AOAC Research Institute

A division of AOAC INTERNATIONAL

PERFORMANCE TESTED METHODS[SM]

PROGRAM

POLICIES and PROCEDURES

Notice: **AOAC Research Institute reserves the right to modify the program at any time. Participants are required to comply with the current program in effect at time of initial application or renewal.**

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POLICIES and PROCEDURES

1. Purpose

The *Performance Tested Methods*SM (PTM) program provides an independent third-party review of proprietary test method performance. Test methods demonstrated to meet acceptable performance criteria are granted PTM status. Method Developers of approved PTM test methods are licensed to use the PTM certification mark. The PTM certification mark assures users that an independent assessment has found that the test method performance meets an appropriate standard for the claimed intended use.

2. Background

The AOAC Research Institute (AOAC RI) is a nonprofit division of AOAC INTERNATIONAL. The mission of the AOAC Research Institute is to promote and carry out activities related to the development, improvement and validation of proprietary methods. A current list of PTM certified methods can be found at the AOAC Research Institute website at: http://www.aoac.org/AOAC_Prod_Imis/AOAC/RI/PTMM/AOAC_Member/RICF/RIVM_M.aspx?hkey=d1da913f-214e-4084-9fec-1f6944bbeb1d.

The AOAC Research Institute cooperates with many US and international organizations including: US Food and Drug Administration, US Department of Agriculture; US Department of Homeland Security; US Department of Defense; US Environmental Protection Agency; Canadian Food Inspection Agency; Health Canada; Association Française de Normalisation; Nordic Committee on Food Analysis; MicroVal; and the International Organization for Standardization.

The PTM program is designed to be complementary to the *Official Methods of Analysis*SM (OMA) program. The PTM evaluation can serve as the OMA "pre-collaborative" study for a microbiology method; or as the single laboratory validation for a chemistry method.

3. Overview

The PTM program has six distinct phases:

1) Consulting
2) PTM Application
3) Method Developer Validation Study
4) Independent Validation Study
5) Validation Study Report
6) PTM Review

A test method is submitted for PTM evaluation by a Method Developer, Distributor, or Certification Mark License Agreement before a test method can be granted PTM status.

The PTM evaluation begins with a Consulting phase in which the Method Developer and an AOAC RI Technical Consultant discuss and decide the aims of the validation. The type of assay, target analyte, matrices, market, and regulatory issues are all considered at this stage. The AOAC RI Technical Consultant works with the Method Developer to prepare a Validation Outline suitable to the claimed intended use of the test method. The Validation Outline is a formal document that includes a detailed description of the Method Developer and Independent Validation Study Protocols necessary for data collection, acceptable performance criteria and report submission. The Validation Outline is reviewed by the appropriate AOAC Volunteer Expert, and once approved the final outline is provided to the Method Developer.

After the Consulting phase is complete and an approved Validation Outline has been delivered, the Method Developer may choose to submit a PTM Application. Method Developers are under no obligation to submit a PTM Application if they elect not to proceed. Method Developers may choose to spend time planning and preparing for the PTM review before submitting an application.

A Method Developer who decides to proceed must submit a PTM application package as per section 4.2. The AOAC RI staff reviews the application package to confirm that the package is complete. The AOAC RI Manager assigns an AOAC RI Project Manager to lead the evaluation. Typically, this is the same person who served as the Technical Consultant.

After the preliminary review confirms that the PTM application package is complete, the AOAC RI Project Manager identifies qualified testing sites to conduct the independent site testing. The Project Manager oversees the execution of a contract between the selected independent site and the AOAC RI.. After the contract is in place, the Project Manager organizes the Independent Validation Study with the cooperation of the Method Developer.

Upon completion of independent site testing, a written Independent Validation Study Report will be delivered to the AOAC RI Project Manager. After review to ensure completeness and adherence to the protocols, the AOAC RI Project Manager delivers the report to the Method Developer. The Method Developer shall prepare a PTM Validation Study Report per the PTM study report format provided in the Validation Outline that includes both the results from the Method Developer's study and the Independent study.

The AOAC Volunteer Expert and 2 Expert Reviewers will review the Method Validation Study Report to determine acceptability as a *Performance Tested* method. The Reviewers will provide recommendations to the AOAC RI Project Manager for awarding or denying PTM status.

PTM status will be granted if there is consensus of the AOAC Volunteer Expert and 2 Expert Reviewers that the performance of the test method is acceptable relative to the appropriate standard (reference method when available) for the method's intended use claim. Once approved, the method is awarded a unique PTM certification number, the Method Developer is licensed to use the PTM certification mark, and the Method Validation Study Report is published in the *Journal of the AOAC INTERNATIONAL*.

PTM status must be re-certified annually for as long as the Licensee elects to

maintain the PTM certificate. PTM status is extended in one-year increments.

4. Procedures

4.1 Consulting

Method Developers seeking PTM status for a test method must use the AOAC Research Institute Consulting Service program. The AOAC Research Institute maintains a pool of Technical Consultants with expertise in PTM program procedures and technical requirements. The AOAC RI Senior Director or Manager will assign a Technical Consultant when a Consulting Application is submitted.

The Method Developer may request a specific Technical Consultant for their validation project, and the request will be honored whenever possible. However, the Senior Director shall have the ultimate decision as to which Technical Consultant is assigned to a project.

Consulting Service fees vary. See the *Performance Tested Methods*SM Fee Schedule in Appendix 1 for details. AOAC Research Institute Contributing Members are eligible for discounted consulting fees.

4.1.1 Consulting Application Package

A Method Developer requesting Consulting Services must submit:

1) Consulting Application (Appendix 2)
2) Consulting Agreement (Appendix 3)
3) Copies of test kit package inserts or user manuals.

Applications are accepted online at:
http://www.aoac.org/AOAC_Prod_Imis/AOAC_Member/RICF/RI_Main.aspx?WebsiteKey=2e25ab5a-1f6d-4d78-a498-19b9763d11b4&hkey=33b744f6-f71e-456a-9305-552469587666&CCO=5#CCO.

4.1.2 Validation Outline

The purpose of the consulting service is to clearly define the intended use claims that a Method Developer seeks to validate, and to deliver a Validation Outline that allows the Method Developer to validate the intended use claims as efficiently as possible. The Technical Consultant will discuss the validation goals with the Method Developer and produce a draft Validation Outline.

The Validation Outline includes:

1) Statement of principle of the method and intended use claim
2) Matrices to be tested to support intended use claim
3) Method Developer Validation Study Protocol
4) Independent Validation Study Protocol
5) Statistical analyses required
6) Acceptance criteria

7) Appropriate reference method(s) or reference materials where applicable and
8) Study Report Template

The draft Validation Outline is reviewed and approved by the appropriate AOAC Volunteer Expert.

Study Protocols approved by the AOAC Volunteer Expert **are binding** and may not be altered or revised *ex post facto* by the Method Developer the Expert Reviewers, or the AOAC Volunteer Expert, except by consensus of all parties.

4.1.3 Payment, Delivery of the Validation Outline, and On-Going Support

The AOAC RI will issue an invoice for the Consulting Service when the Consulting Application package is received at the AOAC Research Institute. The invoice will be on a NET 30-day term from the date of the invoice.

The final approved Validation Outline **will not** be delivered to the Method Developer until the consulting fees are received at the AOAC RI. A consulting project shall be considered completed when the Validation Outline with approval by the appropriate AOAC Volunteer Expert is delivered to the Method Developer.

On-going consulting after completion of the approved Validation Outline can be provided at an hourly rate (see AOAC Research Institute Fee Schedule) until the Method Developer submits a PTM *a*pplication. On-going consulting includes revisions to the Validation Outline at the request of the Method Developer to accommodate changes to the test kit, intended use claims, or other additional changes to the Validation for any reason other than correction of errors or omissions.

4.1.4 Waiver

Method Developers may request a Consulting Service Waiver (Appendix 5) allowing them to generate study protocols without using the AOAC RI Consulting Services program. Waivers are granted on a case-by-case basis, at the sole discretion of the AOAC RI Senior Director.

Warning: Method Developers assume all risks for acceptability of self-generated study protocol. Data that do not comply with acceptable study protocols may not be approvable. Method Developers risk lengthened review time and additional testing

expense due to errors in self-generated study protocols.

4.2 *Performance Tested Methods*SM Application

Method Developers seeking PTM status for test methods must submit a PTM application package for **each** test method to be evaluated. The application for *Performance Tested Methods*SM Method Submission is submitted online at http://www.aoac.org/AOAC_Prod_Imis/AOAC_Member/RICF/RI_Main.aspx?WebsiteKey=2e25ab5a-1f6d-4d78-a498-19b9763d11b4&hkey=33b744f6-f71e-456a-9305-552469587666&CCO=5#CCO.

PTM application packages for test method evaluations must contain the following:

1) Completed *Performance Tested Methods*SM Review Application Form (Appendix 5)
2) Signed *Performance Tested Methods*SM Review Agreement (Appendix 6)
3) Test kit inserts, labels and operator's manual
4) Manufacturing Quality Assurance program description, ISO 9001 certificate, or cGMP certificate.

Method Developers are encouraged to recommend potential Expert Reviewers and potential independent testing sites. However, the AOAC RI is not obligated to accept the recommendations of the Method Developer. The Expert Reviewers cannot relate to the Method Developer or related entities in any way, other than as a customer.

4.2.1 *Performance Tested Methods*SM Application Review

The PTM Application package will be reviewed for completeness by AOAC RI staff. An acknowledgement letter, checklist review, and an invoice will be sent to the Method Developer within two business days of receiving an application.

4.2.2 Check List

The Check List contained in the PTM Application package is intended for use by the Method Developer and the AOAC RI staff to determine if the basic submission requirements have been satisfied. (Appendix 7)

4.2.3 Certification of QA Program and QC Practices

Method Developers must submit a description of the quality assurance program and quality control practices used in the manufacturing, production, storage, and delivery of the test method components. The description must include the sampling system followed with particular reference to the tests used to verify that test method component production meets established production standards. To protect proprietary information, the description may be submitted in the form of a signed letter with no more than a four- to six- page description of the QA/QC program. **Note**: test method components used in the validation

studies must be final GMP manufactured components. Research and development test method components cannot be used.

The Method Developer shall use a performance monitoring system that will provide production management with the information necessary to assure that the test method components continue to meet the requirements of the specifications to which the test method was originally evaluated and granted PTM status. The system shall include the methods, procedures, controls, records, and maintenance of the system to provide continuing assurance of compliance with the performance specifications advertised. The extent of this system will depend on the characteristics of the test method and on the performance specifications. In lieu of a description of QA/QC practices, the Method Developer may submit a copy the ISO 9001 or cGMP certificate that applies to the manufacturing site.

4.2.4 Project Manager

A Project Manager is assigned by the AOAC RI Manager when a PTM application is submitted. Typically, the Technical Consultant who provided the Consulting Service is assigned as the Project Manager for the PTM review. A Method Developer may request a different Project Manager at any time.

4.2.5 Invoicing

The AOAC Research Institute will issue an invoice for the PTM application when the PTM Application package is received at the AOAC Research Institute. The invoice will be on a NET 30-day term from the date of the invoice.

4.2.6 Refunds

A refund of one-half of the application fee will be made if the Method Developer withdraws the application prior to acceptance of a contract with an independent testing site. No refund will be made once a contract with an independent testing site is agreed to by the Method Developer and signed by the AOAC Research Institute Senior Director.

4.3 Independent Testing Site

4.3.1 Selection of Independent Testing Site

The Method Developer may ask the Project Manager to request proposals from more than one independent testing site. Factors in the selection of an independent testing site can include cost, timing, technical expertise, and ease of shipping method components and equipment. Independent testing sites shall be selected from the current list of AOAC RI Qualified Independent Laboratories found here:

http://www.aoac.org/AOAC_Prod_Imis/AOAC_Member/RICF/RI_Main.aspx?WebsiteKey=2e25ab5a-1f6d-4d78-a498-19b9763d11b4&hkey=33b744f6-f71e-456a-9305-552469587666&CCO=10#CCO.

4.3.1.1 Test Kit Method Evaluation

A testing site will not be selected to evaluate a particular test method if that testing site routinely uses the test method under evaluation or has participated in the development of the method. Also, the testing site must not have a financial, corporate, or regulatory relationship with the applicant and must not be a competitor.

Preference will be given to qualified testing sites accredited to the ISO 17025 requirements for the appropriate field(s) of testing. If evidence of appropriate accreditation is not provided, on-site visits by a representative of the AOAC-RI, at the Method Developer's expense will be conducted to assess the testing site's compliance with the General Criteria for Independent Laboratories (Appendix 8).

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4.3.1.2 Service-Based Method Evaluation

A method that is not sold as a kit, instrument, or set of reagents, that is provided as a service, may be evaluated *in situ* at the "primary' laboratory that will provide the service, with the following additional requirements:

1. Test samples must be prepared and blind-coded by an independent laboratory meeting the requirements specified in 4.3.1.1.
2. A separate analyst from the independent laboratory must analyze the blind-coded test samples.
3. An AOAC RI Project Manager must be present during the analysis.
4. Results must be reported back to the independent laboratory.
5. The independent laboratory will decode and analyze the results and prepare a report.
6. If a Service-Based Method is commercialized, i.e., turned into and sold as a test kit, the PTM mark does not apply to the test kit. The test kit must be evaluated at an independent laboratory meeting the requirements of section 4.3.1.1.

4.3.2 Contracts and Invoicing

4.3.2.1 Independent Testing Site Contract

Upon acceptance of the testing proposal by the Method Developer, the AOAC Research Institute and the independent testing site shall enter into a contract agreement describing the responsibilities of the independent testing site. See Appendix 9 for an Independent Laboratory Contract.

Attached to or included in this contract shall be:

1) An Independent Validation Study Protocol describing the tasks to be accomplished. This will include a description of the test method to be evaluated, number of fortification levels, replicate analyses, total number of tests, multiple day testing, etc.
2) Time line for completing the task
3) Independent testing site's fee and responsibility for expenses.

NOTE: The AOAC RI will not enter into any agreement with an independent testing site until all application fees have been paid in full.

4.3.2.2 Agreement for Independent Testing

The Method Developer shall sign an agreement with the AOAC Research Institute for the independent testing stating that the Method Developer:

1) Accepts the selected independent testing site
2) Accepts the independent testing site cost estimates
3) Authorizes the AOAC Research Institute to sign a contract with the independent testing site
4) Agrees to pay the testing site costs unless egregious errors can be proven

See Appendix 10 for the Method Developer Agreement for Independent Testing.

4.3.2.3 Invoices

The AOAC RI will issue an invoice to the Method Developer in an amount equal to the cost estimate of the project. The invoice will be issued on the day the Agreement for Independent Testing is signed. The terms of the invoice are NET 30-day. The invoice must be paid before data from the independent testing site can be forwarded to the Method Developer.

Any additional independent testing site costs must be authorized by the Method Developer. The AOAC Research Institute shall issue a 2nd invoice bill for any deviations from the independent testing site cost estimate.

NOTE: Invoices for additional independent site testing expenses must be paid in full before a test method will be approved.

4.3.3 Logistics, Scheduling & Training:

It is the responsibility of the Project Manager to ensure that all materials needed for the Independent Validation Study are delivered to the independent testing site.

It is the responsibility of the independent testing site to perform the Independent Validation Study. All questions about the study protocol or the method under review should be directed to the Project Manager, who may relay the question to the Method Developer or AOAC Volunteer Expert and then answer back to the independent testing site. The Project Manager may choose to call a group conference call between the independent laboratory and the Method Developer if the questions are particularly difficult, or if the Project Manager feels that the flow of information needs to be improved.

However, in ALL cases, the Project Manager will facilitate and be present at any communication between the independent testing site and the Method Developer, and NO communication shall occur between the Method Developer and the independent testing site without inclusion of the Project Manager.

In some cases, additional testing is required to complete a project. If additional testing is required, the independent testing site should provide the Project Manager with a cost estimate for the additional work. After conferring with the Method Developer, the Project Manager shall approve or decline the additional work.

4.3.4 Independent Testing Site Report

Data will be reported in the format specified in the Independent Validation Study Protocol, which may require the calculation of statistics as defined in the protocol for each test method evaluated. All independent testing site data will be reported directly to the AOAC RI Project Manager.

No reports will be forwarded to the Method Developer until the testing site estimate invoice is paid.

4.4 Method Developer Validation Study

Method Developers are responsible for collecting data for the Method Developer Validation Study. The study should conform exactly to the Method Developer Validation Protocol in the Validation Outline developed during the consulting phase. Any question(s) or proposed deviation(s) from the Method Developer Validation Study Protocol must be submitted to the Project Manager before data collection begins. The Project Manager will confer with the AOAC Volunteer

Expert regarding the question(s) or proposed deviation(s) and report back to the Method Developer.

Method Developers may collect Method Developer Validation Study data at their own facilities, or the Method Developer Validation Study may be contracted out to a contract vendor. Results from the Method Developer Study must be included in the Method Validation Study Report.

4.5 Method Validation Study Report and Review

Method Developers are required to prepare and submit a Method Validation Study Report supporting the intended use claims of the method. See Appendix 11 for the Method Validation Study Report template. The Method Validation Study Report must include the results of the Method Developer Validation Study and the Independent Validation Study, including all original and retest data.

The current draft package insert and/or user manual is reviewed at the same time as the Method Validation Study Report to ensure that the package insert and/or user manual is complete, accurate, and consistent with the Method Validation Study Report. Appendix 12 describes the basic requirements for package inserts.

The Method Validation Study Report and draft package insert and/or user manual shall be submitted directly to the Project Manager, who will forward the documents with the appropriate review form to the AOAC Volunteer Expert and Expert Reviewers. It is the responsibility of the Project Manager to set deadlines during the review process and track progress of the reviews. Generally, reviewers are asked to provide comments and questions within 2 weeks for the first review and 1 week for each review thereafter.

Upon receipt of all review forms, the Project Manager shall compile a list comments with blinding of Reviewers 1, 2, and 3, and forward the compiled comments to the Method Developer. The Method Developer is responsible for responding to all reviewer comments and questions in writing. All responses and revised documents shall be submitted to the Project Manager, who will forward them to the AOAC Volunteer Expert and Expert Reviewers for additional comment or approval. The process continues until consensus is reached among the three reviewers for either approval or rejection.

4.6 Selecting Reviewers

For each application or group of similar applications for PTM status, at least 2 Expert Reviewers and 1 AOAC Volunteer Expert will be assigned to review the Method Validation Study Report. The AOAC RI Project Manager is responsible for recruiting 2 Expert Reviewers,and identifying the correct AOAC Volunteer Expert.

Method Developers are encouraged to recommend individuals as Expert Reviewers; however, the final assignment will be at the sole discretion of the AOAC RI Project Manager. The experts selected to evaluate specific test kits must not have a relationship (including as a financial investor, member of board

of directors, or consultant) with the applicant, competitors, or closely related parties and may have no business relationship other than as a customer.

If there is no AOAC Volunteer Expert for a particular topic area every effort should be made to recruit an AOAC RI method volunteer who is a member of a relevant expert review panel to serve as an AOAC Volunteer Expert. If a relevant expert review panel does not exist then the *Official Methods* Board (OMB) will be consulted for recommendations for an AOAC Volunteer Expert.

4.7 Criteria for Granting *Performance Tested Methods*℠ Status

The AOAC Volunteer Expert and Expert Reviewers, acting as independent reviewers, decide whether the results documented in the Method Validation Study Report merit awarding PTM status.

The reviewers must be satisfied that results from the Method Developer and Independent Validation Studies provide a solid scientific case to for granting PTM status. The criteria for granting PTM status are based on:

1) Results from the Method Developer Validation Study support and confirm all claims made in the test method's descriptive insert
2) Results from the Independent Validation Study corroborate the Method Developer Validation Study results within the statistical limits specified in the testing protocol
3) All results support a conclusion that the candidate method performs as well or better than an appropriate reference method (if one exists)
4) All results meet the acceptance criteria contained in the study protocols
5) All results meet the minimum performance requirements of the application (if one exists)

In some rare cases if an impasse develops between the Method Developer and a reviewer, it is the responsibility of the Senior Director of the AOAC RI to facilitate a resolution. If a resolution cannot be reached then the Senior Director of the AOAC RI may convene a special meeting to resolve all remaining questions.

4.8 Certificate

A PTM certificate is issued by the AOAC RI to the Method Developer for each test method granted PTM status. The certificate carries a unique certificate number and name of the approved test method. (See Appendix 13.)

4.8.1 Certificates Initially Granted Before October 1st of Any Given Year

The initial PTM certificate is granted and effective for a term expiring at the end of the current annual renewal cycle on December 31st of the same year.

4.8.2 Certificates Initially Granted On or After October 1st of Any Given Year:

The initial certificate is granted for a term expiring at the end of the next

annual renewal cycle on December 31st of the **next** year.

PTM certificates are made available to the public though the AOAC website.

4.9 Certification Mark:

Method Developers of approved methods are licensed to use the PTM mark on their packaging and promotional materials. (See Figure 1.) Use of the certification mark is entirely optional but highly encouraged. Method Developers will receive a copy of the certification mark with a unique certification number as soon as the test method is PTM approved.

Figure 1: Certification Mark

4.10 Certification Mark License Agreement

A Certification Mark License Agreement between the AOAC RI and the Method Developer must be signed before the certification mark can be used. The License Agreement describes the rights, obligations, rules, and procedures in the use of the PTM mark. A single agreement may be used to cover all PTM approved test methods in cases where a Method Developer owns more than one method awarded PTM status. See Appendix 14 for a copy of the License Agreement.

A Method Developer company officer must sign the License Agreement to use the PTM certification mark. Method Developers are not required to sign the License Agreement until the PTM review is complete and the candidate test method is granted PTM status. **Method Developers are encouraged to review the License Agreement before submitting a PTM Review Application to the AOAC Research Institute**.

5. *Performance Tested Methods*SM Status

5.1 Publication

The Method Validation Study Report approved by the Reviewers in awarding PTM status must be submitted to AOAC for publication in the *Journal of the AOAC INTERNATIONAL (JAOAC)*. Submissions are made directly to JAOAC via the online submission site. AOAC staff and the Project Manager provide instructions for submission.

A Method Validation Study Report for each *Performance Tested* method must be published in the *JAOAC* within a year of certification and before the annual re-certification to retain PTM status.

5.2 *Inside Laboratory Management*

The Method Developer may prepare and submit an article for the AOAC magazine *Inside Laboratory Management* (ILM). The ILM article should be about 1 – 2 magazine pages in length. The ILM article should be submitted to the ILM editor.

5.3 Roster of *Performance Tested Methods*℠ Test Kits

The AOAC RI will maintain and publish a regularly updated listing and description of test kits granted PTM status on the AOAC website.

6. Re-Certification (Annual Renewal) Process

The AOAC RI Manager is responsible for conducting the Annual Renewal process. PTM status is granted in periods of one calendar year after the initial certification.

Each PTM certificate has an expiration date. An Annual Renewal Application (Appendix 15) and an Annual Renewal Fee (see Fee Schedule, Appendix 1) must be submitted to the AOAC RI by the Licensee for each expiring *Performance Tested* method. Submission is made online at: http://www.aoac.org/AOAC_Prod_Imis/AOAC_Member/RICF/RI_Main.aspx?WebsiteKey=2e25ab5a-1f6d-4d78-a498-19b9763d11b4&hkey=33b744f6-f71e-456a-9305-552469587666&CCO=5#CCO.

Annual Renewal Applications and Fees must be received by the AOAC RI not less than 30 days prior to the expiration date on the certificate.

The AOAC RI will endeavor, to the best of its ability, to provide Licensees with timely notice of the pending certificate expiration by registered mail and by email. **It is the responsibility of the Licensee to provide the AOAC Research Institute with changes in contact information.** Ultimately, it is the responsibility of the Licensee to submit an Annual Renewal Application and Fee for each *Performance Tested* method the Licensee intends to keep in good standing.

The purpose of the Annual Renewal is: to affirm that no changes have been made to the test method since originally receiving PTM status and to confirm that the method performs as originally evaluated; or for the review of any modifications to the test method components, instrumentation, intended use claims, or package insert. Modifications to any of these parameters may require additional data.

The test method will be granted a one-year certificate if: the Licensee certifies that no changes have been made to the test method since originally receiving PTM status, and that the method performs as originally evaluated; or that sufficient data is provided demonstrating that the method performs as well or better than the originally reviewed method if any changes have been made to test method components, instrumentation,

intended use claims, or package insert.

A new or supplemental QA/QC package must be submitted with the Renewal Application if changes have been made in the manufacturing or QC testing processes. The AOAC RI reserves the right to request and review QA/QC records to verify that the consistency of test method performance is maintained throughout the life of the test method.

6.1 Modifications Submitted for Annual Renewal

Method Developers must contact the AOAC RI to determine the modification level. The AOAC RI will consult with the AOAC Volunteer Expert to determine the modification level.

Level 1 or 2 test method modifications (see section 7.2) may be submitted for Annual Renewal at no additional charge.

Level 3 test method modifications (see section 7.2) are assessed at a Level 3 modification fee even if submitted for Annual Renewal.

Method Developers are responsible for preparing all documentation and proposed study protocols supporting the proposed Level 1 and 2 modification(s) or making use of the AOAC RI Consulting Service. AOAC RI will assist the Method Developer by submitting proposed modifications and study protocols to the AOAC Volunteer Expert for review and approval as appropriate.

Method Developers are responsible for collecting data supporting the proposed Level 1 and 2 modification(s). AOAC RI will assist the Method Developer by submitting the Validation Study Report to the AOAC Volunteer Expert for review and approval as appropriate.

6.2 Suspension and Late Fees

PTM status shall be suspended if:

1) Serious adverse comments with supporting data have been received from method users indicating the method does not consistently perform as claimed, and the Method Developer has not provided a satisfactory resolution.
2) Undisclosed modifications are discovered for which the Method Developer did not submit data, or the data submitted in support of modifications is determined to be insufficient to demonstrate equivalency to the original condition of PTM approval (see section 6.).
3) An Annual Review Application is more than 30 days past due.

   Suspended test methods will be removed from the list of approved *Performance Tested Methods* maintained by the AOAC Research Institute on the AOAC website, and the Licensee may not claim that the test method is approved as a *Performance Tested* method.

6.3 Re-Instatement of Suspended Test Methods

Licensees may seek reinstatement of a suspended *Performance Tested Method* for a period of up to six months after the renewal due date by submitting an Annual Review Application with the Annual Review fee **including any late fees** (see Fee Schedule) plus any additional data and/or information addressing serious adverse complaints or undisclosed modifications.

6.4 Revocation

The AOAC RI, at its sole discretion, may revoke PTM status and cancel any license for the use of the certification mark at any time for any of the following reasons:

1) The PTM status of a method shall be revoked if the PTM status of a method has been suspended for more than 6 months.
2) The Licensee has not complied with the original agreement relative to use of the Research Institute's certification mark.
3) The Licensee has not responded adequately or has not taken timely corrective action relative to poor performance of the test method as reported by test method users or others.
4) The Licensee modified the test method in a manner that could reasonably be expected to affect its performance characteristics and failed to notify the AOAC RI.
5) The Licensee failed to make an application for annual renewal.
6) The Licensee requested that PTM status be discontinued.
7) The PTM program requirements change and the Licensee either will not or cannot ensure conformance to the new requirements within a reasonable amount of time. The Licensee will be allowed up to 60 days, but not later than the expiration of the current certificate, to comply with any new program requirements.
8) The Licensee ceased to produce the test method and/or
9) The Licensee failed to meet financial obligations to the AOAC RI.

When the PTM status of a method is revoked or canceled, the PTM certification mark must be removed from all packaging and promotional literature. The Method Developer must cease any claims as a *Performance Tested Method*.

6.5 Re-Instatement of Revoked Test Kits

Revoked *Performance Tested Methods* may be submitted for Re-Instatement if no changes have been made to the test method and **no** serious adverse comments have been received. See Appendix 16 for a Re-Instatement Application.

The Method Developer must collect data (at a new production location if applicable) that compares the performance of the lapsed test kit to the appropriate reference method(s) where applicable.

Comparison data for each reference method must be submitted if more than one reference method was examined in the original validation study. Copies of the original validation study are available from the AOAC RI for a fee (see Fee Schedule). The Method Developer must submit a formal report containing the

results of the comparison study. The new data collected for re-instatement must demonstrate that the method performs as well or better than the original data.

If approved for re-instatement, the method will be certified until the end of the calendar year. Renewal fees for the 1st year following re-certification will be pro-rated based on the month the method is re-certified. For example, a method that is approved for re-certification on October 1, 2008 will be invoiced for 1/4 of the full annual renewal fee.

Thereafter, annual renewal fees will be assessed in full every year as long as the Method Developer desires to maintain the PTM status for the test method (assuming the Method Developer and the method comply with all AOAC RI policies and procedures.)

7. Test Kit Modifications

7.1 Notification

It is the responsibility of the Test Method Licensee to notify the AOAC RI when changes are made to the method that affect in any way: (1) the instructions for using the method; (2) the method's performance; or (3) the manufacture of the method components. **Failure to appropriately notify the AOAC Research Institute of changes may result in revocation of the PTM certificate**.

Licensees are contractually obligated to provide the AOAC RI documentation of changes made in a certified PTM test method. The AOAC RI, generally in consultation with appropriate experts, will determine if the changes are of sufficient magnitude to warrant a complete re-evaluation of the method. If so, the licensee must submit a complete application with the corresponding fee(s).

7.2 Modification Review Levels and Administrative Fees

A Method Modification Application describing the modification must be submitted and the AOAC RI must approve the modification **before** a Licensee may use the certification mark on a modified test method (see Appendix 17). Applications are made online at http://www.aoac.org/AOAC_Prod_Imis/AOAC_Member/RICF/RI_Main.aspx?WebsiteKey=2e25ab5a-1f6d-4d78-a498-19b9763d11b4&hkey=33b744f6-f71e-456a-9305-552469587666&CCO=5#CCO.

Administrative fees to review modifications to test kits are based on the amount of resources required on the part of the AOAC RI and its Reviewers to evaluate the changes (see Fee Schedule). Modification of a validated *Performance Tested* method may require a **Level 1**, **Level 2** or **Level 3 Review** depending on the change to the validated method. Refer to the ***Test Method Definitions and Modifications Guideline*** (Appendix 18) for a detailed description of modification levels. The Licensee must submit a copy of the revised labeling, plus other appropriate data. An exact determination of the level of the modification can only be made by the AOAC RI after a written explanation and a completed application

are received and reviewed by the AOAC RI. Modification Levels will be determined by the AOAC RI with the assistance of the AOAC Volunteer Expert.

Level 1 Reviews - require only an internal AOAC RI review. The Licensee must submit a Method Modification Application with a written explanation of the change(s) including a statement that the modification does not alter the validated performance of the test method. In some cases, data as detailed in the ***Modifications Guideline*** may be required to substantiate claims of unaltered performance.

Examples Are:
1) Labeling changes.
2) Deletion of validated claims or procedures.
3) Restatements of existing validated claims.
4) Add or strengthen an instruction that is intended to enhance the safe use or efficacy of a test kit.
5) Increase/decrease stability claims (may be a Level 2, depending on the change).
6) Additional precaution/warnings or labeling changes that strengthen a warning or precaution and/or
7) Changes to manufacturing process or QA/QC (depending on change).

Level 2 Reviews - require submission of a Method Modification Application with appropriate data submission and labeling, and assignment of the appropriate AOAC Volunteer Expert to review data submitted by the Licensee.

Level 2 and 3 Reviews include, but are not limited to the following:

1) Entirely new procedure.
2) Removal of a precaution statement or warning, depending on the importance of the existing precaution.
3) Modification to reagents such as changes in formulation, concentration, phase (solid or liquid) or format.
4) Modification to, and/or changing of detection or measuring equipment/instrumentation.
5) Addition or deletion of regents and/or measuring instrumentation.
6) Matrix extensions.
7) Change of manufacturing facility.

Level 3 Reviews - require submission of a Method Modification Application with appropriate data submission and labeling, assignment of the AOAC Volunteer Expert, and 2 Expert Reviewers to review data submitted by the applicant, and independent testing.

More detailed information and guidance about the classification of changes to

test kits may be obtained from the AOAC Research Institute Manager. Ask for the ***Test Kit Definitions and Modifications Guideline.***

7.3 Identical Multiple Modifications

Identical modifications (regardless of modification level) to a series of related test methods sharing a common platform may be submitted as one Modification Application. For example, if a Licensee has three PTM approved test kits: one for *Salmonella*, one for *Listeria* genus, and one for *E.coli*; all based on PCR using the same thermocycler platform and reagents, the Licensee may submit to one Method Modification Application that applies to all three if the same modification applies to all three methods. For example, the Method Developer may choose to modify the same liquid reagent to a lyophilized reagent in each of the kits. The Licensee will be assessed one Modification Review fee (appropriate to the modification level).

The Licensee must submit a Method Modification Application and all supporting documents at the same time.

Licensees should contact the AOAC RI to determine the modification level and if the modifications can be considered identical. The AOAC RI will consult with the AOAC Volunteer Expert to determine the modification level and applicability of this policy.

7.4 Approval of Modifications

Licensees will be notified in writing when their modification(s) are approved. The AOAC RI website List of PTM Validated Methods will be updated to reflect any new claims and the PTM certificate will be updated to include the modification and supporting data.

8. Reviewed and Recognized Methods

Methods that have been previously reviewed and recognized by comparable method validation organizations may be applicable for PTM status. Method Developers interested in obtaining PTM status may submit a *Performance Tested Methods*SM Reviewed and Recognized Application (Appendix 19) to the AOAC RI Manager.

9. Complaints

9.1 Licensee Complaints

Formal Licensee complaints must be in writing and directed to the AOAC RI Senior Director. The AOAC RI Senior Director will initiate appropriate action to resolve the complaint.

9.2 User Complaints

Test method user complaints must be in writing and should be directed to the AOAC RI Senior Director. Complaints directed to the AOAC RI Senior Director will be forwarded to the Licensee for resolution**. Failure to adequately address user complaints will result in the AOAC RI initiating an inquiry and could lead to revocation of the test method's PTM status**.

10. Appeals Process

10.1 Right to and Basis for Appeal

Method Developers who have submitted a PTM Application may appeal certain **final** decisions of the AOAC RI. The appeals process is not open to parties that have not submitted test methods to the AOAC RI nor to those seeking to appeal AOAC RI decisions regarding test methods submitted by other Method Developers.

Appellants must comply with all relevant AOAC RI administrative procedures necessary to obtain an AOAC RI **final** decision before a formal appeal can be made to the AOAC RI.

Appellants may appeal an AOAC RI decision to: 1) refuse acceptance of a PTM Application; 2) deny PTM status; 3) revoke PTM status; or 4) refuse renewal of PTM status. Appellants may appeal such final decision(s) of the AOAC RI on the basis of alleged scientific or procedural error. Failure to agree on a testing protocol or the lapse of a certificate is not subject to appeal.

All decisions of the AOAC RI with regard to the action under appeal shall be stayed until the completion of the appeals process described herein.

10.2 Appeal Application:

The appellant shall submit their appeal in writing within 30 calendar days after the date of notification of the **final** action being appealed. All appeals must be delivered by registered mail to:

Senior Director
AOAC Research Institute
2275 Research Blvd.; Suite 300
Rockville, Maryland 20850
United States of America
Fax: *01-301 924-6917

All appeals must include a U.S. one thousand-dollar (US$1000) deposit which will be deposited in an identifiable internal account by the AOAC RI. The deposit will be returned to the appellant or applied to the expenses of conducting the appeal, pending the outcome of the appeal (see section 10.7).

All appeals must be written in English and must include statements or materials

regarding:

1) The **specific** decision being appealed.
2) The **specific** nature of the objection(s) to the decision, including any adverse effects.
3) The basis for the appeal, including the section(s) of the procedure(s) and/or protocol(s) and/or evaluation(s) that are at issue and data and other evidence in support of the appeal. Note: New data or evidence which was not made available to the AOAC RI and its Reviewers prior to reaching the decision under appeal **will not** be considered.
4) The **specific** remedial action(s) that would satisfy the appellant's objection(s)
5) All previous efforts to resolve the objection(s) and the results of each effort and
6) A list of at least five appeals panel nominees who qualify under the conditions of section 10.3, and are acceptable to the appellant.

Upon receipt, the AOAC RI Senior Director will immediately forward a copy of the Appeal to the Chair of the Official Methods Board (OMB).

10.3 Appeals Panel

The Chair of the OMB will determine whether the appeal is complete and acceptable within the requirements of section 10.2. If the Chair determines the appeal to be incomplete or unacceptable, the appeal will be returned to the appellant with instructions on how to correct the deficiencies.

If the Chair finds the appeal acceptable, the Chair will appoint an Appeals Panel of three persons within 30 calendar days of the date the appeal is received at the AOAC RI headquarters. The Chair will appoint one member of the Appeals Panel to serve as the Appeals Panel Chair. At least two members of the Panel must be acceptable to the appellant and at least two members must be acceptable to the Senior Director of the AOAC RI.

The Appeals Panel shall consist of three individuals who have not been directly involved in the matter under appeal, who will not be materially or directly affected by any decision made by the Appeals Panel, and, generally, who possess expertise in the scientific area(s) which are the subject of the appeal. All Appeals Panel members shall be required to execute an agreement to adhere to the AOAC RI's "Trade Secret Non-disclosure Policy" (Appendix 20), "Conflict of Interest Policy" (Appendix 21), and "Anti-Trust Policy" (Appendix 22).

10.4 Appeals Process

Appeals may be conducted by telephone, or by written or electronic correspondence at the discretion of the Appeals Panel; in consultation with the parties.

The appellant has the burden of demonstrating AOAC RI errors, AOAC RI

unreasonable or arbitrary actions or inactions, and the appropriateness of the remedial action requested. The AOAC RI Senior Director has the burden of demonstrating that the AOAC RI took all actions in compliance with its policies and procedures; that the decision reached by the AOAC RI was reasonable, and where applicable, substantiated by scientific facts and data; and/or that the proposed remedial action requested by the appellant would be inappropriate.

The AOAC RI Senior Director shall prepare and submit a written response to the appeal to the Appeals Panel Chairman and appellant within 30 calendar days from the date the appeal is received at AOAC RI headquarters. The Appeals Panel will review all pertinent information and, if necessary, may conduct an oral hearing by either telephone conferencing or a formal meeting of the parties.

10.5 Preliminary Finding

The Appeals Panel shall produce a preliminary report within 30 calendar days of being formed or of receiving the AOAC RI's response to the appeal, whichever is later. The preliminary report shall contain the Appeals Panel's preliminary finding, and an explanation of the preliminary findings. The appellant and the AOAC RI shall have 14 calendar days to submit a response to the preliminary report to the Appeals Panel Chair.

10.6 Final Decision

The Appeals Panel shall make a final decision, by simple majority vote, within 14 calendar days of receiving the responses to the preliminary report. Within an additional 14 calendar days of announcing this final decision, the Chair of the Appeals Panel shall issue a final written report. The final report shall include the original appeal, the AOAC RI's response to the appeal, the Appeals Panel's preliminary findings and explanations, the appellant's and the AOAC RI's responses to the preliminary report, and the Appeals Panel's final decision.

If the Appeals Panel finds for the appellant, the final report shall remand the action to the AOAC RI with specific findings and opinions of the facts and circumstances that demonstrate an incorrect decision was reached or an unreasonable or arbitrary action was taken **and with instructions to implement specific remedial action(s)**.

If the Appeals Panel finds for the AOAC RI, the final report shall contain specific findings and opinions of the facts and circumstances that demonstrate the AOAC RI acted properly and/or reached a reasonable decision based on the information available to it.

The decision of the Appeals Panel shall be final and non-appealable.

10.7 Expenses

If the Appeals Panel finds in favor of the appellant, the entire amount of the $1000 deposit shall be promptly returned to the appellant. If the Appeals Panel

finds in favor of the AOAC RI, the $1000 deposit shall be applied to the expenses associated with the conduct of the appeal including the cost of any investigations, hearings and/or meetings conducted by the Appeals Panel.

10.8 Exceptions to the Procedures

The Appeals Panel may grant to itself and the parties, at its sole discretion, reasonable extensions of deadlines specified in these procedures. The Appeals Panel must notify, in a timely manner one of the parties.

The Appeals Panel serves at the pleasure of the Chair of the OMB. Any or all members of the Appeals Panel may be removed and replaced for failure to act in a timely or professional manner.

11. Program Administration

11.1 AOAC Research Institute

The PTM program is operated by the AOAC RI, a division of AOAC INTERNATIONAL, a nonprofit organization organized under the laws of the District of Columbia.

11.2 AOAC Research Institute Staff and Reviewer Duties

The AOAC RI staff consists of a Senior Director, Manager, Technical Consultants, Project Managers, and administrative support. AOAC-RI Reviewers consist of AOAC Volunteer Experts and Expert Reviewers.

11.2.1 Senior Director Responsibilities:

1) Financial oversight of the program as a whole and all decisions pertaining to product and services fees.
2) Maintenance of and revisions to the Program Policies and Procedures.
3) Enforcement of policies and procedures.
4) Strategic planning.
5) All personnel decisions and
6) Oversight of the issuance of PTM certificates as appropriate, based on final review of the expert reviewer reports and recommendations.

11.2.2 Manager Responsibilities:

1) Provide application materials and assistance to potential Method Developers.
2) Conduct a preliminary review of the application materials for completeness of the package.
3) Establish and maintain a log and tracking system for all applications.
4) Assign projects to Technical Consultants/Project Managers.
5) Collect fees based on established fee structure.
6) Manage annual certificate renewal process.
7) Maintain a database of applications and PTM certificates and

provide status reports as appropriate and

8) Establish and maintain an Expert Reviewers pool.

11.2.3 Technical Consultants/Project Managers:

1) Develop Validation Study Protocols and coordinate review by the appropriate AOAC Volunteer Expert
2) Assign reviewers to specific performance testing applications
3) Resolve situations where the original reviewers do not agree on the recommendation.
4) Select independent testing laboratories, negotiate fees and contracts, and monitor their work.
5) Coordinate and expedite the performance testing process with Method Developers, independent laboratories, and Expert Reviewers and,
6) Complete and issue required forms and reports.

11.2.4 Expert Reviewers:

Expert Reviewer duties include:

1) Reviewing the Method Validation Study Report to determine adequacy and consistency with AOAC RI technical requirements.
2) Reviewing package inserts and user manuals to confirm that the analytical intended use claims in these documents are supported by the Method Developer and independent site data.

Expert Reviewers must:

1) Comply with AOAC RI policies and procedures on conflict of interest, including signing a conflict of interest policy acknowledgment form.
2) Be willing to devote the time necessary to conduct the data reviews and design testing protocols in a timely manner, as determined by the AOAC RI.
3) Have knowledge of method evaluation processes and have the ability to design and evaluate method evaluation protocols and
4) Have a working knowledge of method evaluation statistics.

Experts selected for a particular test method review, in addition to the above must:

1) Not be employed by or have financial ties with the applicant, competitors, or closely related entities
2) Not have a regulatory relationship with the applicant firm seeking PTM status
3) Have technical expertise in the general subject area of the test method technology under review

4) Not routinely use in their work the test method that is under evaluation.

Expert Reviewers may be entitled, but not required, to receive a fixed honorarium from the AOAC Research Institute for services performed. Experts wishing to serve as reviewers should make a written request to the AOAC RI Manager.

If the originally assigned Expert Reviewers cannot reach agreement on a recommendation to grant or deny PTM status, then the AOAC RI Senior Director will direct the Project Manager to assign additional reviewer(s) to provide a deciding recommendation.

11.2.5 AOAC Volunteer Expert

PTM reviews are coordinated with the appropriate AOAC Volunteer Expert from the AOAC OMA program to ensure consistency between programs.

AOAC Volunteer Expert duties include:

1) Replying to technical questions about the validation outline.
2) Reviewing the Validation Study Outline.
3) Reviewing the Method Validation Study Report to determine adequacy and consistency with AOAC technical requirements.
4) Reviewing package inserts and user manuals to confirm that the analytical performance claims in these documents are supported by the Method Developer and independent site data and
5) Determining modification levels and data required, if any, to validate modifications.

11.3 Confidentiality:

All documents generated by AOAC RI or received by the AOAC RI from applicant Method Developer and/or Licensee containing proprietary or confidential information shall be clearly marked as "CONFIDENTIAL".

The AOAC RI considers the following items to be confidential information and therefore subject to this policy:

1) The names of test methods and their manufacturers: a) with test methods under review; b) who are discussing the possibility of submitting a test method for review; or c) who have submitted test kits that the AOAC RI has declined to certify.

2) The contents of data submissions; the results of independent testing; the comments of Expert Reviewers and/or independent testing laboratories; and the progress or status of test kits under evaluation.

3) The progress of negotiations on license, indemnification, or other agreements with specific test kit manufacturers; including the fact of, and progress of an appeal by a test kit manufacturer.

If there is any doubt as to whether information in any form is confidential, it should be handled as confidential information until the AOAC RI Senior Director determines otherwise.

11.3.1 Access to Confidential Information

AOAC RI employees, volunteers, and contractors are expressly forbidden to discuss any confidential or proprietary information with: AOAC International staff employees; Directors or Board members; or with any other persons who are not directly involved in the evaluation of the program who have not executed an AOAC RI Nondisclosure Agreement. Employees of AOAC RI contractors and consultants are contractually obligated by the nondisclosure clause of the contract between their employer and the AOAC RI.

11.3.2 Sanctions to Release Information

AOAC RI employees, volunteers, and contractors may release confidential or proprietary information only if: 1) the release is specifically sanctioned by a majority vote of the AOAC INTERNATIONAL Board of Directors, who may decide to disclose confidential information for purposes of resolving AOAC RI business that cannot be resolved otherwise; or 2) with specific permission from the test kit manufacturer.

The test kit manufacturer will be consulted if the AOAC INTERNATIONAL Board is considering the release of confidential information, and the Method Developer will be notified if confidential information is released. This notice will include a copy of the information that was released, who it was released to, and an explanation of why the information was released.

11.3.3 Expert Reviewers

Volunteers who agree to serve as Expert Reviewers are required to sign a Nondisclosure Agreement. In addition, the AOAC RI requires that Expert Reviewers adhere to this policy.

Upon completion of the evaluation of a test method, Expert Reviewers are required to return all confidential documents to the AOAC RI for storage. The AOAC RI will store the documents for five years, and will retrieve documents for AOAC RI Expert Reviewers for specific applications that do not violate the terms of this policy.

11.3.4 Contractors and Consultants

All contractors and consultants are required to sign a contract that

includes a nondisclosure clause, which is binding on the employees of the contractor. In addition, the AOAC RI requires that all contractors and consultants adhere to this policy, including the document handling procedures of section 11.3.5.

Upon completion of a contract or project, contractors and consultants are required to return all confidential documents to the AOAC RI for storage. AOAC RI will store the documents for five years, and will retrieve documents for specific applications that do not violate the terms of this agreement.

11.3.5 In-House Document Handling:

Mail:
Envelopes and enclosed confidential or proprietary materials should be stamped "Confidential" by the addresser. When receiving confidential materials, the materials are carefully handled to ensure that only the addressee or those working directly with the program have access to the documents.

No confidential material will be circulated in office reading files. All circulated documents should have no references to manufacturers or kits.

AOAC RI staff will maintain a chronological file of all confidential material, in a file drawer that will be locked during non-business hours and will be moved as needed to a locked storage cabinet.

Faxes:
All faxes shall be sent using a cover sheet. When confidential materials are attached, the cover sheet should be stamped "Confidential" and a note should be at the bottom of the page that reads, "This fax contains confidential materials and should be delivered only to the person to whom it is addressed." When faxing documents, they should be removed from the machine immediately upon completion of transmission. Confidential documents should only be handled by those people directly working on the evaluation.

Computer Files:
Confidential documents should not remain on computer networks. They must be kept either on the C: drive or on a disk or other removable drive in a secure locked area, i.e. in a locked case or cabinet.

When copying or printing confidential documents, misprints or unwanted copies must be torn or shredded before being discarded.

Document Storage:
All confidential documents are stored in locked file cabinets, or other secure storage utilities, during non-business hours. Access to secure

documents must be limited to persons who are directly involved in the evaluation of a test kit and have executed an AOAC RI Nondisclosure Agreement.

11.3.6 Telephone Calls

Employees, contractors and volunteers of the AOAC RI may not identify test methods or test method manufacturers who are participating in the AOAC RI method validation program. The AOAC RI does not recommend one certified test method over another. If callers request confidential information; or if a person is unsure if requested information is confidential, a message should be taken and the AOAC RI Senior Director consulted.

12. Flowcharts

See Appendix 22 for schematic flow charts of the PTM program.

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