

The Formula

Mid-Canada Regional Section
January 15, 2016



Cover photo: A glass office tower on South Figueroa near the 2015 venue for the AOAC-International Annual Meeting and Exposition. I have always liked the way that bulging glass slightly warps the reflected look of distant buildings.

Greetings for 2016 from your MidCanada AOAC Executive:

We are working hard on making AOAC-DAY 2016 even better than before. We have other events coming up before spring, so we hope to see you at some of those.

Pages 4 and 5 tell of a short course opportunity. If there is any other form of professional development you feel might benefit you or fellow members, please send one of us an email.

Each year, we send one representative to attend the big set of meetings. This year, I am President as well as newsletter editor, and to save money I decided to drive there. I have included some photos I took along the way, and a little information on the event. If you would like to spend a few hours this year, helping Mid Canada AOAC succeed into the future, please consider letting someone know. We would like to see a few fresh faces on the Executive for 2014-2015.

If you can think of anything that would be of interest to your fellow members, in a presentation or a newsletter article, please let any member of the AOAC Executive know.

Contributions are most welcome for next time!

Why not tell us what is new at your lab?

David Grant, Editor

All photos and text, not otherwise attributed, are by D.Grant

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We are pleased to announce the KEYNOTE SPEAKER for AOAC DAY. Please mark your planners and calendars for June 16, 2016.

Dr. Mark Torchia

Mark is the Director of the Centre for the Advancement of Teaching and Learning at the University of Manitoba, where he and his colleagues collaborate with faculty to provide leadership, expertise, and support in fulfilling the teaching and learning mission of the University of Manitoba (UM). (Pic provided by MT.)



Previous to that appointment, Mark had a 30 year career in the Department of Surgery with St. Boniface General Hospital, the Winnipeg Regional Health Authority, and the Health Sciences Centre. He was the Director of Advanced Technologies for the WRHA and the Director of the Medical Pre-clerkship Curriculum for UM.

Mark continues as a Professor of Surgery where his teaching activities relate to human development and his research activities are focused on minimally invasive surgery and diagnosis.

Mark has founded two successful medical device companies. He is the author of numerous academic papers, two medical textbooks, and holds many patents.

Mark was the Chair of the Committee on Drugs and Related Materials and member of the Official Methods Board for AOAC International (1991-1998) as well as the President, Mid-Canada Section AOAC (1993-4).

There is coverage of
AOAC DAY 2015
beginning on page 14.

Applying the Lifecycle approach to a Method including Relevant Statistical Tools

Presented by Ms. Jane Weitzel

February 18, 2016 Victoria Inn and Conference Center, 1800 Wellington Ave., Winnipeg, Manitoba

\$300, includes lunch and refreshments

Registration Please complete the registration form on the Mid-Canada AOAC web site: <http://midcanadaaoac.org/home/workshops/>
Please register early to save your seat!

ABOUT THE INSTRUCTOR

Ms. Weitzel has worked in analytical chemistry and Quality Assurance for over 30 years and has held positions in Quality Assurance at several pharmaceutical companies. Ms. Weitzel has been active with the Standards Board of Canada, for which she is a technical assessor. She has also served with AOAC International as the past chair of the AOAC International's Technical Division for Laboratory Management and Analytical Laboratory Accreditation Criteria Committee (ALACC), which wrote the *AOAC INTERNATIONAL Accreditation Guidelines for Laboratories* and developed a guide on Method Verification.

WORKSHOP OUTLINE: LIFECYCLE MANAGEMENT OF A METHOD

This workshop will help participants learn about the lifecycle management of analytical procedures. An EXCEL workbook that can simulate analytical procedure data for method qualification will be used to show in real time the impact of performance characteristics such as bias, repeatability, intermediate precision, robustness, and calibration. The workshop is presented in four sessions.

SESSION 1. ANALYTICAL PROCEDURE DESIGN AND PROCEDURE PERFORMANCE QUALIFICATION

The topics that will be presented are:

- Quality by Design (QbD), the Product Lifecycle model applied to analytical procedures during design (development) and qualification (validation)
- New terminology
- How to establish an analytical target lifecycle
- Introduction to Target Measurement Uncertainty
- Measurement uncertainty: what it is, how it is used in the analytical target profile, and how to estimate it from development data
- Identification of the critical performance characteristics and required operational procedure controls
- Risk analysis/control strategy throughout the method design
- Statistical tools to support the development, qualification, and verification of the analytical procedure through analytical procedure development
- Case studies and examples

SESSION 2. ANALYTICAL PROCEDURE PERFORMANCE VERIFICATION

- This stage of the analytical procedure lifecycle includes method transfer and routine use of the method
- How to implement the operational procedure controls
- How to use tools such as control charts and trend analyses
- Change management for all types of changes
- Simplifying regular review of the performance of an analytical procedure
- Continual Improvement
- Current regulatory perspective

SESSION 3 & 4. DECISION RULES AND ASSESSMENT OF COMPLIANCE WITH SPECIFICATIONS

General Background

Setting specifications and establishing procedures for assessing compliance are important steps in pharmaceutical analysis. These two sessions will explain in detail how to use decision rules and measurement uncertainty to both set realistic specifications and assess compliance with those specifications.

SESSION 3: DECISION RULES

The use of decision rules is a new, but essential component in the lifecycle of an analytical procedure. This session will cover the following:

- Define decision rules
- Explain the different types of decision rules and when they are used
- Show how risk analysis is a key tool for defining the decision rule
- Explain how a decision rule fits into QbD and aQbD
(analytical Quality by Design)
- Demonstrate how the user of the data is key to defining the decision rule, ensuring the reportable result is fit for use
- Explain how probability and uncertainty are used
- Show how the decision rule can be used to set or evaluate specifications

SESSION 4: ASSESSMENT OF COMPLIANCE WITH SPECIFICATIONS

With the ATP, target uncertainty, and a decision rule all the data, information and risk information is available to set specifications and to evaluate a specification. This session will cover the following:

- Explain how the reportable result can be compared to the specification correctly
- Provide a tool for assessing the risk of not being in specification
- Explain how these tools can be used for comparing to compendia specifications
- How to use these tools and information in Out of Specification investigations
- Using these tools to support changing specifications



On the road from Monterrey to Los Angeles, we found these 30' tall California farm workers, apparently here to celebrate this Organic Farm. They looked very realistic, even up close! AOAC methods are involved in many aspects of organic farming.





Halfway from our motel to the AOAC meeting, was the impressive office building above at 1010 Wilshire Boulevard. There were many cranes putting up new buildings at right. The urban palm trees below were nicely lit up. The artsy old building at bottom right seems out of place in this land of 300' glass towers.





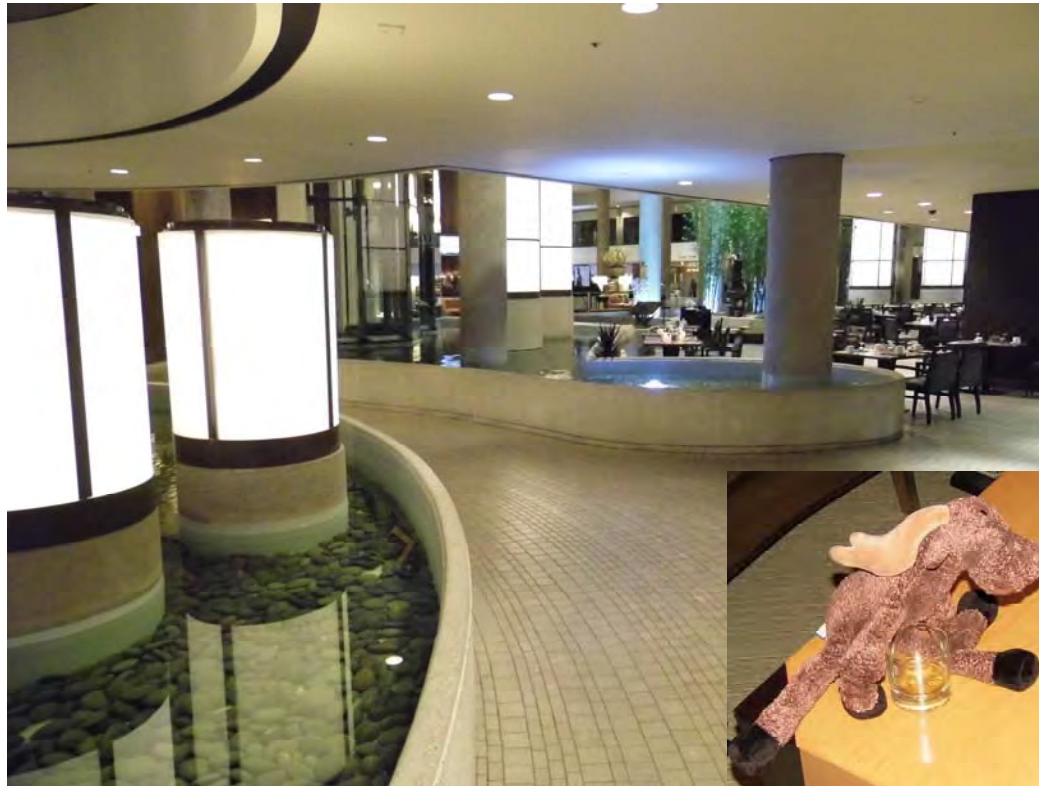
The company building this tall, skinny structure used this crane bolted to its side, supported at the bottom by the steel-work below. For a person who grew up with a big Meccano set, this bolted and welded steel structure was fun to ponder.





More pics from past this construction project. As they lifted these bundles of heavy steel bars over my head, I worried a bit about how loose they looked.





The lower level of the Bonaventure hotel had concrete pillars and a big pebble pool. If you read the Lab Management newsletter, you know about the moose mascot passed from one attendee to the next. Above right, he tips over before finishing his drink. At bottom right, I am awarded a moose wine stopper. The lady at left wears her moose earrings. Runner-up prize was this metal rhino. Jane Wentzel speaks at left.



One evening meeting began with snacks on the Bonaventure's patio at right. Downtown Los Angeles glass towers in the background. The ads on city buses in LA do not sell orthodontists. They focus instead on movies and new TV shows, as shown below right. The front of the hotel was closed to traffic, so this Warner-Bros crew could complete the last episode of SUPERGIRL



which would be released to TV just weeks later.





Nearly all the Sections of AOAC-I were represented in the meeting above. Each of us presented the details of what we do on our big June technical and supplier-contact event. Each section holds a similar event, but there were big differences: some are 2 days long, some smaller and some much bigger than ours. There were a dozen Sections present at the meeting, plus a dozen other executives. Gar Reigler has been key to AOAC-I operations for 16 years, but retired in 2015. Here are some notes from the meeting:

Promote and advertise the meeting by creating a well designed website, Facebook and LinkedIn page, newsletter, email list from AOAC. The India section created personal email for each member of the section with @aoac-India.org. Getting support from industry both international and domestic with key experts of standard methods. Student activities/engagement is best delivered at the Section level. Work with industry to sponsor students and provide an opportunity for education, science fair, training and poster sessions.

Scientific Program content must be relevant. Have a great keynote address, speakers, and topics of interest. Topics must be designed on issues currently based on the country's location (e.g. method validation, regulatory issues and interest, testing laboratories, food safety, laboratory management, adopting AOAC Official Methods.) Topics must also be challenging; finding solutions to problems. Have the focus on one topic with at least 3 sessions. Keep it to no more than a group of 5 diverse speakers.

Venues: make events 'accessible' to students; enable them to attend; offer financial support, reduced rate. Any question-answer session should be late in the day, to try to get 80% of attendees to stay until end-of-day. Your big day should not be close to any other major meeting. Collaborate and have joint meetings. Make use of the AOAC resources. Create a survey for immediate feedback for next meeting.



At the BUSINESS MEETING near the end of the week, President Erik Konings spoke to the roomful of grateful members, and, above, looks to incoming President, Norma Hill, retired from the US Treasury. Erik works for Nestle in Switzerland. As at many such conferences, there were a few specialty sessions held after the main closing ceremony. We left LA after the closing ceremony. We checked out of our room early that morning, and the manager graciously allowed us to park in his lot until the end of the day. Bronze statue seems troubled! LA traffic below!

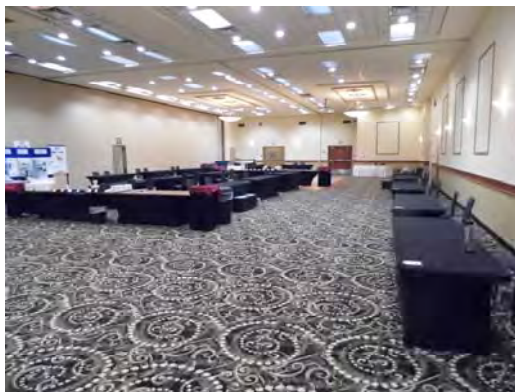




As we approached the 2015 edition of Mid-Canada AOAC Day, I realized that we had not been recording most of our previous events with many photos. This is a more complete photo essay, to tell you

what it was like before and at our big June event last year. Please mark our 2016 date on your calendar. You don't want to take a chance that you will miss out!

Below is the main exhibit hall, the luncheon room below at right, and at bottom left, the buffet area, all taken early the day before the big day. At bottom right, our AOAC team helps our exhibitors, the evening before. Most arrive and set up the night before.





AOAC volunteers helping exhibitors, above left on the night before, and when the show opened on Tuesday morning above right. In the pics below, the show is nearly ready for the crowds of scientists to visit each of the booths.





The heart of our AOAC Day is our selection of technical sessions. Each of us is offered lessons from experts on topics, from how to work safely, to the latest research in local labs. In the main exhibit hall, below local scientists take advantage of the expertise and table-top demonstrations from suppliers and info sources of all kinds.





Local Food Science folks hold a specialized exhibit event each year.

Because the exhibitors at their event, and the attendees, are not all the same as those at AOAC Day, our executive decided a few years ago to explore the idea of each of us telling our attendees about the 'other' event. Below and at right, more potential 'customers' looking over the displays of these vendors.





More scientists enjoying as they learn on the exhibit floor at AOAC Day.





Below right, our President Brian Archer circulated on the exhibit floor in 2015, chatting with our attendees. We like to get more insights into what you folks think about this show. **Write us a reply and let us know your thoughts now !**





Our luncheon speaker is introduced above by Brian, our 2014-2015 AOAC President. Every year, we enjoy one of the biggest and best Conference centers in Winnipeg, even more elegant since their 2015 upgrades. There are refreshment breaks periodically through the day, as shown below.



What's New in AOAC Conformity Assessment

AOAC Official MethodsSM

In 2015, the AOAC Research Institute facilitated nine (9) Expert Review Panel (ERP) meetings through which eight (8) AOAC First Action *Official Methods of Analysis* were adopted and eight (8) methods were recommended for AOAC Final Action *Official Methods* status. ERP recommendation reports for the methods being considered for AOAC Final Action status are being developed and will be submitted to the AOAC Official Methods Board (OMB) for their consideration. The OMB will review and render decisions at their next in person meeting.

Website Updates

In 2016, the AOAC Research Institute will be revamping its resource webpage. The links to paper applications have been disabled. All applications pertaining to method submission for Consulting Service, Performance Tested Methods and Official Methods are accessible on the [Method Submission](#) page on the Research Institute website. Please stay tuned for additional website updates.

Multi-Commodity Claims for Food Microbiology Methods Evaluated for AOAC Performance Tested MethodsSM and AOAC Official Methods of AnalysisSM

The following are the acceptable multiple matrix claims for food microbiology methods being evaluated in the AOAC *Performance Tested MethodsSM* program and in the AOAC *Official Methods of AnalysisSM* program administered in the AOAC Research Institute. This information will be posted on the AOAC Research Institute Resource webpage in 2016.

- Broad Range of Foods = 15 matrices (3/food category) @ 5 food categories. Food categories for this claim are only based on *ISO 16140:2015-2 Annex A, Food Categories*. The ISO 16140: 2015 will be available from the ISO store.
- Variety of Foods = 10 food matrices @ 5 food categories
- Select Foods = 5 food matrices @ 2 food categories
- Food Category = 5 food matrices @ 1 food category
- Environmental Surfaces = 7 surfaces
- Select Surfaces = 2 – 6 surfaces

New Strains of *Listeria*

Recently, there have been discussions regarding the new strains of *Listeria* discovered and how this information should be noted for methods that detect those strains or that detect *Listeria* species. Currently, AOAC has no voluntary consensus Standard Method Performance Requirements (SMPRs®) in which lists the strains that constitute a claim or method applicability for *Listeria* species for the AOAC evaluation of methods. This information is traditionally located in the inclusivity testing portion of the AOAC validation testing protocols that are reviewed and approved and in subsequently reviewed and approved AOAC validation study manuscripts.

Therefore, It is a recommended as a best practice that method developers claiming *Listeria* species list out the new *Listeria* strains. Specifically, a method developer could claim, as an example, “*Listeria* spp. including...(new strains covered by the method claim).” It is only to denote the inclusion of the new strains, and allowing approved methods with the claim of *Listeria* species to maintain their current approval. If you have any questions, please contact Deb McKenzie at dmckenzie@aoac.org.

2016 AOAC INTERNATIONAL Mid-Year Meeting Announced...

The [AOAC INTERNATIONAL Mid -Year Meeting](#) will be held March 14-18, 2016 at the Marriott Washingtonian Center, 9751 Washingtonian Boulevard, Gaithersburg, Maryland 20878. Registration is currently open for AOAC Standards Development activities including Stakeholder Panel meetings and Expert Review Panel sessions. Registration for Expert Review Panels processed through the AOAC Research Institute will be opening in January, 2016.

AOAC Performance Tested MethodsSM (PTM)

The Research Institute has granted AOAC Performance TestedSM certifications. The validation manuscript and method information will be published in the *Journal of AOAC INTERNATIONAL* and AOAC INTERNATIONAL's *Inside Laboratory Management*. All certifications are valid through December 31st of each year. [View the full list of current validated methods.](#)

AOAC Performance Tested MethodsSM (PTM) Certification Renewals

The PTM certification review and renewal process is underway. The deadline for submission of PTM renewal application packages with remittance is due Tuesday, December 15, 2015 to avoid late fees and penalties and in order for renewal certificates to be issued by January 1, 2016. Just a few things to keep in mind:

- If there are changes identified in the review or if there is a Level 1 or Level 2 method modification included in your renewal application package, the issuance of a 2016 PTM certificate by January 1, 2016 cannot be guaranteed.
- PTM certification renewal application packages submitted late after the specified dates noted below will result in the following:
- After December 31, 2015, licensees will experience a lapse in certification with a \$500 USD penalty and a monthly late fee of \$50 USD per certification.
- After January 30, 2016, licensees will experience a suspension of certification.

After March 1, 2016, the certification will be revoked.

AOAC Official Methods of AnalysisSM (OMA) Method Submission Deadlines

In preparation for meetings and events scheduled for the AOAC INTERNATIONAL Mid-Year Meeting in Gaithersburg, Maryland, the [AOAC Official Methods of AnalysisSM \(OMA\)](#) method submission deadline is January 15, 2016. All applications, documentation and remittance of fees must be submitted by the deadline. [View the 2015 OMA submission deadlines!](#)

Dear Colleague:

NOMINATE A COLLEAGUE TODAY!

AOAC INTERNATIONAL is seeking nominations for the **Harvey W. Wiley Award** and for **Fellow of AOAC INTERNATIONAL**. The AOAC Awards Program recognizes significant contributions to the analytical science community and to AOAC itself. This is an opportunity for you to nominate outstanding scientists who deserve recognition.

Foremost among AOAC Awards is the **Harvey W. Wiley Award**. This most prestigious award is presented to a scientist (or group of scientists) who has made an outstanding contribution to analytical method development in an area of interest to AOAC INTERNATIONAL. The Harvey W. Wiley Award is selected from nominations received from members of the analytical science community, with nominations accepted year-round. **All nominating materials for the 2017 Harvey W. Wiley Award must be received no later than January 31, 2016.**

The Fellow of AOAC INTERNATIONAL Award recognizes meritorious service to the Association. This award is given to Members of AOAC whose volunteer efforts have significantly contributed to the success and prestige of the Association. **All nominating materials for 2016 Fellows of AOAC must be received no later than February 15, 2016.**

I encourage you to take a few moments to reflect on the contributions made by your colleagues to AOAC INTERNATIONAL and to submit a nomination today!

For eligibility and nomination guidelines, please contact May Rose Jones, Program Manager, at [+1-301-924-7077 ext. 114](tel:+13019247077) or email at mjones@aoac.org.

Thank you in advance for your assistance and support of the AOAC Awards Program.

Cordially yours,

Norma R. Hill

President, AOAC INTERNATIONAL