be concluded that an analytical method with an allowed precision of 36% relatively, cannot be used to verify a minimum tolerance of 20% and a relative fortification range of 39%. The probability to find a value out of range due to analytical variability of the method is high. Consequently, such a method is not suitable for resolving dispute.

New precision data for low level nutrient concentrations and comparison with Horwitz

Recently a new set state of the art methods have been collaboratively validated for nutrients in infant formulas and adult nutritionals. Performance characteristics are summarized in the Table below.

			MLT				SMPR			Horwitz	
Analyte	AOAC Official Method	ISO/IDF Standard	MLT conc low reconstituted prod	MLT conc high reconstituted product	MLT RSDr	MLT RSDR	SMPR conc	SMPR RSDr	SMPR RSDR	max RSDR conc low	max RSDR conc high
			mg/kg	mg/kg			mg/kg	%	%		
Iodine	AOAC 2012.15	ISO 20647|IDF 234:2015	0.0347	0.185	0.8-4.8	5.4-11.5	0.05-10	<8	<15	44.0	41.2
Pantothenic acid	AOAC 2012.16	ISO 20639:2015	2.88	8.97	1.3-2.9	4.1-7.0	0.5-23	<5	<15	27.3	23.0
Chromium	AOAC 2011.19	ISO 20649|IDF 235:2015	0.016	0.14	2.1-7.0	5.8-13.4	0.02-1.6	<5	<15	44.0	43.0
Molybdenum	AOAC 2011.19	ISO 20649|IDF 235:2015	0.018	0.19	1.0-3.3	3.0-7.9	0.02-1	<5	<15	44.0	41.1
Selenium	AOAC 2011.19	ISO 20649|IDF 235:2015	0.023	0.133	2.3-6.4	2.5-9.3	0.01-0.5	<5	<15	44.0	43.3
Vitamin A	AOAC 2012.10	ISO 20633:2015	0.463	0.674	1.1-16.6	6.5-22.6	0.07-3.82	<8	<16	35.9	34.0
Vitamin E (toc ac)	AOAC 2012.10	ISO 20633:2015	13	127	0.6-3.8	4.2-11.3	2-80	<8	<16	21.7	15.4
Vitamin B12	AOAC 2011.10	ISO 20634:2015	0.002	0.015	3.0-9.8	3.5-19.5	0.0001-0.05	<15-<7	<11	44.0	44.0

In this table the Standard Method Performance Requirements (SMPR) summarize the target performance characteristics agreed before a suitable method was identified, looking among other things to regulatory requirements. For comparison, the maximum allowed RSD_R values according to Horwitz based on the levels analyzed are given.

It can be concluded that current methods are able to have a better precision compared to a maximum allowed precision according to Horwitz.

Proposed language to add to the Codex Procedural Manual, Guidelines for establishing numeric values for method criteria.

In certain cases the $PRSD_R$ and RSD_R values based on the Horwitz/Thompson equation, e.g. for low level nutrients, are too high to verify compliance with regulatory requirements. In these cases it should be evaluated what precision is needed versus what is currently feasible from a technical point of view. This should allow defining more strict criteria.

This proposed language is aligned with what was stated by M. Thompson in 2004: “While it is thus widely useful, it would be unreasonable to expect the Horwitz function to cover every contingency. Applications where very high accuracy is required readily spring to mind, and there is evidence that laboratories can fulfill the enhanced requirement” (AMC Technical Brief No. 17, July 2004).

Additional information to CCMAS agenda item 3 (CX/NFSDU 16/37/3) Appendix IV referring to: PART 1: Methods of analysis in the *Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants* (CODEX STAN 72-1981).

Submitted by AOAC, ISO and IDF

The Codex Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU) agreed during its 37th Session to refer the following eight methods for nutrients in infant formula, as presented in CX/NFSDU 15/37/10 (Rev) to the Codex Committee on Methods of Analysis and Sampling (CCMAS) for technical review; vitamin B12; myo-inositol; chromium, selenium and molybdenum; nucleotides; vitamins A and E; fatty acid profile; iodine; and pantothenic acid. This includes typing, endorsement and inclusion in the Recommended Methods of Analysis and Sampling (CODEX STAN 234- 1999) during its 37th Session, as these methods reflect the most recent scientific methods of analysis for these nutrients and were validated on a broad range of infant formula products (Appendix V, Part I).

All methods are published as AOAC Official Methods of Analysis Final Action and as ISO Standards or ISO|IDF Standards. Each method has been collaboratively tested.

AOAC, ISO and IDF recommend swift adoption of these methods as dispute resolution methods (Type II) for nutrients in Infant Formula because:

- Available methods for certain nutrients do not determine the same analyte(s) or what is claimed on the product label (e.g. different forms of vitamin B12, different forms of vitamin E);
- Problems in international trade can be created when different methods are used, which meet agreed criteria but may give different results, therefore, are not suitable for dispute resolution.; and
- The Codex criteria approach uses the concentration-based Horwitz-Thompson equation as a predictor for $PRSD_R$ and RSD_R. These values, especially for low-level nutrients, are too wide relative to current fortification practices and guidelines as well as product specification ranges. As such, this approach is not sufficient in resolving disputes.

In paragraph 1 below, the validation data as presented in the ISO Standards or ISO|IDF Standards is given.
Paragraph 2 gives an overview of references to the AOAC Official Methods and publications of collaborative study reports by AOAC INTERNATIONAL.
Paragraph 3 explains how the results obtained with the analytical methods can be expressed in alignment with CODEX STAN 72-1981.
Paragraph 4 explains how the AOAC/ISO/IDF methods perform compared to the methods already listed in Codex STAN 234.

1. Scope, Principle and Validation data of 8 proposed methods.

ISO 20639:2015 technically equivalent to AOAC 2012.16

Infant formula and adult nutritionals -- Determination of pantothenic acid by ultra-high performance liquid chromatography and tandem mass spectrometry method (UHPLC-MS/MS)


Scope_principle_ISO_20639.pdf


Annex_B_Precision_data_ISO_20639.pdf

ISO 20637:2015 technically equivalent to AOAC 2011.18

Infant formula and adult nutritionals -- Determination of myo-inositol by liquid chromatography and pulsed amperometry


Scope_principle_ISO_20637.pdf


Annex_B_Precision_data_ISO_20637.pdf

ISO 20634:2015 technically equivalent to AOAC 2011.10

Infant formula and adult nutritionals -- Determination of vitamin B12 by reversed phase high performance liquid chromatography (RP-HPLC)


Scope_principle_ISO_20634.pdf


Annex_B_Precision_data_ISO_20634.pdf

ISO 20638:2015 technically equivalent to AOAC 2011.20

Infant formula -- Determination of nucleotides by liquid chromatography


Scope_principle_ISO_20638.pdf


Annex_B_Precision_data_ISO_20638.pdf

ISO 20633:2015 technically equivalent to AOAC 2012.10

Infant formula and adult nutritionals -- Determination of vitamin E and vitamin A by normal phase high performance liquid chromatography


Scope_principle_ISO_20633.pdf


Annex_B_Precision_data_ISO_20633.pdf

ISO 16958|IDF 231:2015 technically equivalent to AOAC 2012.13

Milk, milk products, infant formula and adult nutritionals -- Determination of fatty acids composition -- Capillary gas chromatographic method


Scope_principle_ISO_16958_IDF_231.pdf


Annex_B_Precision_data_ISO_16958_IDF

ISO 20649|IDF 235:2015 technically equivalent to AOAC 2011.19

Infant formula and adult nutritionals -- Determination of chromium, selenium and molybdenum -- Inductively coupled plasma mass spectrometry (ICP-MS)


Scope_principle_ISO_20649_IDF_235.pdf


Annex_B_Precision_data_ISO_20649_IDF

ISO 20647|IDF 234:2015 technically equivalent to AOAC 2012.15

Infant formula and adult nutritionals -- Determination of total iodine -- Inductively coupled plasma mass spectrometry (ICP-MS)


Scope_principle_ISO_20647_IDF_234.pdf


Annex_B_Precision_data_ISO_20647_IDF

2. References to AOAC INTERNATIONAL Official Methods of Analysis – report from collaborative studies.

All references are available in the electronic version of the Journal of AOAC INTERNATIONAL. Six of the references are published in the printed version of the Journal of AOAC INTERNATIONAL. The remaining two are “in press”.

AOAC 2012.16
Martin, F., & Campos Giménez, E. (2015) J. AOAC Int. 98(6), 1697-1701.
http://aoac.publisher.ingentaconnect.com/content/aoac/jaoac/2015/00000098/00000006/art00025

AOAC 2011.18
Butler-Thompson, L. D-B., Jacobs, W.A., & Schimpf, K.J. (2015) J. AOAC Int. 98(6), 1666-1678.
http://aoac.publisher.ingentaconnect.com/content/aoac/jaoac/2015/00000098/00000006/art00023

AOAC 2011.10
Butler-Thompson, L. D-B., Jacobs, W.A., & Schimpf, K.J. (2015) J. AOAC Int. 98(6), 1655-1665.
http://aoac.publisher.ingentaconnect.com/content/aoac/jaoac/2015/00000098/00000006/art00022

AOAC 2011.20
Gill, B.D., & Indyk, H.E. (2015) J. AOAC Int. 98(4), 971-979.
http://dx.doi.org/10.5740/jaoacint.15-050

AOAC 2012.10
McMahon, A. (2016) J. AOAC Int. 99(1), in press.
http://aoac.publisher.ingentaconnect.com/content/aoac/jaoac/pre-prints/content-9901-1

AOAC 2012.13
Golay, P-A., & Moulin, J. (2016) J. AOAC Int. 99(1), in press.
http://aoac.publisher.ingentaconnect.com/content/aoac/jaoac/pre-prints/content-9801-2

AOAC 2011.19
Pacquette, L., & Thompson, J. (2015) J. AOAC Int. 98(6), 1702-1710.
http://aoac.publisher.ingentaconnect.com/content/aoac/jaoac/2015/00000098/00000006/art00026

AOAC 2012.15
Zywicki, R.S., & Sullivan, D.M. (2015) J. AOAC Int. 98(5), 1407-1416
http://aoac.publisher.ingentaconnect.com/content/aoac/jaoac/2015/00000098/00000005/art00030

3. Expression of results by using proposed methods of analysis

Results obtained by using the proposed methods of analysis for nutrients in infant formula are calculated and expressed in amounts per 100g powder, or per 100g Ready to Feed (RTF) product. RTF samples can be from liquid origin. When RTF is reconstituted from powders, 25 grams of powdered infant formula is to be mixed with 200 grams of water.
In the CODEX Standard for Infant Formula (CODEX STAN 72-1981), the essential composition is expressed in amounts per 100 available kilocalories, and amounts per 100 available kilojoules.

By using the amount of kcal and kjoules per 100g powder, or RTF product, on the product label of the sample analyzed, the nutrient concentrations can be calculated and expressed in amounts per 100 kcalories or kjoules as follows:

$$w = \frac{v}{y} \; x \; 100 \; x \; f$$

w = nutrient concentration in mg/100 kcal or kjoules
v = nutrient concentration in mg/100g
y = amount of kcal or kjoules per 100g powder or RTF as indicated on sample package
f = dilution factor:
Example 1: In case of analysis of powders and of liquid Infant formula, f=1
Example 2: In case of reconstituted powders (25 g powder with 200 g of water), f=9.

4. Specificity of the recently published methods

Chromium, Selenium, Molybdenum:
ISO 20649|IDF 235/AOAC 2011.19 has better performance characteristics, improved specificity, and is specifically validated for infant formula according to Codex STAN-72 and is therefore proposed as type II dispute resolution method. European standards can be kept in Codex STAN-234 as type III.

It is proposed to repeal AOAC 2006.03 (current Type III method for Chromium), as its scope is fertilizers. It is suggested that EN 14082 and EN14083 become Codex Type III for Chromium.

It is proposed to repeal AOAC 2006.03 (current Type III method for Molybdenum), as its scope is fertilizers. It is suggested that EN 14083 become Codex Type III for Molybdenum.

It is proposed that EN 14627, the current Type II method for selenium, is kept as Type III method.

Vitamin A/E:

ISO 20633/AOAC 2012.10 is:

- preferable over EN 12823-1 as type II dispute resolution method for vitamin A because:
  - EN 12823-1 was collaboratively studied on milk powder and margarine. These matrices are not representative of current infant formula matrices. As such, product matrix challenges can be observed compromising method performance,
  - ISO 20633/AOAC 2012.10 has been collaboratively studied using 12 infant formula matrices representative of the wide range and diversity of current formulations for these product categories,
  - ISO 20633/AOAC 2012.10 has improved precision and accuracy.

- preferable over EN 12822 as type II dispute resolution method for vitamin E because:
  - EN 12822 was collaboratively studied using milk powder, margarine and oat powder. These matrices are not representative of current infant formula matrices. As such, product matrix challenges can be observed compromising method performance,
  - ISO 20633/AOAC 2012.10 has been collaboratively studied using 12 infant formula matrices representative of the wide range and diversity of current formulations for these product categories,
  - ISO 20633/AOAC 2012.10 has improved precision and accuracy,
  - separates and quantifies alpha-tocopherol and alpha-tocopherol acetate esters further, as required by current regulatory standards,
  - there is no global agreement on the activity of other forms of vitamin E (EFSA, WHO),
  - results are converted to tocopherol equivalents as per Codex STAN-72,
  - Note: no method differentiates D from DL isomers.
- Specifically validated for vitamin A and vitamin E in infant formula according to Codex STAN-72

Therefore, it is proposed as type II dispute resolution method for vitamin A and vitamin E.
European standards and AOAC 992.03 can be kept in Codex STAN-234 as type III.
It should be noted that AOAC 992.03 is the current Codex Type III method. However, only for follow-on formula and not for infant formula.

Iodine:

ISO 20647|IDF 234/AOAC 2012.15:

- measures total iodine (as stipulated in CODEX STAN 72-1981), where AOAC 992.24 measures only free iodide, and has many interferences,
- has far superior specificity and other performance characteristics to AOAC 992.24,
- is specifically validated for infant formula according to Codex STAN-72.

Therefore, it is proposed as type II dispute resolution method. It is proposed to repeal AOAC 992.24 (Current Type II method), as the ion-selective electrode does not quantify total iodine and may deliver different results compared to ICP-MS.

Hammer & Andrey. JAOAC INTERNATIONAL Vol 91, No6, 2008: 1397

Vitamin B12

ISO 20634:2015 / AOAC 2011.10 is

- preferable over AOAC 986.23 (Current Type II method) as Type II dispute resolution method for vitamin B12 because:
    - AOAC 986.23, Cobalamin in Milk-Based Infant Formula, 1988, is a relatively old method, validated using only milk based infant formula. This matrix is not representative of current infant formula matrices.
    - ISO 20634:2015 / AOAC 2011.10 has been collaboratively tested using 12 infant formula matrices representative of the wide range and diversity of current formulations for these product categories (milk, soy, hydrolysed protein etc.)
    - ISO 20634 / AOAC 2011.10 has improved precision and accuracy compared to the microbiological method where poor repeatability and a high number of failed results has been observed due to poor growth of the organism and/or contamination. Although the microbiological method shows high sensitivity, enabling the detection of low concentrations other food components can cause interference with the assay. It is also expensive to support in the absence of a minimum level of use.
    - AOAC 986.23 is based on non-specific determination known to respond to substances other than cobalamin, Campos-Giménez et al. JAOAC INTERNATIONAL Vol 91, No4, 2008 : 786

- It is proposed that AOAC 986.23 (Current Type II method) be repealed from the Codex list for infant formula.

Pantothenic acid

It is proposed to keep AOAC 992.07, based on microbiology, as Type III method. Results generated by AOAC 992.07 are not different from results generated by AOAC 2012.16 as confirmed by Andrieux et al.: JAOAC INTERNATIONAL Vol.95, No1, 2012: 143.

Fatty acids

Proposed type II method: ISO 16958|IDF 231:2015 / AOAC 2012.13.

It is proposed that AOAC 996.06 (Current Type II method) be kept as Type III method. It should be noted that if trans fatty acids need to be determined that this method is not fit for purpose.

It is proposed that AOCS Ce 1h-05 (Current Type III method) be kept as Type III method. It should be noted that if trans fatty acids need to be determined that this method is not fit for purpose.

AOAC INTERNATIONAL

The Scientific Association Dedicated to Analytical Excellence®

MEMORANDUM

Date: **February 10, 2016**

To: **AOAC INTERNATIONAL Official Methods Board**

From: **Scott Coates, AOAC Chief Scientific Officer**

Subject: **Item II.a. Updating Method Format**

BACKGROUND:

The idea of linking or incorporating the minimum performance requirements from relevant Standard Method Performance Requirements has been discussed in committees and panels for about 2 years. All parties agreed with the general concept but general concept has not been implemented. This proposal contains the details for implementation and an extension of the concept. The original idea was to simply incorporate the minimum performance requirements into Official Methods of Analysis. The new concept in this proposal incorporates a reporting feature. All accredited laboratories are required to verify the performance of analytical methods in their laboratory. The new concept is to use the minimum performance requirements as the acceptance criteria for verification, and even more, to create an anonymous automated reporting system to capture verification data. It is proposed that the method author and relevant expert review panel would have access to the verification data. Presumably, after two years there should be real on-site performance data for the method that could be used to determine Final Action status. The automated data collection system also could be used to verify matrix extensions. The concept was informally discussed with individual BoD members during the December Board meeting and BoD members unanimous supported the concept.

Several examples are attached.

1. Section A contains the proposed addition to the method format.
    a. The concept provides very clear verification acceptance criteria.

b. Methods can only be used if the laboratory can verify they meet the minimum method requirements, so there is a positive self-policing effect.
c. The section provide a link to a reporting site.
d. Section A can be upgraded to "reported" data at the time a method is awarded Final Action status.

RECOMMENDATION:

Please review proposed changes. Revise as needed. Request a formal motion and vote to include **Section A. *Method Performance*** in the Guide to Method Format.

ENCLOSURES:
Example: AOAC Official Method 2015.01
Example: AOAC Official Method 2015.03
Example: AOAC Official Method 2015.11
Current Guide to Method Format
Proposed Guide to Method Format

Example: AOAC Official Method 2015.01

Heavy Metals in Food
Inductively Coupled Plasma–Mass Spectrometry

First Action 2015

Note: The following is not intended to be used as a comprehensive training manual. Analytical procedures are written based on the assumption that they will be performed by technicians who are formally trained in at least the basic principles of chemical analysis and in the use of the subject technology.

{Applicable for the determination of heavy metals [arsenic (As), CAS No. 7440-38-2; cadmium (Cd), CAS No. 7440-43-9; lead (Pb), CAS No. 7439-92-1; and mercury (Hg), CAS No. 7439-97-6] at trace levels in food and beverage samples, including solid chocolate, fruit juice, fish, infant formula, and rice, using microwave digestion and inductively coupled plasma–mass spectrometry (ICP-MS).}

Caution: Nitric acid and hydrochloric acid are corrosive. When working with these acids, wear adequate protective gear, including eye protection, gloves with the appropriate resistance, and a laboratory coat. Use an adequate fume hood for all acids. Hydrogen peroxide is a strong oxidizer and can react violently with organic material to give off oxygen gas and heat. Adequate protective gear should be worn. Many of the chemicals have toxicities that are not well established and must be handled with care. For all known chemicals used, consult the Material Safety Data Sheet (MSDS) in advance. Etc., etc., etc.

A. Method Performance

The performance criteria in Table 2015.01A is prescribed by *Standard Methods Performance Requirements* (SMPR) 2012.007, which was adopted by the AOAC Stakeholder Panel for Dietary Supplements (SPDS). Laboratory(ies) implementing this method should follow ISO Standard 17025 to verify that the performance of this method in your laboratory meets the criteria in Table 2015.11A. Please report verification results to AOAC at this link: AOAC 2015.01.

Table 2015.01A Verification Acceptance Criteria

Limit of Quantitation (LOQ)	

	Parameters	
Ranges	Repeatability (RSD_r)	Recovery
≥ 10 ppb to 100 ppb	≤ 15%	60% - 115%
>100 ppb to 1 ppm	≤ 11%	80% - 115%
> 1 ppm to 10 ppm	≤ 7.3%	80% - 115%

B. Principle

Food samples are thoroughly homogenized and then prepared by microwave digestion and the addition of dilute solutions of gold (Au) and lutetium (Lu). The Au is used to stabilize the Hg in the preparation, and the Lu is used to

Example: AOAC Official Method 2015.03

Sodium Fluoroacetate in Infant Formula
Liquid Chromatography-Tandem Mass Spectrometry
(LC-MS/MS)

First Action 2015

[Applicable for the quantitative determination of sodium fluoroacetate in liquid and powdered milk- and soy-based infant formulas by liquid chromatography-tandem mass spectrometry (LC-MS/MS). The limit of quantification (LOQ) of sodium fluoroacetate is 1 µg/kg by this method. Application of this method to matrices not covered by the scope of application requires an additional validation.]

Caution: Material Safety Data Sheets (MSDS) should be available for all chemicals; inherent risks and corresponding safety precautions shall be identified. Follow general safety precautions and environmental aspects as described in the local Safety, Health and Environment rules in place.

A. Method Performance

The performance criteria in Table 2015.03A is prescribed by *Standard Methods Performance Requirements* (SMPR) 2015.001, which was adopted by the AOAC Stakeholder Panel for Dietary Supplements (SPDS). Laboratory(ies) implementing this method should follow ISO Standard 17025 to verify that the performance of this method in your laboratory meets the criteria in table 2015.11A. Please report verification results to AOAC at this link: AOAC 2015.03 verification data.

Table 2015.03A Verification Criteria

Parameter	Acceptance criteria
Analytical Range	4 ppb – 100 ppm*
Limit of Quantitation (LOQ)	≤ 4 ppb*
Accuracy	± 20%
Repeatability (RSDr)	≤ 14%
* Fluoroacetate expressed as µg of fluoroacetic acid /1000 g of solids.	

B. Principle

Milk powder is first reconstituted in water. Liquid sample is used as such. Acetonitrile is added to precipitate proteins. After centrifugation, the supernatant is washed with hexane and then acidified with concentrated sulfuric acid. QuEChERS salts (MgSO4 and NaCl) are added for phase separation and the mixture is centrifuged. The resulting supernatant is evaporated to 0.5 mL remaining volume and centrifuged before LC-MS/MS analysis in selected reaction monitoring (SRM) by electrospray ionization (ESI) in negative mode. The compound is analyzed as its fluoroacetate anion.

Quantification is performed by the isotopic dilution approach using 13C labeled sodium fluoroacetate as internal standard (IS). Positive identification of fluoroacetate in samples is conducted according to the confirmation criteria defined in EU Commission Decision 2002/657/EC (1).

Example: AOAC Official Method 2015.11

Chondroitin Sulfate Content in Raw Materials and Dietary Supplements
High-Performance Liquid Chromatography with Ultraviolet Detection After Enzymatic Hydrolysis

First Action 2015

A. Method Performance

The performance criteria in Table 2015.11A is prescribed by *Standard Methods Performance Requirements* (SMPR) 2014.009, which was adopted by the AOAC Stakeholder Panel for Dietary Supplements (SPDS). Laboratory(ies) implementing this method should follow ISO Standard 17025 to verify that the performance of this method in your laboratory meets the criteria in table 2015.11A. Please report verification results to AOAC at this link: AOAC 2015.11.

Table 2015.11A: Verification Acceptance Criteria

	Analytical Ranges	
Parameters	1-10% (w/w)	>10-100% (w/w)
Repeatability (RSD_r)	≤ 3%	≤2%
Recovery	92-105%	98-102%

B. Materials

Chondroitin sulfate (CS) raw materials from bovine trachea, porcine skin/cartilage, and shark cartilage, and CS control material from bovine trachea were obtained from Bioiberica (Barcelona, Spain). Dietary supplement products containing CS (hard-shell capsules, tablets, chewables, softgels, and liquids) were obtained from commercial suppliers. Descriptions of the dietary supplement products used in the study are presented in Table **2015.11B**.

C. Apparatus

(**a**) *LC system*.—Beckman 126 dual high pressure mixing pumps (Beckman Coulter, Fullerton, CA, USA), 168 diode array UV detector, 507e autosampler, and 32 Karat software.
(**b**) *Operating conditions*.—Mobile phase flow rate, 1.1 mL/min; column temperature, ambient; injection volume, 30 µL; and detection, 240 nm.
(**c**) *LC column*.—Phenomenex Synergi Polar-RP, 4.6 × 150 mm, 4 µm particle size (Phenomenex, Torrance, CA, USA).
(**d**) *Analytical balance*.—Accu-124 (Fisher Scientific, Pittsburgh, PA, USA), ±0.01 mg readability.
(**e**) *Ultrasonic bath*.—Model FS60H (Fisher Scientific).
(**f**) *pH meter*.—Model pH 500 (Oakton, Vernon Hills, IL, USA), ±0.01 pH unit readability.
(**g**) *Dry block heater*.—Isotemp Dry Bath Incubator (Fisher Scientific), maintained at 37°C.
(**h**) *LC injection vials*.—2 mL, with caps and Teflon-coated septa.
(**i**) *Limited volume inserts*.—200 µL, for LC vials.
(**j**) *Syringes*.—25, 100, and 500 µL Luer-Lok.

D. Reagents

Note: Chemicals from other suppliers meeting the specificationsmay also be used.
(**a**) *Solvents*.—Acetonitrile, LC grade; water, LC grade; hydrochloric acid, concentrated, ACS reagent grade.

Attachment: current Guide to Method Format

Guide to Method Format

(Method shown is incomplete to allow space for description.)

Locator number identifies method by chapter, subchapter, and sequence within the subchapter for easy cross referencing and access. 4 = chapter 4; .10 = subchapter 10; .03 = the third method found in Chapter 4, subchapter 10. The locator number is not the permanent number and is included only for convenient accessibility.

Chemical names of pesticides and drugs are given at end of pertinent chapter.

Calculation symbols are identified and show correct units.

Chemical Abstracts Service Registry Number. A unique identifier that may be used to search a number of data-retrieval systems.

4.10.03

AOAC Official Method 996.13
Ethoxyquin in Feeds
Liquid Chromatographic Method
First Action 1996
Final Action 1997

(Applicable for determination of 0.5–300 μg/g ethoxyquin in dry extruded pet food or meat meal.)

See Table **996.13** for the results of the interlaboratory study supporting acceptance of the method.

A. Principle

Ethoxyquin is extracted with acetonitrile. Extract is analyzed by isocratic liquid chromatography with fluorescence detection.

B. Apparatus

(a) *Liquid chromatograph (LC).* Generating 1500 ± 200 psi; with peak area integrator (manual or computer), isocratic LC pump, and column heater. Operating conditions: injection volume, 20 μL; flow rate, 1.3 mL/min; temperature, 35°C; fluorescence detector output, analog to digital conversion; detector settings: excitation, 360 nm; emission, 432 nm.

(b) *LC column.* 250 × 4.6 mm id, C_{18} octadecylsilane, 5 μm spherical, 100 Å pore size.

C. Reagents

(a) *Water.* LC grade.

(b) *Acetonitrile.* LC grade.

D. Preparation of Standard Solutions

(a) *Ethoxyquin standard stock solution.* 400 μg/mL. Weigh the equivalent of 0.1000 g liquid ethoxyquin into 250 mL amber volumetric flask and dilute to volume with acetonitrile. (*Note:* Amount of ethoxyquin needed for preparation of stock solution is based on purity of liquid, e.g., for purity of 93.5%, amount of liquid ethoxyquin = 0.100/0.935 = 0.1070 g.)

H. Calculations

Calculate concentration of ethoxyquin, μg/g or ppm, in test sample from calibration curve (using linear regression with line forced through zero intercept) as follows:

$$\text{Ethoxyquin, } \mu g/g \text{ or ppm} = \frac{C \times 1.5 \times F}{W}$$

where C = ethoxyquin concentration from LC calibration curve, μg/mL; 1.5 = volume of acetonitrile added to test solution, mL; F = dilution factor; W = weight of test portion, g.

Reference: *J. AOAC Int.* **80**, 725(1997).

CAS-91-53-2 (ethoxyquin) 6-ethoxy-1,2-dihydro-2,2,4-trimethylquinoline

Revised: March 1998

Permanent number identifies method by year of adoption or first appearance in *Official Methods of Analysis of AOAC INTERNATIONAL*. 996 = First Action 1996; .13 = sequence of adoption in 1996.

Title may include analyte and matrix, type of method, and official status.

Applicability statement addresses utility and limitations on use of method or other information.

Specifications for necessary laboratory apparatus and reagent preparations. *See also Definition of Terms and Explanatory Notes.*

Method may be divided into several descriptive sections.

References direct the user to the published collaborative study and any subsequent revisions in the method. Other informative references may be included.

Attachment: Proposed Guide to Method Format

Guide to Method Format

(Method shown is incomplete to allow space for description.)

Locator number identifies method by chapter, subchapter, and sequence within the subchapter for easy cross referencing and access. 4 = chapter 4; .10 = subchapter 10; .03 = the third method found in Chapter 4, subchapter 10. The locator number is not the permanent number and is included only for convenient accessibility.

Permanent number identifies method by year of adoption or first appearance in *Official Methods of Analysis of AOAC INTERNATIONAL*. 996 = First Action 1996; .13 = sequence of adoption in 1996.

Title may include analyte and matrix, type of method, and official status.

Applicability statement addresses utility and limitations on use of method or other information.

Specifications for necessary laboratory apparatus and reagent preparations. *See also Definition of Terms and Explanatory Notes.*

Method may be divided into several descriptive sections.

Chemical names of pesticides and drugs are given at end of pertinent chapter.

Calculation symbols are identified and show correct units.

References direct the user to the published collaborative study and any subsequent revisions in the method. Other informative references may be included.

Chemical Abstracts Service Registry Number. A unique identifier that may be used to search a number of data-retrieval systems.

4.10.03

AOAC Official Method 996.13
Ethoxyquin in Feeds
Liquid Chromatographic Method
First Action 1996

(Applicable for determination of 0.5–300 μg/g ethoxyquin in dry extruded pet food or meat meal.)

A. MethodPerformance

The performance criteria in Table 2015.11A is prescribed by Standard Methods Performance Requirements (SMPR) 2014.009, which was adopted by the AOAC StakeholderPanelforDietarySupplements(SPDS).Laboratory(ies)implementingthis methodshouldfollowISOStandard17025toverifythattheperformanceofthismethodin yourlaboratorymeetsthecriteriaintable2015.11A. Pleasereportverificationresultsto AOACatthislink:AOAC2015.11.

Table 2015.11A: Verification Acceptance Criteria

Parameters	Analytical Ranges	
	1-10% (w/w)	>10-100% (w/w)
Repeatability (RSDr)	≤ 3%	≤2%
Recovery	92-105%	98-102%

B. Principle

Ethoxyquin is extracted with acetonitrile. Extract is analyzed by isocratic liquid chromatography with fluorescence detection.

C. Apparatus

(a) *Liquid chromatograph (LC).* Generating 1500 ± 200 psi; with peak area integrator (manual or computer), isocratic LC pump, and column heater. Operating conditions: injection volume, 20 μL; flow rate, 1.3 mL/min; temperature, 35°C; fluorescence detector output, analog to digital conversion; detector settings: excitation, 360 nm; emission, 432 nm.

D. Reagents

(a) *Water.* LC grade.
(b) *Acetonitrile.* LC grade.

E. Preparation of Standard Solutions

(a) *Ethoxyquin standard stock solution.* 400 μg/mL. Weigh the equivalent of 0.1000 g liquid ethoxyquin into 250 mL amber volumetric flask and dilute to volume with acetonitrile. (*Note:* Amount of ethoxyquin needed for preparation of stock solution is based on purity of liquid, e.g.: for purity of 93.5%, amount of liquid ethoxyquin = 0.100/0.935 = 0.1070 g.)

F. Calculations

Calculate concentration of ethoxyquin, μg/g or ppm, in test sample from calibration curve (using linear regression with line forced through zero intercept) as follows:

$$\text{Ethoxyquin, } \mu g/g \text{ or ppm} = \frac{C \times 1.5 \times F}{W}$$

where C = ethoxyquin concentration from LC calibration curve, μg/mL; 1.5 = volume of acetonitrile added to test solution, mL; F = dilution factor; W = weight of test portion, g.

Reference: *J. AOAC Int.* **80,** 725(1997).

CAS-91-53-2 (ethoxyquin) 6-ethoxy-1,2-dihydro-2,2,4-trimethylquinoline

AOAC INTERNATIONAL
The Scientific Association Dedicated to Analytical Excellence®

MEMORANDUM

Date: **February 10, 2016**

To: **Official Methods Board**

From: **Scott Coates, AOAC Chief Scientific Officer**

Subject: **Item II. b. Updating Appendix F**

BACKGROUND

Appendix F: Guidelines for Standard Methods Performance Requirements (SMPR) was drafted in the 2009 – 2010 timeframe. Since 2010 AOAC has developed and adopted more than 60 SMPRs. The SMPR process has evolved since 2010 and some of the descriptions of processes have become obsolete, and frankly some sections are not needed any more. A revised, streamlined version of Appendix F is attached as attachment 1. An original Appendix F is attached as attachment 2 for reference.

Discussion

1) Most of the proposed changes are sections that have been removed from the narrative descriptions in the first 4 pages. An outdated Figure 1 has been replaced with a schematic that better represents the process as it occurs today.
2) The term “Intermediate repeatability/reproducibility” is added to table A1, defined in table A2, and evaluation recommendations provided in table 3.
3) The term ”LOQ” replaced by “Limit of determination (LOD)” in table A1
4) Question for OMB: the Guideline identifies “bias” as one of recommended parameters, but “bias” has never been used in an SMPR. The terms “accuracy” or “recovery” are routinely used in SMPRs. Should we recommend “bias” to the working groups now working on SMPRs? Or should we replace “bias” in Appendix F with “accuracy” or “recovery”?

RECOMMENDATION:

Please review proposed changes. Revise as needed. Request a formal motion and vote on revisions to Appendix F.

ENCLOSURES: OMA Appendix F

Appendix F: Guidelines for Standard Method Performance Requirements

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Introduction to Standard Method Performance Requirements

Standard method performance requirements (SMPRs) are a unique and novel concept for the analytical methods community. SMPRs are voluntary consensus standards, developed by stakeholders, that prescribe the minimum analytical performance requirements for classes of analytical methods. In the past, analytical methods were evaluated and the results compared to a "gold standard" method, or if a gold standard method did not exist, then reviewers would decide retrospectively if the analytical performance was acceptable. Frequently, method developers concentrated on the process of evaluating the performance parameters of a method, and rarely set acceptance criteria. However, as the *Eurachem Guide* points out: " . . . the judgment of method suitability for its intended use is equally important . . ." (1) to the evaluation process.

International Voluntary Consensus Standards

An SMPR is a form of an international, voluntary consensus standard. A standard is an agreed, repeatable way of doing something that is published as document that contains a technical specification or other precise criteria designed to be used consistently as a rule, guideline, or definition. SMPRs are a *consensus* standards developed by stakeholders in a very controlled process that ensures that users, research organizations, government departments, and consumers work together to create a standard that meets the demands of the analytical community and technology. SMPRs are also *voluntary* standards. AOAC cannot, and does not, impose the use of SMPRs. Users are free to use SMPRs as they see fit. AOAC is very careful to include participants from as many regions of the world as possible so that SMPRs are accepted as *international* standards.

SMPR Format

The general format for an SMPR is provided in *Annex A*.

Each SMPR is identified by a unique SMPR number consisting of the year followed by a sequential identification number (YYYY.XXX). An SMPR number is assigned when the standard is approved. By convention, the SMPR number indicates the year a standard is approved (as opposed to the year the standard is initiated). For example, SMPR 2010.003 indicates the third SMPR adopted in 2010.

The SMPR number is followed by a method name that must include the analyte(s), matrix(es), and analytical technique (unless the SMPR is truly intended to be independent of the analytical technology). The method name may also refer to a "common" name (e.g., "Kjeldahl" method).

The SMPR number and method name are followed by the name of the stakeholder panel or expert review panel that approved the SMPR, and the approval and effective dates.

Information about method requirements is itemized into nine categories: (*1*) intended use; (*2*) applicability; (*3*) analytical technique; (*4*) definitions; (*5*) method performance requirements; (*6*) system suitability; (*7*) reference materials; (*8*) validation guidance; and (*9*) maximum time-to-determination.

An SMPR for qualitative and/or identification methods may include up to three additional annexes: (*1*) inclusivity/selectivity panel; (*2*) exclusivity/cross-reactivity panel; and (*3*) environmental material panels. These annexes not required.

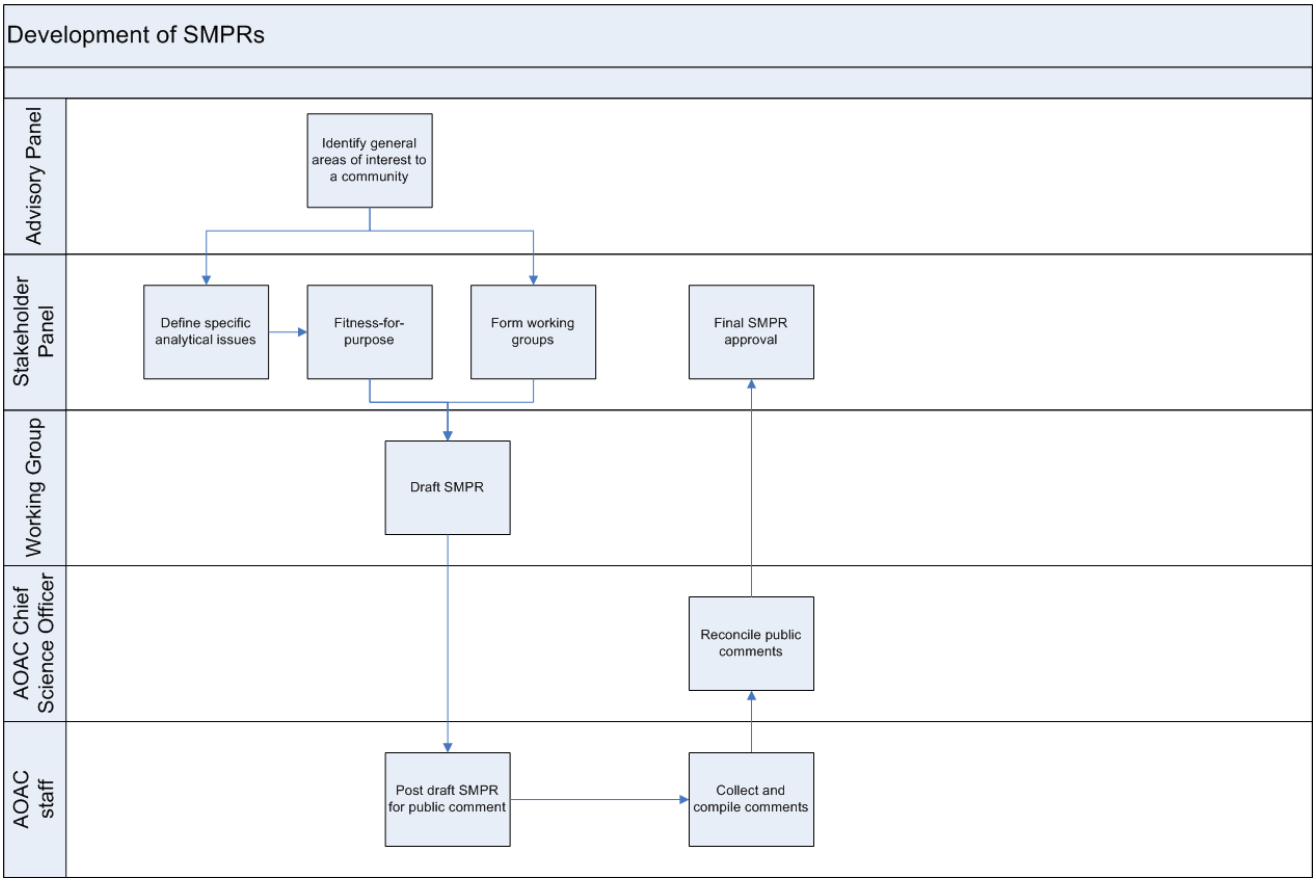


Figure 1. Schematic flowchart diagram of the SMPR development process.

Organizational Structure

Advisory panels.—Most commonly, an SMPR is created in response to an analytical need identified by an advisory panel. Advisory panels normally consist of sponsors and key stakeholders who have organized to address analytical problems. Usually, the advisory panel identifies general analytical problems, such as the need to update analytical methods for determination of nutrients in infant formula. An advisory panel, with the input of appropriate subject matter experts, also prioritizes the specific analytical problems within the general topic. This panel is critical in planning for the stakeholder panel meeting.

Stakeholder panels.—After an advisory panel has identified a general analytical problem, AOAC announces the standards development activity, identifies stakeholders, and organizes a stakeholder panel. Membership on a stakeholder panel is open to anyone materially affected by the proposed standard. AOAC recruits scientists to participate on stakeholder panels on the basis of their expertise with the analytical problem identified by the advisory panel. Experts are recruited from academia, government, nongovernmental organizations (such as ISO), industry, contract research organizations, method developers, and instrument/equipment manufacturers. AOAC employs a representative voting panel model to ensure balance with regards to stakeholder perspective, and to ensure that no particular stakeholder perspective dominates the proceedings of the stakeholder panel. All stakeholder candidates are reviewed by the AOAC Chief Scientific Officer (CSO) for relevant qualifications, and again by the Official Methods Board to ensure that the stakeholder panel is balanced and all stakeholders are fairly represented.

Stakeholder panels are extremely important as they serve several functions: (*1*) identify specific analytical topics within the general analytical problem described by the advisory panel; (*2*) form working groups to address the specific analytical topics; (*3*) identify additional subject matter experts needed for the working groups; (*4*) provide oversight of the SMPR development; and (*5*) formally adopt SMPRs originally drafted by working groups.

Working groups.—Working groups are formed by the stakeholder panel when a specific analytical topic has been identified. The primary purpose of a working group is to draft an SMPR. Working groups may also be formed to make general recommendations, such as developing a common definition to be used by multiple working groups. For example, SPIFAN formed a working group to create a definition for "infant formula" that could be shared and used by all of the SPIFAN working groups.

Creating an SMPR

One of the first steps in organizing a project is creating a fitness-for-purpose statement. In AOAC, the fitness-for-purpose statement is a very general description of the methods needed. It is the responsibility of a working group chair to draft a fitness-for-purpose statement. A working group chair is also asked to prepare a presentation with background information about the analyte, matrix, and the nature of the analytical problem. A working group chair presents the background information and proposes a draft fitness-for-purpose statement to the presiding stakeholder panel. The stakeholder panel is asked to endorse the fitness-for-purpose statement.

Normally, a working chair and/or the AOAC CSO prepares a draft SMPR. A draft SMPR greatly facilitates the process and provides the working group with a structure from which to work.

Working group members are advised to first consider the "intended use" and "maximum time-to-determination" sections as this will greatly affect expectations for candidate methods. For example, methods intended to be used for surveillance probably need to be quick but do not require a great deal of precision, and false-positive results might be more tolerable. Whereas methods intended to be used for dispute resolution will require better accuracy, precision, and reproducibility, but time to determination is not as important.

Once a working group has agreed on the intended use of candidate methods, then it can begin to define the applicability of candidate methods. The applicability section of the SMPR is one of the most important, and sometimes most difficult, sections of the SMPR. The analyte(s) and matrixes must be explicitly identified. For chemical analytes, International Union of Pure and Applied Chemistry (IUPAC) nomenclature and/or Chemical Abstracts Service (CAS) registry numbers should be specified. Matrixes should be clearly identified including the form of the matrix such as raw, cooked, tablets, powders, etc. The nature of the matrix may affect the specific analyte. It may be advantageous to fully identify and describe the matrix before determining the specific analyte(s). It is not uncommon for working groups to revise the initial definition of the analyte(s) after the matrix(es) has been better defined.

Open Comment Period

Once a working group has produced a draft standard, AOAC opens a comment period for the standard. The comment period provides an opportunity for other stakeholders to state their perspective on the draft SMPR. All collected comments are reviewed by the AOAC CSO and the working group chair, and the comments are reconciled. If there are significant changes required to the draft standard as a result of the comments, the working group is convened to discuss and any unresolved issues will be presented for discussion at the stakeholder panel meeting.

Submission of Draft SMPRs to the Stakeholder Panel

Stakeholder panels meet several times a year at various locations. The working group chair (or designee) presents a draft SMPR to the stakeholder panel for review and discussion. A working group chair is expected to be able to explain the conclusions of the working group, discuss comments received, and to answer questions from the stakeholder panel. The members of the stakeholder panel may revise, amend, approve, or defer a decision on the proposed SMPR. A super majority of 2/3 or more of those voting is required to adopt an SMPR as an AOAC voluntary consensus standard.

Publication

Adopted SMPRs are prepared for publication by AOAC staff, and are published in the *Journal of AOAC INTERNATIONAL* and in the AOAC *Official Methods of Analysis*℠ compendium. Often, the AOAC CSO and working group chair prepare a companion article to introduce an SMPR and describe the analytical issues considered and resolved by the SMPR. An SMPR is usually published within 6 months of adoption.

Conclusion

SMPRs are a unique and novel concept for the analytical methods community. SMPRs are voluntary, consensus standards developed by stakeholders that prescribe the minimum analytical performance requirements for classes of analytical methods. The SMPR Guidelines provide a structure for working groups to use as they develop an SMPR. The guidelines have been employed in several AOAC projects and have been proven to be very useful. The guidelines are not a statute that users must conform to; they are a "living" document that is regularly updated, so users should check the AOAC website for the latest version before using the guidelines.

References

(1) Eurachem, *The Fitness for Purpose of Analytical Methods: A Laboratory Guide to Method Validation and Related Topics*, *Validation*, http://www.eurachem.org/guides/pdf/valid.pdf, posted December 1998, accessed March 2012

ANNEX A
Format of a
Standard Method Performance Requirement

AOAC SMPR YYYY.XXX
(YYYY = Year; XXX = sequential identification number)

Method Name: Must include the analyte(s), matrix(es), and analytical technique [unless the standard method performance requirement (SMPR) is truly intended to be independent of the analytical technology]. The method name may refer to a "common" name (e.g., "Kjeldahl" method).

Approved By: Name of stakeholder panel or expert review panel

Final Version Date: Date

Effective Date: Date

1. Intended Use: Additional information about the method and conditions for use.

2. Applicability: List matrixes if more than one. Provide details on matrix such as specific species for biological analytes, or International Union of Pure and Applied Chemistry (IUPAC) nomenclature and Chemical Abstracts Service (CAS) registry number for chemical analytes. Specify the form of the matrix such as raw, cooked, tablets, powders, etc.

3. Analytical Technique: Provide a detailed description of the analytical technique if the SMPR is to apply to a specific analytical technique; or state that the SMPR applies to any method that meets the method performance requirements.

4. Definitions: List and define terms used in the performance parameter table (*see* Table A2 for list of standard terms).

5. Method Performance Requirements: List the performance parameters and acceptance criteria appropriate for each method/analyte/matrix. *See* Table A1 for appropriate performance requirements.

If more than one analyte/matrix, and if acceptance criteria differ for analyte/matrix combinations then organize a table listing each analyte/matrix combination and its minimum acceptance criteria for each performance criteria.

6. System Suitability Tests and/or Analytical Quality Control: Describe minimum system controls and QC procedures.

7. Reference Material(s): Identify the appropriate reference materials if they exist, or state that reference materials are not available. Refer to *Annex E* (*AOAC Method Accuracy Review*) for instructions on the use of reference materials in evaluations.

8. Validation Guidance: Recommendations for type of evaluation or validation program such as single-laboratory validation (SLV), *Official Methods of Analysis*℠ (OMA), or *Performance Tested Methods*℠ (PTM).

9. Maximum Time-to-Determination: Maximum allowable time to complete an analysis starting from the test portion preparation to final determination or measurement.

Annex I: Inclusivity/Selectivity Panel. Recommended for qualitative and identification method SMPRs.

Annex II: Exclusivity/Cross-Reactivity Panel. Recommended for qualitative and identification method SMPRs.

Annex III: Environmental Materials Panel. Recommended for qualitative and identification method SMPRs.

Table A1. Performance requirements

Classifications of methods[a]				
Quantitative method		Qualitative method		
Main component[b]	Trace or contaminant[c]	Main component[b]	Trace or contaminant[c]	Identification method
Parameter				
Single-laboratory validation				
Applicable range	Applicable range	Inclusivity/selectivity	Inclusivity/selectivity	Inclusivity/selectivity
Bias[d]	Bias[d]	Exclusivity/cross-reactivity	Exclusivity/cross-reactivity	Exclusivity/cross-reactivity
Precision (RSDr)	Precision (RSDr)	Environmental interference	Environmental interference	Environmental interference
Intermediate precision/ reproducibility (RSDi)	Intermediate precision/ reproducibility (RSDi)	Laboratory variance	Laboratory variance	
Recovery	Recovery			
Limit of quantitation (LOQ)	Limit of determination (LOD)	Probability of detection (POD)[e]	POD at AMDL[f]	Probability of identification (POI)
Reproducibility				
RSD_R or target measurement uncertainty	RSD_R or target measurement uncertainty	POD (0)	POD (0)	POI (c)
		POD (c)	POD (c)	
		Laboratory POD[g]	Laboratory POD[g]	Laboratory POI

[a] *See Annex B* for additional information on classification of methods.

[b] ≥100 g/kg.

[c] <100 g/kg.

[d] If a reference material is available.

[e] At a critical level.

[f] AMDL = Acceptable minimum detection level.

[g] LPOD = CPOD.

Table A2. Recommended definitions

Bias	Difference between the expectation of the test results and an accepted reference value. Bias is the total systematic error as contrasted to random error. There may be one or more systematic error components contributing to the bias.
Environmental interference	Ability of the assay to detect target organism in the presence of environmental substances and to be free of cross reaction from environmental substances.
Exclusivity	Strains or isolates or variants of the target agent(s) that the method must not detect.
Inclusivity	Strains or isolates or variants of the target agent(s) that the method can detect.
Laboratory probability of detection (POD)	Overall fractional response (mean POD = CPOD) for the method calculated from the pooled POD_j responses of the individual laboratories (j = 1, 2, ..., L).[a] *See Annex C*.
Limit of quantitation (LOQ)	Minimum concentration or mass of analyte in a given matrix that can be reported as a quantitative result.
POD (0)	Probability of the method giving a (+) response when the sample is truly without analyte.
POD (c)	Probability of the method giving a (–) response when the sample is truly without analyte.
POD	Proportion of positive analytical outcomes for a qualitative method for a given matrix at a given analyte level or concentration. Consult *Annex C* for a full explanation.
Probability of identification (POI)	Expected or observed fraction of test portions at a given concentration that gives positive result when tested at a given concentration. Consult *Probability of Identification (POI): A Statistical Model for the Validation of Qualitative Botanical Identification Methods*.[c]
Precision (repeatability)	Closeness of agreement between independent test results obtained under stipulated conditions. The measure of precision is usually expressed in terms of imprecision and computed as a standard deviation of the test results.[d]
Recovery	Fraction or percentage of the analyte that is recovered when the test sample is analyzed using the entire method. There are two types of recovery: (*1*) Total recovery based on recovery of the native plus added analyte, and (*2*) marginal recovery based only on the added analyte (the native analyte is subtracted from both the numerator and denominator).[e]
Repeatability	Precision under repeatability conditions.
Repeatability conditions	Conditions where independent test results are obtained with the same method on identical test items in the same laboratory by the same operator using the same equipment within short intervals of time.
Reproducibility	Precision under reproducibility conditions.
Reproducibility conditions	Conditions where independent test results are obtained with the same method on identical test items in different laboratories with different operators using different equipment.
Relative standard deviation (RSD)	$RSD = s_i \times 100/\bar{x}$
Standard deviation (s_i)	$s_i = [\Sigma(x_i - \bar{x})^2/n]^{0.5}$

[a] *AOAC INTERNATIONAL Methods Committee Guidelines for Validation of Biological Threat Agent Methods and/or Procedures* (*Calculation of CPOD and dCPOD Values from Qualitative Method Collaborative Study Data*), *J. AOAC Int*. **94**, 1359(2011) and *Official Methods of Analysis of AOAC INTERNATIONAL* (2012) 19th Ed., *Appendix I*.

[b] *International Vocabulary of Metrology (VIM)—Basic and General Concepts and Associated Terms* (2008) JCGM 200:2008, Joint Committee for Guides in Metrology (JCGM), www.bipm.org

[c] LaBudde, R.A., & Harnly, J.M. (2012) *J. AOAC Int*. **95**, 273–285.

[d] ISO 5725-1-1994.

[e] *Official Methods of Analysis* (2012) *Appendix D* (*Guidelines for Collaborative Study Procedures to Validate Characteristics of a Method of Analysis*), AOAC INTERNATIONAL, Gaithersburg, MD.

Intermediate precision/reproducibility	The precision of an analytical procedure expressing the closeness of agreement between a series of measurements obtained from multiple sampling of the same homologous sample under certain precribed conditions, i.e., different analysts, different days, different instruments. Designated as RSDi. RSDi lies between within laboratory precision (repeatability or RSDr) and among laboratory precision (reproducibility or RSDR).

Table A3. Recommendations for evaluation

Bias (if a reference material is available)	A minimum of five replicate analyses of a Certified Reference Material.[a]
Environmental interference	Analyze test portions containing a specified concentration of one environmental materials panel member. Materials may be pooled. Consult with AOAC statistician.
Exclusivity/cross-reactivity	Analyze one test portion containing a specified concentration of one exclusivity panel member. More replicates can be used. Consult with AOAC statistician.
Inclusivity/selectivity	Analyze one test portion containing a specified concentration of one inclusivity panel member. More replicates can be used. Consult with AOAC statistician.
Limit of quantitation (LOQ)	Estimate the LOQ = average (blank) + 10 × s_0 (blank). Measure blank samples with analyte at the estimated LOQ. Calculate the mean average and standard deviation of the results. Guidance[b]: For ML ≥ 100 ppm (0.1 mg/kg): LOD = ML × 1/5. For ML < 100 ppm (0.1 mg/kg): LOD = ML × 2/5.
Measurement uncertainty	Use ISO 21748: *Guidance for the use of repeatability, reproducibility, and trueness estimates in measurement uncertainty estimation to analyze data collected for bias, repeatability, and intermediate precision to estimate measurement uncertainty*.
POD(0)	Use data from collaborative study.
POD (c)	
Repeatability	Prepare and homogenize three unknown samples at different concentrations to represent the full, claimed range of the method. Analyze each unknown sample by the candidate method seven times, beginning each analysis from weighing out the test portion through to final result with no additional replication (unless stated to do so in the method). All of the analyses for one unknown sample should be performed within as short a period of time as is allowed by the method. The second and third unknowns may be analyzed in another short time period. Repeat for each claimed matrix.
Probability of detection (POD)	Determine the desired POD at a critical concentration. Consult with Table A7 to determine the number of test portions required to demonstrate the desired POD.
Probability of identification (POI)	Consult *Probability of Identification (POI): A Statistical Model for the Validation of Qualitative Botanical Identification Methods*[c].
Recovery	Determined from spiked blanks or samples with at least seven independent analyses per concentration level at a minimum of three concentration levels covering the analytical range. Independent means at least at different times. If no confirmed (natural) blank is available, the average inherent (naturally containing) level of the analyte should be determined on at least seven independent replicates. Marginal % recovery = $(C_f - C_u) \times 100/C_A$ Total % recovery = $100(C_f)/(C_u + C_A)$ where C_f = concentration of fortified samples, C_u = concentration of unfortified samples, and C_A = concentration of analyte added to the test sample.[d] Usually total recovery is used unless the native analyte is present in amounts greater than about 10% of the amount added, in which case use the method of addition.[e]
Reproducibility (collaborative or interlaboratory study)	Quantitative methods: Recruit 10–12 collaborators; must have eight valid data sets; two blind duplicate replicates at five concentrations for each analyte/matrix combination to each collaborator.
	Qualitative methods: Recruit 12–15 collaborators; must have 10 valid data sets; six replicates at five concentrations for each analyte/matrix combination to each collaborator.

[a] *Guidance for Industry for Bioanalytical Method Validation* (May 2001) U.S. Department of Health and Human Services, U.S. Food and Drug Administration, Center for Drug Evaluation and Research (CDER), Center for Veterinary Medicine (CVM).

[b] Codex Alimentarius Codex Procedure Manual.

[c] LaBudde, R.A., & Harnly, J.M. (2012) *J. AOAC Int.* **95**, 273–285.

[d] *Guidelines for Collaborative Study Procedures to Validate Characteristics of a Method of Analysis* (2012) *Official Methods of Analysis*, 19th Ed., *Appendix D,* AOAC INTERNATIONAL, Gaithersburg, MD.

[e] *AOAC Guidelines for Single-Laboratory Validation of Chemical Methods for Dietary Supplements and Botanicals* (2012) *Official Methods of Analysis*, 19th Ed., *Appendix K*, AOAC INTERNATIONAL, Gaithersburg, MD.

Intermediate precision	Analysis by different analysts, on different days, on different instruments. Analyze at least five sets of replicates on the same test materials under these different conditions for each concentration level that differs by approximately an order of magnitude. (Appendix K of Official Methods of Analysis)

Table A4. Expected precision (repeatability) as a function of analyte concentration[a]

Analyte, %	Analyte ratio	Unit	RSD, %
100	1	100%	1.3
10	10^{-1}	10%	1.9
1	10^{-2}	1%	2.7
0.01	10^{-3}	0.1%	3.7
0.001	10^{-4}	100 ppm (mg/kg)	5.3
0.0001	10^{-5}	10 ppm (mg/kg)	7.3
0.00001	10^{-6}	1 ppm (mg/kg)	11
0.000001	10^{-7}	100 ppb (µg/kg)	15
0.0000001	10^{-8}	10 ppb (µg/kg)	21
0.00000001	10^{-9}	1 ppb (µg/kg)	30

[a] Table excerpted from *AOAC Peer-Verified Methods Program, Manual on Policies and Procedures* (1998) AOAC INTERNATIONAL, Gaithersburg, MD.

The precision of a method is the closeness of agreement between independent test results obtained under stipulated conditions. Precision is usually expressed in terms of imprecision and computed as a relative standard deviation of the test results. The imprecision of a method increases as the concentration of the analyte decreases. This table provides targets RSDs for a range of analyte concentrations.

Table A5. Expected recovery as a function of analyte concentration[a]

Analyte, %	Analyte ratio	Unit	Mean recovery, %
100	1	100%	98–102
10	10^{-1}	10%	98–102
1	10^{-2}	1%	97–103
0.01	10^{-3}	0.1%	95–105
0.001	10^{-4}	100 ppm	90–107
0.0001	10^{-5}	10 ppm	80–110
0.00001	10^{-6}	1 ppm	80–110
0.000001	10^{-7}	100 ppb	80–110
0.0000001	10^{-8}	10 ppb	60–115
0.00000001	10^{-9}	1 ppb	40–120

[a] Table excerpted from *AOAC Peer-Verified Methods Program, Manual on Policies and Procedures* (1998) AOAC INTERNATIONAL, Gaithersburg, MD.

Recovery is defined as the ratio of the observed mean test result to the true value. The range of the acceptable mean recovery expands as the concentration of the analyte decreases. This table provides target mean recovery ranges for analyte concentrations from 100% to 1 ppb.

Table A6. Predicted relative standard deviation of reproducibility ($PRSD_R$)[a]

Concentration (C)	Mass fraction (C)	$PRSD_R$, %
100%	1.0	2
1%	0.01	4
0.01%	0.0001	8
1 ppm	0.000001	16
10 ppb	0.00000001	32
1 ppb	0.000000001	45

[a] Table excerpted from *Definitions and Calculations of HorRat Values from Intralaboratory Data*, HorRat for SLV.doc, 2004-01-18, AOAC INTERNATIONAL, Gaithersburg, MD.

Predicted relative standard deviation = $PRSD_R$. Reproducibility relative standard deviation calculated from the Horwitz formula:

$$PRSD_R = 2C^{-0.15}, \text{ where C is expressed as a mass fraction}$$

This table provides the calculated $PRSD_R$ for a range of concentrations. *See Annex D* for additional information.

Table A7. POD and number of test portions[a,b]

	Sample size required for proportion						
Assume	1. Binary outcome (occur/not occur). 2. Constant probability rho of event occurring. 3. Independent trials (e.g., simple random sample). 4. Fixed number of trials (*N*)						
Inference	95% Confidence interval lies entirely at or above specified minimum rho						
Desired	Sample size *N* needed						
Minimum probability rho, %	Sample size (*N*)	Minimum No. events (*x*)	Maximum No. nonevents (*y*)	1-Sided lower confidence limit on rho[c], %	Expected lower confidence limit on rho, %	Expected upper confidence limit on rho, %	Effective AOQL[d] rho, %
50	3	3	0	52.6	43.8	100.0	71.9
50	10	8	2	54.1	49.0	94.3	71.7
50	20	14	6	51.6	48.1	85.5	66.8
50	40	26	14	52.0	49.5	77.9	63.7
50	80	48	32	50.8	49.0	70.0	59.5
55	4	4	0	59.7	51.0	100.0	75.5
55	10	9	1	65.2	59.6	100.0	79.8
55	20	15	5	56.8	53.1	88.8	71.0
55	40	28	12	57.1	54.6	81.9	68.2
55	80	52	28	55.9	54.1	74.5	64.3
60	5	5	0	64.9	56.5	100.0	78.3
60	10	9	1	65.2	59.6	100.0	79.8
60	20	16	4	62.2	58.4	91.9	75.2
60	40	30	10	62.4	59.8	85.8	72.8
60	80	56	24	61.0	59.2	78.9	69.1
65	6	6	0	68.9	61.0	100.0	80.5
65	10	9	1	65.2	59.6	100.0	79.8
65	20	17	3	67.8	64.0	94.8	79.4
65	40	31	9	65.1	62.5	87.7	75.1
65	80	59	21	65.0	63.2	82.1	72.7
70	7	7	0	72.1	64.6	100.0	82.3
70	10	10	0	78.7	72.2	100.0	86.1
70	20	18	2	73.8	69.9	97.2	83.6
70	40	33	7	70.7	68.0	91.3	79.7
70	80	63	17	70.4	68.6	86.3	77.4
75	9	9	0	76.9	70.1	100.0	85.0
75	10	10	0	78.7	72.2	100.0	86.1
75	20	19	1	80.4	76.4	100.0	88.2
75	40	35	5	76.5	73.9	94.5	84.2
75	80	67	13	75.9	74.2	90.3	82.2
80	11	11	0	80.3	74.1	100.0	87.1
80	20	19	1	80.4	76.4	100.0	88.2
80	40	37	3	82.7	80.1	97.4	88.8
80	80	70	10	80.2	78.5	93.1	85.8
85	20	20	0	88.1	83.9	100.0	91.9
85	40	38	2	86.0	83.5	98.6	91.1
85	80	74	6	86.1	84.6	96.5	90.6
90	40	40	0	93.7	91.2	100.0	95.6
90	60	58	2	90.4	88.6	99.1	93.9
90	80	77	3	91.0	89.5	98.7	94.1
95	60	60	0	95.7	94.0	100.0	97.0
95	80	80	0	96.7	95.4	100.0	97.7
95	90	89	1	95.2	94.0	100.0	97.0
95	96	95	1	95.5	94.3	100.0	97.2
98	130	130	0	98.0	97.1	100.0	98.6
98	240	239	1	98.2	97.7	100.0	98.8
99	280	280	0	99.0	98.6	100.0	99.3
99	480	479	1	99.1	98.8	100.0	99.4

[a] Table excerpted from Technical Report TR308, *Sampling plans to verify the proportion of an event exceeds or falls below a specified value*, LaBudde, R. (June 4, 2010) (not published). The table was produced as part of an informative report for the Working Group for Validation of Identity Methods for Botanical Raw Materials commissioned by the AOAC INTERNATIONAL Presidential Task Force on Dietary Supplements. The project was funded by the Office of Dietary Supplements, National Institutes of Health.

[b] Copyright 2010 by Least Cost Formulations, Ltd. All rights reserved.

[c] Based on modified Wilson score 1-sided confidence interval.

[d] AOQL = Average outgoing quality level.

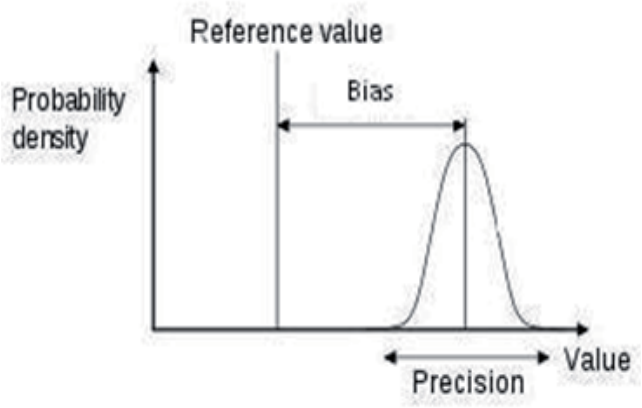


Figure A1. Relationship between precision versus bias (trueness). Trueness is reported as bias. Bias is defined as the difference between the test results and an accepted reference value.

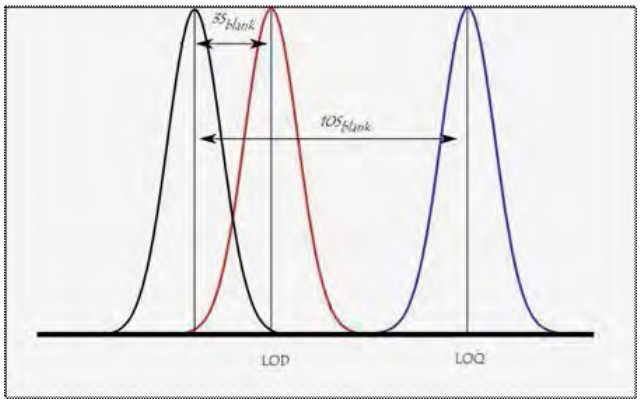


Figure A2. Relationship between LOD and LOQ. LOD is defined as the lowest quantity of a substance that can be distinguished from the absence of that substance (a blank value) within a stated confidence limit. LOQ is the level above which quantitative results may be obtained with a stated degree of confidence.

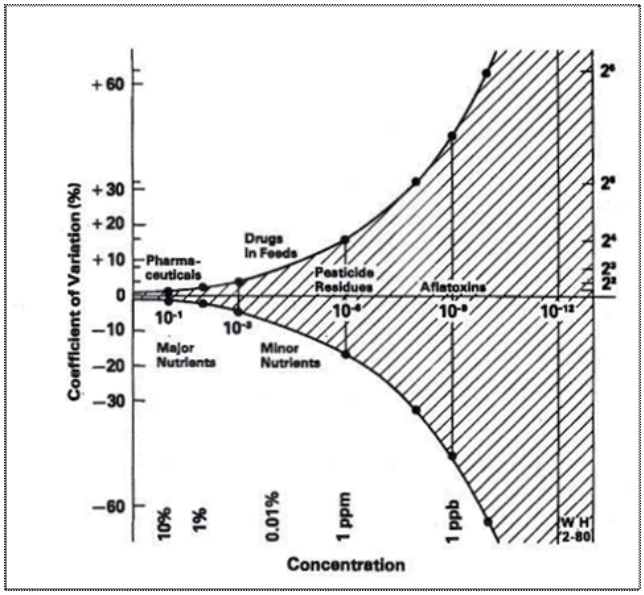


Figure A3. Horwitz Curve, illustrating the exponential increase in the coefficient of variation as the concentration of the analyte decreases [*J. AOAC Int*. 89, 1095(2006)].

ANNEX B
Classification of Methods

The following guidance may be used to determine which performance parameters in Table A1 apply to different classifications of methods. AOAC INTERNATIONAL does not recognize the term "semiquantitative" as a method classification. Methods that have been self-identified as semiquantitative will be classified into one of the following five types:

Type I: Quantitative Methods

Characteristics: Generates a continuous number as a result.

Recommendation: Use performance requirements specified for quantitative method (main or trace component). Use recovery range and maximum precision variation in Tables A4 and A5.

In some cases and for some purposes, methods with less accuracy and precision than recommended in Tables A4 and A5 may be acceptable. Method developers should consult with the appropriate method committee to determine if the recommendations in Tables A4 and A5 do or do not apply to their method.

Type II: Methods that Report Ranges

Characteristics: Generates a "range" indicator such as 0, low, moderate, and high.

Recommendation: Use performance requirements specified for qualitative methods (main component). Specify a range of POD for each range "range" indicator.

Type III: Methods with Cutoff Values

Characteristics: Method may generate a continuous number as an interim result (such as a CT value for a PCR method), which is not reported but converted to a qualitative result (presence/ absence) with the use of a cutoff value.

Recommendation: Use performance requirements specified for qualitative methods.

Type IV: Qualitative Methods

Characteristics: Method of analysis whose response is either the presence or absence of the analyte detected either directly or indirectly in a specified test portion.

Recommendation: Use performance requirements specified for qualitative methods.

Type V: Identification Methods

Characteristics: Method of analysis whose purpose is to determine the identity of an analyte.

Recommendation: Use performance requirements specified for identification methods.

ANNEX C
Understanding the POD Model

Excerpted from AOAC INTERNATIONAL Methods Committee Guidelines for Validation of Biological Threat Agent Methods and/or Procedures, J. AOAC Int. ***94****, 1359(2011) and Official Methods of Analysis of AOAC INTERNATIONAL (2012) 19th Ed., Appendix I.*

The Probability of Detection (POD) model is a way of characterizing the performance of a qualitative (binary) method. A binary qualitative method is one that gives a result as one of two possible outcomes, either positive or negative, presence/absence, or +/–.

The single parameter of interest is the POD, which is defined as the probability at a given concentration of obtaining a positive response by the detection method. POD is assumed to be dependent on concentration, and generally, the probability of a positive response will increase as concentration increases.

For example, at very low concentration, the expectation is that the method will not be sensitive to the analyte, and at very high concentration, a high probability of obtaining a positive response is desired. The goal of method validation is to characterize how method response transitions from low concentration/low response to high concentration/high response.

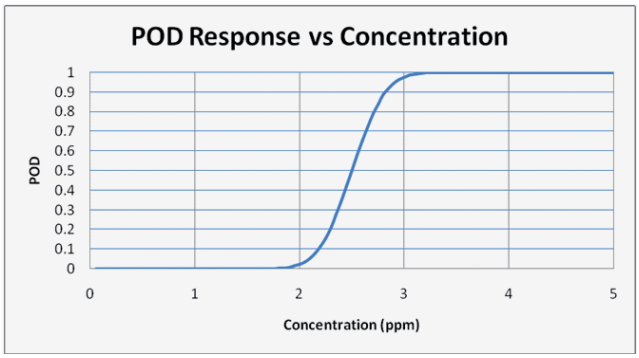


Figure C1. Theoretical POD curve for a qualitative detection method.

POD is always considered to be dependent upon analyte concentration. The POD curve is a graphical representation of method performance, where the probability is plotted as a function of concentration (*see*, for example, Figure C1).

The POD model is designed to allow an objective description of method response without consideration to an a priori expectation of the probabilities at given concentrations. The model is general enough to allow comparisons to any theoretical probability function.

The POD model is also designed to allow for an independent description of method response without consideration to the response of a reference method. The model is general enough to allow for comparisons between reference and candidate method responses, if desired.

Older validation models have used the terms "sensitivity," "specificity," "false positive," and "false negative" to describe method performance. The POD model incorporates all of the performance concepts of these systems into a single parameter, POD.

For example, false positive has been defined by some models as the probability of a positive response, given the sample is truly negative (concentration = 0). The equivalent point on the POD curve for this performance characteristic is the value of the curve at Conc = 0.

Similarly, false negative has sometimes been defined as the probability of a negative response when the sample is truly positive (concentration >0). In the POD curve, this would always be specific to a given sample concentration, but would be represented as the distance from the POD curve to the POD = 1 horizontal top axis at all concentrations except C = 0.

The POD model incorporates all these method characteristics into a single parameter, which is always assumed to vary by concentration. In other models, the terms "false positive," "false negative," "sensitivity," and "specificity" have been defined in a variety of ways, usually not conditional on concentration. For these reasons, these terms are obsolete under this model (*see* Table C1).

The terms "sensitivity," "specificity," "false positive," and "false negative" are obsolete under the POD model (*see* Figure C2).

Table C1. Terminology

Traditional terminology	Concept	POD equivalent	Comment
False positive	Probability of the method giving a (+) response when the sample is truly without analyte	POD(0) POD at conc = 0	POD curve value at conc = 0; "*Y*-intercept" of the POD curve
Specificity	Probability of the method giving a (-) response when the sample is truly without analyte	1-POD(0)	Distance along the POD axis from POD = 1 to the POD curve value
False negative (at a given concentration)	Probability of a (–) response at a given concentration	1-POD(c)	Distance from the POD curve to the POD = 1 "top axis" in the vertical direction
Sensitivity (at a given concentration)	Probability of a (+) response at a given concentration	POD(c)	Value of the POD curve at any given concentration
True negative	A sample that contains no analyte	C = 0	Point on concentration axis where c = 0
True positive	A sample that contains analyte at some positive concentration	C > 0	Range of concentration where c > 0

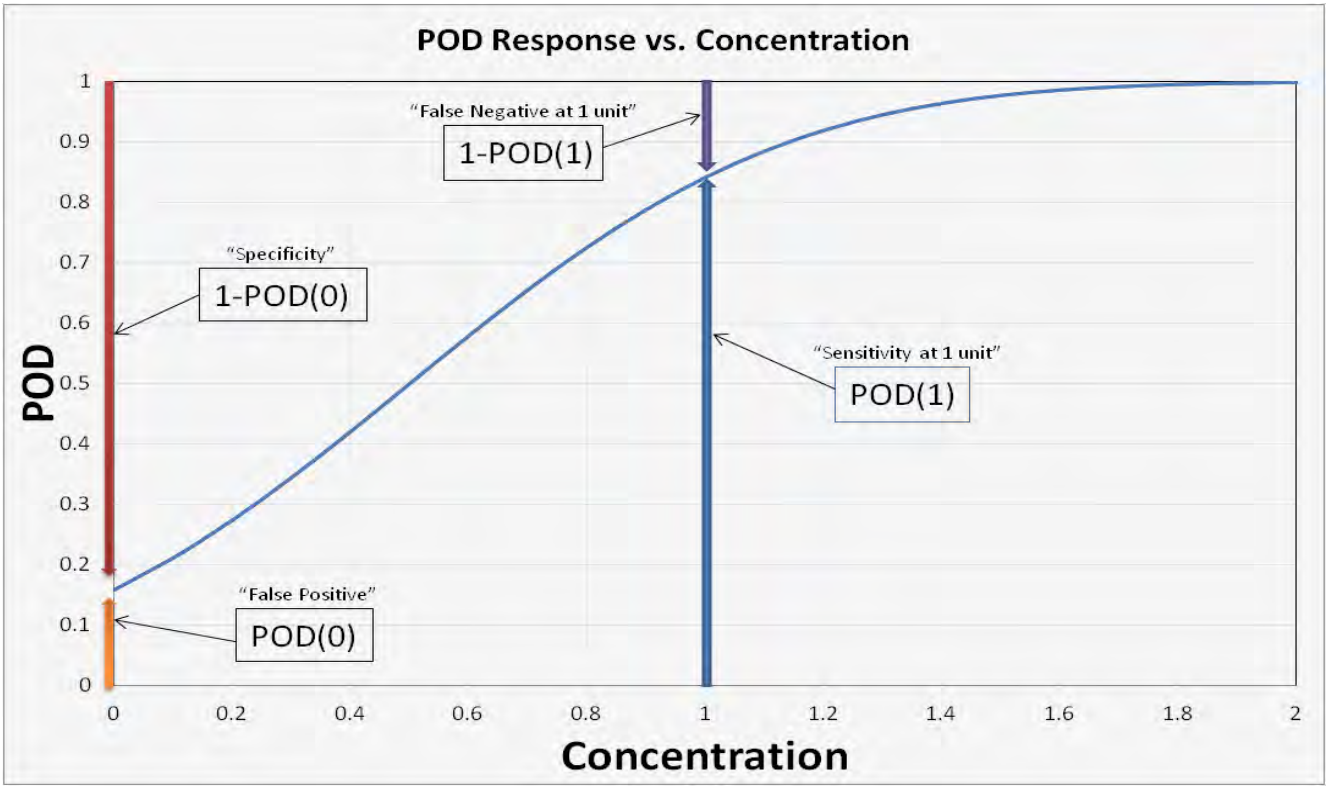


Figure C2. Comparison of POD model terminology to other obsolete terms.

ANNEX D
Definitions and Calculations of HorRat Values from Intralaboratory Data

Excerpted from Definitions and Calculations of HorRat Values from Intralaboratory Data, AOAC INTERNATIONAL, HorRat for SLV.doc, 2004-01-18.

1. Definitions

1.1 Replicate Data

Data developed under common conditions in the same laboratory: simultaneous performance, or, if necessary to obtain sufficient values, same series, same analyst, same day. Such data provides "repeatability statistical parameters."

1.2 Pooled Data

Replicate data developed in the same laboratory under different conditions but considered sufficiently similar that, for the purpose of statistical analysis, they may be considered together. These may include different runs, different instruments, different analysts, and different days.

1.3 Average

0 = Sum of the individual values, x_i, divided by the number of individual values, *n*.

$$0 = (\Sigma\, x_i)/n$$

1.4 Standard Deviation

$$s_i = [\Sigma(x_i - (\bar{x})^2/n]^{0.5}$$

1.5 Relative Standard Deviation

$$RSD = s_i \times 100/\bar{x}$$

1.5.1 Repeatability Relative Standard Deviation [RSD(r) or RSD_r]

The relative standard deviation calculated from within-laboratory data.

1.5.2 Reproducibility Relative Standard Deviation [RSD(R) or RSD_R]

The relative standard deviation calculated from among-laboratory data.

Table D1. Predicted relative standard deviations

Concentration (C)	Mass fraction (C)	$PRSD_R$, %
100%	1.0	2
1%	0.01	4
0.01%	0.0001	8
1 ppm	0.000001	16
10 ppb	0.00000001	32
1 ppb	0.000000001	45

1.6 Mass Fraction

Concentration, C, expressed as a decimal fraction. For calculating and reporting statistical parameters, data may be expressed in any convenient units (e.g., %, ppm, ppb, mg/g, µg/g; µg/kg; µg/L, µg/µL, etc.). For reporting HorRat values, data must be reported as a mass fraction where the units of the numerator and denominator are the same: e.g., for 100% (pure materials), the mass fraction C = 1.00; for 1 µg/g (ppm), C = 0.000001 = (E-6). *See* Table D1 for other examples.

1.7 Predicted Relative Standard Deviation [PRSD(R) or $PRSD_R$]

The reproducibility relative standard deviation calculated from the Horwitz formula:

$$PRSD(R) = 2C^{-0.15}$$

where C is expressed as a mass fraction. *See* Table D1.

In spreadsheet notation: PRSD(R) = 2 * C ^(–0.15).

1.8 HorRat Value

The ratio of the reproducibility relative standard deviation calculated from the data to the PRSD(R) calculated from the Horwitz formula:

$$HorRat = RSD(R)/PRSD(R)$$

To differentiate the usual HorRat value calculated from reproducibility data from the HorRat value calculated from repeatability data, attach an R for the former and an r for the latter. But note that the denominator always uses the PRSD(R) calculated from reproducibility data because this parameter is more predictable than the parameter calculated from repeatability data:

$$HorRat(R) = RSD_R/PRSD(R)$$

$$HorRat(r) = RSD_r/PRSD(R)$$

Some expected, predicted relative standard deviations are given in Table D1.

2 *Acceptable HorRat Values*

2.1 For Interlaboratory Studies

HorRat(R): The original data developed from interlaboratory (among-laboratory) studies assigned a HorRat value of 1.0 with limits of acceptability of 0.5 to 2.0. The corresponding within-laboratory relative standard deviations were found to be typically 1/2 to 2/3 the among-laboratory relative standard deviations.

Table D2. Predicted relative standard deviations

Concentration (C)	$PRSD_R$, %	$PRSD_r$, %
100%	2	1
1%	4	2
0.01%	8	4
1 ppm	16	8
10 ppb	32	16
1 ppb	45	22

2.1.1 Limitations

HorRat values do not apply to method-defined (empirical) analytes (moisture, ash, fiber, carbohydrates by difference, etc.), physical properties or physical methods (pH, viscosity, drained weight, etc.), and ill-defined analytes (polymers, products of enzyme reactions).

2.2 For Intralaboratory Studies

2.2.1 Repeatability

Within-laboratory acceptable predicted target values for repeatability are given in Table D2 at 1/2 of PRSD(R), which represents the best case.

2.2.2 HorRat(r)

Based on experience and for the purpose of exploring the extrapolation of HorRat values to SLV studies, take as the minimum acceptability 1/2 of the lower limit ($0.5 \times 0.5 \approx 0.3$) and as the maximum acceptability 2/3 of the upper limit ($0.67 \times 2.0 \approx 1.3$).

Calculate HorRat(r) from the SLV data:

$$HorRat(r) = RSD(r)/PRSD(R)$$

Acceptable HorRat(r) values are 0.3–1.3. Values at the extremes must be interpreted with caution. With a series of low values, check for unreported averaging or prior knowledge of the analyte content; with a series of high values, check for method deficiencies such as unrestricted times, temperatures, masses, volumes, and concentrations; unrecognized impurities (detergent residues on glassware, peroxides in ether); incomplete extractions and transfers and uncontrolled parameters in specific instrumental techniques.

2.3 Other Limitations and Extrapolations

The HorRat value is a very rough but useful summary of the precision in analytical chemistry. It overestimates the precision at the extremes, predicting more variability than observed at the high end of the scale (C > ca 0.1; i.e., >10%) and at the low end of the scale (C < E-8; i.e., 10 ng/g; 10 ppb).

ANNEX E
AOAC Method Accuracy Review

Accuracy of Method Based on Reference Material

Reference material (RM) used.—The use of RMs should be seen as integral to the process of method development, validation, and performance evaluation. RMs are not the only component of a quality system, but correct use of RMs is essential to appropriate quality management. RMs with or without assigned quantity values can be used for measurement precision control, whereas only RMs with assigned quantity values can be used for calibration or measurement trueness control. Method development and validation for matrices within the scope of the method is done to characterize attributes such as recovery, selectivity, "trueness" (accuracy, bias), precision (repeatability and reproducibility), uncertainty estimation, ruggedness, LOQ or LOD, and dynamic range. RMs should be chosen that are fit-for-purpose. When certified reference materials (CRMs) are available with matrices that match the method scope, much of the work involved in method development has already been completed, and that work is documented through the certificate. RMs with analyte values in the range of test samples, as well as "blank" matrix RMs, with values below or near detection limits, are needed.

Availability of RM.—Consideration needs to be given to the future availability of the chosen RM. Well-documented methods that cannot be verified in the future due to lack of material may lose credibility or be seen as inferior.

Fit to method scope.—Natural matrix CRMs provide the greatest assurance that the method is capable of producing accurate results for that matrix. When selecting an RM to perform a method validation, analysts should consider the method to material fit. An example of a good fit would be a method for specified organic molecules in infant formula and using an infant formula or powder milk RM. A poor fit would be a method for specified organic molecules in infant formula and using a sediment material.

Stability.—Providing a stable RM can be challenging where analytes are biologically active, easily oxidized, or interactive with other components of the matrix. CRM producers provide assurance of material stability, as well as homogeneity.CRMs are accompanied by a certificate that includes the following key criteria:

(*1*) Assigned values with measurement uncertainty and metrological traceability
(*2*) Homogeneity
(*3*) Stability, with the expiration date for the certificate
(*4*) Storage requirements
(*5*) Information on intended use
(*6*) Identity of matrix

For some RMs, such as botanical RMs, the source and/or authenticity can be a very important piece of information that should be included with the certificate. Even under ideal storage conditions, many analytes have some rate of change. Recertification may be done by the supplier, and a certificate reissued with a different expiration date and with certain analyte data updated or removed.

Definition of CRM.—Refer to the AOAC TDRM document for definitions from ISO Guide 30, Amd. 1 (2008), http://www.aoac.org/divisions/References.pdf.

Information on source of RM is available.—It is the responsibility of the material producer to provide reliable authentication of the RM and make a clear statement in the accompanying documentation. This should be an as detailed listing as possible, including handling of ingredients, identification of plant materials as completely as feasible (species, type, subtype, growing region), etc. This is comparable to other required information on an RM for judging its suitability for a specific application purpose (e.g., containing how much of the targeted analyte, stabilized by adding acid—therefore not suited for certain parameters/procedures, etc.).

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

Blank RM used where appropriate.—Blank matrix RMs are useful for ensuring performance at or near the detection limits. These are particularly useful for routine quality control in methods measuring, for instance, trace levels of allergens, mycotoxins, or drug residues.

Storage requirements were maintained.—Method developers should maintain good documentation showing that the RM producer's recommended storage conditions were followed.

Cost.—The cost of ongoing method checks should be considered. Daily use of CRMs can be cost prohibitive. Monthly or quarterly analysis of these materials may be an option.

Concentration of analyte fits intended method.—Concentration of the analyte of interest is appropriate for standard method performance requirements (SMPRs).

Uncertainty available.—Every measurement result has an uncertainty associated with it, and the individual contributions toward the combined uncertainty arise from multiple sources. Achieving the target measurement uncertainty set by the customer for his/her problem of interest is often one of the criteria used in selecting a method for a given application. Estimation of measurement uncertainty can be accomplished by different approaches, but the use of RMs greatly facilitates this part of a method validation.

Demonstration of Method Accuracy when No Reference Material Is Available

If an RM is not available, how is accuracy demonstrated?

There are many analytes for which a CRM with a suitable matrix is not available. This leaves the analyst with few options. For some methods, there may be proficiency testing programs that include a matrix of interest for the analyte. Proficiency testing allows an analyst to compare results with results from other laboratories, which may or may not be using similar methods. Spiking is another technique that may be used. When alternative methods are available, results may be compared between the different methods. These alternatives do not provide the same level of assurance that is gained through the use of a CRM.

Spike recovery.—In the absence of an available CRM, one technique that is sometimes used for assessing performance is the spiking of a matrix RM with a known quantity of the analyte. When this method is used, it cannot be assumed that the analyte is bound in the same way as it would be in a natural matrix. Nevertheless, a certified blank RM would be the preferred choice for constructing a spiked material.

When preparing reference solutions, the pure standards must be completely soluble in the solvent. For insoluble materials in a liquid suspension or for powdered forms of dry materials, validation is required to demonstrate that the analyte is homogeneously distributed and that the response of the detection system to the analyte is not affected by the matrix or preparation technique. When a matrix material is selected for spiking, it should be reasonably

The document, *AOAC Method Accuracy Review*, was prepared by the AOAC Technical Division on Reference Materials (TDRM) and approved by the AOAC Official Methods Board in June 2012.

characterized to determine that it is sufficiently representative of the matrix of interest. Spiked samples must be carried through all steps of the method. Many analytes are bound in a natural matrix and whether the spiked analyte will behave the same as the analyte in a natural matrix is unknown.

Other.—Use of a substitute RM involves the replacement of the CRM with an alternative matrix RM matching the matrix of interest as close as possible based on technical knowledge.

ANNEX F
Development and Use of In-House Reference Materials

The use of reference materials is a vital part of any analytical quality assurance program. However, you may have questions about their creation and use. The purpose of this document is to help answer many of these questions.

- What is a reference material?
- Why use reference materials?
- What certified reference materials are currently available?
- Why use an in-house reference material?
- How do I create an in-house reference material?
- How do I use the data from an in-house reference material?

What Is a Reference Material?

The International Organization for Standardization (ISO) defines a reference material as a "material or substance one or more of whose property values are sufficiently homogeneous and well established to be used for the calibration of an apparatus, the assessment of a measurement method, or for assigning values to materials" (1). In plain English, natural-matrix reference materials, such as those you might prepare for use in-house, can be used to validate an analytical method or for quality assurance while you're using your method to analyze your samples. (Natural-matrix materials are not generally used as calibrants because of the increased uncertainty that this would add to an analysis.) The assigned values for the target analytes of an in-house reference material can be used to establish the precision of your analytical method and, if used in conjunction with a CRM, to establish the accuracy of your method.

ISO defines a certified reference material (CRM) as a "reference material, accompanied by a certificate, one or more of whose property values are certified by a procedure which establishes traceability to an accurate realization of the unit in which the property values are expressed, and for which each certified value is accompanied by an uncertainty at a stated level of confidence" (1).

Why Use Reference Materials?

Certified reference materials can be used across the entire scope of an analytical method and can provide traceability of results to the International System of Units (SI). During method development, CRMs can be used to optimize your method. During method validation, they can be used to ensure that your method is capable of producing the "right" answer, and to determine how close your result is to that answer. During routine use, they can be used to determine within-day and between-day repeatability, and so demonstrate that your method is in control and is producing accurate results every time it is used.

Natural-matrix reference materials should mimic the real samples that will be analyzed with a method. They should behave just as your samples would during a procedure, so if you obtain accurate and precise values for your reference material, you should obtain accurate and precise values for your samples as well.

What Certified Reference Materials Are Currently Available?

CRMs are available from a number of sources, including (but not limited to):

- American Association of Cereal Chemists (AACC)
- American Oil Chemists Society (AOCS)
- International Atomic Energy Agency (IAEA)
- Institute for Reference Materials and Measurements (IRMM)
- LGC Promochem
- National Institute of Standards and Technology (NIST)
- National Research Council Canada (NRC Canada)
- UK Food Analysis Proficiency Assessment Program (FAPAS)

A number of websites provide general overviews and catalogs of producers' and distributors' reference materials:

http://www.aocs.org/tech/crm/
http://www.comar.bam.de
http://www.erm-crm.org
http://www.iaea.org/oregrammeslaqcs
http://www.aaccnet.org/checksample
http://www.irmm·ire.be/mrm.html
http://www.lgcpromochem.com
http://www.naweb.iaea.org/nahu/nmrm/
http://www.nist.gov/srm
http://www.fapas.com/index. cfm
http://www.virm.net.

Because new reference materials are produced regularly, it is important to check these websites to determine what is currently available.

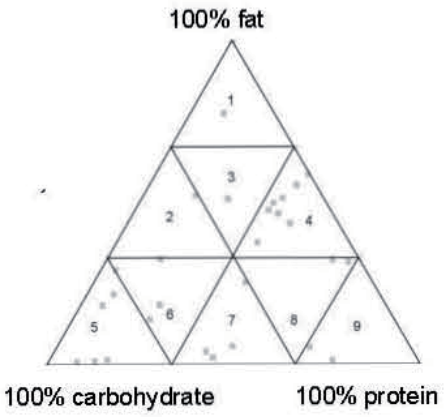
Why Use an In-House Reference Material?

There are many benefits to the use of a CRM. CRMs have been prepared to be homogeneous and, if stored under the proper conditions, stable. You are provided with a certified value as well as the statistical data for theconcentration of your analyte; this is about as close as you can come to knowing the true value of the concentration of the analyte. The material has been tested by experienced analysts in leading laboratories, so you have the security of knowing that your method is generating values similar to those generated in other competent laboratories. The CRMs from the sources mentioned above are nationally and/or internationally recognized, so when you obtain acceptable results for a CRM using your analytical method, you give credibility to your methodology and traceability to your results.

But there are some drawbacks associated with CRMs. Unfortunately, many analyte/matrix combinations are not currently available. When testing food products for nutrient content, for example, a laboratory can be asked to analyze anything that might be found in a kitchen or grocery store. Reference materials that represent all of the types of foods that need to be tested are not available, and most CRMs are certified for a limited number of analytes. It is important to match the reference material matrix to your sample matrix. (Food examples dominate the discussion below, but the same processes apply to the development of in-house RMs in other areas of analytical chemistry.)

To demonstrate the applicability of an analytical method to a wide variety of food matrices, AOAC INTERNATIONAL's Task

Excerpted from *Development and Use of In-House Reference Materials*, Rev. 2, 2009. Copyright 2005 by the AOAC Technical Division on Reference Materials (TDRM).



Force on Methods for Nutrition Labeling developed a triangle partitioned into sectors in which foods are placed based on their protein, fat, and carbohydrate content (2, 3). Since ash does not have a great impact on the performance of an analytical method for organic-material foods, and water can be added or removed, it can be assumed that the behavior of an analytical method is determined to large extent by the relative proportions of these proximates. AOAC INTERNATIONAL anticipated that one or two foods in a given sector would be representative of other foods in that sector and therefore would be useful for method assessment. Similarly, one or two reference materials in a given sector (or near each other in adjacent sectors) should be useful for quality assurance for analyses involving the other foods in the sector. The positions of many of the food-matrix CRMs from the sources listed above are shown in the triangle and are provided in the list.

These food-matrix reference materials are spread through all sectors of the triangle, thereby making it likely that you can find an appropriate CRM to match to your samples. Ultimately, however, the routine use of a CRM can be cost prohibitive, and is not really the purpose of CRMs. For example, in order to use NIST's Standard Reference Material (SRM) 2387 Peanut Butter for all mandatory nutrition labeling analyses, you could buy one sales unit (three jars, each containing 170 g material) for $649 (2009 price). If you charge your customer about $1000 for analysis of all mandatory nutrients in a test material, the control material would account for more than 60% of your fees. Therefore, many laboratories have found it more cost-effective to create in-house reference materials for routine quality control and characterize them in conjunction with the analysis of a CRM (4). You can prepare larger quantities of a reference material by preparing it in-house, and you have more flexibility in the types of matrices you can use. There are not many limitations on what can be purchased.

How Do I Create an In-House Reference Material?

There are basically three steps to preparing an in-house reference material: selection (including consideration of homogeneity and stability), preparation, and characterization. Additional guidance through these steps can be provided from TDRM as well as in ISO Guides 34 (5) and 35 (6).

References

(1) JCGM 200:2008, *International vocabulary of metrology—Basic and general concepts and associated terms (VIM)*, International Bureau of Weights and Measures (www.bipm.org)

Sector	RM No.	Matrix
	NIST 1563	Coconut oil
1	NIST 3274	Fatty acids in botanical oils
1	NIST 3276	Carrot extract in oil
1	LGC 7104	Sterilized cream
2	NIST 2384	Baking chocolate
3	NIST 2387	Peanut butter
4	NIST 1546	Meat homogenate
4	LGC 7106	Processed cheese
4	LGC 7000	Beef/pork meat
4	LGC 7150	Processed meat
4	LGC 7151	Processed meat
4	LGC 7152	Processed meat
4	SMRD 2000	Fresh meat
4	LGC 7101	Mackerel paste
4	LGC QC1001	Meat paste 1
4	LGC QC1004	Fish paste 1
5	BCR-382	Wleat flour
5	BCR-381	Rye flour
5	LGC 7103	Sweet digestive biscuit
5	LGC 7107	Madeira cake
5	LGC QC1002	Flour 1
6	NIST 1544	Fatty acids
6	NIST 1548a	Typical diet
6	NIST 1849	Infant/adult nutritional formula
6	LGC 7105	Rice pudding
7	LGC 7001	Pork meat
7	NIST 1566b	Oyster tissue
7	NIST 1570a	Spinach leaves
7	NIST 2385	Spinach
8	NIST 1946	Lake trout
8	LGC 7176	Canned pet food
9	NIST 1974a	Mussel tissue
9	NIST 3244	Protein powder

(2) Wolf, W.R., & Andrews, K.W. (1995) *Fresenius' J. Anal. Chem.* **352**, 73–76

(3) Wolf, W.R. (1993) *Methods of Analysis for Nutrition Labeling*, D.R. Sullivan & D.E. Carpenter (Eds), AOAC INTERNATIONAL, Gaithersburg, MD

(4) European Reference Materials (2005) *Comparison of a Measurement Result with the Certified Value*, Application Note 1

(5) *ISO Guide 34 General Requirements for the Competence of Reference Material Producers* (2009) 2nd, International Organization for Standardization, Geneva, Switzerland

(6) *Guide 35 Certification of Reference Materials—General and Statistical Principles* (2006) International Organization for Standardization, Geneva, Switzerland

For more information about the AOAC Technical Division on Reference Materials, visit http://aoac.org/divisions/tdrm.

Appendix F: Guidelines for Standard Method Performance Requirements

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Introduction to Standard Method Performance Requirements

Standard method performance requirements (SMPRs) are a unique and novel concept for the analytical methods community. SMPRs are voluntary consensus standards, developed by stakeholders, that prescribe the minimum analytical performance requirements for classes of analytical methods. In the past, analytical methods were evaluated and the results compared to a "gold standard" method, or if a gold standard method did not exist, then reviewers would decide retrospectively if the analytical performance was acceptable. Frequently, method developers concentrated on the process of evaluating the performance parameters of a method, and rarely set acceptance criteria. However, as the *Eurachem Guide* points out: " . . . the judgment of method suitability for its intended use is equally important . . ." (1) to the evaluation process.

International Voluntary Consensus Standards

An SMPR is a form of an international, voluntary consensus standard. A standard is an agreed, repeatable way of doing something that is published as document that contains a technical specification or other precise criteria designed to be used consistently as a rule, guideline, or definition. SMPRs are a *consensus* standards developed by stakeholders in a very controlled process that ensures that users, research organizations, government departments, and consumers work together to create a standard that meets the demands of the analytical community and technology. SMPRs are also *voluntary* standards. AOAC cannot, and does not, impose the use of SMPRs. Users are free to use SMPRs as they see fit. AOAC is very careful to include participants from as many regions of the world as possible so that SMPRs are accepted as *international* standards.

Guidance for Standard Method Performance Requirements

Commonly known as the "SMPR Guidelines." The first version of the SMPR Guidelines were drafted in 2010 in response to the increasing use and popularity of SMPRs as a vehicle to describe the analytical requirements of a method. Several early "acceptance criteria" documents were prepared for publication in late 2009, but the format of the acceptance criteria documents diverged significantly from one another in basic format. AOAC realized that a guidance document was needed to promote uniformity.

An early version of the SMPR Guidelines were used for a project to define the analytical requirements for endocrine disruptors in potable water. The guidelines proved to be extremely useful in guiding the work of the experts and resulted in uniform SMPRs. Subsequent versions of the SMPR Guidelines were used in the Stakeholder Panel for Infant Formula and Adult Nutritionals (SPIFAN) project with very positive results. The SMPR Guidelines are now published for the first time in the *Journal of AOAC INTERNATIONAL* and *Official Methods of Analysis*.

Users of the guidelines are advised that they are: (*1*) a *guidance* document, not a statute that users must conform to; and (*2*) a "living" document that is regularly updated, so users should check the AOAC website for the latest version before using these guidelines.

The SMPR Guidelines are intended to provide basic information for working groups assigned to prepare SMPRs. The guidelines consist of the standard format of an SMPR, followed by a series of informative tables and annexes.

SMPR Format

The general format for an SMPR is provided in *Annex A*.

Each SMPR is identified by a unique SMPR number consisting of the year followed by a sequential identification number (YYYY.XXX). An SMPR number is assigned when the standard is approved. By convention, the SMPR number indicates the year a standard is approved (as opposed to the year the standard is initiated). For example, SMPR 2010.003 indicates the third SMPR adopted in 2010.

The SMPR number is followed by a method name that must include the analyte(s), matrix(es), and analytical technique (unless the SMPR is truly intended to be independent of the analytical technology). The method name may also refer to a "common" name (e.g., "Kjeldahl" method).

The SMPR number and method name are followed by the name of the stakeholder panel or expert review panel that approved the SMPR, and the approval and effective dates.

Information about method requirements is itemized into nine categories: (*1*) intended use; (*2*) applicability; (*3*) analytical technique; (*4*) definitions; (*5*) method performance requirements; (*6*) system suitability; (*7*) reference materials; (*8*) validation guidance; and (*9*) maximum time-to-determination.

An SMPR for qualitative and/or identification methods may include up to three additional annexes: (*1*) inclusivity/selectivity panel; (*2*) exclusivity/cross-reactivity panel; and (*3*) environmental material panels. These annexes not required.

Informative tables.—The SMPR Guidelines contain seven informative tables that represent the distilled knowledge of many years of method evaluation, and are intended as guidance for SMPR working groups. The informative tables are not necessarily AOAC

policy. SMPR working groups are expected to apply their expertise in the development of SMPRs.

Table A1: Performance Requirements. Provides recommended performance parameters to be included into an SMPR. Table A1 is organized by five method classifications: (*1*) main component quantitative methods; (*2*) trace or contaminant quantitative methods; (*3*) main component qualitative methods; (*4*) trace or contaminant quantitative methods; and (*5*) identification methods. The table is designed to accommodate both microbiological and chemical methods. Alternate microbiological/chemical terms are provided for equivalent concepts.

Table A2: Recommended Definitions. Provides definitions for standard terms in the SMPR Guidelines. AOAC relies on *The International Vocabulary of Metrology Basic and General Concepts and Associated Terms* (VIM) and the International Organization for Standadization (ISO) for definition of terms not included in Table A2.

Table A3: Recommendations for Evaluation. Provides general guidance for evaluation of performance parameters. More detailed evaluation guidance can be found in *Appendix D, Guidelines for Collaborative Study Procedures to Validate Characteristics of a Method of Analysis* (2); *Appendix I, Guidelines for Validation of Biological Threat Agent Methods and/or Procedures* (3); *Appendix K, AOAC Guidelines for Single-Laboratory Validation of Chemical Methods for Dietary Supplements and Botanicals* (4); Codex Alimentarius Codex Procedure Manual (5); and ISO Standard 5725-1-1994 (6).

Table A4: Expected Precision (Repeatability) as a Function of Analyte Concentration. The precision of a method is the closeness of agreement between independent test results obtained under stipulated conditions. Precision is usually expressed in terms of imprecision and computed as a relative standard deviation (RSD) of the test results. The imprecision of a method increases as the concentration of the analyte decreases. This table provides target RSDs for a range of analyte concentrations.

Table A5: Expected Recovery as a Function of Analyte Concentration. Recovery is defined as the ratio of the observed mean test result to the true value. The range of the acceptable mean recovery expands as the concentration of the analyte decreases. This table provides target mean recovery ranges for analyte concentrations from 1 ppb to 100%.

Table A6: Predicted Relative Standard Deviation of Reproducibility ($PRSD_R$). This table provides the calculated $PRSD_R$ using the Horwitz formula:

$$PRSD_R = 2C^{-0.15}$$

where C is expressed as a mass fraction.

Table A7: POD and Number of Test Portions. This table provides the calculated probability of detection (POD) for given sample sizes and events (detections). A method developer can use this table to determine the number of analyses required to obtain a specific POD.

Informative annexes.—The SMPR Guidelines contain informative annexes on the topics of classification of methods, POD model, HorRat values, reference materials, and method accuracy and review. As with the informative tables, these annexes are intended to provide guidance and information to the working groups.

Initiation of an SMPR

See Figure 1 for a schematic flowchart diagram of the SMPR development process.

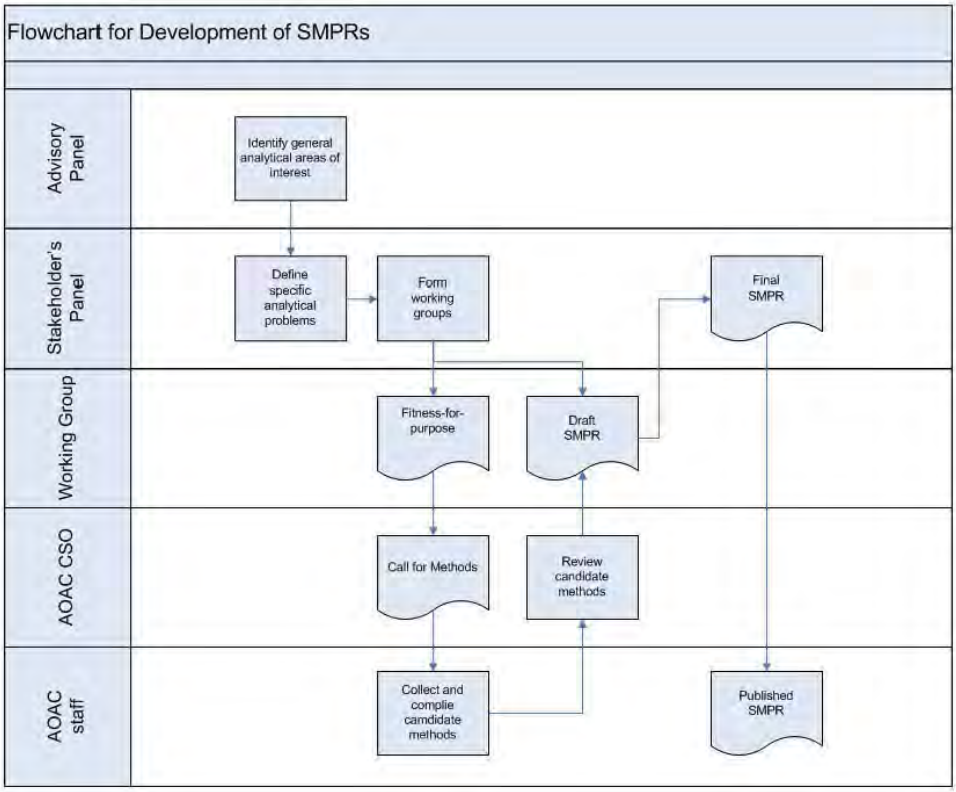


Figure 1. Schematic flowchart diagram of the SMPR development process.

Advisory panels.—Most commonly, an SMPR is created in response to an analytical need identified by an advisory panel. Advisory panels normally consist of sponsors and key stakeholders who have organized to address analytical problems. Usually, the advisory panel identifies general analytical problems, such as the need to update analytical methods for determination of nutrients in infant formula. An advisory panel, with the input of appropriate subject matter experts, also prioritizes the specific analytical problems within the general topic. This panel is critical in planning for the stakeholder panel meeting.

Stakeholder panels.—After an advisory panel has identified a general analytical problem, AOAC announces the standards development activity, identifies stakeholders, and organizes a stakeholder panel. Membership on a stakeholder panel is open to anyone materially affected by the proposed standard. AOAC recruits scientists to participate on stakeholder panels on the basis of their expertise with the analytical problem identified by the advisory panel. Experts are recruited from academia, government, nongovernmental organizations (such as ISO), industry, contract research organizations, method developers, and instrument/equipment manufacturers. AOAC employs a representative voting panel model to ensure balance with regards to stakeholder perspective, and to ensure that no particular stakeholder perspective dominates the proceedings of the stakeholder panel. All stakeholder candidates are reviewed by the AOAC Chief Scientific Officer (CSO) for relevant qualifications, and again by the Official Methods Board to ensure that the stakeholder panel is balanced and all stakeholders are fairly represented.

Stakeholder panels are extremely important as they serve several functions: (*1*) identify specific analytical topics within the general analytical problem described by the advisory panel; (*2*) form working groups to address the specific analytical topics; (*3*) identify additional subject matter experts needed for the working groups; (*4*) provide oversight of the SMPR development; and (*5*) formally adopt SMPRs originally drafted by working groups.

Working groups.—Working groups are formed by the stakeholder panel when a specific analytical topic has been identified. The primary purpose of a working group is to draft an SMPR. Working groups may also be formed to make general recommendations, such as developing a common definition to be used by multiple working groups. For example, SPIFAN formed a working group to create a definition for "infant formula" that could be shared and used by all of the SPIFAN working groups.

The process of drafting an SMPR usually requires several months, and several meetings and conference calls. An SMPR drafted by a working group is presented to a stakeholder panel. A stakeholder panel may revise, amend, or adopt a proposed SMPR on behalf of AOAC.

Fitness-for-Purpose Statement and Call for Methods

One of the first steps in organizing a project is creating a fitness-for-purpose statement. In AOAC, the fitness-for-purpose statement is a very general description of the methods needed. It is the responsibility of a working group chair to draft a fitness-for-purpose statement. A working group chair is also asked to prepare a presentation with background information about the analyte, matrix, and the nature of the analytical problem. A working group chair presents the background information and proposes a draft fitness-for-purpose statement to the presiding stakeholder panel. The stakeholder panel is asked to endorse the fitness-for-purpose statement.

The AOAC CSO prepares a call for methods based on the stakeholder panel-approved fitness-for-purpose statement. The call for methods is posted on the AOAC website and/or e-mailed to the AOAC membership and other known interested parties. AOAC staff collects and compiles candidate methods submitted in response to the call for methods. The CSO reviews and categorizes the methods.

Creating an SMPR

Starting the process of developing an SMPR can be a daunting challenge. In fact, drafting an SMPR should be a daunting challenge because the advisory panel has specifically identified an analytical problem that has yet to be resolved. Completing an SMPR can be a very rewarding experience because working group members will have worked with their colleagues through a tangle of problems and reached a consensus where before there were only questions.

It is advisable to have some representative candidate methods available for reference when a working group starts to develop an SMPR. These methods may have been submitted in response to the call for methods, or may be known to a working group member. In any case, whatever the origin of the method, candidate methods may assist working group members to determine reasonable performance requirements to be specified in the SMPR. The performance capabilities of exisiting analytical methodologies is a common question facing a working group.

Normally, a working chair and/or the AOAC CSO prepares a draft SMPR. A draft SMPR greatly facilitates the process and provides the working group with a structure from which to work.

Working group members are advised to first consider the "intended use" and "maximum time-to-determination" sections as this will greatly affect expectations for candidate methods. For example, methods intended to be used for surveillance probably need to be quick but do not require a great deal of precision, and false-positive results might be more tolerable. Whereas methods intended to be used for dispute resolution will require better accuracy, precision, and reproducibility, but time to determination is not as important.

Once a working group has agreed on the intended use of candidate methods, then it can begin to define the applicability of candidate methods. The applicability section of the SMPR is one of the most important, and sometimes most difficult, sections of the SMPR. The analyte(s) and matrixes must be explicitly identified. For chemical analytes, International Union of Pure and Applied Chemistry (IUPAC) nomenclature and/or Chemical Abstracts Service (CAS) registry numbers should be specified. Matrixes should be clearly identified including the form of the matrix such as raw, cooked, tablets, powders, etc. The nature of the matrix may affect the specific analyte. It may be advantageous to fully identify and describe the matrix before determining the specific analyte(s). It is not uncommon for working groups to revise the initial definition of the analyte(s) after the matrix(es) has been better defined.

Table 1. Example of method performance table for a single analyte

Analytical range	7.0–382.6 µg/mL	
Limit of quantitation (LOQ)	≤7.0 µg/mL	
Repeatability (RSD_r)	<10 µg/mL	≤8%
	≥10 µg/mL	≤6%

Table 2. Example of method performance table for multiple analytes

	Analyte 1		Analyte 2		Analyte 3	
Analytical range	10–20 µg/mL		100–200 µg/mL		200–500 µg/mL	
Limit of quantitation (LOQ)	≤10 µg/mL		≤100 µg/mL		≤200 µg/mL	
Repeatability (RSD_r)	<10 µg/mL	≤8%	<10 µg/mL	≤8%	<200 µg/mL	≤10%
	≥10 µg/mL	≤6%	≥10 µg/mL	≤6%	≥200 µg/mL	≤8%

For projects with multiple analytes, for example, vitamins A, D, E, and K in infant formula, it may be useful to organize a separate working group to fully describe the matrix(es) so that a common description of the matrix(es) can be applied to all of the analytes.

For single analyte SMPRs, it is most common to organize the method performance requirements into a table with 2–3 columns as illustrated in Table 1. For multiple analyte SMPRs, it is often convenient to present the requirements in an expanded table with analytes forming additional columns as illustrated in Table 2.

Once the intended use, analytical techniques, and method performance requirements have been determined, then a working group can proceed to consider the quality control parameters, such as the minimum validation requirements, system suitability procedures, and reference materials (if available). It is not uncommon that an appropriate reference material is not available. *Annex F* of the SMPR Guidelines provides comprehensive guidance for the development and use of in-house reference materials.

Most working groups are able to prepare a consensus SMPR in about 3 months.

Open Comment Period

Once a working group has produced a draft standard, AOAC opens a comment period for the standard. The comment period provides an opportunity for other stakeholders to state their perspective on the draft SMPR. All collected comments are reviewed by the AOAC CSO and the working group chair, and the comments are reconciled. If there are significant changes required to the draft standard as a result of the comments, the working group is convened to discuss and any unresolved issues will be presented for discussion at the stakeholder panel meeting.

Submission of Draft SMPRs to the Stakeholder Panel

Stakeholder panels meet several times a year at various locations. The working group chair (or designee) presents a draft SMPR to the stakeholder panel for review and discussion. A working group chair is expected to be able to explain the conclusions of the working group, discuss comments received, and to answer questions from the stakeholder panel. The members of the stakeholder panel may revise, amend, approve, or defer a decision on the proposed SMPR. A super majority of 2/3 or more of those voting is required to adopt an SMPR as an AOAC voluntary consensus standard.

Publication

Adopted SMPRs are prepared for publication by AOAC staff, and are published in the *Journal of AOAC INTERNATIONAL* and in the AOAC *Official Methods of Analysis*℠ compendium. Often, the AOAC CSO and working group chair prepare a companion article to introduce an SMPR and describe the analytical issues considered and resolved by the SMPR. An SMPR is usually published within 6 months of adoption.

Conclusion

SMPRs are a unique and novel concept for the analytical methods community. SMPRs are voluntary, consensus standards developed by stakeholders that prescribe the minimum analytical performance requirements for classes of analytical methods. The SMPR Guidelines provide a structure for working groups to use as they develop an SMPR. The guidelines have been employed in several AOAC projects and have been proven to be very useful. The guidelines are not a statute that users must conform to; they are a "living" document that is regularly updated, so users should check the AOAC website for the latest version before using the guidelines.

References

(1) Eurachem, *The Fitness for Purpose of Analytical Methods: A Laboratory Guide to Method Validation and Related Topics, Validation*, http://www.eurachem.org/guides/pdf/valid.pdf, posted December 1998, accessed March 2012

(2) *Guidelines for Collaborative Study Procedures to Validate Characteristics of a Method of Analysis* (2012) *Official Methods of Analysis, Appendix D*, AOAC INTERNATIONAL, Gaithersburg, MD

(3) *AOAC INTERNATIONAL Methods Committee Guidelines for Validation of Biological Threat Agent Methods and/or Procedures* (2012) *Official Methods of Analysis*, 19th Ed., *Appendix I, Calculation of CPOD and dCPOD Values from Qualitative Method Collaborative Study Data*, AOAC INTERNATIONAL, Gaithersburg, MD

(4) *AOAC Guidelines for Single-Laboratory Validation of Chemical Methods for Dietary Supplements and Botanicals* (2012) *Official Methods of Analysis*, 19th Ed., *Appendix K*, AOAC INTERNATIONAL, Gaithersburg, MD

(5) Codex Alimentarius Codex Procedure Manual

(6) International Organization for Standardization, Geneva, Switzlerland

ANNEX A
Format of a
Standard Method Performance Requirement

AOAC SMPR YYYY.XXX
(YYYY = Year; XXX = sequential identification number)

Method Name: Must include the analyte(s), matrix(es), and analytical technique [unless the standard method performance requirement (SMPR) is truly intended to be independent of the analytical technology]. The method name may refer to a "common" name (e.g., "Kjeldahl" method).

Approved By: Name of stakeholder panel or expert review panel

Final Version Date: Date

Effective Date: Date

1. Intended Use: Additional information about the method and conditions for use.

2. Applicability: List matrixes if more than one. Provide details on matrix such as specific species for biological analytes, or International Union of Pure and Applied Chemistry (IUPAC) nomenclature and Chemical Abstracts Service (CAS) registry number for chemical analytes. Specify the form of the matrix such as raw, cooked, tablets, powders, etc.

3. Analytical Technique: Provide a detailed description of the analytical technique if the SMPR is to apply to a specific analytical technique; or state that the SMPR applies to any method that meets the method performance requirements.

4. Definitions: List and define terms used in the performance parameter table (*see* Table A2 for list of standard terms).

5. Method Performance Requirements: List the performance parameters and acceptance criteria appropriate for each method/analyte/matrix. *See* Table A1 for appropriate performance requirements.

If more than one analyte/matrix, and if acceptance criteria differ for analyte/matrix combinations then organize a table listing each analyte/matrix combination and its minimum acceptance criteria for each performance criteria.

6. System Suitability Tests and/or Analytical Quality Control: Describe minimum system controls and QC procedures.

7. Reference Material(s): Identify the appropriate reference materials if they exist, or state that reference materials are not available. Refer to *Annex E* (*AOAC Method Accuracy Review*) for instructions on the use of reference materials in evaluations.

8. Validation Guidance: Recommendations for type of evaluation or validation program such as single-laboratory validation (SLV), *Official Methods of Analysis*℠ (OMA), or *Performance Tested Methods*℠ (PTM).

9. Maximum Time-to-Determination: Maximum allowable time to complete an analysis starting from the test portion preparation to final determination or measurement.

Annex I: Inclusivity/Selectivity Panel. Recommended for qualitative and identification method SMPRs.

Annex II: Exclusivity/Cross-Reactivity Panel. Recommended for qualitative and identification method SMPRs.

Annex III: Environmental Materials Panel. Recommended for qualitative and identification method SMPRs.

Table A1. Performance requirements

Classifications of methods[a]				
Quantitative method		Qualitative method		
Main component[b]	Trace or contaminant[c]	Main component[b]	Trace or contaminant[c]	Identification method
Parameter				
Single-laboratory validation				
Applicable range	Applicable range	Inclusivity/selectivity	Inclusivity/selectivity	Inclusivity/selectivity
Bias[d]	Bias[d]	Exclusivity/cross-reactivity	Exclusivity/cross-reactivity	Exclusivity/cross-reactivity
Precision	Precision	Environmental interference	Environmental interference	Environmental interference
Recovery	Recovery	Laboratory variance	Laboratory variance	
Limit of quantitation (LOQ)	LOQ			
		Probability of detection (POD)[e]	POD at AMDL[f]	Probability of identification (POI)
Reproducibility				
RSD_R or target measurement uncertainty	RSD_R or target measurement uncertainty	POD (0)	POD (0)	POI (c)
		POD (c)	POD (c)	
		Laboratory POD[g]	Laboratory POD[g]	Laboratory POI

[a] *See Annex B* for additional information on classification of methods.

[b] ≥100 g/kg.

[c] <100 g/kg.

[d] If a reference material is available.

[e] At a critical level.

[f] AMDL = Acceptable minimum detection level.

[g] LPOD = CPOD.

Table A2. Recommended definitions

Bias	Difference between the expectation of the test results and an accepted reference value. Bias is the total systematic error as contrasted to random error. There may be one or more systematic error components contributing to the bias.
Environmental interference	Ability of the assay to detect target organism in the presence of environmental substances and to be free of cross reaction from environmental substances.
Exclusivity	Strains or isolates or variants of the target agent(s) that the method must not detect.
Inclusivity	Strains or isolates or variants of the target agent(s) that the method can detect.
Laboratory probability of detection (POD)	Overall fractional response (mean POD = CPOD) for the method calculated from the pooled POD_j responses of the individual laboratories (j = 1, 2, ..., L).[a] *See Annex C*.
Limit of quantitation (LOQ)	Minimum concentration or mass of analyte in a given matrix that can be reported as a quantitative result.
POD (0)	Probability of the method giving a (+) response when the sample is truly without analyte.
POD (c)	Probability of the method giving a (–) response when the sample is truly without analyte.
POD	Proportion of positive analytical outcomes for a qualitative method for a given matrix at a given analyte level or concentration. Consult *Annex C* for a full explanation.
Probability of identification (POI)	Expected or observed fraction of test portions at a given concentration that gives positive result when tested at a given concentration. Consult *Probability of Identification (POI): A Statistical Model for the Validation of Qualitative Botanical Identification Methods*.[c]
Precision (repeatability)	Closeness of agreement between independent test results obtained under stipulated conditions. The measure of precision is usually expressed in terms of imprecision and computed as a standard deviation of the test results.[d]
Recovery	Fraction or percentage of the analyte that is recovered when the test sample is analyzed using the entire method. There are two types of recovery: (*1*) Total recovery based on recovery of the native plus added analyte, and (*2*) marginal recovery based only on the added analyte (the native analyte is subtracted from both the numerator and denominator).[e]
Repeatability	Precision under repeatability conditions.
Repeatability conditions	Conditions where independent test results are obtained with the same method on identical test items in the same laboratory by the same operator using the same equipment within short intervals of time.
Reproducibility	Precision under reproducibility conditions.
Reproducibility conditions	Conditions where independent test results are obtained with the same method on identical test items in different laboratories with different operators using different equipment.
Relative standard deviation (RSD)	$RSD = s_i \times 100/\bar{x}$
Standard deviation (s_i)	$s_i = [\Sigma(x_i - \bar{x})^2/n]^{0.5}$

[a] *AOAC INTERNATIONAL Methods Committee Guidelines for Validation of Biological Threat Agent Methods and/or Procedures* (*Calculation of CPOD and dCPOD Values from Qualitative Method Collaborative Study Data*), *J. AOAC Int*. **94**, 1359(2011) and *Official Methods of Analysis of AOAC INTERNATIONAL* (2012) 19th Ed., *Appendix I*.

[b] *International Vocabulary of Metrology (VIM)—Basic and General Concepts and Associated Terms* (2008) JCGM 200:2008, Joint Committee for Guides in Metrology (JCGM), www.bipm.org

[c] LaBudde, R.A., & Harnly, J.M. (2012) *J. AOAC Int*. **95**, 273–285.

[d] ISO 5725-1-1994.

[e] *Official Methods of Analysis* (2012) *Appendix D* (*Guidelines for Collaborative Study Procedures to Validate Characteristics of a Method of Analysis*), AOAC INTERNATIONAL, Gaithersburg, MD.

Table A3. Recommendations for evaluation

Bias (if a reference material is available)	A minimum of five replicate analyses of a Certified Reference Material.[a]
Environmental interference	Analyze test portions containing a specified concentration of one environmental materials panel member. Materials may be pooled. Consult with AOAC statistician.
Exclusivity/cross-reactivity	Analyze one test portion containing a specified concentration of one exclusivity panel member. More replicates can be used. Consult with AOAC statistician.
Inclusivity/selectivity	Analyze one test portion containing a specified concentration of one inclusivity panel member. More replicates can be used. Consult with AOAC statistician.
Limit of quantitation (LOQ)	Estimate the LOQ = average (blank) + 10 × s_0 (blank). Measure blank samples with analyte at the estimated LOQ. Calculate the mean average and standard deviation of the results. Guidance[b]: For ML ≥ 100 ppm (0.1 mg/kg): LOD = ML × 1/5. For ML < 100 ppm (0.1 mg/kg): LOD = ML × 2/5.
Measurement uncertainty	Use ISO 21748: *Guidance for the use of repeatability, reproducibility, and trueness estimates in measurement uncertainty estimation to analyze data collected for bias, repeatability, and intermediate precision to estimate measurement uncertainty*.
POD(0)	Use data from collaborative study.
POD (c)	
Repeatability	Prepare and homogenize three unknown samples at different concentrations to represent the full, claimed range of the method. Analyze each unknown sample by the candidate method seven times, beginning each analysis from weighing out the test portion through to final result with no additional replication (unless stated to do so in the method). All of the analyses for one unknown sample should be performed within as short a period of time as is allowed by the method. The second and third unknowns may be analyzed in another short time period. Repeat for each claimed matrix.
Probability of detection (POD)	Determine the desired POD at a critical concentration. Consult with Table A7 to determine the number of test portions required to demonstrate the desired POD.
Probability of identification (POI)	Consult *Probability of Identification (POI): A Statistical Model for the Validation of Qualitative Botanical Identification Methods*[c].
Recovery	Determined from spiked blanks or samples with at least seven independent analyses per concentration level at a minimum of three concentration levels covering the analytical range. Independent means at least at different times. If no confirmed (natural) blank is available, the average inherent (naturally containing) level of the analyte should be determined on at least seven independent replicates. Marginal % recovery = $(C_f - C_u) \times 100/C_A$ Total % recovery = $100(C_f)/(C_u + C_A)$ where C_f = concentration of fortified samples, C_u = concentration of unfortified samples, and C_A = concentration of analyte added to the test sample.[d] Usually total recovery is used unless the native analyte is present in amounts greater than about 10% of the amount added, in which case use the method of addition.[e]
Reproducibility (collaborative or interlaboratory study)	Quantitative methods: Recruit 10–12 collaborators; must have eight valid data sets; two blind duplicate replicates at five concentrations for each analyte/matrix combination to each collaborator.
	Qualitative methods: Recruit 12–15 collaborators; must have 10 valid data sets; six replicates at five concentrations for each analyte/matrix combination to each collaborator.

[a] *Guidance for Industry for Bioanalytical Method Validation* (May 2001) U.S. Department of Health and Human Services, U.S. Food and Drug Administration, Center for Drug Evaluation and Research (CDER), Center for Veterinary Medicine (CVM).

[b] Codex Alimentarius Codex Procedure Manual.

[c] LaBudde, R.A., & Harnly, J.M. (2012) *J. AOAC Int.* **95**, 273–285.

[d] *Guidelines for Collaborative Study Procedures to Validate Characteristics of a Method of Analysis* (2012) *Official Methods of Analysis*, 19th Ed., *Appendix D,* AOAC INTERNATIONAL, Gaithersburg, MD.

[e] *AOAC Guidelines for Single-Laboratory Validation of Chemical Methods for Dietary Supplements and Botanicals* (2012) *Official Methods of Analysis*, 19th Ed., *Appendix K*, AOAC INTERNATIONAL, Gaithersburg, MD.

Table A4. Expected precision (repeatability) as a function of analyte concentration[a]

Analyte, %	Analyte ratio	Unit	RSD, %
100	1	100%	1.3
10	10^{-1}	10%	1.9
1	10^{-2}	1%	2.7
0.01	10^{-3}	0.1%	3.7
0.001	10^{-4}	100 ppm (mg/kg)	5.3
0.0001	10^{-5}	10 ppm (mg/kg)	7.3
0.00001	10^{-6}	1 ppm (mg/kg)	11
0.000001	10^{-7}	100 ppb (µg/kg)	15
0.0000001	10^{-8}	10 ppb (µg/kg)	21
0.00000001	10^{-9}	1 ppb (µg/kg)	30

[a] Table excerpted from *AOAC Peer-Verified Methods Program, Manual on Policies and Procedures* (1998) AOAC INTERNATIONAL, Gaithersburg, MD.

The precision of a method is the closeness of agreement between independent test results obtained under stipulated conditions. Precision is usually expressed in terms of imprecision and computed as a relative standard deviation of the test results. The imprecision of a method increases as the concentration of the analyte decreases. This table provides targets RSDs for a range of analyte concentrations.

Table A5. Expected recovery as a function of analyte concentration[a]

Analyte, %	Analyte ratio	Unit	Mean recovery, %
100	1	100%	98–102
10	10^{-1}	10%	98–102
1	10^{-2}	1%	97–103
0.01	10^{-3}	0.1%	95–105
0.001	10^{-4}	100 ppm	90–107
0.0001	10^{-5}	10 ppm	80–110
0.00001	10^{-6}	1 ppm	80–110
0.000001	10^{-7}	100 ppb	80–110
0.0000001	10^{-8}	10 ppb	60–115
0.00000001	10^{-9}	1 ppb	40–120

[a] Table excerpted from *AOAC Peer-Verified Methods Program, Manual on Policies and Procedures* (1998) AOAC INTERNATIONAL, Gaithersburg, MD.

Recovery is defined as the ratio of the observed mean test result to the true value. The range of the acceptable mean recovery expands as the concentration of the analyte decreases. This table provides target mean recovery ranges for analyte concentrations from 100% to 1 ppb.

Table A6. Predicted relative standard deviation of reproducibility ($PRSD_R$)[a]

Concentration (C)	Mass fraction (C)	$PRSD_R$, %
100%	1.0	2
1%	0.01	4
0.01%	0.0001	8
1 ppm	0.000001	16
10 ppb	0.00000001	32
1 ppb	0.000000001	45

[a] Table excerpted from *Definitions and Calculations of HorRat Values from Intralaboratory Data*, HorRat for SLV.doc, 2004-01-18, AOAC INTERNATIONAL, Gaithersburg, MD.

Predicted relative standard deviation = $PRSD_R$. Reproducibility relative standard deviation calculated from the Horwitz formula:

$$PRSD_R = 2C^{-0.15}, \text{ where C is expressed as a mass fraction}$$

This table provides the calculated $PRSD_R$ for a range of concentrations. *See Annex D* for additional information.

Table A7. POD and number of test portions[a,b]

	Sample size required for proportion						
Assume	1. Binary outcome (occur/not occur). 2. Constant probability rho of event occurring. 3. Independent trials (e.g., simple random sample). 4. Fixed number of trials (*N*)						
Inference	95% Confidence interval lies entirely at or above specified minimum rho						
Desired	Sample size *N* needed						
Minimum probability rho, %	Sample size (*N*)	Minimum No. events (*x*)	Maximum No. nonevents (*y*)	1-Sided lower confidence limit on rho[c], %	Expected lower confidence limit on rho, %	Expected upper confidence limit on rho, %	Effective AOQL[d] rho, %
50	3	3	0	52.6	43.8	100.0	71.9
50	10	8	2	54.1	49.0	94.3	71.7
50	20	14	6	51.6	48.1	85.5	66.8
50	40	26	14	52.0	49.5	77.9	63.7
50	80	48	32	50.8	49.0	70.0	59.5
55	4	4	0	59.7	51.0	100.0	75.5
55	10	9	1	65.2	59.6	100.0	79.8
55	20	15	5	56.8	53.1	88.8	71.0
55	40	28	12	57.1	54.6	81.9	68.2
55	80	52	28	55.9	54.1	74.5	64.3
60	5	5	0	64.9	56.5	100.0	78.3
60	10	9	1	65.2	59.6	100.0	79.8
60	20	16	4	62.2	58.4	91.9	75.2
60	40	30	10	62.4	59.8	85.8	72.8
60	80	56	24	61.0	59.2	78.9	69.1
65	6	6	0	68.9	61.0	100.0	80.5
65	10	9	1	65.2	59.6	100.0	79.8
65	20	17	3	67.8	64.0	94.8	79.4
65	40	31	9	65.1	62.5	87.7	75.1
65	80	59	21	65.0	63.2	82.1	72.7
70	7	7	0	72.1	64.6	100.0	82.3
70	10	10	0	78.7	72.2	100.0	86.1
70	20	18	2	73.8	69.9	97.2	83.6
70	40	33	7	70.7	68.0	91.3	79.7
70	80	63	17	70.4	68.6	86.3	77.4
75	9	9	0	76.9	70.1	100.0	85.0
75	10	10	0	78.7	72.2	100.0	86.1
75	20	19	1	80.4	76.4	100.0	88.2
75	40	35	5	76.5	73.9	94.5	84.2
75	80	67	13	75.9	74.2	90.3	82.2
80	11	11	0	80.3	74.1	100.0	87.1
80	20	19	1	80.4	76.4	100.0	88.2
80	40	37	3	82.7	80.1	97.4	88.8
80	80	70	10	80.2	78.5	93.1	85.8
85	20	20	0	88.1	83.9	100.0	91.9
85	40	38	2	86.0	83.5	98.6	91.1
85	80	74	6	86.1	84.6	96.5	90.6
90	40	40	0	93.7	91.2	100.0	95.6
90	60	58	2	90.4	88.6	99.1	93.9
90	80	77	3	91.0	89.5	98.7	94.1
95	60	60	0	95.7	94.0	100.0	97.0
95	80	80	0	96.7	95.4	100.0	97.7
95	90	89	1	95.2	94.0	100.0	97.0
95	96	95	1	95.5	94.3	100.0	97.2
98	130	130	0	98.0	97.1	100.0	98.6
98	240	239	1	98.2	97.7	100.0	98.8
99	280	280	0	99.0	98.6	100.0	99.3
99	480	479	1	99.1	98.8	100.0	99.4

[a] Table excerpted from Technical Report TR308, *Sampling plans to verify the proportion of an event exceeds or falls below a specified value*, LaBudde, R. (June 4, 2010) (not published). The table was produced as part of an informative report for the Working Group for Validation of Identity Methods for Botanical Raw Materials commissioned by the AOAC INTERNATIONAL Presidential Task Force on Dietary Supplements. The project was funded by the Office of Dietary Supplements, National Institutes of Health.

[b] Copyright 2010 by Least Cost Formulations, Ltd. All rights reserved.

[c] Based on modified Wilson score 1-sided confidence interval.

[d] AOQL = Average outgoing quality level.

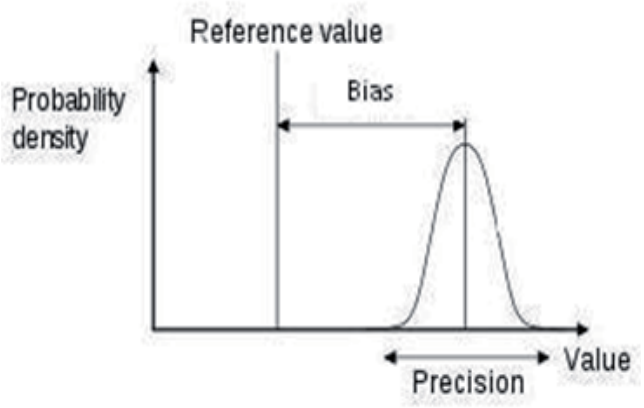


Figure A1. Relationship between precision versus bias (trueness). Trueness is reported as bias. Bias is defined as the difference between the test results and an accepted reference value.

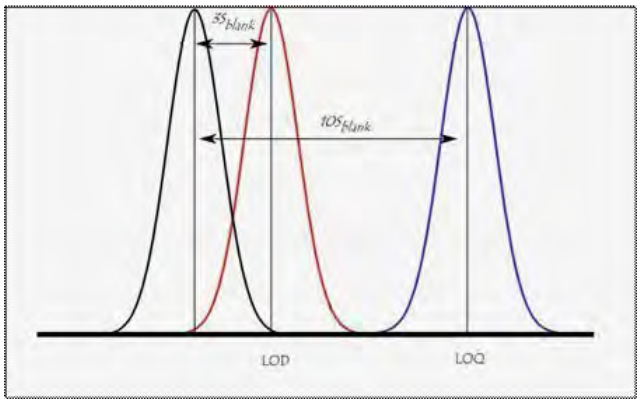


Figure A2. Relationship between LOD and LOQ. LOD is defined as the lowest quantity of a substance that can be distinguished from the absence of that substance (a blank value) within a stated confidence limit. LOQ is the level above which quantitative results may be obtained with a stated degree of confidence.

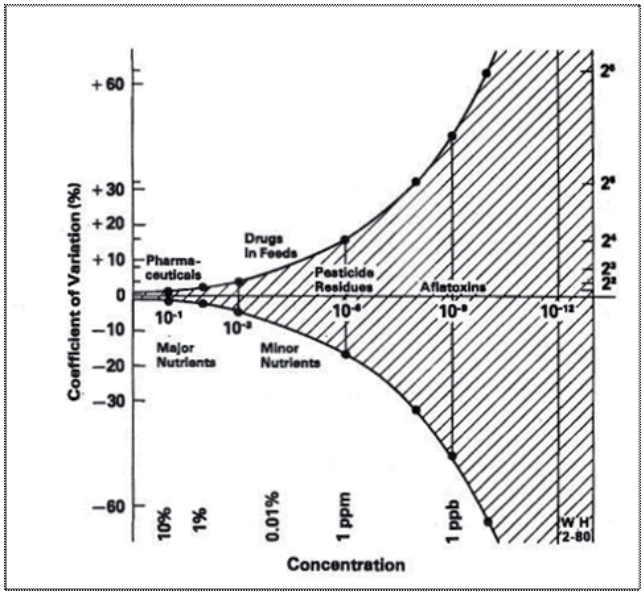


Figure A3. Horwitz Curve, illustrating the exponential increase in the coefficient of variation as the concentration of the analyte decreases [*J. AOAC Int*. 89, 1095(2006)].

Table C1. Terminology

Traditional terminology	Concept	POD equivalent	Comment
False positive	Probability of the method giving a (+) response when the sample is truly without analyte	POD(0) POD at conc = 0	POD curve value at conc = 0; "*Y*-intercept" of the POD curve
Specificity	Probability of the method giving a (-) response when the sample is truly without analyte	1-POD(0)	Distance along the POD axis from POD = 1 to the POD curve value
False negative (at a given concentration)	Probability of a (–) response at a given concentration	1-POD(c)	Distance from the POD curve to the POD = 1 "top axis" in the vertical direction
Sensitivity (at a given concentration)	Probability of a (+) response at a given concentration	POD(c)	Value of the POD curve at any given concentration
True negative	A sample that contains no analyte	C = 0	Point on concentration axis where c = 0
True positive	A sample that contains analyte at some positive concentration	C > 0	Range of concentration where c > 0

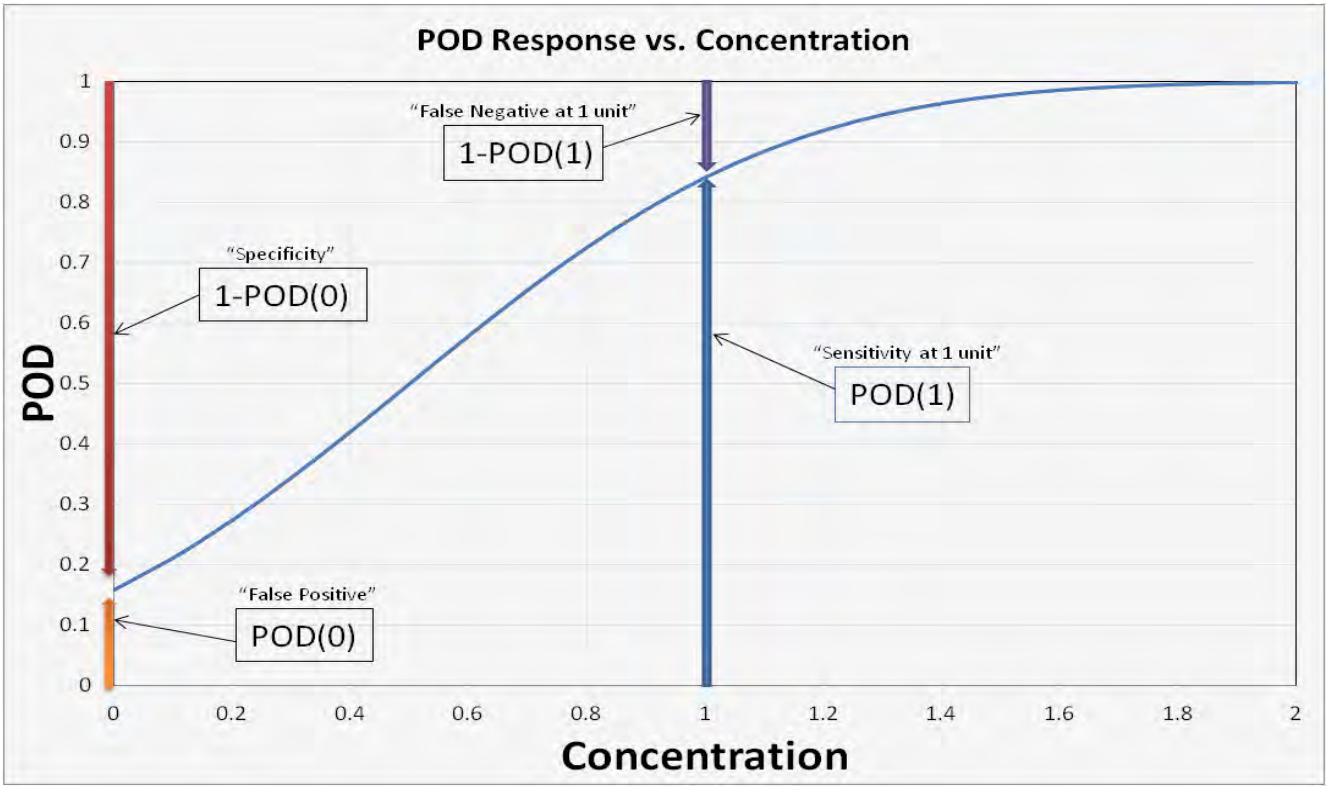


Figure C2. Comparison of POD model terminology to other obsolete terms.

ANNEX D
Definitions and Calculations of HorRat Values from Intralaboratory Data

Excerpted from Definitions and Calculations of HorRat Values from Intralaboratory Data, AOAC INTERNATIONAL, HorRat for SLV.doc, 2004-01-18.

1. Definitions

1.1 Replicate Data

Data developed under common conditions in the same laboratory: simultaneous performance, or, if necessary to obtain sufficient values, same series, same analyst, same day. Such data provides "repeatability statistical parameters."

1.2 Pooled Data

Replicate data developed in the same laboratory under different conditions but considered sufficiently similar that, for the purpose of statistical analysis, they may be considered together. These may include different runs, different instruments, different analysts, and different days.

1.3 Average

0 = Sum of the individual values, x_i, divided by the number of individual values, *n*.

$$0 = (\Sigma\, x_i)/n$$

1.4 Standard Deviation

$$s_i = [\Sigma(x_i - (\bar{x})^2/n]^{0.5}$$

1.5 Relative Standard Deviation

$$RSD = s_i \times 100/\bar{x}$$

1.5.1 Repeatability Relative Standard Deviation [RSD(r) or RSD_r]

The relative standard deviation calculated from within-laboratory data.

1.5.2 Reproducibility Relative Standard Deviation [RSD(R) or RSD_R]

The relative standard deviation calculated from among-laboratory data.

Table D1. Predicted relative standard deviations

Concentration (C)	Mass fraction (C)	$PRSD_R$, %
100%	1.0	2
1%	0.01	4
0.01%	0.0001	8
1 ppm	0.000001	16
10 ppb	0.00000001	32
1 ppb	0.000000001	45

1.6 Mass Fraction

Concentration, C, expressed as a decimal fraction. For calculating and reporting statistical parameters, data may be expressed in any convenient units (e.g., %, ppm, ppb, mg/g, µg/g; µg/kg; µg/L, µg/µL, etc.). For reporting HorRat values, data must be reported as a mass fraction where the units of the numerator and denominator are the same: e.g., for 100% (pure materials), the mass fraction C = 1.00; for 1 µg/g (ppm), C = 0.000001 = (E-6). *See* Table D1 for other examples.

1.7 Predicted Relative Standard Deviation [PRSD(R) or $PRSD_R$]

The reproducibility relative standard deviation calculated from the Horwitz formula:

$$PRSD(R) = 2C^{-0.15}$$

where C is expressed as a mass fraction. *See* Table D1.

In spreadsheet notation: PRSD(R) = 2 * C ^(–0.15).

1.8 HorRat Value

The ratio of the reproducibility relative standard deviation calculated from the data to the PRSD(R) calculated from the Horwitz formula:

$$HorRat = RSD(R)/PRSD(R)$$

To differentiate the usual HorRat value calculated from reproducibility data from the HorRat value calculated from repeatability data, attach an R for the former and an r for the latter. But note that the denominator always uses the PRSD(R) calculated from reproducibility data because this parameter is more predictable than the parameter calculated from repeatability data:

$$HorRat(R) = RSD_R/PRSD(R)$$

$$HorRat(r) = RSD_r/PRSD(R)$$

Some expected, predicted relative standard deviations are given in Table D1.

2 *Acceptable HorRat Values*

2.1 For Interlaboratory Studies

HorRat(R): The original data developed from interlaboratory (among-laboratory) studies assigned a HorRat value of 1.0 with limits of acceptability of 0.5 to 2.0. The corresponding within-laboratory relative standard deviations were found to be typically 1/2 to 2/3 the among-laboratory relative standard deviations.

Table D2. Predicted relative standard deviations

Concentration (C)	$PRSD_R$, %	$PRSD_r$, %
100%	2	1
1%	4	2
0.01%	8	4
1 ppm	16	8
10 ppb	32	16
1 ppb	45	22

2.1.1 Limitations

HorRat values do not apply to method-defined (empirical) analytes (moisture, ash, fiber, carbohydrates by difference, etc.), physical properties or physical methods (pH, viscosity, drained weight, etc.), and ill-defined analytes (polymers, products of enzyme reactions).

2.2 For Intralaboratory Studies

2.2.1 Repeatability

Within-laboratory acceptable predicted target values for repeatability are given in Table D2 at 1/2 of PRSD(R), which represents the best case.

2.2.2 HorRat(r)

Based on experience and for the purpose of exploring the extrapolation of HorRat values to SLV studies, take as the minimum acceptability 1/2 of the lower limit ($0.5 \times 0.5 \approx 0.3$) and as the maximum acceptability 2/3 of the upper limit ($0.67 \times 2.0 \approx 1.3$).

Calculate HorRat(r) from the SLV data:

$$HorRat(r) = RSD(r)/PRSD(R)$$

Acceptable HorRat(r) values are 0.3–1.3. Values at the extremes must be interpreted with caution. With a series of low values, check for unreported averaging or prior knowledge of the analyte content; with a series of high values, check for method deficiencies such as unrestricted times, temperatures, masses, volumes, and concentrations; unrecognized impurities (detergent residues on glassware, peroxides in ether); incomplete extractions and transfers and uncontrolled parameters in specific instrumental techniques.

2.3 Other Limitations and Extrapolations

The HorRat value is a very rough but useful summary of the precision in analytical chemistry. It overestimates the precision at the extremes, predicting more variability than observed at the high end of the scale (C > ca 0.1; i.e., >10%) and at the low end of the scale (C < E-8; i.e., 10 ng/g; 10 ppb).

ANNEX E
AOAC Method Accuracy Review

Accuracy of Method Based on Reference Material

Reference material (RM) used.—The use of RMs should be seen as integral to the process of method development, validation, and performance evaluation. RMs are not the only component of a quality system, but correct use of RMs is essential to appropriate quality management. RMs with or without assigned quantity values can be used for measurement precision control, whereas only RMs with assigned quantity values can be used for calibration or measurement trueness control. Method development and validation for matrices within the scope of the method is done to characterize attributes such as recovery, selectivity, "trueness" (accuracy, bias), precision (repeatability and reproducibility), uncertainty estimation, ruggedness, LOQ or LOD, and dynamic range. RMs should be chosen that are fit-for-purpose. When certified reference materials (CRMs) are available with matrices that match the method scope, much of the work involved in method development has already been completed, and that work is documented through the certificate. RMs with analyte values in the range of test samples, as well as "blank" matrix RMs, with values below or near detection limits, are needed.

Availability of RM.—Consideration needs to be given to the future availability of the chosen RM. Well-documented methods that cannot be verified in the future due to lack of material may lose credibility or be seen as inferior.

Fit to method scope.—Natural matrix CRMs provide the greatest assurance that the method is capable of producing accurate results for that matrix. When selecting an RM to perform a method validation, analysts should consider the method to material fit. An example of a good fit would be a method for specified organic molecules in infant formula and using an infant formula or powder milk RM. A poor fit would be a method for specified organic molecules in infant formula and using a sediment material.

Stability.—Providing a stable RM can be challenging where analytes are biologically active, easily oxidized, or interactive with other components of the matrix. CRM producers provide assurance of material stability, as well as homogeneity.CRMs are accompanied by a certificate that includes the following key criteria:

(*1*) Assigned values with measurement uncertainty and metrological traceability
(*2*) Homogeneity
(*3*) Stability, with the expiration date for the certificate
(*4*) Storage requirements
(*5*) Information on intended use
(*6*) Identity of matrix

For some RMs, such as botanical RMs, the source and/or authenticity can be a very important piece of information that should be included with the certificate. Even under ideal storage conditions, many analytes have some rate of change. Recertification may be done by the supplier, and a certificate reissued with a different expiration date and with certain analyte data updated or removed.

Definition of CRM.—Refer to the AOAC TDRM document for definitions from ISO Guide 30, Amd. 1 (2008), http://www.aoac.org/divisions/References.pdf.

Information on source of RM is available.—It is the responsibility of the material producer to provide reliable authentication of the RM and make a clear statement in the accompanying documentation. This should be an as detailed listing as possible, including handling of ingredients, identification of plant materials as completely as feasible (species, type, subtype, growing region), etc. This is comparable to other required information on an RM for judging its suitability for a specific application purpose (e.g., containing how much of the targeted analyte, stabilized by adding acid—therefore not suited for certain parameters/procedures, etc.).

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

Blank RM used where appropriate.—Blank matrix RMs are useful for ensuring performance at or near the detection limits. These are particularly useful for routine quality control in methods measuring, for instance, trace levels of allergens, mycotoxins, or drug residues.

Storage requirements were maintained.—Method developers should maintain good documentation showing that the RM producer's recommended storage conditions were followed.

Cost.—The cost of ongoing method checks should be considered. Daily use of CRMs can be cost prohibitive. Monthly or quarterly analysis of these materials may be an option.

Concentration of analyte fits intended method.—Concentration of the analyte of interest is appropriate for standard method performance requirements (SMPRs).

Uncertainty available.—Every measurement result has an uncertainty associated with it, and the individual contributions toward the combined uncertainty arise from multiple sources. Achieving the target measurement uncertainty set by the customer for his/her problem of interest is often one of the criteria used in selecting a method for a given application. Estimation of measurement uncertainty can be accomplished by different approaches, but the use of RMs greatly facilitates this part of a method validation.

Demonstration of Method Accuracy when No Reference Material Is Available

If an RM is not available, how is accuracy demonstrated?

There are many analytes for which a CRM with a suitable matrix is not available. This leaves the analyst with few options. For some methods, there may be proficiency testing programs that include a matrix of interest for the analyte. Proficiency testing allows an analyst to compare results with results from other laboratories, which may or may not be using similar methods. Spiking is another technique that may be used. When alternative methods are available, results may be compared between the different methods. These alternatives do not provide the same level of assurance that is gained through the use of a CRM.

Spike recovery.—In the absence of an available CRM, one technique that is sometimes used for assessing performance is the spiking of a matrix RM with a known quantity of the analyte. When this method is used, it cannot be assumed that the analyte is bound in the same way as it would be in a natural matrix. Nevertheless, a certified blank RM would be the preferred choice for constructing a spiked material.

When preparing reference solutions, the pure standards must be completely soluble in the solvent. For insoluble materials in a liquid suspension or for powdered forms of dry materials, validation is required to demonstrate that the analyte is homogeneously distributed and that the response of the detection system to the analyte is not affected by the matrix or preparation technique. When a matrix material is selected for spiking, it should be reasonably

The document, *AOAC Method Accuracy Review*, was prepared by the AOAC Technical Division on Reference Materials (TDRM) and approved by the AOAC Official Methods Board in June 2012.

characterized to determine that it is sufficiently representative of the matrix of interest. Spiked samples must be carried through all steps of the method. Many analytes are bound in a natural matrix and whether the spiked analyte will behave the same as the analyte in a natural matrix is unknown.

Other.—Use of a substitute RM involves the replacement of the CRM with an alternative matrix RM matching the matrix of interest as close as possible based on technical knowledge.

ANNEX F
Development and Use of In-House Reference Materials

The use of reference materials is a vital part of any analytical quality assurance program. However, you may have questions about their creation and use. The purpose of this document is to help answer many of these questions.

- What is a reference material?
- Why use reference materials?
- What certified reference materials are currently available?
- Why use an in-house reference material?
- How do I create an in-house reference material?
- How do I use the data from an in-house reference material?

What Is a Reference Material?

The International Organization for Standardization (ISO) defines a reference material as a "material or substance one or more of whose property values are sufficiently homogeneous and well established to be used for the calibration of an apparatus, the assessment of a measurement method, or for assigning values to materials" (1). In plain English, natural-matrix reference materials, such as those you might prepare for use in-house, can be used to validate an analytical method or for quality assurance while you're using your method to analyze your samples. (Natural-matrix materials are not generally used as calibrants because of the increased uncertainty that this would add to an analysis.) The assigned values for the target analytes of an in-house reference material can be used to establish the precision of your analytical method and, if used in conjunction with a CRM, to establish the accuracy of your method.

ISO defines a certified reference material (CRM) as a "reference material, accompanied by a certificate, one or more of whose property values are certified by a procedure which establishes traceability to an accurate realization of the unit in which the property values are expressed, and for which each certified value is accompanied by an uncertainty at a stated level of confidence" (1).

Why Use Reference Materials?

Certified reference materials can be used across the entire scope of an analytical method and can provide traceability of results to the International System of Units (SI). During method development, CRMs can be used to optimize your method. During method validation, they can be used to ensure that your method is capable of producing the "right" answer, and to determine how close your result is to that answer. During routine use, they can be used to determine within-day and between-day repeatability, and so demonstrate that your method is in control and is producing accurate results every time it is used.

Natural-matrix reference materials should mimic the real samples that will be analyzed with a method. They should behave just as your samples would during a procedure, so if you obtain accurate and precise values for your reference material, you should obtain accurate and precise values for your samples as well.

What Certified Reference Materials Are Currently Available?

CRMs are available from a number of sources, including (but not limited to):

- American Association of Cereal Chemists (AACC)
- American Oil Chemists Society (AOCS)
- International Atomic Energy Agency (IAEA)
- Institute for Reference Materials and Measurements (IRMM)
- LGC Promochem
- National Institute of Standards and Technology (NIST)
- National Research Council Canada (NRC Canada)
- UK Food Analysis Proficiency Assessment Program (FAPAS)

A number of websites provide general overviews and catalogs of producers' and distributors' reference materials:

http://www.aocs.org/tech/crm/
http://www.comar.bam.de
http://www.erm-crm.org
http://www.iaea.org/oregrammeslaqcs
http://www.aaccnet.org/checksample
http://www.irmm·ire.be/mrm.html
http://www.lgcpromochem.com
http://www.naweb.iaea.org/nahu/nmrm/
http://www.nist.gov/srm
http://www.fapas.com/index. cfm
http://www.virm.net.

Because new reference materials are produced regularly, it is important to check these websites to determine what is currently available.

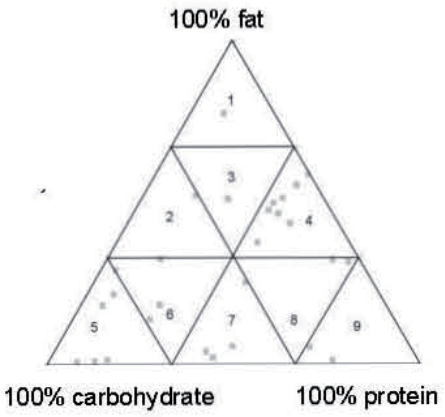
Why Use an In-House Reference Material?

There are many benefits to the use of a CRM. CRMs have been prepared to be homogeneous and, if stored under the proper conditions, stable. You are provided with a certified value as well as the statistical data for theconcentration of your analyte; this is about as close as you can come to knowing the true value of the concentration of the analyte. The material has been tested by experienced analysts in leading laboratories, so you have the security of knowing that your method is generating values similar to those generated in other competent laboratories. The CRMs from the sources mentioned above are nationally and/or internationally recognized, so when you obtain acceptable results for a CRM using your analytical method, you give credibility to your methodology and traceability to your results.

But there are some drawbacks associated with CRMs. Unfortunately, many analyte/matrix combinations are not currently available. When testing food products for nutrient content, for example, a laboratory can be asked to analyze anything that might be found in a kitchen or grocery store. Reference materials that represent all of the types of foods that need to be tested are not available, and most CRMs are certified for a limited number of analytes. It is important to match the reference material matrix to your sample matrix. (Food examples dominate the discussion below, but the same processes apply to the development of in-house RMs in other areas of analytical chemistry.)

To demonstrate the applicability of an analytical method to a wide variety of food matrices, AOAC INTERNATIONAL's Task

Excerpted from *Development and Use of In-House Reference Materials*, Rev. 2, 2009. Copyright 2005 by the AOAC Technical Division on Reference Materials (TDRM).



Force on Methods for Nutrition Labeling developed a triangle partitioned into sectors in which foods are placed based on their protein, fat, and carbohydrate content (2, 3). Since ash does not have a great impact on the performance of an analytical method for organic-material foods, and water can be added or removed, it can be assumed that the behavior of an analytical method is determined to large extent by the relative proportions of these proximates. AOAC INTERNATIONAL anticipated that one or two foods in a given sector would be representative of other foods in that sector and therefore would be useful for method assessment. Similarly, one or two reference materials in a given sector (or near each other in adjacent sectors) should be useful for quality assurance for analyses involving the other foods in the sector. The positions of many of the food-matrix CRMs from the sources listed above are shown in the triangle and are provided in the list.

These food-matrix reference materials are spread through all sectors of the triangle, thereby making it likely that you can find an appropriate CRM to match to your samples. Ultimately, however, the routine use of a CRM can be cost prohibitive, and is not really the purpose of CRMs. For example, in order to use NIST's Standard Reference Material (SRM) 2387 Peanut Butter for all mandatory nutrition labeling analyses, you could buy one sales unit (three jars, each containing 170 g material) for $649 (2009 price). If you charge your customer about $1000 for analysis of all mandatory nutrients in a test material, the control material would account for more than 60% of your fees. Therefore, many laboratories have found it more cost-effective to create in-house reference materials for routine quality control and characterize them in conjunction with the analysis of a CRM (4). You can prepare larger quantities of a reference material by preparing it in-house, and you have more flexibility in the types of matrices you can use. There are not many limitations on what can be purchased.

How Do I Create an In-House Reference Material?

There are basically three steps to preparing an in-house reference material: selection (including consideration of homogeneity and stability), preparation, and characterization. Additional guidance through these steps can be provided from TDRM as well as in ISO Guides 34 (5) and 35 (6).

References

(1) JCGM 200:2008, *International vocabulary of metrology—Basic and general concepts and associated terms (VIM)*, International Bureau of Weights and Measures (www.bipm.org)

Sector	RM No.	Matrix
	NIST 1563	Coconut oil
1	NIST 3274	Fatty acids in botanical oils
1	NIST 3276	Carrot extract in oil
1	LGC 7104	Sterilized cream
2	NIST 2384	Baking chocolate
3	NIST 2387	Peanut butter
4	NIST 1546	Meat homogenate
4	LGC 7106	Processed cheese
4	LGC 7000	Beef/pork meat
4	LGC 7150	Processed meat
4	LGC 7151	Processed meat
4	LGC 7152	Processed meat
4	SMRD 2000	Fresh meat
4	LGC 7101	Mackerel paste
4	LGC QC1001	Meat paste 1
4	LGC QC1004	Fish paste 1
5	BCR-382	Wleat flour
5	BCR-381	Rye flour
5	LGC 7103	Sweet digestive biscuit
5	LGC 7107	Madeira cake
5	LGC QC1002	Flour 1
6	NIST 1544	Fatty acids
6	NIST 1548a	Typical diet
6	NIST 1849	Infant/adult nutritional formula
6	LGC 7105	Rice pudding
7	LGC 7001	Pork meat
7	NIST 1566b	Oyster tissue
7	NIST 1570a	Spinach leaves
7	NIST 2385	Spinach
8	NIST 1946	Lake trout
8	LGC 7176	Canned pet food
9	NIST 1974a	Mussel tissue
9	NIST 3244	Protein powder

(2) Wolf, W.R., & Andrews, K.W. (1995) *Fresenius' J. Anal. Chem.* **352**, 73–76

(3) Wolf, W.R. (1993) *Methods of Analysis for Nutrition Labeling*, D.R. Sullivan & D.E. Carpenter (Eds), AOAC INTERNATIONAL, Gaithersburg, MD

(4) European Reference Materials (2005) *Comparison of a Measurement Result with the Certified Value*, Application Note 1

(5) *ISO Guide 34 General Requirements for the Competence of Reference Material Producers* (2009) 2nd, International Organization for Standardization, Geneva, Switzerland

(6) *Guide 35 Certification of Reference Materials—General and Statistical Principles* (2006) International Organization for Standardization, Geneva, Switzerland

For more information about the AOAC Technical Division on Reference Materials, visit http://aoac.org/divisions/tdrm.

AOAC INTERNATIONAL
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MEMORANDUM

Date: **February 10, 2016**

To: **AOAC INTERNATIONAL Official Methods Board**

From: **Deborah McKenzie, Staff Liaison – AOAC Official Methods Board**

Subject: **Item II.c. 20th Edition of the OMA**

The AOAC Publications Department is busy working on the upcoming 20th edition of the *Official Methods of Analysis of AOAC INTERNATIONAL*. Bob Rathbone, Sr. Director for Publications will share with the OMB some of the highlights of the new edition as well as the timeline for release. This will be a verbal report.

Recommendations: None.

Enclosures: None.

AOAC INTERNATIONAL
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MEMORANDUM

Date: **February 10, 2016**

To: **AOAC INTERNATIONAL Official Methods Board**

From: **Deborah McKenzie, Staff Liaison – AOAC Official Methods Board**

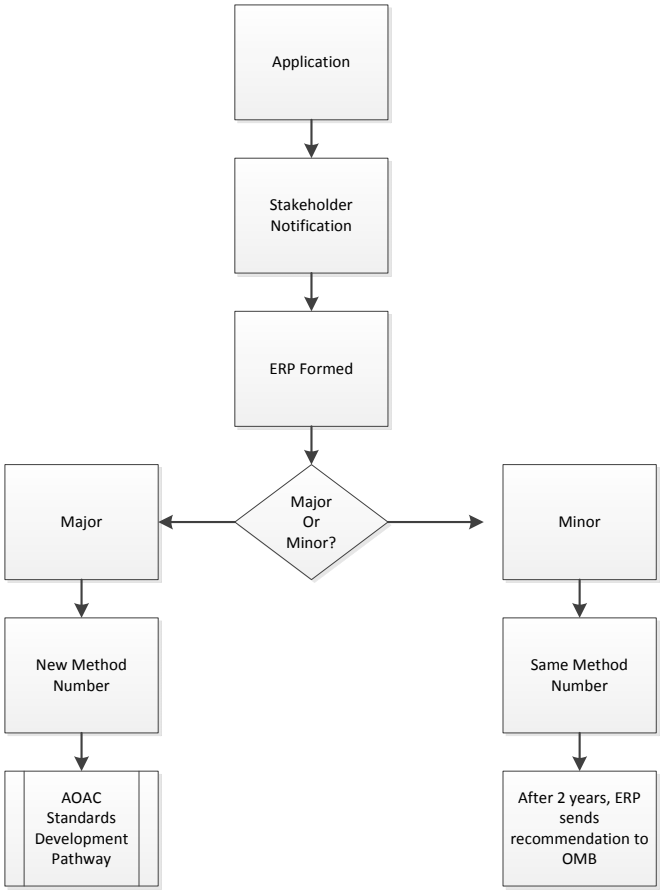
Subject: **Item II.d. Sole Source Modification of *Official Methods of Analysis***

The AOAC OMB Sole Source Modification Working Group has met several times during 2015 and in January to discuss a process that is credible, defensible, includes stakeholder input while protecting the Association. The working group has examines a couple of options and is nearing a prospective solution. President Hill mentioned on the last working group teleconference that a major concern of members of the AOAC Board of Directors are those method modifications that result in achieving different results from the original Official Method, such that any procedure should address this issue.

RECOMMENDATIONS: To approve and recommend a procedure for handling sole source method modifications submitted to the AOAC Research Institute.

ENCLOSURES: Basic Flowchart – Roman
Blended Flowchart - McKenzie

SFR Notes from 10Nov2015 Call



SFR Notes from 10Nov2015 Call

Document to go to OMB Working Group:
Developed by OMB on June 26, 2015
Editorial Modification:
The applicant must submit a written explanation of the change(s) including a statement that the modification does not alter the validated performance of the method.
Examples include: Typos or editorial corrections or clarifications that strengthen instruction.
Methods that have undergone an editorial modification will retain the same number. A list of the methods with editorial modifications will be published in *Inside Laboratory Management* and on the Website. Methods with editorial modifications will be listed along with all method changes and are included in the print version of the OMA.
Method Modifications:
A minor modification results in no changes to the current validated performance. There is no significant effect to the results. Examples include: Reagent change, a change in a column or consumables that do not impact the validated method performance. Supporting data to justify the proposed modification must be submitted. Equivalency data is required unless adequate justification to exclude this data is provided.
A major modification results in a change to the current validated performance of the method. This level of modification will result in a new method as part of AOAC standards development. Examples include: significant change to the technology, sample preparation, or chemistry.
A matrix and/or analyte applicability extension may be either a minor or major modification based on its method performance.

Comment [RS1]: ERP decides

Comment [RS2]: Same method # for minor

Comment [RS3]: New method # for major

AOAC INTERNATIONAL
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MEMORANDUM

Date: January 14, 2016

To: AOAC INTERNATIONAL Official Methods Board Sole Source OMA Modification Working Group

From: Deborah McKenzie, Sr. Director, Standards Development & Research Institute

Subject: Revised Flow for Sole Source Modifications

During the last teleconference of the working group, the following suggestions were made regarding the flow chart based on discussions of the latest version of the flow chart and the new proposal on handling method modifications:

1. Revise the flow chart to a hybrid between both the process for new methods and the process for discussed previously by the working group.
    a. Let the ERP determine type of modification
    b. OMB can provide guidance
    c. Can publish the modification
    d. Working will still need to consider impact on OMAs
2. Both the modification proposal and the Call for Experts for the ERP can be posted at the same time.
3. ERP makes the decision on type of modification.

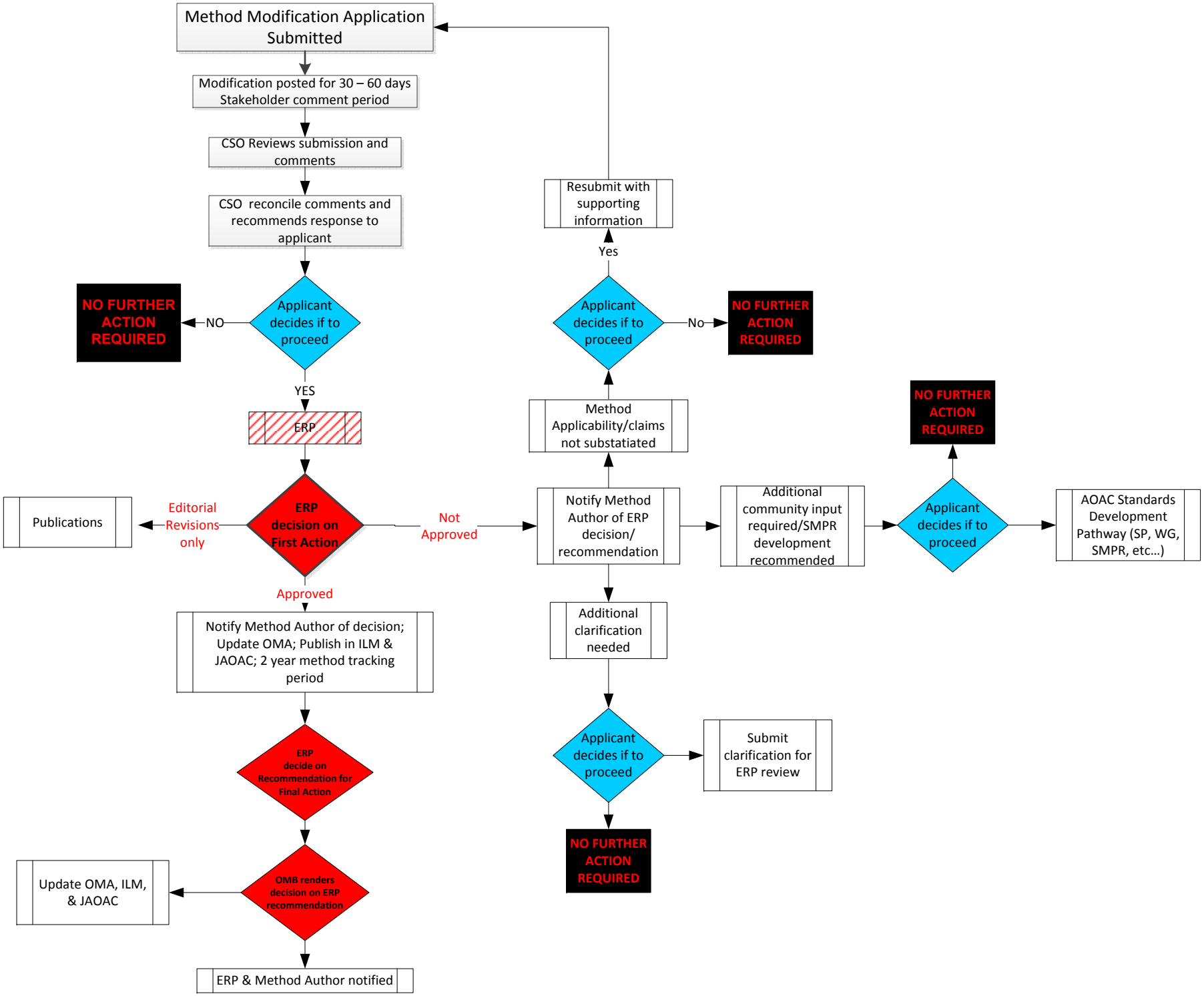
Attached is a revised flow chart that combines the procedures for submission of new methods and the flow charts. There are some things that are reworded or reconfigured:

1. ERPs review submitted methods and documentation for review of First Action and they track methods and make a recommendation to OMB on Final Action status or not. Keeping this theme, the following are changes to the flow chart:
    a. CSO review of the application prior to posting for public comment was removed as it is not defined what purpose it serves at this point.
    b. Call for Experts will be posted with the posting of the modification proposal, although not on the flow chart, this is part of our internal process in anticipation of any ERP. The earlier we can issue the Call, the better.
    c. Applicant can decide to proceed onward or withdraw the proposal based on CSO review and reconciliation of the comments received from the posting.
    d. If the Applicant withdraws, then no further action is needed and ERP recruitment ceases with notification to all parties.
    e. If the Applicant continues, then the ERP meets and reviews the information on the method.

f. ERP makes its decision
    i. Decide if it is an editorial change, then it goes to publications, no change in First or Final Action status.
    ii. Decide if the method modification is substantiated by the submitted supporting documentation
    iii. Decide if the method modification cannot be approved at all.
g. If the method is approved, it continues on through the normal pathway. It goes back to First Actions status.
h. If method is not approved, there are three possibilities
    i. The ERP needs additional clarification or some missing piece of pertinent information is needed prior to approval.
        1. Applicant notified that additional clarification or information is needed. Applicant can decide to submit clarification or information for the ERP's consideration.
    ii. The ERP determined that the supporting information does not support the modification, etiher in appropriate conclusions, etc…
        1. Applicant notified that applicability, method, and/or documentation are not adequately supported. Applicant can decide to do a new submission or not.
    iii. The ERP cannot make a decision due to a need for additional consensus from community/stakeholders.
        1. Applicant notified that standards development is needed. Applicant can decide what to do.

Key points are:

1. OMB maintains its oversight
2. Input is sought
3. Still need to decide on new OMA number verses old OMA number
4. ERP maintains its role


Method Modification Application Submitted
Modification posted for 30 – 60 days Stakeholder comment period
CSO Reviews submission and comments
CSO reconcile comments and recommends response to applicant
Applicant decides if to proceed
NO
NO FURTHER ACTION REQUIRED
YES
ERP
ERP decision on First Action
Editorial Revisions only
Publications
Not Approved
Approved
Notify Method Author of decision; Update OMA; Publish in ILM & JAOAC; 2 year method tracking period
ERP decide on Recommendation for Final Action
OMB renders decision on ERP recommendation
Update OMA, ILM, & JAOAC
ERP & Method Author notified
Notify Method Author of ERP decision/ recommendation
Additional community input required/SMPR development recommended
Applicant decides if to proceed
NO FURTHER ACTION REQUIRED
AOAC Standards Development Pathway (SP, WG, SMPR, etc…)
Method Applicability/claims not substatiated
Applicant decides if to proceed
No
NO FURTHER ACTION REQUIRED
Yes
Resubmit with supporting information
Additional clarification needed
Applicant decides if to proceed
Submit clarification for ERP review
NO FURTHER ACTION REQUIRED

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MEMORANDUM

Date: **February 10, 2016**

To: **AOAC INTERNATIONAL Official Methods Board**

From: **Deborah McKenzie, Staff Liaison – AOAC Official Methods Board**

Subject: **Item III.a. First Action to Final Action Guidance to ERPs**

The OMB First Action to Final Action Working Group have met throughout 2015 and in January to discuss options for revising and clarifying the OMB expectations of ERPs and the documentation OMB wants to see as part of an ERP's recommendation for a First Action method. The group will continue to discuss this topic, investigating gaps and clarifying role of ERP chairs and OMB liaisons with the goal of offering concrete guidance information that will translate into straightforward recommendations for First Action OMAs for OMB's review.

Recommendations: To recommend and/or approve revised documentation.

Enclosures: August 5, 2015 Working Group Notes
OMA Appendix G
OMB ERP Guidance document
OMB First Action to Final Action Presentation

OMB FIRST TO FINAL ACTION WORKING GROUP

First to Final Action Methods Brainstorming Session

Meeting Notes for August 5, 2015

WORKING GROUP MEMBERS

Shauna Roman
Brad Stawick
Delia Boyd
Deborah McKenzie
Jean Pan
Erin Crowley

WORKING GROUP MEMBERS UNABLE TO ATTEND

Jo Marie Cook
John Szpylka

REFERENCES: OMA Appendix G

- **Appendix G**, page 3, section H. "ERP Recommendations to Repeal First Action Method"- "Recommendations to repeal First Action methods shall be accompanied with detailed reasons for the decision".
    - Perhaps we need to expand on what is needed – "report" and/or "minutes" from the ERP meeting?
    - Include a list of what information may be needed or example of format/template of the report (start with the report Deborah put together)
        1. When did the method receive First Action status
        2. When was the method recommended for Final Action status including the vote
        3. What were the outcomes/discussions
            - Suggestion of a checklist for the OMB Liasion to use during the ERP discussions of first to final action; attaching an example was discussed to include:
- OMB is requiring to review the draft of the final action journal manuscript (w/reproducibility data), if available.
    - The OMA Final Action method will be based on the Final Action journal manuscript
    - There may be situations where the first and final action manuscripts are the same (just waiting on feedback, ERP recommendation to final action). This needs to be stated in the report.
- A copy of ERP report where the first to final action decision was made needs to be available

- There are a number of ERPs where methods were not based on a comparison to a SMPRs- How is OMB going to deal with these methods

Next steps:

- Shauna to send these notes to Delia she will put the two together and distribute to the group
- Discuss how to modify Appendix G
- Next meeting, 8-19-15 at 11:00 am EST
- Need to decide if we need to modify the Appendix G, page 3 and the training presentation
    - Modification requires approval from the BOD (Appendix G is a policy document)

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

Expert Review Panels, Official Methods Board, First and Final Action *Official Methods*℠

In early 2011, an AOAC Presidential Task Force recommended that AOAC use Expert review panels (ERPs) to assess candidate methods against standard method performance requirements (SMPRs) to ensure that adopted First Action Official Methods℠ are fit for purpose.

Formation of an ERP

AOAC ERPs are authorized to adopt candidate methods as First Action *Official Methods* and to recommend adoption of these methods to Final Action *Official Methods* status. Scientists are recruited to serve on ERPs by a variety of ways. Normally, a call for experts is published at the same time as a call for methods is posted. Interested scientists are invited to submit their *curriculum vitae* (CV) for consideration. Advisory panel, stakeholder panel, and working group members may make recommendations to AOAC for ERP members. All CVs are reviewed and evaluated for expertise by the AOAC Chief Scientific Officer (CSO). The CVs and CSO evaluations are forwarded to the OMB for formal review. Both the CSO and OMB strive to ensure that the composition of a proposed ERP is both qualified and represent the various stakeholder groups. The recommended ERP members are submitted to the AOAC president who then appoints the ERP members.

Review of Methods

Methods submitted to AOAC in response to a call for methods are collected and compiled by AOAC staff. The AOAC CSO and working group chair perform a preliminary review of the methods and classify them into three categories: (*1*) fully developed and written methods that appear to meet SMPRs; (*2*) fully developed and written methods that may or may not meet SMPRs; and (*3*) incomplete methods with no performance data. Method submitters are apprised of the evaluation of their methods. Method developers with submissions that are classified as Category 2 or 3 are encouraged to provide additional information if available. A list of all the submitted methods and their classifications are posted for public review.

Usually, two ERP members (sometimes more) are assigned to lead the review of each Category 1 method. An ERP meeting is convened to review the methods. ERP meetings are open to all interested parties, and are usually well-attended events with about 50–60 attendees common. Each Category 1 method is reviewed and discussed by the ERP. If stakeholders have designated the method to be a dispute resolution method (as stated in the SMPR), then the ERP is asked to identify the single best candidate method to be adopted as a First Action *Official Method*. If the SMPR does not specify the need for a dispute resolution method, then the ERP may choose to adopt all methods that meet the SMPRs, or may choose to adopt the single best method in their collective, expert opinion.

In addition, an ERP may choose to require changes to a candidate method as part of its First Action adoption and/or identify issues that are required to be resolved prior to adoption as a Final Action *Official Method.*

Methods adopted by an ERP as First Action *Official Methods* may not be in AOAC *Official Methods* format. Method developers/authors are asked to assist AOAC to rewrite the method and accompanying manuscript into an AOAC-acceptable format.

Two-Year First Action Evaluation Period

Under the new pathway, a method may be designated as a First Action *Official Method* based on the collective judgment of an ERP. *Official Methods* remain as First Action for a period of about 2 years. During the First Action period, the method will be used in laboratories, and method users will be asked to provide feedback on the performance of the method.

As previously described, two (or more) ERP members are assigned to lead the review of candidate methods for adoption as First Action *Official Methods*. After a method has been adopted as First Action, these lead reviewers are expected to keep track of the use of and experience with the First Action *Official Method*. At the conclusion of the 2-year evaluation period, one or both of the lead reviewers will report back to the ERP on the experience of the First Action *Official Method.*

The presiding ERP will monitor the performance of the method, and, at the completion of the 2-year First Action evaluation period, determine whether the method should be recommended to the OMB for adoption as an AOAC Final Action *Official Method*.

It is also possible that First Action *Official Methods* are not recommended for Final Action. There are two possibilities for an ERP to decide not to proceed with a First Action method: (*1*) feedback from method users indicates that a First Action method is not performing as well in the field as was expected; or (*2*) another method with better performance characteristics has been developed and reviewed. In either case, the ERP may choose to repeal the First Action status of a method.

OMB Review

The OMB will review all methods recommended for Final Action or repeal by the ERP, and will consider a number of factors in their decision. A guidance document for factors to consider is provided on the AOAC website at http://www.aoac.org/vmeth/OMB_ERP_Guidance.pdf. Some of the factors identified by the guidance document for OMB consideration are (*1*) feedback from method users, (*2*) comparison to the appropriate SMPR, (*3*) results from single-laboratory validation, (*4*) reproducibility/uncertainty and probability of detection, (*5*) availability of reference materials, and (*6*) safety concerns.

Conclusion

The new pathway to *Official Methods*℠ is deliberately designed to avoid creation of elaborate review systems. The intent of the model is for method experts to use their scientific knowledge, experience, and good judgment to identify and adopt the best methods possible for the analytical need.

These methods are then published as First Action *Official Methods*, and used by analysts while additional information about the method is collected.

Method reviewers may consider other forms of information in lieu of the traditional collaborative study to demonstrate method reproducibility.

Additional Information

Coates, S. (2012) "Alternative Pathway," *Inside Laboratory Management* **16**(3), pp 10–12

Expert Review Panels, Policies and Procedures, AOAC INTERNATIONAL, http://www.aoac.org/News/EXPERT%20REVIEW%20PANELS%20final%20revision.pdf

Standard Format and Guidance for AOAC Standard Method Performance Requirement (SMPR) Documents, AOAC INTERNATIONAL, http://www.aoac.org/ISPAM/pdf/3.5%20SMPR%20Guideline%20v12.1.pdf

Guidance Documents

Requirements for First Action Official Methods℠ Status

See Figure 1 for process flowchart.

Expert Review Panels

(*1*) Supported by relevant stakeholders.

(*2*) Constituted solely for the ERP purpose, not for SMPR purposes or as an extension of an SMPR.

(*3*) Consist of a minimum of seven members representing a balance of key stakeholders. A quorum is the presence of seven members or 2/3 of total vetted ERP membership, whichever is greater.

(*4*) ERP constituency must be approved by the OMB.

(*5*) Hold transparent public meetings only.

(*6*) Remain in force as long as method in First Action status.

First Action Official Method℠ Status Decision

(*1*) Must be made by an ERP constituted or reinstated post March 28, 2011 for First Action *Official Method℠* status approval.

(*2*) Must be made by an ERP vetted for First Action *Official Method℠* status purposes by OMB post March 28, 2011.

(*3*) Method adopted by ERP must perform adequately against the SMPR set forth by the stakeholders.

(*4*) Method must be adopted by unanimous decision of ERP on first ballot. If not unanimous, negative votes must delineate scientific reasons.

(*5*) Negative voter(s) can be overridden by 2/3 of voting ERP members after due consideration.

(*6*) Method becomes Official First Action on date when ERP decision is made.

(*7*) Methods to be drafted into AOAC format by a knowledgeable AOAC staff member or designee in collaboration with the ERP and method author.

(*8*) Report of First Action *Official Method℠* status decision complete with ERP report regarding decision, including scientific background (references, etc.), to be published concurrently with method in traditional AOAC publication venues.

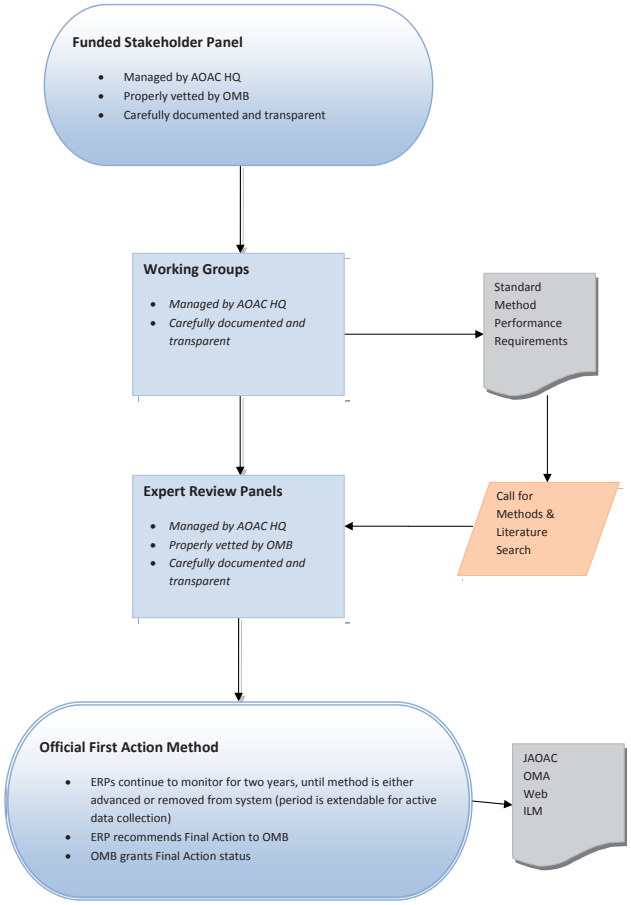

Figure 1. Summary of standards development through *Official Methods of Analysis*.

Method in First Action Status and Transitioning to Final Action Status

(*1*) Further data indicative of adequate method reproducibility (between laboratory) performance to be collected. Data may be collected via a collaborative study or by proficiency or other testing data of similar magnitude.

(*2*) Two years maximum transition time [additional year(s) if ERP determines a relevant collaborative study or proficiency or other data collection is in progress].

(*3*) Method removed from Official First Action and OMA if no evidence of method use available at the end of the transition time.

(*4*) Method removed from Official First Action and OMA if no data indicative of adequate method reproducibility is forthcoming as outlined above at the end of the transition time.

(*5*) ERP to recommend method to Final Action Official status to the OMB.

(*6*) OMB decision on First to Final Action status.

These guidance documents were approved by the AOAC Board of Directors on May 25, 2011. Revised in February 2014 to include the definition of a quorum under the section *Expert Review Panels*, item (*3*).

First Action to Final Action Methods: Guidance for AOAC Expert Review Panels

In December 2011, the Official Methods Board (OMB) approved a guidance document for ERPs to support their work as they deliberate on methods, adopt methods as Official First Action, and, subsequently, track method usage and performance between First Action status and Final Action consideration. The guideline is based on parameters of a method that the OMB will consider when deliberating on methods recommended for Final Action status. ERPs are to use this guideline in their deliberations.

ERPs working within the AOAC process may recommend a First Action status method be elevated to Final Action status. Such a recommendation leverages the ERP's high level of expertise supported by data from the initial evaluation, and results from the subsequent 2-year method performance evaluation period.

The OMB receives the recommendation with supporting documentation, and determines if Final Action status is warranted. OMB's review verifies the method process was conducted in compliance with the guidelines and protocols of the Association.

For transparency and to expedite the review process, the main areas OMB will review when evaluating ERP recommendations to promote methods to Final Action are listed below. Documentation of the areas listed below will also increase confidence in method performance and assist users to properly and safely perform the methods at their locations.

A. Method Applicability

(**a**) A method's applicability to the identified stakeholder needs is best assessed by the stakeholder panel and should be a part of the process from the onset. OMB liaisons will remind stakeholder panels to maintain this focus point.

(**b**) OMB may ask ERPs and stakeholder panels for feedback to improve the applicability of the method, such as potential method scope expansions and potential points of concern.

B. Safety Concerns

(**a**) A safety review must be performed for a method to be recognized as First Action.

(**b**) All safety concerns identified during the 2-year evaluation period must be addressed.

(**c**) Guidance and support can be obtained from the AOAC Safety Committee.

C. Reference Materials

(**a**) Document efforts undertaken to locate reference materials. Methods may still progress to Final Action even if reference materials are not available.

(**b**) Guidance and support can be obtained from the AOAC Technical Division on Reference Materials.

D. Single-Laboratory Validation

(**a**) Data demonstrating response linearity, accuracy, repeatability, LOD/LOQ, and matrix scope must be present. Experimental designs to collect this data may vary with the method protocol and the intended use of the method.

(**b**) Resources can be identified by the AOAC Statistics Committee.

E. Reproducibility/Uncertainty and Probability of Detection

(**a**) For quantitative methods, data demonstrating reproducibility and uncertainty must be present. 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.).

(**b**) For qualitative methods, data must be present demonstrating the probability of detection at specified concentration levels as defined by the SMPR. Experimental designs to collect this data may vary with the method protocol, available laboratories, and the intended use of the method.

(**c**) Guidance and support can be obtained from the AOAC Statistics Committee.

F. Comparison to SMPR

(**a**) Document method performance versus SMPR criteria. Note which SMPR criteria are met. For SMPR criteria not met, the ERP documents the reasoning why the method is still acceptable.

(**b**) Data is present to assure the matrix and analyte scopes are covered. This is critical for methods used for dispute resolutions.

G. Feedback from Users of Method

(**a**) Document positive and negative feedback from users of the method during the trial period.

(**b**) Feedback from users demonstrating method ruggedness should be documented.

(**c**) Assess the future availability of vital equipment, reference materials, and supplies.

H. ERP Recommendations to Repeal First Action Methods

Recommendations to repeal First Action methods shall be accompanied with detailed reasons for the decision.

The First to Final Action guidance for ERPs was approved by the OMB in December 2011 and effective as of February 1, 2012.

AOAC INTERNATIONAL

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FIRST ACTION TO FINAL ACTION METHODS

GUIDANCE FOR AOAC EXPERT REVIEW PANELS

Expert Review Panels working within the AOAC alternate pathway process may recommend a First Action status method be elevated to Final Action status. Such a recommendation leverages the ERP's high level of expertise supported by data from the initial evaluation, and results from the subsequent two year method performance evaluation period.

The Official Methods Board receives the recommendation with supporting documentation, and determines if Final Action status is warranted. OMB's review verifies the method process was conducted in compliance with the guidelines and protocols of the Association.

For transparency and to expedite the review process, the main areas OMB will review when evaluating ERP recommendations to promote methods to Final Action are listed below. Documentation of the areas listed below will also increase confidence in method performance and assist users to properly and safely perform the methods at their locations.

A. Method Applicability
   a. A method's applicability to the identified Stakeholder needs is best assessed by the Stakeholder Panel and should be a part of the process from the onset. OMB liaisons will remind Stakeholder Panels to maintain this focus point.
   b. OMB may ask ERPs and Stakeholder Panels for feedback to improve the applicability of the method such as potential method scope expansions and potential points of concern.

B. Safety Concerns
   a. A safety review must be performed for a method to be recognized as First Action.
   b. All safety concerns identified during the 2 year evaluation period must be addressed.
   c. Guidance and support can be obtained from the AOAC Safety Committee.

C. Reference Materials
   a. Document efforts undertaken to locate reference materials. Methods may still progress to Final Action even if reference materials are not available.
   b. Guidance and support can be obtained from the AOAC Technical Division on Reference Materials.

D. Single Laboratory Validation
   a. Data demonstrating Response Linearity, Accuracy, Repeatability, LOD/LOQ, and Matrix Scope must be present. Experimental designs to collect this data may vary with the method protocol and the intended use of the method.

b. Resources can be identified by the AOAC Statistics Committee.

E. Reproducibility/Uncertainty and Probability of Detection
   a. For quantitative methods, data demonstrating Reproducibility & Uncertainty must be present. 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.).
   b. For qualitative methods, data must be present demonstrating the probability of detection at specified concentration levels as defined by the SMPR. Experimental designs to collect this data may vary with the method protocol, available laboratories, and the intended use of the method.
   c. Guidance and support can be obtained from the AOAC Statistics Committee.

F. Comparison to SMPR
   a. Document method performance versus SMPR criteria. Note which SMPR criteria are met. For SMPR criteria not met, the ERP documents the reasoning why the method is still acceptable.
   b. Data is present to assure the matrix and analyte scopes are covered. This is critical for methods used for dispute resolutions.

G. Feedback From Users of Method
   a. Document positive and negative feedback from users of the method during the trial period.
   b. Feedback from users demonstrating method ruggedness should be documented.
   c. Assess the future availability of vital equipment, reference materials, and supplies.

H. ERP Recommendations to Repeal First Action Methods
   a. Recommendations to repeal First Action methods shall be accompanied with detailed reasons for the decision.

Path to Final Action

What to Expect from Official Method Board (OMB) Review of ERP Method Recommendations

Standard Method Performance Pathway

- Standard Method Performance Requirements authored by Working Groups and established by Stakeholders
- Expert Review Panel (ERP) vetted by OMB
- ERP approves methods for First Action
- Method reproducibility data collected
- ERP monitors method performance
- ERP recommendations sent to OMB within 2 years
  - Final Action, continuation, or repeal

OMB Liaison

- OMB member or designee is assigned to your ERP
- Liaison monitors First Action to Final Action process
- Monitors ERP's documentation of all items in OMB Guidance document (OMA Appendix G)

Method Applicability

- Determine how method meets stakeholder's needs
  - scope, accuracy, precision, etc.
- Are ERP recommendations & improvements implemented?
- Assess method limitations & concerns

Safety Concerns

- Safety review completed for 1st Action
  - Participation by Safety Committee
- All safety issues identified during 2 year review addressed
  - Participation by Safety Committee

Reference Materials

- Identification of potential reference materials (RM)
  - If none found, define alternative options
- RM performance expectations
- Available resource is the AOAC Technical Division on Reference Materials (TDRM)

Single Laboratory Validation

Chemistry

- Linearity
- Accuracy
- Repeatability
- LOD / LOQ
- Matrix scope
- Selectivity

Microbiology

- Inclusivity/Exclusivity
- Robustness
- Repeatability
- POD or equivalent
- Matrix scope

- Statistics Committee is your resource

Quantitative Reproducibility/Uncertainty

- Experimental designs may vary
  - Collaborative study
  - PT data
  - Multi-lab study variations
- Committee on Statistics
  - is available to discuss new study design protocols
  - Formalized tools were presented at the 2013 Annual Meeting

Qualitative Reproducibility/Uncertainty

- Experimental designs may vary
- Committee on Statistics is available to discuss new study protocols designs

Compare to SMPR

- Method meets Performance Criteria
- Method does not meet Performance Criteria
  - Acceptable or not? List reasoning
- Document acceptability to Stakeholders

Feedback from Users

- Solicit and document user feedback
  - ERP Chair determines mechanism
  - May take form of
    - Proactive calls to users
    - Tally of incoming calls
    - Emails
    - Web surveys

Feedback from Users

- Method performance
- Safety Concerns
  - Warnings
  - Alternatives
- Equipment and supply availability
  - Readily available
  - Practicality
  - Suggested improvements
  - Failures
- Reference material availability

ERP Recommendations

- Supply all documentation to AOAC by established deadline
  - Documentation includes ERP review details
- Representative from ERP present at OMB review meeting
- If method to be repealed, document reasoning

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MEMORANDUM

Date: February 10, 2016

To: AOAC INTERNATIONAL Official Methods Board

From: Deborah McKenzie, Staff Liaison – AOAC Official Methods Board

Subject: Item III.b.i. Recommendations for Final Action – ERP for Microbiology Methods for Food and Environmental Surfaces

During the AOAC Annual Meeting, the ERP for Microbiology Methods for Food and Environmental Surfaces met to review methods for First Action and to consider the feedback process for making Final Action review and recommendation. During their meeting, the ERP discussed seven (7) First Action methods and recommended these methods for Final Action.

Recommendations: For OMB to discuss review the ERPs recommendations and render a decision.

Enclosures: Recommendations and supporting information for the seven (7) methods.

CHECKLIST FOR FINAL ACTION METHOD RECOMMENDATION

AOAC 2012.02	**Gram-Positive Bacteria Identification** **VITEK® 2 Gram Positive (GP)** **Bacterial Identification Method**

OMB GUIDANCE FOR AOAC ERPS	Considered?	Comments
Method Applicability	Yes	
Safety Concerns	Yes	All addressed prior to First Action
Reference Materials	No	Any reference materials is addressed in the protocols for SLV including the sourcing of strains
Single Laboratory Validation	Yes	Harmonized PTM/OMA: AOAC PTM cert.: 120702 – decommissioned
Reproducibility/Uncertainty and Probability of Detection	Yes	Crowley et al.: Journal of AOA C International Vol. 95, No. 5, 2012 p.1425
Comparison to SMPR	No	No SMPR available; however, it was validated using OMA Appendix X (now revised and is OMA Appendix J)
Feedback from Users of Method	Yes	Discussed in ERP meeting
ERP Recommendation to Repeal First Action Method	Not Applicable	

DOCUMENTATION	Available?	Comments
Safety Evaluation	Yes	Completed
Reference Materials	No	In manuscript
SLV or PTMs	Yes	AOAC PTM cert.: 120702
Approved Validation Protocols	Yes	Precollaborative, Independent, Collaborative
Statistics Review	Yes	Completed
Method Published in OMA	Yes	2012.02
Method Performance vs SMPR criteria	No	No SMPR available; however, it was validated using OMA Appendix X (now revised and is OMA Appendix J)
Feedback Information	Yes	Discussed during ERP meeting
Additional Recognition(s)	Yes	AOAC PTM cert.: 120702 – decommissioned
ERP Reports	Yes	Original approval was via method committee.
Manuscript(s) Published in JAOAC	Yes	Crowley et al.: Journal of AOA C International Vol. 95, No. 5, 2012 p.1425
Method Recommended for Final Action	Yes	No changes to original First Action method

CHECKLIST FOR FINAL ACTION METHOD RECOMMENDATION

AOAC 2013.01	***Salmonella* in a Variety of Foods** **VIDAS® UP *Salmonella* (SPT) Method**

OMB GUIDANCE FOR AOAC ERPS	Considered?	Comments
Method Applicability	Yes	Variety of Foods as specified in applicability statement.
Safety Concerns	Yes	All addressed prior to First Action
Reference Materials	No	Any reference materials is addressed in the protocols for SLV including the sourcing of strains
Single Laboratory Validation	Yes	Harmonized PTM/OMA: PTM cert.: 071101
Reproducibility/Uncertainty and Probability of Detection	Yes	Bird et. al., *J. AOAC Int*. **96**, 808(2013)
Comparison to SMPR	No	No SMPR available; however, it was validated using OMA Appendix X (now revised and is OMA Appendix J)
Feedback from Users of Method	Yes	Discussed in ERP meeting
ERP Recommendation to Repeal First Action Method	Not Applicable	

DOCUMENTATION	Available?	Comments
Safety Evaluation	Yes	Completed
Reference Materials	No	In manuscript
SLV or PTMs	Yes	AOAC PTM cert.: 071101
Approved Validation Protocols	Yes	Precollaborative, Independent, Collaborative
Statistics Review	Yes	Completed
Method Published in OMA	Yes	2013.01
Method Performance vs SMPR criteria	No	No SMPR available; however, it was validated using OMA Appendix X (now revised and is OMA Appendix J)
Feedback Information	Yes	Discussed during ERP meeting
Additional Recognition(s)	Yes	AOAC PTM cert.: 071101 – current
ERP Reports	Yes	Original approval was via method committee.
Manuscript(s) Published in JAOAC	Yes	Bird et. al., *J. AOAC Int*. **96**, 808(2013)
Method Recommended for Final Action	Yes	No changes to original First Action method

CHECKLIST FOR FINAL ACTION METHOD RECOMMENDATION

AOAC 2013.02	***Salmonella* Species in a Variety of Foods and Environmental Surfaces BAX® System Real-Time PCR Assay for *Salmonella***

OMB GUIDANCE FOR AOAC ERPS	Considered?	Comments
Method Applicability	Yes	Variety of Foods and Environmental Surfaces as specified in applicability statement.
Safety Concerns	Yes	All addressed prior to First Action
Reference Materials	No	Any reference materials is addressed in the protocols for SLV including the sourcing of strains
Single Laboratory Validation	Yes	Harmonized PTM/OMA: PTM cert.: 081201
Reproducibility/Uncertainty and Probability of Detection	Yes	Wallace et. al., *J. AOAC Int*. **97**, 868(2014)
Comparison to SMPR	No	No SMPR available; however, it was validated using OMA Appendix J
Feedback from Users of Method	Yes	Discussed in ERP meeting
ERP Recommendation to Repeal First Action Method	Not Applicable	

DOCUMENTATION	Available?	Comments
Safety Evaluation	Yes	Completed
Reference Materials	No	In manuscript
SLV or PTMs	Yes	AOAC PTM cert.: 081201
Approved Validation Protocols	Yes	Precollaborative, Independent, Collaborative
Statistics Review	Yes	Completed
Method Published in OMA	Yes	2013.02
Method Performance vs SMPR criteria	No	No SMPR available; however, it was validated using OMA Appendix J
Feedback Information	Yes	Discussed during ERP meeting
Additional Recognition(s)	Yes	AOAC PTM cert.: 0081201 – current
ERP Reports	Yes	3/12/2013; 9/27/2015
Manuscript(s) Published in JAOAC	Yes	Wallace et. al., *J. AOAC Int*. **97**, 868(2014)
Method Recommended for Final Action	Yes	No changes to original First Action method

CHECKLIST FOR FINAL ACTION METHOD RECOMMENDATION

AOAC 2013.09	***Salmonella* in Selected Foods** **3M™ Molecular Detection Assay (MDA) *Salmonella* Method**

OMB GUIDANCE FOR AOAC ERPS	Considered?	Comments
Method Applicability	Yes	Selected Foods as specified in applicability statement.
Safety Concerns	Yes	All addressed prior to First Action.
Reference Materials	No	Any reference materials is addressed in the protocols for SLV including the sourcing of strains
Single Laboratory Validation	Yes	AOAC *Performance Tested*^{SM} cert.: 031208; Harmonize PTM-OMA
Reproducibility/Uncertainty and Probability of Detection	Yes	Bird et. al., *J. AOAC Int*. **96**, 1325(2013)
Comparison to SMPR	No	No SMPR available; however, it was validated using OMA Appendix X which was revised and is now Appendix J.
Feedback from Users of Method	Yes	Discussed in ERP meeting
ERP Recommendation to Repeal First Action Method	Not Applicable	

DOCUMENTATION	Available?	Comments
Safety Evaluation	Yes	Completed
Reference Materials	No	In manuscript
SLV or PTMs	Yes	AOAC PTM cert.: 031208; Harmonized PTM-OMA
Approved Validation Protocols	Yes	Precollaborative, Independent, Collaborative
Statistics Review	Yes	Completed
Method Published in OMA	Yes	2013.09; modification approved in 2014
Method Performance vs SMPR criteria	No	No SMPR available; however, it was validated using OMA Appendix X which was revised and is now Appendix J
Feedback Information	Yes	Discussed in ERP meeting
Additional Recognition(s)	Yes	AOAC PTM cert.: 031208 – current; Method modification/matrix extension was approved in 2014
ERP Reports	Yes	6/23/2013; 3/20/2014; 9/27/2015
Manuscript(s) Published in JAOAC	Yes	Bird et. al., *J. AOAC Int*. **96**, 1325(2013) Bird et. al., *J. AOAC Int*. **97**, 1329(2014)
Method Recommended for Final Action	Yes	No changes to the method since 2014 modification.

CHECKLIST FOR FINAL ACTION METHOD RECOMMENDATION

AOAC 2013.10	***Listeria* species in a Variety of Foods and Environmental Surfaces** **VIDAS® UP *Listeria* (LPT) Method**

OMB GUIDANCE FOR AOAC ERPS	Considered?	Comments
Method Applicability	Yes	Variety of Foods and Environmental Surfaces as specified in applicability statement.
Safety Concerns	Yes	Addressed prior to First Action
Reference Materials	No	Any reference materials is addressed in the protocols for SLV including the sourcing of strains
Single Laboratory Validation	Yes	Precollaborative study
Reproducibility/Uncertainty and Probability of Detection	Yes	Crowley et al., *J. AOAC Int.* **97**, 431 (2014)
Comparison to SMPR	No	No SMPR available; however, it was validated using OMA Appendix J
Feedback from Users of Method	Yes	Discussed in ERP Meeting
ERP Recommendation to Repeal First Action Method	Not Applicable	

DOCUMENTATION	Available?	Comments
Safety Evaluation	Yes	Completed prior to First Action
Reference Materials	No	In manuscript
SLV or PTMs	Yes	SLV completed
Approved Validation Protocols	Yes	Precollaborative and collaborative
Statistics Review	Yes	Completed
Method Published in OMA	Yes	2013.10
Method Performance vs SMPR criteria	No	No SMPR available; however, it was validated using OMA Appendix J
Feedback Information	Yes	Discussed in ERP meeting
Additional Recognition(s)	Yes	*Multi Laboratory Study of the Year* in 2014
ERP Reports	Yes	6/2013; 9/27/2015
Manuscript(s) Published in JAOAC	Yes	Crowley et. al., *J. AOAC Int*. **97**, 431(2014)
Method Recommended for Final Action	Yes	No changes to method.

CHECKLIST FOR FINAL ACTION METHOD RECOMMENDATION

AOAC 2013.11	***Listeria monocytogenes* in a Variety of Foods** **VIDAS® *Listeria monocytogenes* Xpress (LMX) Method**

OMB GUIDANCE FOR AOAC ERPS	Considered?	Comments
Method Applicability	Yes	Variety of Foods as specified in applicability statement.
Safety Concerns	Yes	Completed prior to First Action
Reference Materials	No	Any reference materials is addressed in the protocols for SLV including the sourcing of strains
Single Laboratory Validation	Yes	AOAC PTM cert.: 091103 – current; Harmonized PTM-OMA
Reproducibility/Uncertainty and Probability of Detection	Yes	Crowley et. al., *J. AOAC Int*. **97**, 442(2014)
Comparison to SMPR	No	No SMPR available; however, it was validated using OMA Appendix J
Feedback from Users of Method	Yes	Discussed in ERP meeting
ERP Recommendation to Repeal First Action Method	Not Applicable	

DOCUMENTATION	Available?	Comments
Safety Evaluation	Yes	Completed
Reference Materials	No	In manuscript
SLV or PTMs	Yes	AOAC PTM cert.: 091103 – current; Harmonized PTM-OMA
Approved Validation Protocols	Yes	PTM (precollaborative and independent), collaborative
Statistics Review	Yes	Completed.
Method Published in OMA	Yes	2013.11
Method Performance vs SMPR criteria	No	No SMPR available; however, it was validated using OMA Appendix J
Feedback Information	Yes	Discussed in ERP meeting
Additional Recognition(s)	Yes	AOAC PTM cert.: 091103 – current; *Multi Laboratory Study of the Year* in 2014
ERP Reports	Yes	6/2013; 9/2015
Manuscript(s) Published in JAOAC	Yes	Crowley et. al., *J. AOAC Int*. **97**, 442(2014)
Method Recommended for Final Action	Yes	No changes to method.

CHECKLIST FOR FINAL ACTION METHOD RECOMMENDATION

AOAC 2013.14	**Identification of *Salmonella* spp.** **ANSR® *Salmonella* Confirmation Test**

OMB GUIDANCE FOR AOAC ERPS	Considered?	Comments
Method Applicability	Yes	Variety of Foods as specified in applicability statement.
Safety Concerns	Yes	Completed prior to First Action
Reference Materials	No	Any reference materials is addressed in the protocols for SLV including the sourcing of strains
Single Laboratory Validation	Yes	Precollaborative, Independent, Collaborative
Reproducibility/Uncertainty and Probability of Detection	Yes	Mozola et. al., *J. AOAC Int*. **97**, 829(2014)
Comparison to SMPR	No	No SMPR available; however, it was validated using OMA Appendix J
Feedback from Users of Method	Yes	Discussed in ERP meeting
ERP Recommendation to Repeal First Action Method	Not Applicable	

DOCUMENTATION	Available?	Comments
Safety Evaluation	Yes	Completed prior to First Action
Reference Materials	No	In manuscript
SLV or PTMs	Yes	Precollaborative, Independent,
Approved Validation Protocols	Yes	Precollaborative, Independent, Collaborative
Statistics Review	Yes	Completed
Method Published in OMA	Yes	2013.14
Method Performance vs SMPR criteria	No	No SMPR available; however, it was validated using OMA Appendix J
Feedback Information	Yes	Discussed in ERP meeting
Additional Recognition(s)	Yes	*Achievement in Technical and Scientific Excellence* Award in 2014
ERP Reports	Yes	12/2013; 9/2015
Manuscript(s) Published in JAOAC	Yes	Mozola et. al., *J. AOAC Int*. **97**, 829(2014)
Method Recommended for Final Action	Yes	No change to method.

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MEMORANDUM

Date: February 10, 2016

To: AOAC INTERNATIONAL Official Methods Board

From: Deborah McKenzie, Staff Liaison – AOAC Official Methods Board

Subject: Item III.b.ii. Recommendations for Final Action – ERP for Veterinary Drug Residues

On December 7, 2015, the AOAC ERP for Veterinary Drug Residues met via teleconference for the sole purpose of discussing a First Action method to consider its potential for and impact of the method being a Final Action method. During their teleconference, the ERP discussed the First Action method and recommended it for Final Action.

Recommendations: For OMB to discuss review the ERPs recommendation and render a decision.

Enclosures: Recommendations and supporting information for the method.

CHECKLIST FOR FINAL ACTION METHOD RECOMMENDATION

AOAC 2012.25	**Residues of Three Triphenylmethane Dyes and Their Metabolites (Malachite Green, Leuco Malachite Green, Crystal Violet, and Brilliant Green) in Aquaculture Products** **Liquid Chromatography/Tandem Mass Spectrometry**

OMB GUIDANCE FOR AOAC ERPS	Considered?	Comments
Method Applicability	Yes	Triphenylmethane dyes as specified in applicability statement.
Safety Concerns	Yes	
Reference Materials	Yes	Currently no reference materials available for these types of drugs
Single Laboratory Validation	Yes	Hurtaud-Pessel et al., *J. AOAC Int*. **96**, 1152(2013) Andersen et al., *J. AOAC Int*. **98**, 636(2015) – modification – matrix extension
Reproducibility/Uncertainty and Probability of Detection	Yes	Schneider & Andersen *J. AOAC Int*. **98**, 658(2015)
Comparison to SMPR	No	SMPR 2009.001 – SMPR for Quantitative Methods for Drug Residues in Shrimp, Tilapia, Catfish, and Salmon
Feedback from Users of Method	Yes	Discussed in ERP Meeting

DOCUMENTATION	Available?	Comments
Safety Evaluation	Yes	Completed; Discussed in ERP meeting
Reference Materials	No	None specified in SMPR; none available
SLV or PTMs	Yes	Hurtaud-Pessel et al., *J. AOAC Int*. **96**, 1152(2013) Andersen et al., *J. AOAC Int*. **98**, 636(2015)
Approved Validation Protocols	No	Used SMPR; OMA appendix D, and help from Chemical Contaminants Community subgroup
Statistics Review	Yes	Completed
Method Published in OMA	Yes	2012.25
Method Performance vs SMPR criteria	No	SMPR 2009.001 – SMPR for Quantitative Methods for Drug Residues in Shrimp, Tilapia, Catfish, and Salmon
Feedback Information	Yes	Discussed in ERP meeting
Additional Recognition(s)	No	
ERP Reports	Yes	10/2012; 12/2015
Manuscript(s) Published in JAOAC	Yes	Hurtaud-Pessel et al., *J. AOAC Int*. **96**, 1152(2013) Andersen et al., *J. AOAC Int*. **98**, 636(2015) Schneider & Andersen *J. AOAC Int*. **98**, 658(2015)
Method Recommended for Final Action	Yes	Method scope expanded and the latest version of the method approved by ERP is in Collaborative Study Manuscript published in 2015 by Schneider and Andersen.

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MEMORANDUM

Date: **February 10, 2016**

To: **AOAC INTERNATIONAL Official Methods Board**

From: **Deborah McKenzie, Staff Liaison – AOAC Official Methods Board**

Subject: **Item III.b. AOAC ERP Review of Methods – Process Overview**

Deborah McKenzie will provide an overview of the ERP process with respect to methods and how they are reviewed prior to the meeting and then during the meeting. She will identify places where ERPs tend to get stuck.

Recommendations: Additional guidance for ERPs

Enclosures: Presentation

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MEMORANDUM

Date: February 10, 2016

To: AOAC INTERNATIONAL Official Methods Board

From: Deborah McKenzie, Staff Liaison – AOAC Official Methods Board

Subject: Item III.d.i. AOAC ERP for Dietary Supplements – Ashwagandha, Folin C, and Kratom

On December 9-10, 2015, the AOAC ERP for Dietary Supplements – Ashwagandha, Folin C, and Kratom met at AOAC headquarters. There were times when there was not a quorum and the OMB chair approved qualified observers to be ERP members. Additional Folin C ERP members arrived late.

KRATOM

ORIGINAL VETTED KRATOM ERP	VETTED MEMBERS AT MEETING	REVISED ERP PER OMB CHAIR
Darryl Sullivan, Covance (Chair)	Darryl Sullivan, Covance (Chair)	Darryl Sullivan, Covance (Chair)
Christine Casey, FDA*	Nour Eddine Es-Safi, Mohammed V University	Joseph Betz, NIH
Nour Eddine Es-Safi, Mohammed V University	Charles Metcalfe, Custom Analytics	Nour Eddine Es-Safi, Mohammed V University
Charles Metcalfe, Custom Analytics	Tom Phillips, State of MD	Charles Metcalfe, Custom Analytics
Tom Phillips, State of MD	John Spzylka, Mérieux Nutrisciences	Tom Phillips, State of MD
Catherine Rimmer, NIST*	Yan-Hong Wang, Univ. of Mississippi	John Spzylka, Mérieux Nutrisciences
John Spzylka, Mérieux Nutrisciences		Yan-Hong Wang, Univ. of Mississippi
Yan-Hong Wang, Univ. of Mississippi		

FOLIN C

ORIGINAL VETTED FOLIN C ERP	VETTED MEMBERS AT MEETING	REVISED ERP PER OMB CHAIR
Darryl Sullivan, Covance (Chair)	Darryl Sullivan, Covance (Chair)	Darryl Sullivan, Covance (Chair)
Nour Eddine Es-Safi, Mohammad V University	Nour Eddine Es-Safi, Mohammed V University	Nour Eddine Es-Safi, Mohammed V University
John Finley, LSU (Retired)*	Martha Jennens, Covance	Martha Jennens, Covance
Prashant Ingle, Herbalife*	Dana Krueger, Krueger Food Laboratories	Dana Krueger, Krueger Food Laboratories
Martha Jennens, Covance	Tom Phillips, State of MD	Tom Phillips, State of MD
Dana Krueger, Krueger Food Laboratories	Catherine Rimmer, NIST	Catherine Rimmer, NIST
Jungmin Lee, USDA*	Aniko Solyom, GAAS Analytical	Aniko Solyom, GAAS Analytical
Tom Phillips, State of MD	Joseph Zhou, Sunshineville Health Products	Joseph Zhou, Sunshineville Health Products
Catherine Rimmer, NIST		John Spzylka, Mérieux Nutrisciences
Aniko Solyom, GAAS Analytical		
Joseph Zhou, Sunshineville Health Products		

RECOMMENDATIONS: To review and approved Revise ERP slate.

ENCLOSURES: None.

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MEMORANDUM

Date: **February 10, 2016**

To: **AOAC INTERNATIONAL Official Methods Board**

From: **Christopher Dent, Standards Development Coordinator**

Subject: **Item III.d.ii. Revisions to the ERP for SPSFAM Heavy Metal Methods**

Per the chart below, the following changes are being recommended for the AOAC ERP for SPSFAM Heavy Metal Methods due to lack of communication and or participation. Their participation removes academia and EU and Asia perspectives on the ERP. However, these perspectives have yet to participate on the ERP.

Original Vetted ERP Roster	New Proposed ERP Roster
Rick Reba, Nestle	Rick Reba, Nestle
Bill Mindak, FDA	Bill Mindak, FDA
Jenny Scifres, USDA	Jenny Scifres, USDA
Min Huang, Frontage	Min Huang, Frontage
Darryl Sullivan, Covance	Darryl Sullivan, Covance
Christopher Smith, Coca Cola	Christopher Smith, Coca Cola
Michelle Briscoe, Brooks Applied Labs	Michelle Briscoe, Brooks Applied Labs
Jenny Nelson, USDA FSIS	Jenny Nelson, USDA FSIS
Li Sheng, EPL Bio Analytical Services	Li Sheng, EPL Bio Analytical Services
Farzaneh Maniei, Coca Cola	Farzaneh Maniei, Coca Cola
Cory Murphy, CFIA	Cory Murphy, CFIA
Sneh Bhandari, Merieux NurtiSciences	Sneh Bhandari, Merieux NurtiSciences
Jameel Ahmed Baig, International Islamic University Islamabad	
Barbro Kollander, National Food Agency, Sweden	

RECOMMENDATIONS: For OMB to remove Baig and Kollander from the ERP roster.

ENCLOSURES: None.

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EXPERT REVIEW PANEL

Stakeholder Panel on Infant Formula and Adult Nutritionals (SPIFAN)

DOCUMENTS REVIEW

Friday, February 5, 2016

AOAC INTERNATIONAL
2275 Research Blvd. Ste. 300
Rockville, MD, 20850
UNITED STATES
dboyd@aoac.org
301.924.7077 x126

AOAC INTERNATIONAL

Expert Review Panel

Stakeholder Panel on Infant Formula & Adult Nutritionals (SPIFAN)

(February 2016)

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MEMORANDUM

DATE: **February 5, 2016**

TO: **AOAC Official Methods Board**

FROM: **Delia Boyd, Program Manager**

SUBJECT: **Expert Review Panel (ERP) for SPIFAN**

Background:
In accordance with the policy for Official First Action, an expert review panel is being assembled to review the methods down selected by the SPIFAN ERP for the priority nutrients.

AOAC staff has collected CVs and they are on file at AOAC in accordance with the revised ERP policies and procedures. A proposal for the SPIFAN Expert Review Panel is submitted for your consideration.

The attached package contains the following information:

- CVs for all proposed candidate(s)
- List of Expert Review Panel (ERP) members

This expert review panel operates under AOAC policies and procedures. Each expert is required to sign the AOAC Volunteer Acceptance Form which includes adherence to the AOAC policy for Volunteer Conflict of Interest, Antitrust and Use of Association Name, Letterhead and Logo.

These will be enforced by the Expert Review Panel chair and facilitated by AOAC staff. OMB is to confirm the expertise of proposed candidates and the balance of the panel and conflicts of interest of panel members.

This Expert Review Panel is scheduled to meet on March 16, 2016. Your review and approval of the panel is requested. Please address questions regarding the attached package to me and thank you for your consideration.

Recommendation:

Additional Name(s) for Vetting SPIFAN Nutrients Expert Review Panel (ERP)

1. David Woollard Hill Labs Nutrients ERP *(Vitamin B only)*

AOAC INTERNATIONAL

Stakeholder Panel on Infant Formula & Adult Nutritionals (SPIFAN)

Expert Review Panels (ERP)

(Nutrients)

February 2016

NUTRIENT PANEL

1.	***Darryl Sullivan***	***Covance Labs*** *(Chair)*
2.	John Austad	Covance Labs
3.	Sean Austin	Nestlé ***(Fos/Gos Only)***
4.	Sneh Bhandari	Silliker Labs & OMB
5.	Esther Campos-Gimenez/Adrienne McMahon	Nestlé
6.	Scott Christiansen	Perrigo
7.	Hans Cruijsen/Wil van Loon	FrieslandCampina
8.	Jon DeVries	General Mills/Medallion Labs
9.	Brendon Gill	Fonterra
10.	Don Gilliland/Karen Schimpf	Abbott Nutrition
11.	Min Huang	Frontage Labs
12.	Estela Kneeteman	INTI
13.	Bill Mindak	FDA ***(Minerals Only)***
14.	Maria Ofitserova	Pickering Lab
15.	Shay Phillips	Mead Johnson
16.	Guenther Raffler	CLF-Eurofins
17.	Kate Rimmer/Melissa Phillips	NIST ***(Non-Voting)***
18.	Jinchuan Yang	Waters Corp.

Proposed changes for:

Add for (Vitamin B)

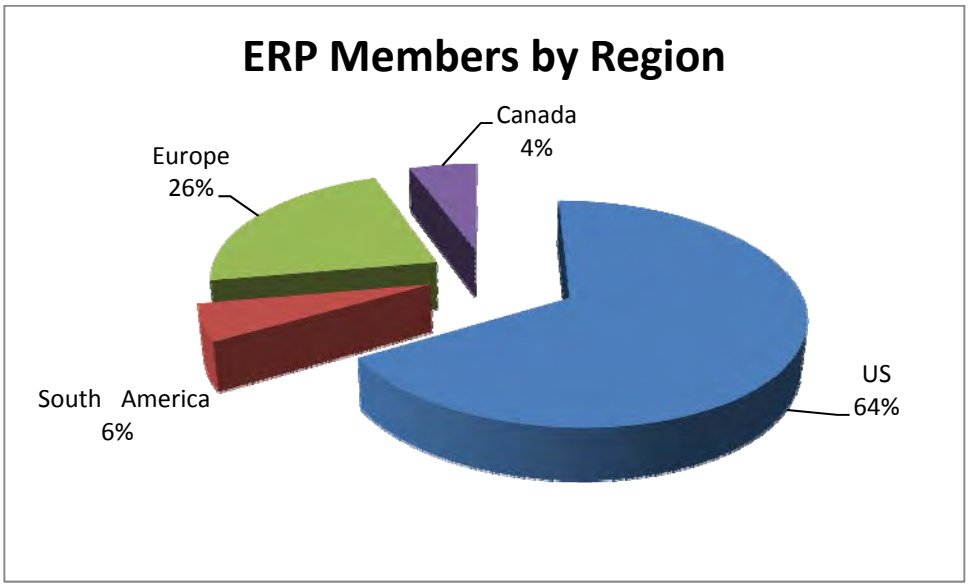
1.	David Woollard	Hill Laboratory

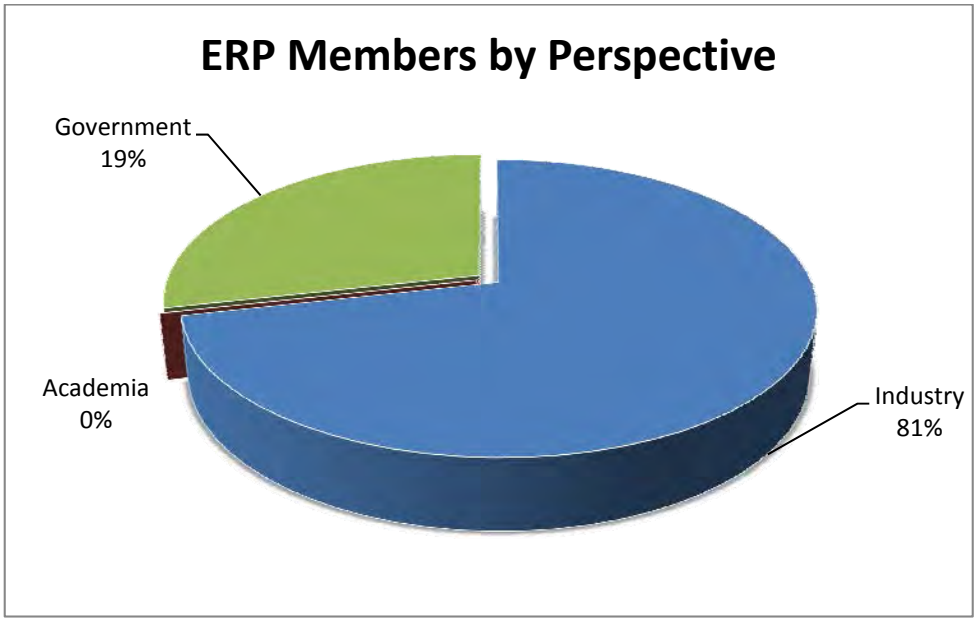
AOAC INTERNATIONAL

Expert Review Panel

STAKEHOLDER PANEL ON INFANT FORMULA & ADULT NUTRITIONALS (SPIFAN)

(BALANCE OF REGION/PERSPECTIVE)





Personal Profile

David Woollard

TECHNICAL DEVELOPMENT SCIENTIST – FOOD and NUTRITION

QUALIFICATIONS

- BSc – University of Auckland
- MSc (Hons) – Chemistry, University of Auckland
- PhD Chemistry, University of Auckland

EXPERIENCE

- 28 years in dairy and food laboratories
- Fellow of AOAC International and member of the Official Methods Board
- Member of the NZ Institute of Food Science and Technology. Riddet Award winner in Dairy Chemistry
- Professional member of Royal Society of New Zealand
- Member of CEN Technical Committee 275, WG9; vitamin testing for the European Union
- Consultant to national and international food and pharmaceutical companies
- Technical advisor to international regularly organisations such as FDA
- Active member of International Dairy Federation.
- Introduced Auto-Analyser, HPLC and NIR technologies to New Zealand
- Author of over sixty scientific articles
- Editor and reviewer of books and journals
- Regular speaker at international conferences and training seminars
- Approved IANZ signatory.

SPECIALIST FIELDS

- Dairy and food laboratory methodology (chemistry)
- Specialist in vitamin, amino acid and food additive testing
- Method development, particularly the micronutrients
- Toxin testing, natural and synthetic
- Laboratory quality systems to ISO17025
- Technical problem solving
- External and in-house staff training
- In-process control testing

CURRICULUM VITAE FOR DAVID CHARLES WOOLLARD

Email: david.woollard@hill-labs.co.nz

Phone (64) 022 313 4424 [mobile] (64) 09 534 1231 [home]

Personal Details:

- Born in Egypt on January 13th 1950 with twin brother (now 64 years old)
- Educated in United Kingdom at Kent College in Canterbury and at Karamu High School, Hastings NZ (7th form)
- University education at University of Auckland
- Father of 6 daughters and 6 grandchildren
- Regular past participant in sports at a local and regional level; retaining strong interest in many sports. Black belt in TaekwonDo
- Queen Scout and Scout Leader for many years

- Major hobby is amateur coin collection

Educational Attainment:

- "O" levels gained in eight subjects in UK. University Entrance and Bursary gained in NZ

- University of Auckland

  - **BSc** (1971),
  - **MSc hons II** (1972)
  - **PhD** (1978).

Work Experience:

- Senior Technologist, Hill Laboratories, Hamilton NZ (2014 – current). Implement a new laboratory for vitamin and mineral premix testing, followed by infant formulation and general dairy chemistry testing.

- Short contract at Cawthron Institute, Nelson NZ (2013) to set up new analytical capabilities for fat-soluble vitamin testing.

- Technical Manager, Eurofins NZLabs, Auckland NZ (2012 – 2013), responsible for method development, validation and accreditation of new analytical applications.

- Laboratory and Business Manager, NZ Laboratory Services, (2006 – 2012) Auckland NZ. Operated under successive ownership by Amdel (Australia) and then Bureau Veritas (France). Responsible for all aspects of human and technical resources plus the spending and profitability of the Auckland chemistry laboratory.

- Technical Director, Global Quality Operations, Wyeth Nutritionals USA (2005), based in Singapore. Responsible for the technology and methodology in all Wyeth Nutrition (now Nestle) laboratories.

- Technical Development Consultant (2001-2005) AgriQuality [now AsureQuality], Auckland NZ. Advised local laboratories but mostly contracted to other international organisations to advise their laboratory quality and technology performances.

- Micronutrient Laboratory Manager, AgriQuality NZ Ltd (1998-2001). Routine supervision of the commercial operations of this new State-Owned Enterprise. Transitioned a government facility into a truly commercial facility.

- Scientist then later Senior R&D Chemist, NZ Ministry of Agriculture and Fisheries (1975 to 1998). Various locations, mostly Auckland NZ. The very first researcher and operator of HPLC equipment in Australasia. Also helped design and install a new large laboratory at Lynfield as replacement for aging government buildings.

Current Work Duties:

- Design and develop analytical procedures for micronutrient testing, initially vitamin and mineral testing of premixes used in the infant formula industries.

- Implement vitamin A, D and C testing of fortified dairy products, followed by other vitamins incorporated into infant formulations.

- Assist with gaining a new client base in the NZ dairy industry.

- Install new UPLC and LCMS equipment, and assist with laboratory modifications.

- Obtain ISO17025 accreditation for all new methods.

Notable Attributes:

- Skilled at method development across a wide range of disciplines.
- Author of scientific papers and review articles.
- Effective laboratory manager.
- Enthusiastic educator of laboratory staff.
- Highly knowledgeable of financial systems and budgetary processes.
- Proficient in software applications.

Professional Achievements:

- Development of over 200 methods in food and dairy science, chief author of MAF (now NZTM) manuals.
- Author and co-author of over 70 peer-reviewed papers and encyclopaedia articles. (List available as required)
- Active member of AOAC International since 1984. Former Chairman of the Food Nutrition Committee, Active Member of the AOAC Official Methods Board. Current member of Expert Review Panel for infant formula testing.
- Lifetime Fellow of AOAC International

- Familiar with many regulations concerning food and pharmaceutical safety. Skilled in testing under GMP/GLP guidelines.

- Co-founder of the International Vitamin Conference series.

- Past Member of International Dairy Federation (IDF) as National Representative for Food Additives and Vitamins

- Past New Zealand National Member of IUPAC in Commission for Fats and Oils

- Past member CEN Technical Working Group 275 (European Union)

- Current Member NZ Royal Society

- Past advisor to United Nations Food and Agricultural Organisation (FAO)

- Regular speaker at analytical science conventions and conferences

- Former Editor of Journal of Micronutrient Analysis, and Food Chemistry.

- Current expert reviewer of articles for several analytical science journals, including J Food Additives and Composition, J AOAC International, Food Nutrition Research and International Dairy Journal

David C Woollard, PhD MRSNZ

Fellow AOAC International

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MEMORANDUM

Date: **February 10, 2016**

To: **AOAC INTERNATIONAL Official Methods Board**

From: **Deborah McKenzie, Staff Liaison – AOAC Official Methods Board**

Subject: **Item IV.a. AOAC Mid-Year Meetings and OMB Liaisons**

Deborah McKenzie will provide a synopsis of the Mid-Year meeting activities for the OMB. Roman will entertain volunteers to serve as OMB Liaisons during the various meetings.

Mid-Year Meeting Event	Date & Time	Chair	OMB Liaison
ERP for SPSFAM Heavy Metals	3/14; 8:00am-12:00pm	Reba	
SPSFAM	3/14; 1:00pm-6:00pm	Konings	
SPIFAN	3/15; 8:30am-12:00pm	Sullivan	
ISPAM	3/15; 1:00pm-6:00pm	Crowley	
ERP for SPIFAN Nutrients	3/16; 10:30am-7:00pm	Sullivan	
ERP for Microbiology Methods	3/16; 1:00pm-5:00pm	Brodsky, McMahon	
SPDS	3/17; 8:30am-5:00pm	Sullivan	
SPDS Working Groups	3/18; 8:30am-5:00pm	Sullivan	

RECOMMENDATION: None.

ENCLOSURES: Draft Meeting Agendas.

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MEMORANDUM

Date: **February 10, 2016**

To: **AOAC INTERNATIONAL Official Methods Board**

From: **Krystyna McIver, SPADA Project Lead**

Subject: **Item IV.b. AOAC Stakeholder Panel Co-Chairs**

AOAC SPADA has been active since February 2007. Since its inception, it has developed standard method performance requirements for the Department of Homeland Security and currently for the Department of Defense. It has also revised the sampling standard and developed implementation guidance used by first response teams as well developed validation guidance that is used in conjunction with the standard method performance requirements. Overall it has developed 17 different products across ten (10) biological threat agents. Four (4) methods have been evaluated and approved as a result.

While Dr. Matthew Davenport has done a remarkable job as chair of SPADA, he appreciates the leadership some key stakeholders have demonstrated in and outside of the meeting. One stakeholder in particular is Dr. Linda Beck, formerly with the BioWatch program in the Office of Health Affairs at the Department of Homeland Security and currently Lead Scientist/Microbiologist with the CBR and Defense Concepts and Experimentation Branch of the Navel Surface Warfare Center. Linda has been instrumental providing leads that have led to sponsorship of SPADA activities. When she was at BioWatch, she assisted AOAC in securing the funding to develop SMPRs for Variola that reinvigorated SPADA in 2013. In her role in the Department of Defense, she has been invaluable in networking the merits of AOAC and SPADA's work to secure our current contract with DoD as well as looking at new threat agents for SPADA's consideration.

In addition, she has been a voice of reason during SPADA meetings and during each working group meeting/teleconference allowing everyone to reach consensus and still meeting the goals of the contract. At first, the consideration was for vice chair of SPADA; however after further consideration and with the support of Dr. Davenport, Dr. Linda Beck is being nominated, for your approval, to serve as co-chair of AOAC SPADA.

RECOMMENDATION: Approve Dr. Linda Beck as co-chair of AOAC SPADA.

ENCLOSURES: None.

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MEMORANDUM

Date: **February 10, 2016**

To: **AOAC INTERNATIONAL Official Methods Board**

From: **Deborah McKenzie, Staff Liaison – AOAC Official Methods Board**

Subject: **Item V.a. OMB Maintenance Documentation**

During the OMB October 1, 2015 meeting, it was stated that there are several OMB documents that are either slated for review and/or require some revision to bring them to current AOAC policies and procedures. These include the OMB Terms of Reference, OMB Vice Chair Selection, OMB New Member Selection, etc… It is proposed that OMB establishes a working group to begin to examine the documents for the purposes of making recommendations to OMB regarding any revisions that may or may not be necessary. Furthermore, it is also recommended that the AOAC Committees on Safety and Statistics begin reviewing their Terms of Reference with guidance from OMB.

RECOMMENDATIONS: To approve an OMB Documents Working Group and assign members.

ENCLOSURES: OMB Terms of Reference
OMB New Member Selection
OMB Vice Chair Selection
OMB Vetting of Stakeholder Panel Voting Members (new)
OMB Vetting of ERPs (new)
Committee on Saftey Terms of Reference
Committee on Statistics Terms of Reference

AOAC INTERNATIONAL

TERMS OF REFERENCE

I. NAME:

OFFICIAL METHODS BOARD (OMB)

II. MISSION:

To serve the Association in a scientific and advisory capacity on standards and methods with ethical, timely, open and independent scientific oversight for the implementation of standards development and conformity assessment policies and procedures of AOAC INTERNATIONAL.

III. RESPONSIBILITIES:

To provide ethical, timely, open and independent scientific oversight for the policies and procedures of AOAC INTERNATIONAL.

To approve "Final Action" status for First Action Methods (new and revised) following a proactive review;

To repeal methods, if necessary, in accordance with established policies and procedures;

To participate in addressing appeals and requests for action or guidance, and in resolving disputes;

To endorse and monitor all voluntary consensus panels for appropriate representation and balance of stakeholders' perspectives;

To endorse and monitor all volunteer subject matter experts for volunteer conformity assessment activities;

To adopt and monitor scientific and technical guidance and references;

To acknowledge outstanding scientific and technical volunteer activity and achievement within AOAC;

To actively participate in AOAC standards development activities and maintain and communicate explicit knowledge of AOAC standards development and conformity assessment;

IV. COMPOSITION AND ORGANIZATION:

The Official Methods Board shall consist of up to 13 voting members including a Chair, a Vice-chair, the Chair of the Committee on Safety and the Chair of the Committee on Statistics. The Committee on Safety and the Committee on Statistics may contain co-chairs. The co-chairs for these committees represent one vote on the OMB. Members of the OMB may serve in multiple volunteer roles for the benefit of the Association. The Chair of the Official Methods Board shall have previously served as a member of the Official Methods Board. The Chair, Vice-chair, and members of the Official Methods Board including the chairs of standing committees shall be appointed for a term of three years. A member of the OMB may be reappointed upon the recommendation of the Chair of the Official Methods Board with a maximum term of service of six (6) years. Exceptions may be made at the discretion of the President. The Chair of the Official Methods Board is eligible to serve an additional post chair term of up to three (3) years as an *ex-officio* member. Members of the Official Methods Board must be members of AOAC.

All members of the Official Methods Board are recommended by the Chair and appointed by the President. All Official Methods Board members serve at the pleasure of the President.

The Official Methods Board represents the membership of AOAC INTERNATIONAL. It shall be composed of members representing a balance of scientific expertise, government, industry, and academia as appropriate to the scope of the Board. Every effort should be made to include international representation on the Board.

Additional working groups, task forces, and other appropriate subgroups shall be appointed as needs arise by the Chair of the Official Methods Board.

V. STAFF LIAISON:

The Executive Director shall assign a member of the staff to serve as staff liaison.

VI. REVIEW SCHEDULE:

Every three years.

VII. DATE ESTABLISHED:

Renamed in 1981

VIII. DATES REVIEWED

01/08,

IX. DATES REVISED:

9/89; 5/90; 1/91; 8/06;
02/07; 07/07; 2/08; 4/13; 8/13

Process for Selecting Members of the Official Methods Board (OMB)

The process begins with the OMB Search Committee.

Composition

The Search Committee shall consist of three (3) members: two members of the current OMB and the Immediate Past Chair of the OMB who shall serve as chair of the Search Committee.

Purpose

The objective of the Search Committee is to identify and recommend a slate of nominees as potential candidates for membership on the OMB. They shall seek candidates from such sources as the Association Membership, the Communities, and Stakeholders Groups. The OMB will select a nominee from this slate.

Process

Criteria for Member of the OMB

- Must provide a current Curriculum Vitae
- Must be a member of AOAC INTERATIONAL in good standing
  - Must have a letter of support from the sponsoring organization [employer/supervisor]
  - Must have an executed AOAC Volunteer Acceptance Form
  - Must provide two letters of recommendation from someone other than an employee, employer or supervisor.
- Should be willing and capable of acting as a Liaison with the Communities, Technical Divisions, Research Institute, and other major Stakeholders.
- Should possess the minimum of a Bachelor's degree in chemistry, biology, mathematics or a related scientific field
- Should demonstrate technically competent written and oral communication and networking skills
- Should demonstrate leadership capabilities through documentation of project management, supervisory experience, or leadership positions within AOAC
- Should have experience in the AOAC collaborative study process
- Should be familiar with the AOAC Program Manual and the Official Methods of Analysis appendices
- Should have successfully completed OMB training in the method validation process, demonstrate ability to perform adequate review of AOAC collaborative studies, and agree to appropriate retraining at least every three years.

Appointment of the Candidate

The nominee shall be contacted by the Chair of the OMB to confirm his/her willingness and ability to serve. Once confirmation has been received, the nominee shall be presented to the Board of Directors for their approval and subsequent appointment by the President of the Association.

Composition of The Official Methods Board

The OMB shall be composed of the Chair, Vice Chair, the Chair of the Committee on Safety, the Chair of the Committee on Statistics, and up to 9 more members not to exceed a total of 13 members at any given time. The 9 appointed members are to represent a balance of government, industry, and academia as appropriate to the needs of the Association. No more than one-half of the members of the OMB may be from a single agency and no more than one-half of the members may be from industry.

PROCESS FOR SELECTING THE VICE CHAIR OF THE OFFICIAL METHODS BOARD (OMB)

The process begins with the OMB.

Criteria for the Vice Chair of the OMB

- Must have served for at least one year as a Member of the OMB
- Must fulfill all the criteria for a Member of the OMB

The members of the OMB serve as the search committee for a Vice Chair. They identify and recommend a slate of nominees as potential candidates for Vice Chair. The nominees shall be contacted by the Chair of the OMB to confirm his/her willingness and ability to serve. Once confirmation has been received, the nominee(s) will be presented to the OMB for a vote. An email ballot shall be sent out to the members of the OMB with the slate of nominees. The current Vice Chair collects and tallies the ballots.

The selection of the Vice Chair will be decided by at least a majority vote of the OMB. If there is a tie, the Chair will cast the determinative vote. If no one receives a majority vote, another email ballot will be sent out with the top two nominees who received the highest number of votes.

Committee on Safety

The Committee on Safety promotes an awareness of safety and health matters within the AOAC membership and gives guidance in that area with particular emphasis on consideration of safety as part of the AOAC *Official Methods*SM Program.

There shall be a minimum of five members, including the chair and past chair.

Safety Advisors should be consulted and included at any point in the method validation and collaboration process as requested by any AOAC groups.

Duties and Responsibilities of Safety Committee Members

a. Evaluate collaborative study protocols and manuscripts with regard to inclusion of safety related information. Transmit comments via safety checklist. Respond to protocols and manuscripts in a timely manner.
b. Make recommendations as to any cautionary statements that should be included in the method for final publication in OMA.
c. Clarify any procedural or other questions with the Study Director(s) that might have an impact on the safety of the method, if necessary.
d. Serve as advisors to Methods Committees by giving comments and advice to Methods Committees on safety matters.
e. Make recommendations for modification of the safety checklist as necessary to the OMB.
f. Participate as non-voting members on committee conference calls when requested.
g. Propose updates to Appendix B, Laboratory Safety, in the OMA as needed.
h. Stay current on the latest laboratory issues.
i. Committee on Safety chair serves as a member of the Official Methods Board.

Criteria for Serving as a Safety Advisor

a. Must be a member of AOAC INTERNATIONAL.
b. Must have a letter of support from the sponsoring organization (employer.
c. Must have an executed AOAC Volunteer Acceptance Form.
d. Must have experience in organizational safety functions (e.g. Chemical Hygiene Officer, Laboratory Safety Officer, or equivalent experience).
e. Must have documented formal safety training.
f. Must be familiar with OMA, Appendix B, and Laboratory Safety.
g. Must have successfully completed training from the AOAC Committee on Safety to ensure the member is able to perform adequate safety reviews of methods.

Process for Appointing a Member of the Committee on Safety

If members are needed on the Committee on Safety, the general membership is solicited. Interested parties are asked to submit letters of interest addressing the criteria, resumes/CVs, and a letter of support from their sponsoring organization when applicable, to the AOAC staff. These letters are forwarded to the chair of the Committee on Safety.

The Committee on Safety chair recommends members to the OMB chair. Upon agreement by the OMB, the OMB chair requests that the President send a letter of appointment to the Committee on Safety candidate selected. Copies of the letter will be sent to Committee on Safety chair and the candidate's supervisor. The appointment is generally for a three-year term unless otherwise recommended by the Committee on Safety's chair.

The President sends a thank you letter and a Certificate of Appreciation to the Committee member, with copies sent to the Committee chair and OMB chair at the conclusion of a Committee appointment. Letters are also sent if a Committee member resigns his/her appointment because of retirement, changes in employment responsibilities, removal, or if he/she becomes unable to carry out the duties of a Committee member.

Process for Removing a Committee on Safety Member

If a member of the Committee is not performing the duties appropriately; the Committee chair will recommend replacement of the member to the OMB chair. The OMB chair will bring the matter before the OMB for discussion and a vote. It will take at least two-thirds of the OMB to remove a Committee member. Upon a determination by the OMB to remove a Committee member, the OMB chair will notify the President.

Upon removal, a thank you letter from the President is sent to the Committee member, with copies sent to the Committee chair and the Official Methods Board Chair.

Committee on Statistics

The Committee on Statistics develops and recommends harmonized statistical guidelines for the AOAC *Official Methods* Program and encourages greater use of standardized statistical techniques. The committee advised the Official Methods Board and Methods Committees on statistical matters concerning collaborative study design and criteria for approval.

There shall be a minimum of 5, including the chair and past chair.

Members of the Committee on Statistics should be consulted and included at any point in the method validation and collaboration process as requested by any AOAC groups.

Members of the Committee on Statistics can be voting members of the Methods Committee provided they are not statistics members for that method.

Duties and Responsibilities of Committee on Statistics Members:

a. Statistically evaluate interlaboratory study design, results, and respond to questions and concerns in a timely manner.
b. Serve as advisor to Methods Committees by giving comments and advice to Methods Committee on statistical matters, in particular, the precision and accuracy parameters of interlaboratory studies.
c. Participate as non-voting participants on committee conference calls.
d. Provide statistical review of protocols and collaborative studies submitted to the Methods Committee.
e. Propose updates to Appendix D in the OMA and Appendix X in the Program Manual as needed.
f. Work with Study Directors and potential Study Directors in designing interlaboratory studies, preparing reporting work sheets, and using correct statistical procedures.
g. Committee on Statistics chair serves as a member of the Official Methods Board.

Criteria for Serving as a Committee on Statistics Member:

a. Should be a member of AOAC INTERNATIONAL.
b. Must have a letter of support from the sponsoring organization.
c. Must have an executed AOAC Volunteer Acceptance Form.
d. Documented formal training in statistics.
e. Must be familiar with OMA Appendix D, Guidelines for Collaborative Study Procedures to Validate Characteristics of a Method of Analysis and Appendix X, Method Committee Guidelines for Validation of Qualitative and Quantitative Food Microbiological Official Methods of Analysis.

f. Must have successfully completed training from the AOAC Committee on Statistics to ensure the member is able to perform adequate statistical reviews of AOAC pre-collaborative/collaborative studies with appropriate refresher training.

Process for Appointing a Member of the Committee on Statistics

If members are needed on the Committee on Statistics, the general membership is solicited. Interested parities are asked to submit letters of interest addressing the criteria, resumes/CVs, and a letter of support from their sponsoring organization when applicable, to the AOAC staff. These letters are forwarded to the chair of the Committee on Statistics.

The Committee on Statistics chair recommends members to the OMB chair. Upon agreement by the OMB, the OMB chair requests that the President send a letter of appointment to the Committee on Statistics candidate selected. Copies of the letter will be sent to Committee on Statistics chair and the candidate's supervisor. The appointment is generally for a three-year term unless otherwise recommended by the Committee on Statistics chair.

The President sends a thank you letter and a Certificate of Appreciation to the Committee member, with copies sent to the Committee chair and OMB chair at the conclusion of a Committee appointment. Letters are also sent if a Committee member resigns his/her appointment because of retirement, changes in employment responsibilities, removal, or if he/she becomes unable to carry out the duties of a Committee member.

Process for Removing a Member of the Committee on Statistics

If a member of the Committee is not performing the duties appropriately; the Committee chair will recommend replacement of the member to the OMB chair. The OMB chair will bring the matter before the OMB for discussion and a vote. It will take at least two-thirds of the OMB to remove a Committee member. Upon a determination by the OMB to remove a Committee member, the OMB chair will notify the President.

Upon removal, a thank you letter from the President is sent to the Committee member, with copies sent to the Committee chair and the Official Methods Board Chair.

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MEMORANDUM

Date: **February 10, 2016**

To: **AOAC INTERNATIONAL Official Methods Board**

From: **Deborah McKenzie, Staff Liaison – AOAC Official Methods Board**

Subject: **Item V.b. OMB Awards Update**

McKenzie will provide an update to the OMB on the Awards process. This year, ERP chairs are being asked to submit their nominations with justification for Method of the Year as a way to assist the OMB in making its determination. Additionally, OMB will be asked to begin looking at potential options for the Award in Recognition of Technical and Scientific Excellence. Currently, the Awards information will run in the ILM and notification will be sent via email blast seeking nominations for Technical Service Award.

In the meantime, AOAC is gathering assembling the ERPs and Methods eligible for award consideration.

RECOMMENDATIONS: None.

ENCLOSURES: OMB Awards Program.

***OFFICIAL METHODS*[SM] PROGRAM AWARDS**

Contents

Team Awards:

Award in Recognition of Technical and Scientific Excellence

Expert Review Panel of the Year

Individual Achievement Awards:

Technical Service Award

Method of the Year

AWARD IN RECOGNITION OF TECHNICAL AND SCIENTIFIC EXCELLENCE

Selection Criteria

The purpose of this award is for the Official Methods Board (OMB) to recognize a team, stakeholder panel or working group that has published a major document or other body of work that demonstrates a unique or particularly noteworthy level of technical and scientific expertise.

The minimum criteria for selection are:

a. The body of work includes major initiatives or technical guidelines accepted, completed or published within the last three years.
b. The team has been instrumental in developing or modifying technical guidelines or method validation processes.
c. The team product demonstrates significant merit as to the scope of the project, the involvement of a diverse and/or international group of stakeholders or an innovative approach to difficult analytical challenges.
d. The award recognizes teamwork that enhances the reputation of the Association and fosters the mission of AOAC INTERNATIONAL.

Selection Process:

a. The chair of the OMB solicits the OMB members for nominees.
b. Written recommendations and supporting information will be submitted to the OMB chair. The information will be distributed to the members of the OMB.
c. The OMB selects the recipient of this award. The winner is selected by a 2/3 vote. If necessary, the OMB chair may cast the tie-breaking vote.

Award

An appropriate letter of appreciation and thanks will be sent to the recipient(s) of this award. The winner will be announced at the appropriate session of the AOAC INTERNATIONAL annual meeting, with presentation of an award. All members participating in the winning team will be acknowledged at the annual meeting, receive an award and a letter of appreciation. The name of the winner, with supporting story, will be carried in the announcement in the *ILM*.

EXPERT REVIEW PANEL OF THE YEAR

Selection Criteria

The minimum criteria for selection are:

a. The expert review panel must have completed a significant milestone (e.g. First Action Method, Final Action Method, method modification) within the last three years.
b. Generally, some unique or particularly noteworthy aspect of the ERP's work is highlighted as making the ERP worthy of the award, such as innovative technology or application, breadth of applicability, critical need, difficult analysis, or timeliness.
c. The panel report demonstrates significant merit as to the scope of the project, the involvement of a diverse and/or international group of recognized experts or an innovative approach to difficult analytical challenge.

Selection Process:

a. AOAC staff lists all eligible panels for consideration and forwards that list along with the ERP report to the Chair of the Official Methods Board (OMB).
b. The OMB Chair forwards the list along with any supporting information to the OMB.
c. The OMB selects the Expert Review Panel of the Year. Winner is selected by a 2/3 vote. If necessary, the OMB chair may cast tie-breaking vote.

Award

An appropriate letter of appreciation and thanks will be sent to the members of the winning Expert Review Panel. The winning panel will be announced at the appropriate session of the AOAC INTERNATIONAL annual meeting, with presentation of an award. All panelists participating in the winning panel will be acknowledged at the annual meeting, receive an award and a letter of appreciation. The name of the winning ERP, with supporting story, will be carried in the announcement in the *ILM*.

TECHNICAL SERVICE AWARD

More than one volunteer may be selected in this category each year. In each case the area of expertise should be noted at the time of presentation of the award.

Selection Criteria includes:

a. Has demonstrated timely, competent, and continuous service in an exemplary manner to a Stakeholder Panel (SP), Expert Review Panel (ERP), Working Group (WG), Section, Community, and Committee and/or to the Official Methods Board (OMB).
b. Has donated this service within the three years prior to nomination.
c. Gives outstanding expert guidance and support in all technical aspects as needed and requested.

Additional support for selection is exemplary performance in one or more of the areas below:

a. Has provided guidance on safety, statistical, technical matters, or process expertise.
b. Has been instrumental in developing, modifying or validating a high quality method for publication in the Official Methods of Analysis.
c. Communicates related activities through the appropriate channels, either through the panel/group/community chairs, the Committee on Statistics or Safety or through the Chief Scientific Officer or other staff designees.
d. Contributes significantly to AOAC INTERNATIONAL over a period of years with other accomplishments related to his/her area of expertise (e.g symposium presentations, poster presentations, publications, workshops, meetings).
e. Contributes to the development and improvement of AOAC INTERNATIONAL guidelines, OMA methods, statistics or safety programs.
f. Helps guide AOAC in the decision-making process to make the organization a leader in the field of analytical science.

Selection Process

a. The Official Method Board (OMB) will solicit the Chairs of the Stakeholder Panels, Expert Review Panels, Working Groups, Committees, Community, and the Association membership for nominees. Recommendations based on input from anyone qualified to discuss the contribution of the nominee can be submitted.
b. Written recommendations and supporting information must be submitted to the OMB Chair. The OMB chair will distribute the information to the members of the OMB.
c. The OMB selects the winner(s) of the Technical Service Award by a 2/3 vote. If necessary, the OMB chair may cast tie-breaking vote.

Award

An appropriate letter of appreciation and thanks will be sent to the recipient(s) of this award. The winner will be announced at the appropriate session of the AOAC INTERNATIONAL annual meeting, with presentation of an award. The recipient(s) will be acknowledged at the annual meeting, receive an award and a letter of appreciation. The name of the winner, with supporting story, will be carried in the announcement in the *ILM*.

METHOD OF THE YEAR

OMB may select more than one method in this category each year.

Selection Criteria

The minimum criteria for selection are:

a. The method must have been approved for first or final action within the last three years.
b. Generally, some unique or particularly noteworthy aspect of the method is highlighted as making it worthy of the award, such as innovative technology or application, breadth of applicability, critical need, difficult analysis, and/or range of collaborators.
c. The method demonstrates significant merit in scope or is an innovative approach to an analytical problem.

Selection Process:

a. AOAC staff lists all eligible methods for consideration and forwards that list with supporting documentation (e.g. ERP chair recommendation(s)) to the Chair of the Official Methods Board (OMB).
b. The Chair forwards the list along with any supporting information to the members of the OMB.
c. The OMB selects the Method of the Year. The winner is selected by 2/3 vote. If necessary, the OMB chair may cast tie-breaking vote.

Award

An appropriate letter of appreciation and thanks will be sent to the author(s) of the winning method. The corresponding author will be announced at the appropriate session of the AOAC INTERNATIONAL annual meeting, with presentation of an award. All authors will be acknowledged at the annual meeting, will receive an award and a letter of appreciation. The name of the winner(s), with supporting story, will be carried in the announcement in the *ILM*.

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MEMORANDUM

Date: **February 10, 2016**

To: **AOAC INTERNATIONAL Official Methods Board**

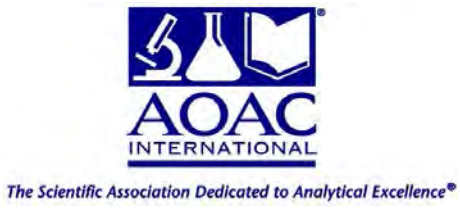
From: **Deborah McKenzie, Staff Liaison – AOAC Official Methods Board**

Subject: **Item V.c. OMB New Member Selection**

The AOAC OMB New Member Selection Working Group met in fall 2015. Crowley will provide a verbal update to OMB on the working group activity.

RECOMMENDATIONS: None.

ENCLOSURES: None.



MEMORANDUM

Date: **February 10, 2016**

To: **AOAC INTERNATIONAL Official Methods Board**

From: **Deborah McKenzie, Staff Liaison – AOAC Official Methods Board**

Subject: **Item V.d. OMB Next Teleconference**

The AOAC OMB next teleconference is scheduled for Thursday, March 10, 2016. This is a few days from the beginning of the Mid-Year meeting. Since voting panels will need to be vetted, is it possible to have this meeting in the first week of March so as to facilitate the notification of voting members.

RECOMMENDATIONS: For OMB to agree to a date for a teleconference during the week of March 1st.

ENCLOSURES: None.