



The Scientific Association Dedicated to Analytical Excellence®



AOAC INTERNATIONAL Committee on Statistics

December 14, 2016

Meeting Book

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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.



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.



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.

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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



The Scientific Association Dedicated to Analytical Excellence®

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

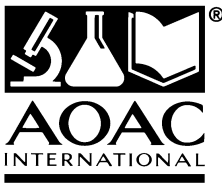
Each volunteer elected or appointed to an AOAC position of responsibility shall be sent, at the time of election or appointment, a copy of this policy and shall be advised of the requirement to adhere to the provisions herein as a condition for active participation in the business of the Association. 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



Statistics
Committee As of:
October 21, 2016

Sidney Sudberg, Chair

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Term: October 1, 2012 - September 30, 2018

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Term: October 13, 2010 - September 30, 2017

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Term: May 2, 2016 - December 31, 2019

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Term: October 1, 2013 - December 31, 2016

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Term: January 10, 2011 - December 31, 2017

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Term: March 13, 2013 - September 30, 2017

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Term: September 30, 2009 - September 30, 2018

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Deborah McKenzie, AOAC Staff Liaison

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Term: October 13, 2010 - September 30, 2017



AOAC INTERNATIONAL COMMITTEE ON STATISTICS Draft Meeting Agenda

Wednesday, December 14, 2016

Meeting Start Time: 11:00AM (Eastern US)

Chair: Sidney Sudberg
(*Alkemists Pharmaceuticals*)

(Need member to volunteer to take the minutes)

- I. **WELCOME & INTRODUCTION (Sudberg – 11:00AM-11:10AM) ***
Sidney Sudberg will call the meeting to order, welcome and introduce the members of Statistics Committee. Members will review the AOAC policy documents and vote on the draft meeting agenda.

- II. **REVIEW OF MEETING MINUTES (All – 11:10AM-11:15AM)***
The members of the Statistics Committee will review and vote on the November 22, 2016 meeting minutes.

- III. **CURRENT METHOD CONFORMITY ASSESSMENT PROJECTS
(Wehling/LaBudde/Sudberg/Thompson/Graves/AOAC Consultants – 11:15AM-11:40AM)
(Progress updates)**
 - a. **Statistics for Microbiology methods validation, Robert has new ways for confidence interval (based on ISO and TR342)**
 1. Waiting for Maria & Sharon to report any findings until January for any progress made from users
 2. Any feedback from Scott, re: the RI test kit users?

 - b. **Changes to Appendix J**
 1. Quantitative methods need changes
 - i. Candidate minus Reference
 - ii. New method of calculating the CI for the paired DPod
 - iii. Use of Z (n) vs. t (n-1)
 - iv. Submit to OMB for approval, when?
 - v. Paul to put this together?

 - c. **Robert's Chi-Square Test Calculator (Please help testing it) <http://lcf ltd.com/AOAC/aoc-binary-v2-5.xlsx>**
 1. Anyone have anything to report?
 2. Any volunteers?

 - d. **Revising the Statistics Committee's Terms of Reference (ToR)**
 1. 3 versions have been circulated for review
 1. One from this Committee & one from Staff (Deborah) & the original version

 - e. **Statistics Advisor Review form**
The committee has decided to modify the form on the AOAC web into 2 separate forms for Quantitative and Qualitative. Robert and Caryn are taking lead on the new forms (Qualitative and Quantitative). All comments are welcome.

IV. OTHER PROJECTS & DISCUSSIONS (All – 11:40AM-11:55AM)

(Other projects and discussions)

a. Possible new committee members:

1. Tom Phillips (MD. Dept. of Agriculture)
2. Dan Morse (3M)
3. Jim Harnly (USDA)
 - i. Discuss candidates & possibilities

b. New Business:

1. Scott Coates opened discussion on intermediate precision & possibly making modifications to Appendix J in an effort to harmonize with ISO?
 - i. Any updates?
2. The Call for Scientific Session for the 2017 AOAC Annual Meeting is currently open until December 14.
 - i. See [AOAC website](#)

V. SCHEDULE NEXT STATISTICS COMMITTEE MEETING (All – 11:55AM-12:00PM)

Next Statistics Committee meeting dates (11:00am–12:00pm ET or other options, if necessary)

a. Wednesday, January 11, 2017

b. Tuesday, January 17, 2017

Conference number/code:

1-877-647-3411 (US/Canada)
800-56094 (Norway)

To view a list of toll-free international dial-in numbers [Click Here](#)

Pass code: 3735235702#

AOAC Statistics Committee Minutes (November 22, 2016)

AOAC INTERNATIONAL

Committee on Statistics Teleconference

Tuesday November 22, 2016

At 11:00 am (US EDT) to 12:00am (US EDT)

Committee Members Present

Sidney Sudberg (Alkemists Pharm) Chair
 Qian Graves (FDA) Past Chair
 Robert LaBudde (Least Cost Formulations Ltd)
 Paul Wehling (GenMills)
 Jane Weitzel (Independent Consultant)
 Anli Gao (University of Guelph)
 Mei-Ling Lee (Univ. of MD)

AOAC Staff

Delia Boyd
 Scott Coates

Committee Members absent

Mike Zapf (CM Zapf LLC)
 Caryn Thompson (Elanco Animal Health)
 Hilde Skaar- Norli (NMKL)
 Jimmy Yuk (Waters)
 Wolfhard Wegscheider (University of Leoben)

Minutes Taken By

Qian Graves

Item #	Discussion/Action Item	Person Responsible
1	Introduction	Sidney
2	Stats Committee new chair: Sidney Sudberg	Sidney
3	Minutes from 8/29/2016 meeting - Qian made a motion, Jane 2nd, and it was approved.	All

4	<p>Report: 2016 Annual Meeting two Sessions. Success!!! a). 2016 Statistics Symposium on Tue Sept. 20, 2016 (8:15 am to 9:45 am): “Improved methodologies for performing quantitative collaborative studies”</p> <p style="margin-left: 40px;">Session Chair: Qian Graves We have invited an VIP guest, the current OMB chair, Shauna Roman to provide the Opening Remarks (~5 minutes) Three speakers:</p> <ul style="list-style-type: none"> ▪ Paul Wehling (co-author: Robert LaBudde) 	<p>LaBudde Sudberg Wehling Weitzel Graves Shauna Roman</p>
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AOAC Statistics Committee Minutes (November 22, 2016)

	<ul style="list-style-type: none"> ▪ Sidney Sudberg (co-author: Robert LaBudde) ▪ Jane Weitzel <p>Sidney: some improvement from last year's Paul: Went well. generated more discussed Jane: was well received, more questions and discussions</p> <p>b). Workshops on Sunday, Sept 18, 2016 (8:30 am – 12:00 pm):</p> <ul style="list-style-type: none"> • (see details under 5.) Paul took lead to the workshop on statistics software for microbiology methods validation (more info in 4.). <p>Paul: given out 45 software USBs, at least 40 showed up, full house. Maria and Sharon - continue working on the excel file. Sidney and Qian also attended the workshop, and they commented that it went well.</p>	<p>Paul Sharon Maria</p>
<p>5</p>	<p>Current projects</p> <ul style="list-style-type: none"> • Paul took lead to the workshop on Statistics for Microbiology methods validation, and he has been leading a group of volunteers testing software, etc. <p>Paul: Robert has new ways for confidence interval (based on ISO and TR342), Paul, Maria, Sharon made the Excel calculations. No more work since the workshop, need to collect feedback. Next: Working with Maria, Sharon (those 2 will hear from users), Paul will contact them cc-Sidney, come back in Jan. Scott: AOAC Research Institute asked for this, asked by a few test kits companies, they are using this so they will give feedback. A bit later Sharon responded to Paul by e-mail: no feedback since the annual meeting, just a few folks asking when it is official so people can start using it.</p> <ul style="list-style-type: none"> • Changes in the Appendix J <p>Paul: Was focused on Qualitative methods, later they found quantitative sometimes does not work, (We need to set: Candidate minus Reference), incl. ISO new method of calculating CI, CI for the paired DPod, Will need to send to OMB for approval, Paul and Robert will do this. Paul: need to put a package together. Anli: Paul and Robert: will you publish this? Jane offered help if publish. Paul said will call committee for help later on as needed for review.</p> <p>Robert: change of Appen. J, testing homogeneity among labs) Now we are use Z, so we need to use n d.f. (not n-1); if we use t then it would be n-1 d.f.</p>	<p>ALL</p>

AOAC Statistics Committee Minutes (November 22, 2016)

	<ul style="list-style-type: none"> • (Continuing) Revising our committee’s TOR <p>So far we have 3 versions, 1. Original/old, 2. Mike, Paul, Qian were working on the old version and made some changes and has an unfinished version, 3. Deb. worked on the old version and made some changes so it is also an unfinished version. So we will need to discuss all the changes and to add all the changes the committee selected to produce a new version.</p> <ul style="list-style-type: none"> • (Continuing) Statistics Advisor Review form (Robert, Caryn) <p>The committee has decided to modify the form on the AOAC web into 2 separate forms for Quantitative, and Qualitative. Robert and Caryn are taking lead on the new forms (Qualitative and Quantitative). All comments are welcome.</p> <p>Sidney will look up the old emails and gather files and we can resume this work.</p>	
6	<p>Other projects and discussions</p> <ul style="list-style-type: none"> • Possible new committee members: <ol style="list-style-type: none"> 1. Tom Phillips 2. Dan Morse from 3M 3. Jim Harnly from USDA <p>Scott: wants to add intermediate precision on Appen J Scott:, over last 2 years, ISO has applied some methods using different labs, different times, different analysts, etc, but how to pool data together ISO called this “Intermediate Repeatability”, and reproducibility, it is very confusing. We need guidance. Scott: OMB: Paula Brown at BC Institute of Technology volunteered to help. Robert: use effect, not repeatability, and reproducibility. Paul: ISO 5725 part 4, part 6, done everything, incl. all definitions. Jane: If you have the targeted uncertainty then you have an idea on how to measure this. Jane said she can help.</p> <p>Scott: Robert, Paul, Jane, Paola Brown, Scott, we will hold a T-con in Dec. for about 2 hours. Sidney asked if he could join. Scott said he wants to keep the group small, but since Sidney is chair, so it is OK. Delia will send up the call.</p> <p>Membership: Delia will discuss this next call.</p>	ALL

AOAC Statistics Committee Minutes (November 22, 2016)

7	Next T-con will be Wednesday, Dec. 14th 11:00am – 12:00am Eastern Time Jane made a motion to move to adjourn the meeting, Qian 2nded her.	12:05pm
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AOAC INTERNATIONAL

TERMS OF REFERENCE

I. NAME:

COMMITTEE ON STATISTICS

II. MISSION:

To develop and recommend harmonized statistical guidelines for AOAC interlaboratory collaborative studies, and to encourage greater use of standardized statistical techniques.

III. RESPONSIBILITIES:

To advise the Official Methods Board on statistical matters concerning the methods approval process; to educate AOAC volunteers in proper application of statistical techniques.

All Committee members, other than those holding *ex officio* appointments, serve at the pleasure of the President. All Committee members are expected to actively participate in the work of the Committee; including, but not limited to, promptly responding to communications, attending and actively participating in meetings, reviewing meeting background materials and agendas prior to meetings, and accepting and following through on assignments. Persons who do not actively participate will be removed from the committee by the President at the request of the chair.

IV. COMPOSITION AND ORGANIZATION:

There shall be a minimum of 5 and a maximum of 12 members, including the chair and past chair. A member shall be appointed for a three-year term, with no maximum term limitation. The chair is appointed for one three-year term and may serve one additional year on the Committee as immediate past chair.

Methods Committee statisticians are appointed as ex-officio members of the Committee, serving in an advisory capacity.

All members of the Committee are appointed by the President Elect and assume office immediately following the Annual Meeting of the appointment year.

The Committee shall be composed of members representing a balance of government, industry, and academia as appropriate to the scope of the

Committee. No more than one-half of the members may be from a single agency. Less than one-half of the members must be from industry.

Committee members should be experienced in designing and evaluating laboratory studies, as well as understanding statistics. Subcommittees, task forces, and other appropriate subgroups shall be appointed as the needs arise.

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:

1962

VIII. DATES REVISED:

8/91; 3/99; 9/99

AOAC INTERNATIONAL TERMS OF REFERENCE

Committee on Statistics

The AOAC Committee on Statistics serves the Association in an advisory capacity on statistical matters including but not limited to AOAC standards development and conformity assessment activities, programs, and services. The committee's work includes but is not limited to providing guidance and advice on the use of statistical techniques and tools, statistical data analysis, and making recommendations on new or improved statistical approaches. This committee reports to the AOAC Official Method Board, and the committee chair serves as a member of the AOAC Official Methods Board. All members of the committee are appointed volunteers of AOAC and serve at the pleasure of the President of AOAC INTERNATIONAL.

I. Committee Composition

The committee shall be comprised of a minimum of seven members and not to exceed a maximum of 12 members, including the chair. A member shall be appointed for a three-year term that begins and ends with the AOAC Annual Business Meeting. Members may serve a maximum of two three year terms. Requests to serve additional terms must be approved with rationale by the Official Methods Board and the President of AOAC. The chair is appointed for one three-year term and may serve one additional three-year term as a member of the committee. The committee must have a quorum to have a meeting making decisions. Consensus of the Committee is demonstrated with a minimum of 7 voting members of the Committee in favor of a motion.

Comment [D1]: For ERPs, a quorum is defined as a minimum of seven

II. Summary of Duties and Responsibilities for Members of the Committee on Statistics:

- a. Guide and advise on appropriate application and use of statistical techniques and tools;
- b. Statistically evaluate and advise on study designs, numerical results, and address questions in a timely manner as requested by staff and Official Methods Board;
- c. Advise AOAC stakeholder panels, working groups, and expert review panels as requested by Official Methods Board;
- d. Advise Official Methods Board on changes to statistical tools, guidance, and approaches as it applies to standards development and conformity assessment activities;
- e. Evaluate and/or provide guidance and advice on designing multi-laboratory studies, assigned method manuscripts, reporting work sheets, and use of appropriate statistical procedures; and
- f. Other projects as assigned through AOAC staff or Official Methods Board.

III. Summary of Duties and Responsibilities for the Chair of the Committee on Statistics

- a. Serve as primary representative of the Committee;
- b. Must be a member of AOAC INTERNATIONAL in good standing
- c. Facilitate and moderate discussions of the Committee Meetings;

- d. Present and report on Committee activities and/or recommendations to AOAC Official Methods Board (OMB) and actively serve as primary Committee representative and participate on the OMB;
- e. Oversee the implementation of AOAC policies and procedures in the Committee;
- f. Work with staff on assigning Committee members for method reviews;
- g. Work with staff and Official Methods Board on priorities to be addressed by the Committee; and
- h. Work with staff and OMB on identification and approval of Committee membership.

IV. Criteria for Serving as a Committee on Statistics Member:

- a. Must be a trained statistician, or have documented formal training in statistics, applied statistics, or other sufficient relevant expertise;
- b. Must be willing to carry out the duties and responsibilities described in the Section II;
- c. Must be able to work cooperatively with other volunteers, stakeholders, experts, and staff;
- d. Must submit a CV and a statement of expertise;
- e. Must have a letter of support from the sponsoring organization; and
- f. Must have an executed AOAC Volunteer Acceptance Form.

V. Committee Member Appointment

If members are needed on the Committee on Statistics, AOAC will issue a Call for Experts. Interested candidates will complete an application that will include the submission of 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 a draft of the revised Committee roster along with appropriate documentation and to the OMB. A two-thirds vote in favor of approving the revised draft roster by OMB approves the addition of a new Committee member or an additional term of a current Committee member. Upon approval by the OMB, the revised roster is sent to the President of AOAC INTERNATIONAL with a request for volunteer appointments. A letter confirming the appointment is sent to all newly approved members. Copies of the letter and a final version of the revised Committee roster will be sent to Committee on Statistics chair. The appointment is generally for a three-year term unless otherwise recommended and approved by OMB.

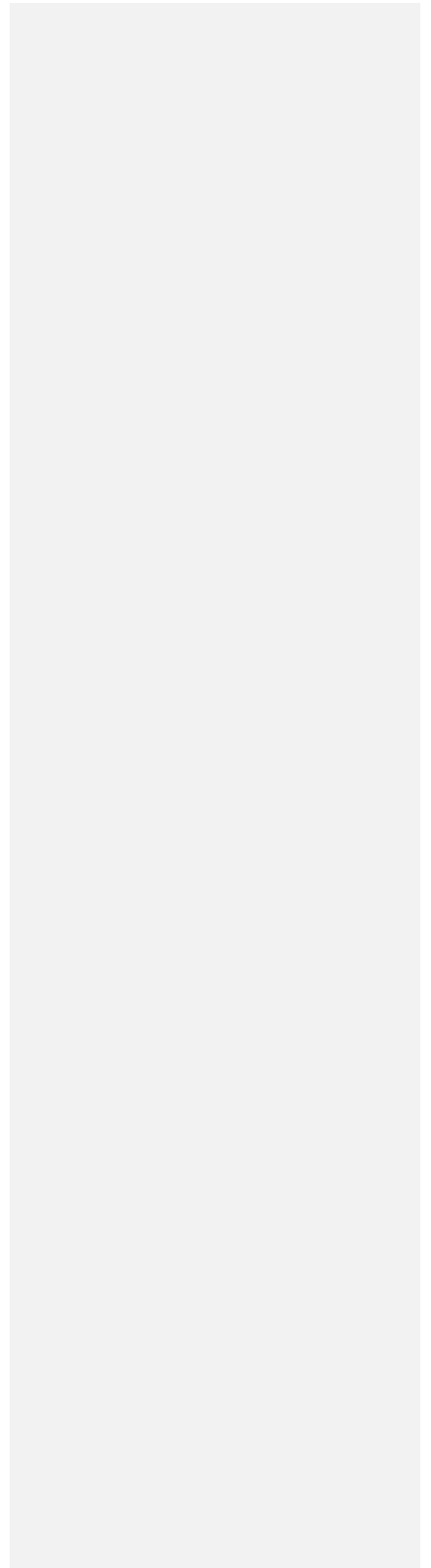
At the conclusion of a Committee member's term, a thank you letter from the President is sent along with Certificate of Appreciation to the Committee member. A copy of the letter is sent to the Committee chair and OMB chair.

Committee Member Removal or Resignation

If a member of the Committee is not performing the duties appropriately, the Committee chair will submit a revised draft roster that recommends removal of the Committee member to the OMB for its consideration. A two-thirds vote in favor of approving the revised draft roster by OMB approves the removal of a Committee member.

If a member is not able or is no longer able to serve because of retirement, changes in employment responsibilities, removal, or if he/she becomes unable to carry out the duties of a Committee member, the member must notify AOAC staff and the Committee chair in writing regarding their need to resign from the Committee. The Committee chair will submit a revised draft roster that recommends removal of the Committee member to the OMB for its consideration. A two-thirds vote in favor of approving the revised draft roster by OMB approves the removal of a Committee member.

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. A thank you letter is sent if a Committee member resigns his/her appointment.



AOAC INTERNATIONAL TERMS OF REFERENCE

Committee on Statistics

The AOAC Committee on Statistics develops and recommends harmonized statistical guidelines and encourages greater use of standardized statistical techniques. The committee advises the Official Methods Board on statistical matters concerning study design and criteria for approval.

Comment [D1]: Broaden the language

There shall be a minimum of seven and a maximum of 12 members, including the chair and past chair. A member shall be appointed for a three-year term, with no maximum term limitation. The chair is appointed for one three-year term and may serve one additional three-year term. The past chair may also become eligible to serve again as chair for one three-year term.

Comment [D2]: Separate section on Committee composition and add more details. Since this committee has folks interested in serving on it, it needs a the opportunity for turn over so that new people can serve on the committee without the awkward discussion of inviting people off of the committee

The Committee may appoint a secretary, if requested by the chair. The committee selects the secretary for a three-year term.

Comment [D3]: This followed the structure of the method committees for which the secretary was being groomed as next chair; this is no longer the process. While there are recording secretaries for minutes, no one currently serves the role of what the original committee sects served.

Summary of Duties and Responsibilities for Members of the Committee on Statistics-Members:

- a. Committee on Statistics chair serves as a member of the Official Methods Board.
- b. Committee members statistically evaluate study designs, numerical results, and responds to Expert Review Panel concerns in a timely manner.
- c. Serve as advisor to Panels and ERP's as requested by Official Methods Board.
- d. Advise OMB on changes to statistical policies and guidelines needed for proper function of the Methods Program
- e. Work with Method Authors in designing interlaboratory studies, preparing reporting work sheets, and using correct statistical procedures.

Comment [D4]: Add a little more specificity.

Add a section for the chair's duties and responsibilities.

Criteria for Serving as a Committee on Statistics Member:

Comment [D5]: Add a little more specificity.

- 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 or describe how practical experience suffices as presented in the requisite CV.
- e. Review OMA documents as submitted by Research Institute.

Committee member appointment

Comment [D6]: Make consistent with standard current practixces

If members are needed on the Committee on Statistics, the general membership is solicited. Interested parties then 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 appoint the candidate to the committee, and send a letter of appointment to the Committee on Statistics chair and the candidate. The appointment is generally for a three-year term unless otherwise recommended by the Committee on Statistics chair. The Committee on Statistics chair recommends members to the OMB chair. Upon agreement by the OMB, the OMB chair requests that the.

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.

Committee member removal

Comment [D7]: Make consistent with standard current practixces

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.

AOAC INTERNATIONAL TERMS OF REFERENCE

Committee on Statistics

The AOAC Committee on Statistics serves the Association in an advisory capacity on statistical matters including but not limited to AOAC standards development and conformity assessment activities, programs, and services. The committee's work includes but is not limited to providing guidance and advice on the use of statistical techniques and tools, statistical data analysis, and making recommendations on new or improved statistical approaches. This committee reports to the AOAC Official Method Board, and the committee chair serves as a member of the AOAC Official Methods Board. All members of the committee are appointed volunteers of AOAC and serve at the pleasure of the President of AOAC INTERNATIONAL.

I. Committee Composition

The committee shall be comprised of a minimum of seven members and not to exceed a maximum of 12 members, including the chair. A member shall be appointed for a three-year term that begins and ends with the AOAC Annual Business Meeting. Members may serve a maximum of two three year terms. Requests to serve additional terms must be approved with rationale by the Official Methods Board and the President of AOAC. The chair is appointed for one three-year term and may serve one additional three-year term as a member of the committee. The committee must have a quorum to have a meeting making decisions. Consensus of the Committee is demonstrated with a 2/3 vote in favor of a motion.

Comment [D1]: For ERPs, a quorum is defined as a minimum of seven

II. Summary of Duties and Responsibilities for Members of the Committee on Statistics:

- a. Guide and advise on appropriate application and use of statistical techniques and tools;
- b. Statistically evaluate and advise on study designs, numerical results, and address questions in a timely manners as requested by staff and Official Methods Board;
- c. Advise AOAC stakeholder panels, working groups, and expert review panels as requested by Official Methods Board;
- d. Advise Official Methods Board on changes to statistical tools, guidance, and approaches as it applies to standards development and conformity assessment activities;
- e. Evaluate and/or provide guidance and advice on designing multi-laboratory studies, assigned method manuscripts, reporting work sheets, and use of appropriate statistical procedures; and
- f. Other projects as assigned through AOAC staff or Official Methods Board.

III. Summary of Duties and Responsibilities for the Chair of the Committee on Statistics

- a. Serve as primary representative of the Committee;
- b. Must be a member of AOAC INTERNATIONAL in good standing
- c. Facilitate and moderate discussions of the Committee Meetings;

- d. Present and report on Committee activities and/or recommendations to AOAC Official Methods Board (OMB) and actively serve as primary Committee representative and participate on the OMB;
- e. Oversee the implementation of AOAC policies and procedures in the Committee;
- f. Work with staff on assigning Committee members for method reviews;
- g. Work with staff and Official Methods Board on priorities to be addressed by the Committee; and
- h. Work with staff and OMB on identification and approval of Committee membership.

IV. Criteria for Serving as a Committee on Statistics Member:

- a. Must be a trained statistician, or have documented formal training in statistics, applied statistics, or other sufficient relevant expertise;
- b. Must be willing to carry out the duties and responsibilities described in the Section II;
- c. Must be able to work cooperatively with other volunteers, stakeholders, experts, and staff;
- d. Must submit a CV and a statement of expertise;
- e. Must have a letter of support from the sponsoring organization; and
- f. Must have an executed AOAC Volunteer Acceptance Form.

V. Committee Member Appointment

If members are needed on the Committee on Statistics, AOAC will issue a Call for Experts. Interested candidates will complete an application that will include the submission of 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 a draft of the revised Committee roster along with appropriate documentation and to the OMB. A two-thirds vote in favor of approving the revised draft roster by OMB approves the addition of a new Committee member or an additional term of a current Committee member. Upon approval by the OMB, the revised roster is sent to the President of AOAC INTERNATIONAL with a request for volunteer appointments. A letter confirming the appointment is sent to all newly approved members. Copies of the letter and a final version of the revised Committee roster will be sent to Committee on Statistics chair. The appointment is generally for a three-year term unless otherwise recommended and approved by OMB.

At the conclusion of a Committee member's term, a thank you letter from the President is sent along with Certificate of Appreciation to the Committee member. A copy of the letter is sent to the Committee chair and OMB chair.

Committee Member Removal or Resignation

If a member of the Committee is not performing the duties appropriately, the Committee chair will submit a revised draft roster that recommends removal of the Committee member to the OMB for its consideration. A two-thirds vote in favor of approving the revised draft roster by OMB approves the removal of a Committee member.

If a member is not able or no longer to serve because of retirement, changes in employment responsibilities, removal, or if he/she becomes unable to carry out the duties of a Committee member, the member must notify AOAC staff and the Committee chair in writing regarding their need to resign from the Committee. The Committee chair will submit a revised draft roster that recommends removal of the Committee member to the OMB for its consideration. A two-thirds vote in favor of approving the revised draft roster by OMB approves the removal of a Committee member.

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. A thank you letter is sent if a Committee member resigns his/her appointment.



AOAC INTERNATIONAL

Memorandum

Date: December 13, 2016

To: Statistics Working group on Intermediate Precision

From: Scott Coates

Intermediate Precision [RSD_i]

1. Should AOAC specify/include Intermediate precision in method evaluations?

- a. Required in Appendix L: AOAC Recommended Guidelines for Stakeholder Panel on Infant Formula and Adult Nutritionals (SPIFAN) Single-Laboratory Validation (attachment 1)
- b. Required or optional in validation manuscript ?
- c. In place of RSD_r, or in addition to RSD_r ?
- d. In SMPRs ?

2. Which definition to use?

- a. Appendix K: *Guideline for Dietary Supplements and Botanicals* includes a definition (attachment 2) but does not provide guidance for evaluation.
- b. Specific minimum requirements (minimum number of analysts, instruments, days, etc.)

3. Expected value?

- a. Predicted RSD_r is estimated as $\frac{2}{3} * (PRSDR)$.
- b. $PRSDR = 2C^{-0.15}$.
- c. Predicted RSD_i ?

4. In which document should this guidance reside ?

Appendix L: AOAC Recommended Guidelines for Stakeholder Panel on Infant Formula and Adult Nutritionals (SPIFAN) Single-Laboratory Validation

1 General

(a) All methods for a given nutrient or nutrient group will be subjected to a common single-laboratory validation (SLV) protocol utilizing the available SPIFAN matrices.

(b) SLV protocols may vary somewhat *between* nutrients, depending on the specific demands associated with each.

(c) Study directors (SDs) for each nutrient or nutrient group will agree on final details of the required SLV protocol.

(d) Suitability criteria indicating method/system performance is acceptable will be generated during SLV.

2 Linearity/Calibration Fit

(a) Minimum of six levels (levels to be agreed upon by SDs) that span the desired working range.

(b) Relative error of back-calculated concentrations determined within the desired working range. (No specific criterion in standard method performance requirement. Recommend calibration errors to be <5%.)

(c) Minimum of three independent experiments. (Independently prepared standards, if feasible.)

3 LOD/LOQ

Ten independent analyses of blank or blank spiked at low level (to be agreed upon by SDs) (if there is no detectable blank signal):

$$\text{LOD} = \text{blank mean} + 3 \text{ standard deviations}$$

$$\text{LOQ} = \text{blank mean} + 10 \text{ standard deviations}$$

(concentration of blank to be <10% of the estimated LOQ)

4 Specificity

(a) No explicit proposals for evaluating specificity have been suggested.

(b) Because useful strategies for doing this vary from analyte to analyte, SDs for each nutrient will agree on acceptable practice.

(c) An adequate evaluation of specificity may have already been done for some methods, in which case it would not have to be repeated.

5 Precision

(a) All samples selected for precision studies will be analyzed in duplicate on each of 6 days using multiple analysts and instruments as practical for the different days. Fresh reagents and working standards will be used each day. Reports will include information of number of analysts, instruments, etc.

(b) Precision data using SRM 1849a should be included for *all* methods. For each nutrient or nutrient group, precision data shall be collected using an appropriate variety of SPIFAN matrices that contain the nutrient or nutrient group (as agreed upon by the SDs). The number of matrices may vary between nutrients.

(c) Estimate within-day (repeatability), day-to-day, and overall (intermediate precision) for each sample type. Estimates pooled across sample types may also be useful.

6 Accuracy (Trueness)

(a) *Analysis of SRM 1849a.*—Comparison to SRM values may not always be applicable because nutrient definitions are not aligned. SDs will agree on whether this should be part of the accuracy assessment.

(b) *Spike recovery.*—(1) Recovery will be determined from an appropriate sampling of SPIFAN matrices. Either unfortified (preferably) and/or fully fortified products may be used.

(2) Each selected matrix will be spiked at two levels. Recommended spike levels are 50 and 150% of typical target; or 50 and 100% overspikes. SDs will agree on levels used.

(3) Spiked and unspiked samples will be analyzed in duplicate on each of 3 days.

(4) The overall mean of unspiked samples will be used for computing recoveries.

(5) Matrices used for estimating recoveries may or may not coincide with one or more of those selected for precision studies. If there is overlap, then a single 2×6 replication of the unspiked matrix covers both requirements for that sample type.

(c) *Comparison to reference methods.*—(1) This is not required as matter of routine, because the additional effort and lack of appropriate reference methods.

(2) SDs may choose to collect reference method comparison data.

of the found value for RSD_R to that calculated from the formula designated as $HorRat_R$. Acceptable values for this ratio are typically 0.5 to 2:

$$HorRat_R = RSD_R(\text{found, \%}) / RSD_R(\text{calculated, \%})$$

As stated by Thompson and Lowthian ("The Horwitz Function Revisited," (1997) *J. AOAC Int.* **80**, 676–679), "Indeed, a precision falling within this 'Horwitz Band' is now regarded as a criterion for a successful collaborative trial."

The typical limits for $HorRat$ values may not apply to indefinite analytes (enzymes, polymers), physical properties, or to the results from empirical methods expressed in arbitrary units. Better than expected results are often reported at both the high (>10%) and low (<E-8) ends of the concentration scale. Better than predicted results can also be attained if extraordinary effort or resources are invested in education and training of analysts and in quality control.

3.4.5 Intermediate Precision

The precision determined from replicate determinations conducted within a single laboratory not simultaneously, i.e., on different days, with different calibration curves, with different instruments, by different analysts, etc. is called intermediate precision. It lies between the within- and among-laboratories precision, depending on the conditions that are varied. If the analysis will be conducted by different analysts, on different days, on different instruments, conduct at least five sets of replicate analyses on the same test materials under these different conditions for each concentration level that differs by approximately an order of magnitude.

3.4.6 Limit of Determination

The limit of determination is a very simple concept: It is the smallest amount or concentration of an analyte that can be estimated with acceptable reliability. But this statement contains an inherent contradiction: the smaller the amount of analyte measured, the greater the unreliability of the estimate. As we go down the concentration scale, the standard deviation increases to the point where a substantial fraction of values of the distribution of results overlaps 0 and false negatives appear. Therefore the definition of the limit comes down to a question of what fraction of values are we willing to tolerate as false negatives.

Thompson and Lowthian (loc. cit.) consider the point defined by $RSD_R = 33\%$ as the upper bound for useful data, derived from the fact that $3RSD_R$ should contain 100% of the data from a normal distribution. This is equivalent to a concentration of about 8×10^{-9} (as a mass fraction) or 8 ng/g (ppb). Below this level false negatives appear and the data goes "out of control." From the formula, this value is also equivalent to an $RSD_i \approx 20\%$. The penalty for operating below the equivalent concentration level is the generation of false negative values. Such signals are generally accepted as negative and are not repeated.

An alternative definition of the limit of detection and limit of determination is based upon the variability of the blank. The blank value, x_{bl} , plus 3 times the standard deviation of the blank ($x_{bl} + 3s_{bl}$) is taken as the detection limit and the blank value plus 10 times the standard deviation of the blank ($x_{bl} + 10s_{bl}$) is taken as the determination limit. The problem with this approach is that the blank is often difficult to measure or is highly variable. Furthermore, the value determined in this manner is independent of the analyte. If blank values are accumulated over a period of time, the average is likely to be fairly representative as a basis for the

limits and will probably provide a value of the same magnitude as that derived from the relative standard deviation formulae.

The detection limit is only useful for control of undesirable impurities that are specified as "not more than" a specified low level and for low-level contaminants. Useful ingredients must be present at high enough concentrations to be functional. The specification level must be set high enough in the working range that acceptable materials do not produce more than 5% false-positive values, the default statistical acceptance level. Limits are often at the mercy of instrument performance, which can be checked by use of pure standard compounds. Limits of detection and determination are unnecessary for composition specifications although the statistical problem of whether or not a limit is violated is the same near zero as it is at a finite value.

Blank values must be monitored continuously as a control of reagents, cleaning of glassware, and instrument operation. The necessity for a matrix blank would be characteristic of the matrix. Abrupt changes require investigation of the source and correction. Taylor [J.K. Taylor (1987) "Quality Assurance of Chemical Measurements," Lewis Publishers, Chelsea, MI, p. 127] provides two empirical rules for applying a correction in trace analysis: (1) The blank should be no more than 10% of the "limit of error of the measurement", and (2) it should not exceed the concentration level.

3.4.7 Reporting Low-Level Values

Although on an absolute scale low level values are miniscule, they become important in three situations:

- (1) When legislation or specifications decrees the absence of an analyte (zero tolerance situation).
- (2) When very low regulatory or guideline limits have been established in a region of high uncertainty (e.g., a tolerance of 0.005 $\mu\text{g}/\text{kg}$ aflatoxin M₁ in milk).
- (3) When dietary intakes of low-level nutrients or contaminants must be determined to permit establishment of minimum recommended levels for nutrients and maximum limits for contaminants.

Analytical work in such situations not only strains the limits of instrumentation but also the ability of the analyst to interpret and report the findings. Consider a blank that is truly 0 and that the 10% point of the calibration curve corresponds to a concentration of 1 $\mu\text{g}/\text{kg}$ (E-9). By the Horwitz formula this leads to an expected RSD_i in a single laboratory of about 23%. If we assume a normal distribution and we are willing to be wrong 5% of the time, what concentration levels would be expected to appear? From 2-tail normal distribution tables (the errant value could appear at either end), 2.5% of the values will be below 0.72 $\mu\text{g}/\text{kg}$ and 2.5% will be above 1.6 $\mu\text{g}/\text{kg}$. Note the asymmetry of the potential results, from 0.7 to 1.6 $\mu\text{g}/\text{kg}$ for a nominal 1.0 $\mu\text{g}/\text{kg}$ value from the nature of the multiplicative scale when the RSD_i is relatively large.

But what does the distribution look like at zero? Mathematically it is intractable because it collapses to zero. Practically, we can assume the distribution looks like the previous one but this time we will assume it is symmetrical to avoid complications. The point to be made will be the same. For a distribution to have a mean equal to 0, it must have negative as well as positive values. But negative concentration values per se are forbidden but here they are merely an artifact of transforming measured signals. Negative signals are typical in electromotive force and absorbance measurements.

Analysts have an aversion to reporting a zero concentration value because of the possibility that the analyte might be present, but below the detection limit. Likewise, analysts avoid reporting

AOAC

ANNUAL MEETING & EXPOSITION

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131ST ANNUAL MEETING • SEPTEMBER 24–27, 2017 • ATLANTA, GA USA

2017 Annual Meeting

Call for Scientific Sessions

The AOAC Technical Programming Council (TPC) invites all AOAC Members, Community groups, and other interested individuals to submit proposals for the scientific sessions that will be offered at the 131st Annual Meeting & Exposition in Atlanta, Georgia at the Marriott Atlanta Marquis (September 24–27, 2017). Proposals may be submitted between **OCTOBER 10** and **DECEMBER 14, 2016**.

The TPC will accept proposals within the following AOAC Communities:

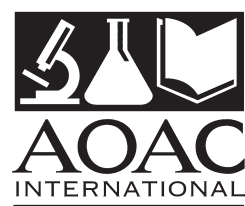
- **Chemical Contaminants in Food**
 - Metals
 - Pesticides
 - Veterinary Drugs
 - Unknowns
- **Dietary Supplements**
- **Food Allergens**
- **Food Nutrition**
 - Dietary Fiber
 - Nutrients
- **Microbiology**
- **Mycotoxins**
- **Technical Division for Laboratory Management (TDLM)**
- **Technical Division on Reference Materials (TDRM)**

All scientific sessions at the 2017 Annual Meeting will be 90 minutes in length. AOAC will forward the proposals to the corresponding TPC Member. TPC Members will review proposals and AOAC will send out acceptance/rejection letters no later than December 31, 2016. Please submit the following information to lhelf@aoac.org by

DECEMBER 14, 2016:

- Community to which you are submitting
- Scientific session title
- Abstract of the scientific session
- Individuals participating on the session—names, affiliations, and email addresses (Chair and Speakers for a symposium, Chair and Participants for a roundtable or a workshop)
- Your name, affiliation, phone number, and e-mail address

** Please note: Once a proposal is accepted, all participants must pre-register for the Annual Meeting. Because there is only a limited budget for travel funding, most participants are responsible for their travel and lodging expenses.*



PROPOSAL DEADLINE:
December 14, 2016

SUBMIT PROPOSALS TO:
Lauren Chelf at lhelf@aoac.org

QUESTIONS OR ASSISTANCE:
Call 240-912-1449

