AOAC Capabilities

About AOAC

AOAC INTERNATIONAL is a globally recognized, 501(c)3, independent, not-for-profit association founded in 1884. To attain its vision of "worldwide confidence in analytical results," AOAC serves communities of the analytical sciences by providing the tools and processes necessary to develop voluntary consensus standards or technical standards through stakeholder consensus and working groups in which the fit-for-purpose and method performance criteria are established and fully documented. AOAC provides a science-based solution and its *Official Methods of Analysis* gives defensibility, credibility, and confidence in decision-making. AOAC *Official Methods*SM are accepted and recognized worldwide. AOAC has become a very valuable tool to government and industry as public and private sectors have seen the need to work more closely with each other.

AOAC INTERNATIONAL®

The Scientific Association Dedicated to Analytical Excellence®

The AOAC Process

After an established history of dependency on publication sales for revenue, in 2001 AOAC took a new approach as a **problem solver** and provider of **science-based solutions**. AOAC has and continues to help resolve conflicts that impact trade, fair competition, and a level playing field. AOAC can also help assist in saving lives and protecting health. For example, in order to improve the quality control and monitoring of the food supply, reliable consensus methods and a global quality system infrastructure are needed to solve the problem. If the problem has a serious impact, AOAC can use its expertise and experience to locate methods quickly through consensus among those most affected (stakeholders) and then oversee the validation of methods and quality measurements (training, proficiency testing, etc.) that could help alleviate the problem. For over a century, AOAC has played a vital scientific role in validating analytical methods. Now, the Association is bringing science to situations where it is most needed; AOAC is beginning to play a role in seeing that science-based analytical methods are used where they can make a serious difference.

AOAC INTERNATIONAL ● Tel: +1-301-924-7077 ● Fax: +1-301-924-7089
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Bringing science to solve analytical problems, AOAC has established various analytical communities that can be tapped for their expertise and experience. An AOAC community is a group of individuals interested in a specific scientific area, such as dietary supplements, agricultural materials, or marine and freshwater toxins. Communities network; engage international, federal, and state governments, academia, industry, business, and trade groups; identify stakeholders; prioritize issues of concern; and work to provide solutions to scientific problems. A community can set methods priorities, establish performance criteria, select best methods via an expert review panel, then coordinate a single-laboratory validation and collaborative study. The community may also assist in qualifying analysts and collaborating laboratories, disseminating and updating approved methods, and identifying financial support. Stakeholders are representatives worldwide from government, industry, academia, and other organizations that have an interest or major stake in the outcome.

Application Fees

For more information on regular and discounted application fees for methods submitted to the Official Methods℠ or Performance-Tested Methods℠ programs, contact Joyce Schumacher at jschumacher@aoac.org or 1-301-924-7077 ext. 122.

Methods may be submitted as a result of a contract with a government agency or industry group. In addition, companies may submit a method independently with an accompanying application fee. *Official Methods*℠ status is only granted to methods meeting AOAC technical and statistical requirements for approval, as established through a collaborative study.

Business Development

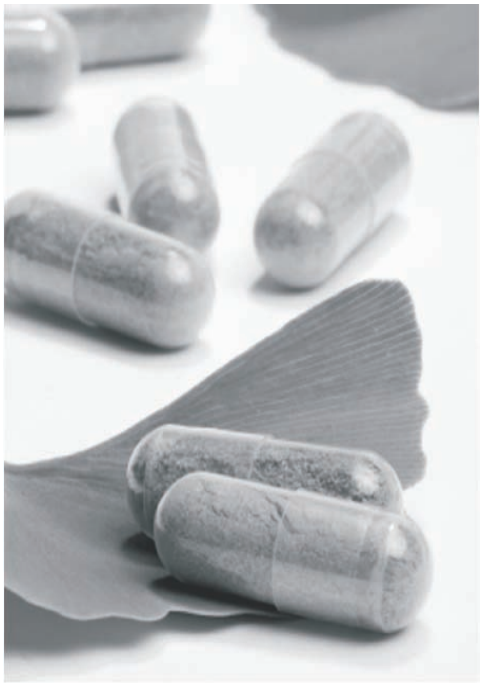
AOAC is committed to linking the success of its business model with a resolve to helping its clients reach their institutional and corporate goals. To this end, AOAC is poised to tailor its services to meet the analytical quality needs of its customers. A turnkey approach may be utilized to develop a package of services for our clients. If your organization is interested in learning how AOAC can help, contact Anita Mishra, Executive for Scientific Business Development, at amishra@aoac.org or 1-301-924-7077 ext. 131.

Past Experiences/Projects

National Institutes of Health

Under a 5-year contract with the National Institutes of Health-Office of Dietary Supplements, through the U.S. Food and Drug Administration, AOAC undertook an

effort to validate methods for dietary supplements ingredients of interest. As part of this initiative, AOAC accomplished the following objectives:



- Completed 15 full collaborative studies and many more single-laboratory validations
- Established expert review panels to technically review methods and select fit-for-purpose methods for validation
- Organized and offered training courses on methods development and validation
- Developed an electronic methods peer-review system
- Engaged producers of reference standards to assist in supplying these reference standards for validation studies and making them available for commercial use
- Adapted and revised the traditional *Official Methods*SM process to include single-laboratory validation
- Established a Presidential Task Force on Dietary Supplements, Ingredient Ranking Subgroup, and ingredient-specific industry working groups
- Heightened awareness of dietary supplements initiative through the AOAC Web site and by publishing nearly 100 papers in the *Journal of AOAC INTERNATIONAL*

U.S. Food and Drug Administration

In 2004, under a contract with the U.S. Food and Drug Administration, AOAC was charged with making recommendations on Best Practices for the validation of Microbiological Methods (BPMM). The results included the following:

- Created a steering committee and working groups of experts
- Submitted a final BPMM report with recommendations

In 2005, AOAC was contracted to peer review the U.S. Food and Drug Administration-Center For Food Safety and Applied Nutrition's *Enterobacter sakazakii* method (or another suitable method) by an expert review panel to evaluate the technical merits of the method. In 2006, AOAC was contracted to evaluate and validate a method for *Clostridium botulinum*. The results included:

- Implemented an efficient process of performing a single-laboratory validation as an indicator of success before proceeding with a full collaborative study

- Engaged infant formula industry to provide technical and financial support

U.S. Department of Homeland Security

In 2003, AOAC was contracted by the Department of Homeland Security through the U.S. Food and Drug Administration to bring together industry and government stakeholders to reach consensus on the performance and acceptance criteria and validation protocol for candidate hand-held assays (HHAs) and confirmatory assays for *Bacillus anthracis* for evaluation through the AOAC *Official Methods*SM program. Results under this contract included:

- Formed a Presidential Task Force on *Bacillus anthracis* and various working groups
- Evaluated five candidate HHA methods and one confirmatory assay through collaborative studies
- Approved one HHA test through the *Official Methods*SM program
- Approved two confirmatory tests for detecting *Bacillus anthracis* through the AOAC *Official Methods*SM program
- Trained analysts for the collaborative studies
- Audited for performance laboratories participating in collaborative studies

In 2004, AOAC was contracted to bring stakeholders from industry and government to discuss a sample collection method and evaluate the approved HHA for field use. The results included:

- Evaluated and validated a sample collection procedure
- Evaluated the HHA method previously approved for field use, specifically focusing on combined use with the sample collection method and the collection of white powder on different hard surfaces by trained first responders (following validation, this field method also attained *Official Method*SM status)

In 2006, AOAC was contracted by DHS to establish an enduring national capacity to evaluate and validate threat detection assays. Results include:

- Recruited over 100 experts from government, industry, and academia to form the Stakeholders Panel on Agent Detection Assays (SPADA) to develop method performance requirements and testing plans by consensus
- Created working groups on *Bacillus anthracis*, *Yersinia pestis*, *Francisella tularensis*, and Environmental Factors

- Convened a "town hall" style meeting to give emergency responders, the public health community, government representatives, and the private sector technology providers a voice on a strategy that will help DHS drive the future direction of the program

U.S. Department of Defense

AOAC contracted with the Department of Defense and the National Guard Bureau through the U.S. Food and Drug Administration to validate sample collection systems coupled with multisignature polymerase chain reaction (PCR) detectors for the detection of *Bacillus anthracis* through AOAC's *Performance-Tested Methods*SM and *Official Methods*SM programs. Results included:

- Recruited and selected BSL3 laboratories
- Conducted onsite laboratory competency reviews
- Conducted laboratory analyst training
- Developed new, or adapted existing, structures for the volunteer, consensus-based evaluation of many analytical technologies for the detection of select agents
- Coordinated single-laboratory validation studies of Department of Defense and National Guard Bureau methodologies
- Coordinated a full collaborative study of *Bacillus anthracis* detection technology

U.S. Department of Agriculture-Food Safety and Inspection Service

In 2003, AOAC was contracted to use the U.S. Department of Agriculture checklist to audit 107 food chemistry accredited laboratories on a rotating 2 year schedule. The results included:

- Recruited assessors to conduct on-site reviews of accredited laboratories using Food Safety and Inspection Service review materials
- Reviewed laboratory deficiencies with the Contract Officer Technical Representative or appropriate designee and reviewed the audit results on a summary basis (monthly and quarterly)
- Provided in-depth written laboratory final reports submitted within 3 weeks of completing each review

AOAC's performance on this contract merited the **2005 Small Business of the Year Award** of the U.S. Department of Agriculture.

Also in 2003, the U.S. Department of Agriculture-Food Safety and Inspection Service contracted with AOAC to evaluate the proficiency of laboratories in the analysis of agency surveillance–sample egg products for *Salmonella*. This project involved approximately 50 laboratories in the U.S. Department of Agriculture-Food Safety and Inspection Service, Laboratory Quality Assurance Division, Pasteurized Egg Product Recognized Laboratory Program. Some results included:

- Prepared pasteurized liquid whole egg product proficiency test samples
- Shipped samples to laboratories with reports prior to shipment
- Conducted on-site evaluations of the laboratory
- Provided summary results report

U.S. Environmental Protection Agency

AOAC was contracted by the U.S. Environmental Protection Agency-Office of Pesticide Programs to revise and replace AOAC methods for the efficacy testing of disinfectants. Accomplishments under two separate contracts included:

- Validated modifications to AOAC Method **966.04**, the Sporicidal Activity Test
- Approved as First Action **2008.05** the quantitative Three Step Method
- Produced a video to accompany Method **2008.05**
- Conducted editorial revisions of various disinfectant methods from Chapter 6 of the *Official Methods of Analysis of AOAC INTERNATIONAL*
- Established an Expert Review Panel for the Sporicidal Activity Test
- Created a new methods committee of disinfectant experts, the Methods Committee on Antimicrobial Efficacy Testing
- Facilitated roundtable discussions involving the U.S. Environmental Protection Agency and the industry group Consumer Specialty Products Association

National Institute of Standards and Technology

In May 2008, AOAC contracted with the National Institute of Standards and Technology to revise ASTM E 2458-06, *Standard Practices for Bulk Sample Collection and Swab Sample Collection of Visible Powders Suspected of Being Biological Agents from Nonporous Surfaces.* In implementing the standard, approved by AOAC as *Official Method*℠ **2006.04** and released by ASTM, it was determined that a need exists for additional review and input to better meet the

needs of first responders and emergency response, public health, and law enforcement agencies.

Pepsi/Coke

In August 2006, AOAC was awarded a contract to implement a fair and transparent process for involving stakeholders and expert review panels in discerning best methods for detecting pesticide residues in soft drinks. Accomplishments included:

- Organized two stakeholder meetings, one of which was held in India
- Formed a Task Force on Pesticides in Soft Drinks
- Issued a Call for Methods and collected 19 pesticide residue methods
- Coordinated an expert review panel in India, where three methods were selected based on fitness-for-purpose
- Granted AOAC First Action status to LC/MS/MS (**2007.08**) and GC/MS (**2007.09**) methods for determination of pesticides residues in soft drinks and sports beverages

AOAC continues to proactively find solutions to scientific, regulatory and trade problems encountered by its clients. With the successes of these government contracts, analytical communities, and other similar projects, AOAC has established a track record of quality service to its stakeholders in government and industry.

Board of Directors

The main governing body of AOAC INTERNATIONAL is its Board of Directors, elected from the membership of AOAC INTERNATIONAL. It establishes the vision and mission of the Association and guides the strategic direction of AOAC.

Executive Committee:

- President: **Darryl Sullivan**, Covance Laboratories, Madison, Wisconsin, USA
- Past-President: **Sam Page**, New Castle, New Hampshire, USA

2008–2009 AOAC Board of Directors: (seated, l to r) Xiumei Liu, Gayle Lancette, Darryl Sullivan, Sam Page, Russ Flowers, and Hilde Skaar Norli; (standing, l to r) James Harnly, Mark Coleman, Ronald Johnson, Douglas Hite, Stan Bacler, and Robert Brackett (not pictured, Jonathan DeVries and Barry Titlow)

- President-Elect: **Gayle Lancette**, U.S. Food and Drug Administration (retired), Peachtree City, Georgia, USA
- Treasurer: **Jonathan DeVries**, General Mills, Inc./Medallion Laboratories, Minneapolis, Minnesota, USA
- Secretary: **Russell Flowers**, Silliker Laboratories Group, Inc., Homewood, Illinois, USA

Directors:

- **Stan Bacler**, Canadian Food Inspection Agency, Ottawa, Ontario, Canada
- **Mark Coleman**, Eli Lilly and Co., Greenfield, Indiana, USA
- **Douglas Hite**, Tennessee Department of Agriculture, Nashville, Tennessee, USA
- **Xiumei Liu**, Institute of Nutrition and Food Safety, Chinese Center for Disease Control and Prevention, Beijing, People's Republic of China
- **Hilde Skaar Norli**, Nordic Committee on Food Analysis (NMKL), Oslo, Norway
- **Barry Titlow**, Compound Solutions, Inc., Escondido, California, USA

Directors-at-Large:

- **Robert E. Brackett**, Grocery Manufacturers Association, Washington, DC, USA
- **James M. Harnly**, U.S. Department of Agriculture, Beltsville, Maryland, USA
- **Ronald Johnson**, bioMérieux, Inc., Hazelwood, Missouri, USA

Membership

AOAC is comprised of an international membership of chemists, microbiologists, laboratory managers, and statisticians. AOAC membership numbers nearly 3200 members from more than 90 countries. AOAC has 17 Sections located in the United States, China, Europe, Japan, Latin America and the Caribbean, Canada, Taiwan, and Thailand. Corporations, government agencies, and academic institutions may join AOAC as either Organizational Affiliates or Sustaining Member Organizations. The chief governing body of AOAC is its Board of Directors, whose members are elected from the membership. The Official Methods Board oversees the technical and scientific programs of AOAC; the Editorial Board oversees the organization's print and electronic media; and the Research Institute Board of Directors presides over the AOAC Research Institute. AOAC members may serve on methods committees to review methods submitted for validation. They may participate in communities that promote methods development and validation in specific areas such as (but not limited to):

- Agricultural Materials
  http://www.aoac.org/Ag_Materials/community.htm
- Chemical Contaminants and Residues in Food
  http://www.aoac.org/chem_contam/cc_homepage.html
- Dietary Supplements
  http://www.aoac.org/dietsupp6/Dietary-Supplement-web-site/DSHomePage2.html
- Marine and Freshwater Toxins
  http://www.aoac.org/marine_toxins/task_force.htm

Staff

Day-to-day operations of AOAC are handled by a staff located at headquarters in Gaithersburg, Maryland, USA. The staff team is led by Executive Director E. James Bradford. Senior Directors and Directors lead departments that oversee the specific programs and services of the organization. Within each department, there are Managers and Coordinators with responsibilities specific to the department or interdepartmental projects. In addition to on-site staff, independent consultants contract with AOAC to assist with the organization's initiatives.

E. James Bradford
AOAC Executive Director

Who to Contact			
Department	Contact	E-mail	Extension (Dial: 1-301-924-7077)
Executive Office	Alicia Meiklejohn	ameiklejohn@aoac.org	101
Business Development	Anita Mishra	amishra@aoac.org	131
Communications	Krystyna McIver	kmciver@aoac.org	111
Customer Service	Customer Service Rep	customerservice@aoac.org	170
Human Resources and Administration	Gar Riegler	griegler@aoac.org	132
International Affairs	Al Pohland	apohland@aoac.org	123
Membership and Professional Development	Dawn Frazier	dfrazier@aoac.org	117
Method Validation	Bob Rathbone	rrathbone@aoac.org	105
Publications	Bob Rathbone	rrathbone@aoac.org	105
Proficiency Testing	Arlene Fox	afox@aoac.org	143
Research Institute	Scott Coates	scoates@aoac.org	121
Standards Development	Deborah McKenzie	dmckenzie@aoac.org	157

Product Portfolio

AOAC provides credibility, acceptability, and defensibility that are the results of the Association's status as an independent, science-based, third-party organization with a 125-year-old brand name. AOAC offers numerous products and services to meet the needs of the analytical sciences community in validating standard methodology through stakeholder consensus and science-based solutions. From the traditional *Official Methods*SM and Annual Meetings to the newer consensus-building activities and prevalidation documentation, AOAC aims to continue to serve its members and maintain the Association's relevance.

Consensus Products

Stakeholder Panels. Stakeholders provide participation and buy-in and acceptability that come with that participation. The tangible product of a stakeholder panel is an articulated fitness-for-purpose statement of what a method(s) needs to accomplish.

AOAC Capabilities

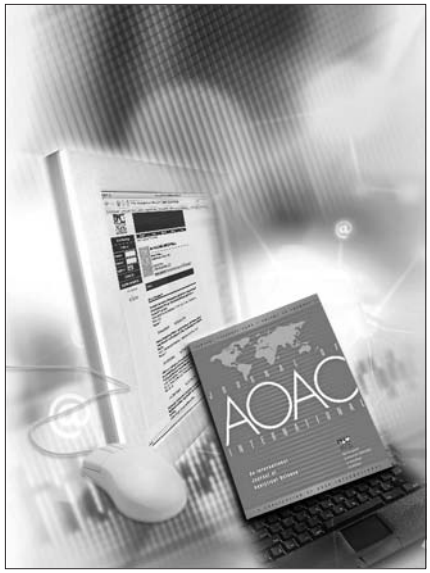
Working Groups. AOAC working groups provide scientific credibility in establishing method performance requirements, including sensitivity, specificity, analytical range, and limit of detection, as articulated by stakeholder consensus-based fitness-for-purpose statements. The working groups often find eligible methods for validation and provide free test samples and volunteer laboratories for collaborative studies. The tangible product of a working group is an articulated list of performance requirements for a method(s).

Resolution Task Forces. These groups provide a credible mechanism to resolve intractable problems encountered by the working groups. The tangible product of a resolution task force is a recommendation for a resolution of a problem.

Through its communities and membership, AOAC can form ad hoc task forces to respond to emerging needs and crises. The tangible product of such a task force is a recommendation on how to approach a problem with a science-based, peer-developed analytical solution.

Call for Methods. A Call for Methods is issued, based on performance requirements as established by working groups and approved by the stakeholder panel, to identify methods and available validation data for consideration by an expert review panel. A Call for Methods is issued via electronic and print announcements in AOAC and industry publications.

Expert Review Panels. These groups of experts provide scientific defensibility in the determination of a method's potential to meet the established performance requirements. AOAC expert review panels are comprised of recognized specialists in a specific topic area. They provide an unbiased, science-based peer review and evaluation of available methodology, utilizing established criteria for method selection and performing gap analysis. The tangible product of an expert review panel is a candidate method, one that has been peer reviewed and selected by volunteer scientists.



Communications and Documentation Products

AOAC publishes a variety of print and electronic materials of interest to the scientific community.

***Official Methods of Analysis*SM**. The *Official Methods of Analysis*SM (print and online) contains over 3,000 analytical methods and has a strong international reputation.

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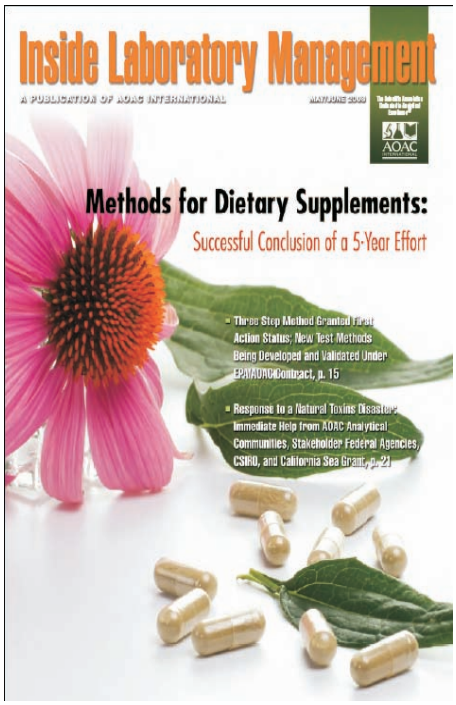
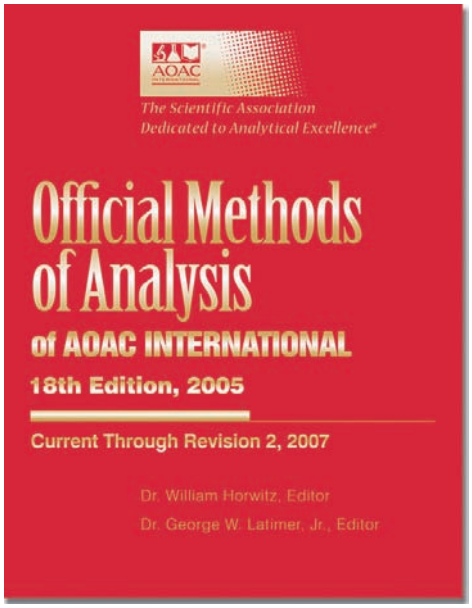
AOAC
Capabilities



Journal of AOAC INTERNATIONAL. The *Journal of AOAC INTERNATIONAL* is a scientific, bimonthly online and print publication containing peer-reviewed articles. Books on various analytical testing topics are also available through AOAC.

Inside Laboratory Management. *Inside Laboratory Management* (ILM), the Association's membership magazine, is issued bimonthly with the latest Association news and highlights of activities related to AOAC analytical communities and contract efforts. The Referee section of ILM is a vehicle that documents, from beginning to end, all of the activities of AOAC's consensus products.

AOAC Web Site. Serves to provide up-to-date communications about AOAC activities as well as product information. The Web site now features frequent "News Flashes" that provide timely Association updates.



AOAC's **communications**, **fact-finding**, and **feasibility** programs can provide careful confirmation of the suitability of the directions of planned contracts with government and industry. The tangible product of a fact-finding effort is a reality check white paper.

Service Products

Chief Scientific Officer-Led Presubmission Reviews. This service can save much time and effort for those methods that come into AOAC that are not submitted by a formal community or contract.

Turnkey Service. This service speeds the work of any organization that engages AOAC. The tangible product of this service is a great savings of time.

Identification and Securing Participants and Funding Partners. AOAC itself does not need methods but can help put a team together for an organization that does need methods.

***Performance-Tested Methods*℠ and *Official Methods*℠ Validations**. The *Performance-Tested Methods*℠ program provides an independent third-party review of test kit performance claims and is a rapid entry point into the AOAC validation process. The *Official Method*℠ is the hallmark of AOAC

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INTERNATIONAL. To attain this status, methods are subjected to a rigorous validation study in at least eight (for quantitative chemical methods) laboratories to demonstrate their fitness-for-purpose and establish performance characteristics. Approved methods are published in the *Official Methods of Analysis of AOAC INTERNATIONAL* online and hardcopy. *Official Methods*SM can be used as regulatory standards or to facilitate international trade.

Candidate Method(s). Candidate methods are best method(s) chosen by an expert review panel for further validation based on fitness-for-purpose and method performance as established by existing validation data. Candidate methods can be a milestone on a method's journey to full validation, if not an endpoint if that is all that is warranted.

Laboratory Proficiency Testing Program. The AOAC Proficiency Testing Program is accredited by A2LA to help food safety laboratories monitor their competency. In this way, laboratories can demonstrate their commitment to quality, facilitate global trade, and establish international credibility. AOAC plans to expand the already successful program to be method-specific.

Training. AOAC offers training courses for professional development in the areas of methods validation, laboratory management, quality assurance, and accreditation. AOAC also facilitates training of laboratory personnel in the conduct of collaborative studies. AOAC hopes to expand the already successful program to be method-specific.

Annual Meetings. AOAC INTERNATIONAL hosts an Annual Meeting at a different U.S. location each September. The Annual Meeting is a venue for scientists to gather, share ideas at topic-specific meetings, present research findings in symposia and poster presentations, exhibit products, and participate in training courses.

Laboratory Auditing. Increasingly, laboratory auditing and accreditation support are becoming valuable products for AOAC. AOAC has performed numerous

laboratory audits under contract with the U.S. Department of Agriculture. The organization received a USDA 2005 Small Business of the Year Award for this effort. Laboratory auditing was also a part of AOAC's initiative with the Department of Defense in providing an independent third-party certification that anthrax detection assays met established performance requirements.

Reputation Products

AOAC is the go-to place for credibility, acceptability, and defensibility. For 125 years, AOAC has had volunteers serving on its Board of Directors, Official Methods Board, Methods Committees, and all its functions. The credibility that volunteers render enables AOAC to speak with great authority on many issues.

Contact Us

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