

Minutes

AOAC Research Institute Strategic Planning Meeting Intercontinental Hotel Tampa, Florida March 16 – March 18, 2009

RI Board Members:	RI Staff	Advisory Council Members:
Mark Coleman – Chairman	Scott Coates	Morgan Wallace
Bert Pöpping – Vice Chairman	Sharon Brunelle	Mark Mozola
Ronald Johnson	Maria Nelson	Jennifer Manion (half day 3-16-09)
P. Frank Ross	Karen Silbernagel	
Paul In't Veld	Mark Roman	
	Dawn Dowell	
	Zerlinde Johnson	
	Nora Marshall	

1. Agenda

Coates reviewed the Agenda and asked for additions, deletions or revisions. The group accepted the Agenda as provided. Attachment 1.

2. Organizational History and Update: Coates

Coates provided a verbal report on the history of the AOAC Research Institute from 1992 to 2009.

The verbal report covered:

- 1) the original concept of the *Performance Tested Methods* program as a stand-alone program;
- 2) the integration of the *Performance Tested Methods and Official Methods* programs;
- 3) the financial difficulties in 1995 and the AOACRI's corrective action;
- 4) attempts at international harmonization;
- 5) creation of a consulting service;
- 6) development of contract consultants;
- 7) international expansion to Europe in the early 2000s.
- 8) development of the bacteriological threat agent program.

3. Policies & Procedures

The Board reviewed and voted by e-mail on a 2009 edition of the AOAC Research Institute Policies and Procedures in December 2008. See attachment 2. The Board ratified approval of the 2009 edition of the AOAC Research Institute Policies and Procedures in December 2008

Mark Coleman motioned to accept the 2009 edition of the AOAC Research Institute Policies and Procedures. Ron Johnson seconded.
Accepted Unanimously.

4. Emergency Response Validation (ERV) Update:

Review: Coates

Participation: 10 Method Developers and Health Canada,
Canadian Food Safety and FDA.

Lessons Learned:

- All 20 sets of samples claimed. Need to retain at least one set for master template. Implement guideline for securing additional matrix samples if set amount is at critical participation.
- Independent Laboratories: Set-up a Call for Independent Laboratories versus Invitation.
- Press Release and Website News Flash for Call for Methods for ERV participation, instead of invitation.
- Discuss future inoculation control to ensure proper levels have been reached for optimal results.
- Possibility of conducting 3 levels of testing (high, medium and low) for improved fractional achievement.
- Validation criteria needs to be reviewed for modification potential for the ERV.
- Retain a Master Sample set dutifully.

Unexpected:

- Low inoculation numbers, lack of adequate homogeneity from Q-Laboratories.
- Low fractional numbers from Method Developers
- All 20 sample set utilized.
- Companies opting to run additional testing for possible OMA entrance.
- Increased number of companies opting to run paired samples versus unpaired.

- FDA results designated “ invalid” due to contamination.
- Concern raised regarding Q-Laboratories packaging of inoculated and uninoculated sets. Visible difference discernable to Method Developers upon receiving samples.
- Q-Laboratories use of bags for packaging. Method Developers concerned that double bags would have ensured better protection against contamination or use of sample jar.

Review of possible resolution of Low Results:

(Z. Johnson):

- Retests are probable for companies not achieving fractional positives.
- Acquire new samples with better inoculate
- Retest could include Method Developers that were unable to participate due to the lack of samples.
- General Referee not content with results, and not in favor of splitting unpaired data.
- Further discussion will ensue with conference call with General Referee, including Paul In’t Veld, to discuss statistical analysis to find equivalency.

(Group Discussion – evaluating the first ERV performance):

- Samples may require inoculate of 6-7 spike levels to insure viability, instead of the present 2-3 levels of spiking.
- Quality control of Independent Laboratory to refer to Master sample as process progresses.
- Time Line:
 - *The possibility that the time line used was too fast for inoculate to become seeded.
 - *Was the Independent Laboratory rushed with sample preparation deadline?
 - *How fast is too fast? Public expectation versus scientific reality.
 - *Consider 16 weeks for a more realistic timeline.
- More homogeneity in testing.
- Individual spiking may be more reliable versus lot spiking.
- Cost: Advisory Council agreed that Method Developers would accept an increase in cost for samples to assure that samples contain the correct inoculants’.
- Consider running only unpaired samples.
- Consider Method Developers conducting single test (their method only) and not run the FDA BAM concurrently.

ERV Potential:

- Consider practical elements to apply to other situations and opportunities. (ie. At home drug kits/pregnancy tests)

- Consider Test Kits and Methods that have not been evaluated. (i.e. Melamine)
- No certificate granted, just a published report of evaluation and results. Eliminating any potential for certificate misuse by method developers.
- Consider extending the ERV to non-PTM and non-OMA methods.
- Advisory Council and Board looks favorably on the new ERV and its potential.
- Matrix extension is gained by Method Developers participating.

Future of the ERV Program:

- (Coates): Formal contract will still require signature from Method Developers as previously done, however, the contract will now clearly indicate that by “passing” the validation there will not be a certificate extended. Although, a fully published report will be disseminated.
- (Coates): The contract will be modified on a case-by-case basis. Interpretation of criteria will outline how Method Developers will analyze and interpret results within the acceptable criteria outlined.
- (Pöpping): ERV program has a working basis to devise a formal guideline.
- (Board): Unanimously agreed that the value of continuing with the development of the ERV program is essential for future success and new markets.
- (Coates): Managing Director will develop a budget and bring this to the Board for approval.
- (Pöpping): Would like to develop a list for ERV to anticipate probable outbreaks, (Coates: Possible outbreaks: melamine, campylobacter, E. coli 0157, etc.) have a running list of Method Developers both established and in the process of becoming validated for these possibilities and devise an outline and template so that reaction time will be minimal.
- Cooperation with USDA. Other venues may include AMS – School Lunch check, ARS and AIFS.
- (In’t Veld): European regulation requires a collaborative validated method. If a company wants to use an alternative method they must show better or equal performance to the collaborative validated method (use of ISO 16140 in microbiology). There may be opportunities for RI involvement.

5. Advisory Council Members

Advisory Council members were invited to discuss their needs, problems, and/or suggestions for the Performance Tested Methods program:

- Consensus: Happy. Review times are good. In fact, it is now the Method Developer who is usually holding up the progression.
- Billing issues are reduced.
- (R. Johnson): Advisory Council Meetings and participation are almost non-existent. There is an immediate concern, the A.C. is an essential voice that is needed and relied upon.
- (K. Johnson): Is concerned with the reputation of the AOAC since there isn't any quality control follow-up with OMA products as there is with the Annual Renewal process of the Research Institute. Concerned in today's market with companies being sold to unknown, untested companies all over the world and the huge potential for once validated kits to be adulterated without knowledge of the end user.

Possible Advisory Council (Contributing Member) improvements:

- (R. Johnson): Challenge Advisory Council. Make meeting more attractive and rewarding for their participation. (i.e. assist Research Institute with implementation of new protocols for testing, etc.)
- (R. Johnson): Pacific Rim/China both would like to participate and have a voice.
- Conference calls to critique AOAC Research Institute performance.
- Provide an agenda.
- Arrange for guest speakers.
- Arrange conference calls to be prior to AOAC-RI meetings.
- Institute quarterly conference calls.
- More solicitation for Advisory Council participants (Consider expanding benefits for Advisory Council participants.)
- (Z.Johnson): Believes that the reason that participation is low, is that participants don't want to voice too much in front of competitors regarding what works or problems they are experiencing.
- Expand acceptance of Independent laboratories and regulators as Advisory Council Members. This would give an added benefit to the Method Developers and Laboratories for Networking opportunities.

6. **SWOT (Strength, Weaknesses, Opportunities & Threats):**

All meeting attendees were sent blank SWOT forms to fill out prior to the meeting. Responses were compiled and reviewed. Duplicate ideas and answers were merged or culled, then reviewed and prioritized.

See attachment 3 for final prioritized SWOT.

7. **Brainstorming Ideas:**

ERV:

- Documents for Independent Laboratories as “approved” site.
- Documents addressed to “specific” laboratory site.
- European laboratories may be interested in participating in ERV program.
- Statement of progression from ERV: Clearly state that after the ERV validation, Proficiency Testing will commence if desired by Method Developer.

Voice of Advisory Council:

- IAFP possible arena for Advisory Council meeting location.
- Make the Advisory Council more useful for its members.
- Let Advisory Council give input on testing design.
- Allow Advisory Council to assist with areas of weakness, (i.e. Environmental surface testing)
- Focus on technical issue for the Advisory Council. What is important for their companies. Have more Consultants and Advisory Council interaction.
- Benefits for Advisory Council:
 - *Discount on PTMs. Consulting service and Annual Renewals.
 - *Free online OMA.
 - *Networking.

Method Modernization Validation (MMV):

- Concept: Propose a minimum result bar, Method Developers that make or exceed the bar are then eligible for FDA consideration of FDA method.
- Use of both OMA and PTM methods.
- Address the possibility for major change to reference Method due to the changes in advancements. (i.e. E.coli methods, past and present after current change to reference method)

New Markets:

- MONIQA:

- China, Laboratories, Method Developers, (FDA start-up reference laboratory.)
- Korea: very interested in PTM program
- Japan : very interested in PTM program
- Others: Thailand, Malaysia, India and European Union.
- Wholesale Companies purchasing raw materials: how are they checking their purchases for safety?

7. **Biological Threat Agents:**

- Limited market
- Difficult for companies to invest for validations, small percent of development.
- Validations should ultimately be performed as method is indented for use, out in the field.
- HHAs are more expensive due to unique conditions.
- Difficult to ship
- Very slow expansion
- Kits have expiration dates and new kits need to be purchased.
- Unknown direction of market. Growth or stagnant.
- AOAC RI has opportunity to give method developer guidance on “how to validate” their method/kits.
- Independent laboratory qualification. What laboratories are willing to participate with bio-threat agents?
- Discovery is required to test the market size and viability. Military, HLS, BioWatch, local governments. Marketing Survey proposed.
- Contract opportunity.
- Uncertainty of new administration’s devotion to HLS & DOD funding.
- Possibility to work with DHS to spark interest from Method Developers to participate.
- Participation from FERN with Call for Methods.
- Participation from the Minister of Defense, Penelope Spencer for Biothreat & statistical analysis.
- Incentives for Method Developers to consider PTM validation.
 - (a) Recognition, quality. Consideration by the US Government to be utilized.
 - (b) AOAC-RI could validate for the CDC and the government would accept.
 - (c) Pre-emptive. Consider applications for PTM for a group of test kits with best guess of which may be needed in priority.

8. Vision & Mission Statements

Terms and Concepts to include in Mission and Vision

Innovative
Global
Analytical tools/ solutions
Facilitator
Vanguard
Forward looking
Harmonization
Cooperation
Mutual acceptance of analytical results

Ideas for Vision Statement - where do we envision the AOACRI in 5 years

1. Innovative approach to method validation.
2. Important role in the international Harmonization effort with standard organizations.
3. Supports a level playing field for performance based method evaluations.
4. Partner with key stakeholders to create and support a level playing field based on performance based method evaluations in food safety & security. Worldwide scope, nexus with working with other orgs Microval, AFNOR etc...
5. Serve as the focus of all the analytical support
6. Best in industry
7. The RI will become the vanguard for global analytical solutions in the area of food safety and security.

Draft Mission Statement

A global facilitator of total microbiological and chemical solutions in the method validation arena in promoting food safety & security, improved commodities

Coates to mold the concepts and discussion into a cohesive set of Vision and Mission statements and circulate to the Board for review.

See attachment 4.

9) Strategic Goals: 2009-2010

- Internal Procedures
- Independent Laboratories & PTM certifications support ISO 17025 Laboratory accreditation.
- ERV Program
- Committee on Statistics
- Advisory Council / Contributing Membership
- MONIQA / Market Research
- General Referee

See attachment 5 for details.

10) Strategic Goals: 2010-215

- Expand into China/Japan (Pacific Rim)
- Brand Recognition
- Expand Chemistry Recognition
- Method Verification Program at Annual Meeting
- Increase attendance of Test Kit Users at Annual Meeting
- Method update validation Program. (MUV)

See attachment 5 for details.

Attachment 1: 2009 Strategic Planning Session Agenda

Strategic Planning – Tampa, Fl.
March 16 – 18, 2009
AGENDA

Sunday 15th, Atrium Skylight Reception – 7:30 p.m.

Monday, March 16th, (Breakfast 7:30 am) 8:00 a.m. Start:

1. Update –History
 2. Policies & Procedures:
 - Summary of changes
 - Action Item: Adopt

(break -10:00 a.m.)
 3. Emergency Response Validation (ERV) Update
 4. Advisory Council Members:
 - Needs
 - Suggestions
 - Problems

(Plated Lunch- Noon)
 5. SWOT
- (afternoon break – 2:30p.m.)
(Dinner 8:00 pm– Shula’s Steak House – Hotel)

Tuesday, March 17th, (Breakfast 7:30a.m.) 8:00 a.m. Start:

1. Brainstorming
- (break – 10:00 a.m.)
2. Prioritize Ideas
- (Plated Lunch – Noon)
3. Recap SWOT & brainstorming
4. Vision, Mission
- (afternoon break – 2:30p.m.)
5. Strategic Goals: 2009-2010

6. Strategic Goals: 2015

(Dinner – individual choice)

Wednesday March 18th, (Breakfast 7:30am) 8:00am Start:

1. BIOTREAT Agents – Discussion/Brainstorming

Recap Strategic Goals

2. Develop Action Items for 2009-2010

(break – 10:00 a.m.)

3. Strategies for Action Items

(Plated Lunch – Noon)

4. Summary & Conclusion

Attachment 2: AOAC Research institute Polices and Procedures

To be provided as a separate correspondence..

Attachment 3: AOAC-RI SWOT Analysis for Strategic Planning Meeting

Strengths (Assessment of Internal Functions)

X (Y) X = indicates how well the RI is doing with 1 indicating the best and 5 indicating very poor.
Y = indicates the priority rating with 1 being the highest priority and 5 being the lowest.

A “Strength” receiving a 5 (1) rating indicates a very high priority with very poor execution. A Strength receiving a 1 (5) indicates a very low priority rating with a very good execution.

Strengths are organized so that high priority strengths with poor execution are listed first.

2 (1) Process clearly defined and Expectations clearly defined. PTM process is running relatively efficiently and is of high value to both test kit manufacturers and end users.

2 (1) Respected expert reviewers.

TBD (1) ERV Program

1 (1) Technical expertise and relevant hands on laboratory validation experience

1 (1) Staff is very accessible to clients and Willing to work closely with clients to resolve issues when necessary

1 (1) Progressive & Innovative, Very adaptable

1 (1) Harmonized OMA validation process with staff experienced with both OMA and RI validations

1 (1) Viable and growing business model with new validations and renewals

1 (1) PTM program is strong enough in weeding out weak test kits

1 (1) Annual Renewal Process

1 (1) Forward thinking Managing Director and Dedication to purpose of the Research Institute

4 (2) Voice for test kit companies through the advisory council

4 (2) Part of a well known organization

3 (2) Fast validations

2 (2) Validated method database online

1 (2) PTM Workshops (Chemistry and Microbiology) available

1 (4) RI staff involvement with AOACI contracts provides added credibility & opportunities

Weaknesses (Assessment of Internal Functions)

X (Y) X = indicates how well the RI is doing with 5 indicating very poor and 1 indicating the best.

Y = indicates the priority rating with 1 being the highest priority and 5 being the lowest.

(Same scale used for Strengths)

A "Weakness" receiving a 5 (1) rating indicates a very high priority problem with a very poor or no corrective action plan. A Weakness receiving a 1 (5) indicates a very low priority problem with very good execution.

Weaknesses are organized so that high priority Weaknesses with a very poor or no corrective action plan are listed first.

5 (1) Staff attendance at off site meetings/tradeshows (IAFP, AOAC section meetings, etc.) to:
promote relationships with clients
promote AOAC RI PTM Program,
promote continuing education of staff

5 (1) Inconsistent statistical advice from the Committee on Statistics

5 (1) Lack of appropriate approved statistical model for qualitative method validation

5 (1) Budgetary autonomy

4 (1) Problems with billing function – delays and confusion in invoicing for projects completed. (Seems to have improved in recent months.)

3 (1) PTM published in *J. AOAC Intl.*, etc

4 (1) Document control – internally and website

3 (2) Lack of recognition and promotion within AOAC INTERNATIONAL

4 (2) Marketing

4 (2) PTM program is the only "product" that the RI sells.

4 (3) Need to increase scientific "presence" of AOAC RI – stronger technical program at annual meeting and

3 (3) Competition for staff time (both in office and remote)

3 (3) Expensive

3 (3) More accountability to follow through with side projects – Technical Bulletins, Independent Lab Qualification

3 (3) Orientated towards North America

3 (3) Growing pains

Opportunities (Assessment of External Factors)

X (Y) X = indicates how well the RI is doing with 1 indicating very well and 5 indicating very poor.

Y = indicates the priority rating with 1 being the highest priority and 5 being the lowest.

(Same scale used for Strengths and Weaknesses)

An "Opportunity" receiving a 5 (1) rating indicates a very high priority opportunity for which there is no or a poor plan to exploit an opportunity. An "Opportunity" receiving a 1 (5) rating indicates a very low priority opportunity with a very good plan.

Opportunities are organized so that high priority opportunities for which there is no or a very poor plan to exploit the opportunity are listed first.

- 3 (1)** Brand recognition of PTM, The program is credible, recognized worldwide by both test kit and food companies, Value added (licensed certification) for commercial use in labeling and advertisement
- 3 (1)** Greater connection to laboratories through ERV
- 2 (1)** Harmonization of standardization organizations
- 1 (1)** Harmonized with ISO 16140 (need for harmonized study designs for methods)
- 3 (2)** Expanding PTM program to new markets in Asia
- 3 (2)** Develop closer ties with reference labs worldwide,
- 3 (2)** PTM certification supports ISO 17025 lab accreditations
- 4 (3)** Continued open relationships and harmonization with Canadian validation organizations
- 3 (3)** AOAC RI has a leadership opportunity to co-sponsor food safety workshops and expanded program training throughout the world
- 3 (3)** Pregnancy test readers & home drug tests
- 5 (5)** Expanding PTM program to new markets in South America
- 5 (5)** Continued open relationships and harmonization with EU food safety authorities

Threats (External Assessment)

X (Y) X = indicates how well the RI is doing with 1 indicating that the RI has a very good plan to combat a threat and 5 indicating the RI has no plan to combat a threat.

Y = indicates the priority rating with 1 being the highest priority and 5 being the lowest.

(Same scale used for Strengths and Weaknesses)

A "Threat" receiving a 5 (1) rating indicates a very high priority threat with little or no plan to mitigate the threat. A Threat receiving a 1 (5) indicates a very low level threat but with a good threat mitigation plan.

Threats are prioritized so that high priority threats with poor or no threat mitigation plans are listed first.

- 5 (2)** Low attendance from food industry test kit users at the annual meeting
- 4 (2)** Perceived to focus on microbiological more than chemical test methods
- 2 (2)** Only one General Referee for Food Microbiology
- 3 (3)** Lack of acceptance of PTM validated methods for import/export of products
- 4 (4)** Weak connection to FDA as a whole
- 3 (4)** Poor economic situation, Weakening global economy
- 2 (4)** Some of our customers do not accept RI validation and request OMA

Attachment 4: Draft Mission and Vision Statements

Draft Mission Statement:

The AOAC Research Institute will serve as a global provider of a complete range of products and services needed for the rapid validation and conformity assessment of commercial, analytical methods. These products and services will support public health, food safety & security, biological threat agent mitigation, and international trade.

Draft Vision Statement:

The AOAC Research Institute will:

- 1) Strive to be the vanguard for global analytical solutions for the validation and conformity assessment of commercial, analytical methods
- 2) Continue to create innovative approaches to method validation and conformity assessment.
- 3) Establish itself and AOAC INTERNATIONAL as one of the leaders in the international harmonization effort with other international standard organizations.
- 4) Establish itself as the “benchmark” program for conformity assessment of commercial, analytical methods.

Attachment 5: AOAC Research Institute Strategic Goals and Action Items

2009 STRATEGIC GOALS

1. Increase the 2009 Total Income by 15%

2008 Gross Income =	\$	982,162
15% Increase =	\$	147,324
Total =	\$	1,129,486

- a. 1 to 3 PTM applications from the MicroVal harmonization efforts
(PTM Applications - \$15 to \$45 K increase)
- b. Increase Advisory Council from 15 to 17 Contributing Members by end of 2009
(5 CM dues at \$5 K each = \$ 25 K increase)
- c. Increase the total number of approved PTM certified methods by 5 to 10%.
(Annual renewals at \$3K = \$15K to \$30K)
- d. 2 to 3 Consulting apps; and 1 to 3 PTM apps from Japan
(Consulting - \$4K to \$6K)
(PTM Applications - \$15 to \$45 K increase)
- e. ERV Applications
(Pilot Project - 14 application at \$2000 = \$28,000)
(Additional - 10 application = \$20,000)

2. Complete the ERV Pilot Project

- a. Create and Present a Lessons Learned
- b. Publish a technical bulletin on the ERV program
- c. Utilize MONIQA as a vehicle for emerging outbreaks and information; link on the websites (AOACRI & MONIQA)
- d. Present the ERV program at 6 scientific meetings and regulatory agency

3. Improved RI PTM Program efficiency

- a. PTM certification retention rate of 95 to 98%.
- b. Invoice within 3 to 10 working days.
- c. Collect payment within 30 to 40 working days.
- d. Finalize revised food micro guidelines (implementation plan).
- e. Action plan for GR transition by end 2009.

2009 Action Items:

- 1) Joint RI BoD & AOACI BoD Mtg to review RI Business Plan
 - a. Ideally 2 mtgs/yr minimum 1 mtgs/yr

- 2) Market research for method developer companies to Asia / Pacific Rim, Australia / New Zealand, India,
- 3) Communicate with accreditation bodies on how the PTM program can aide ISO 17025 labs
- 4) MONIQA

2010 - 2015 Strategic Goals for the Research Institute

4. 2 PTM applications per year from Asian market
5. Increase Advisory Council to 20 CM by end of 2010
6. Increase Advisory Council to 25 CM by end of 2015

Action Items 2015

- 1) Visit Japan 4 out of 6 years to present training courses
- 2) Gain more Japanese clients
- 3) Market research for method developer companies to Eastern Europe (includes Russia)