

**AOAC Research Institute**  
***PERFORMANCE TESTED METHODS*<sup>SM</sup>**  
**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*<sup>SM</sup> (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 (RI) was incorporated in 1991 as a nonprofit subsidiary of the AOAC INTERNATIONAL (formerly know as the *Association of Official Analytical Chemists*). The AOAC Research Institute operates as an independent corporation with its own Board of Directors and dedicated staff.

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 list of currently approved methods can be found at the AOAC Research Institute website at <http://www.aoac.org/testkits/testedmethods.html>.

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 Service, 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*<sup>SM</sup> (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 may be 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 General Referee or Topic Advisor, 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 application package is reviewed by the AOAC RI staff to confirm that the package is complete. The AOAC-RI Program 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, the AOAC RI, and the Method Developer. 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 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 General Referee/Topic Advisor 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 the performance of the test method is determined to be acceptable relative to the appropriate standard (reference method when available) for the method's intended use claim. Once approved, the Method Developer is awarded a unique

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PTM certification number and 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 Managing Director or Program 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 Managing 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*<sup>SM</sup> 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.

Electronic Consulting Applications are preferred. Send electronic Consulting Applications to [aoacri@aoac.org](mailto:aoacri@aoac.org).

Hard copies of the Consulting Application will be accepted in an un-bound format, no larger than 8 ½" x 14".

Send to:

**AOAC Research Institute Program Manager  
481 North Frederick Avenue Suite 500  
Gaithersburg, Maryland, 20877- 2504  
United States of America  
Fax: \*01-301- 924-6917**

#### 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 meet with the Method Developer or by telephone to discuss the validation goals. The Technical Consultant will produce a written Validation Outline after this initial meeting.

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) if applicable and
- 8) Study Report Template

\*These items are reviewed and approved by the appropriate AOAC-RI General Referee or Topic Advisor.

Study Protocols approved by the General Referee or Topic Advisor **are binding** and may not be altered or revised *ex post facto* by the Method Developer, the Expert Reviewers, the General Referee/Topic Advisor, or by Method Committee reviewers without the express consent of the Official Methods Board Chair.

#### 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 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 approved Study Protocols by the appropriate General Referee or Topic Advisor 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 application. 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

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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 Managing Director, based on the experience of the Method Developer. Method Developers with a history of several successful validation projects will be considered for waivers.

**Warning: Method Developers assume all risks for acceptability of self-generated study protocol. Data that does 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<sup>SM</sup> Application:

Method Developers seeking PTM status for test methods must submit a PTM application package for **each** test method to be evaluated. The *Performance Tested Methods<sup>SM</sup> Review Application Form* and the *Performance Tested Methods<sup>SM</sup> Review Agreement* may be requested from the AOAC-RI Program Manager or obtained online at <http://www.aoac.org/testkits/testkits.html>.

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

- 1) Completed *Performance Tested Methods<sup>SM</sup> Review Application Form* (Appendix 5)
- 2) Signed *Performance Tested Methods<sup>SM</sup> Review Agreement* (Appendix 6)
- 3) Test kit inserts, labels and operator's manual
- 4) Manufacturing Quality Assurance program description or copy of International Organization for Standardization- ISO 17025 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. Neither the independent testing site nor the Expert Reviewers may be connected with the Method Developer or related entities in any way, other than as a customer.

Electronic applications are preferred. Send electronic applications to [aoacri@aoac.org](mailto:aoacri@aoac.org).

Hard copies will be accepted in an un-bound format, no larger than 8 ½" x 14".  
Send to:

**AOAC Research Institute Program Manager  
481 North Frederick Avenue Suite 500  
Gaithersburg, Maryland, 20877- 2504**

**United States of America**  
**Fax: \*01-301 924-6917**

#### **4.2.1 Performance Tested Methods<sup>SM</sup> 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 certification may be submitted in the form of a signed letter with no more than 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.

#### **4.2.4 Project Manager:**

A Project Manager is assigned by the AOAC-RI Program 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 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 Managing Director.

### **4.3 Independent Testing Site:**

The Independent Validation Study Protocol is intended to verify the performance of the test method under controlled laboratory conditions and to characterize the method under the intended use conditions. A subset of the intended use conditions claimed by the Method Developer must be evaluated by the independent testing site.

The Independent Validation Study Proposal must be accepted by all parties before testing begins. The AOAC-RI will in turn invoice the Method Developer for reimbursement, separate from the application fee.

#### **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. A testing site will not be selected to evaluate a particular test method if that testing site routinely uses the test method under evaluation. 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).

## **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 a contract 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 an agreement 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 site testing costs must be authorized by the Method Developer. The AOAC Research Institute shall issue a 2<sup>nd</sup> 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 General Referee/Topic Advisor 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 General Referee/Topic Advisor 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 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 and accurate. 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 General Referee/Topic Advisor 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, the Project Manager shall forward each reviewer's review form 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 General Referee/Topic Advisor 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 General Referee or Topic advisor 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-RI General Referee or Topic Advisor.

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 General Referee for a particular topic area every effort should be made to recruit an AOAC-RI method volunteer who is a member of a relevant, standing method committee to serve as a Topic Advisor. If a relevant, method committee does not exist then the *Official Methods Board* (OMB) will be consulted for recommendations for a reviewer.

#### 4.7 **Criteria for Granting *Performance Tested Methods*<sup>SM</sup> Status:**

The General Referee/Topic Advisor 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 Project Manager to facilitate a resolution. If a

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resolution cannot be reached then the AOAC-RI Managing Director 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 1<sup>st</sup> 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 31<sup>st</sup> of the same year.

##### **4.8.2 Certificates Initially Granted On or After October 1<sup>st</sup> of Any Given Year:**

The initial certificate is granted for a term expiring at the end of the next annual renewal cycle on December 31<sup>st</sup> of the **next** year.

PTM certificates are made available to the public through 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<sup>SM</sup> Status**

### 5.1 **Publication:**

The Method Validation Study Report approved by the Reviewers in awarding PTM status must be submitted to the AOAC for publication in the *Journal of the AOAC INTERNATIONAL (JAOAC)*. AOAC-RI Staff will coordinate publication of this Technical Communication.

A Method Validation Study Report for each *Performance Tested* method must be published in the *JAOAC* within a year 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 Project Manager who will forward the ILM article to the AOAC publication department.

### 5.3 **Roster of Performance Tested Methods<sup>SM</sup> 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 Program Manager is responsible for conducting the Annual Renewal. The PTM status is granted in periods of one 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) must be submitted to the AOAC- RI by the Licensee for each expiring *Performance Tested* method.

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 General Referee/Topic Advisor 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). AOAC-RI will assist the Method Developer by submitting proposed modifications and study protocols to the General Referee/Topic Advisor for review and approval as appropriate.

Method Developers are responsible for collecting data supporting the proposed

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Level 1 and 2 modification(s). AOAC-RI will assist the Method Developer by submitting the Validation Study Report to the General Referee/Topic Advisor 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 *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 prorated 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 AOACRI 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 which affects in any way: (1) the instructions for using the method or (2) the method's performance. **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 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 Review Form describing the modification must be submitted and the modification must be approved by the AOAC-RI **before** a Licensee may use the certification mark on a modified test method (see Appendix 17).

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 existing 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 and supporting data are received and reviewed by the AOAC-RI. Modification Levels will be determined by the AOAC-RI with the assistance of the General Referee/Topic Advisor.

**Level 1 Reviews** - require only an internal AOAC-RI review. The Licensee must submit a Method Modification Review Form 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 Review Form with

AOAC Research Institute Policies and Procedures appropriate data submission and labeling, and assignment of the General Referee/Topic Advisor 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 and/or
- 5) Addition or deletion of reagents and/or measuring instrumentation  
Matrix extensions.

**Level 3 Reviews** - require submission of a Method Modification Review Form with appropriate data submission and labeling, assignment of the General Referee/Topic Advisor, 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 Managing Director. 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 Review. 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 Review form that applies to all three if the 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 Review Form and all supporting documents at the same time.

Licensees should contact the AOAC Research Institute to determine the modification level and if the modifications can be considered identical. The AOAC-RI will consult with the General Referee/Topic Advisor 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 Approved Methods will be updated to reflect any new claims.

## 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*<sup>SM</sup> Reviewed and Recognized Application (Appendix 19) to the AOAC RI Program Manager.

## 9. Complaints

### 9.1 Licensee Complaints:

Formal Licensee complaints must be in writing and directed to the AOAC-RI Managing Director. The AOAC-RI Managing 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 Managing Director. Complaints directed to the AOAC-RI Managing Director will be forwarded to the Licensee for resolution. **Failure to adequately address user complaints will result in the Institute 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, in writing, their appeal within 30 calendar days after the date of notification of the **final** action being appealed. All appeals must be delivered by registered mail to:

**Managing Director  
AOAC Research Institute  
481 N. Frederick Ave., Suite 500  
Gaithersburg, MD 20877-2417 USA**

**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 and 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; 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 Managing Director will immediately forward a copy of the Appeal to the Chair of the AOAC RI Board of Directors (BOD).

### **10.3 Appeals Panel:**

The Chairman of the AOAC-RI BOD will determine whether the appeal is complete and acceptable within the requirements of section 10.2. If the Chairman 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 Chairman finds the appeal acceptable, the Chairman 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 Chairman will appoint one member of the Appeals Panel to serve as the Panel Chairman. At least two members of the Panel must be

AOAC Research Institute Policies and Procedures acceptable to the appellant and at least two members must be acceptable to the Chairman of the AOAC-RI BOD.

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 Managing 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 Managing 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 Chairman.

#### **10.6 Final Decision:**

The 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 Chairman 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 Panel's preliminary findings and explanations, the appellant's and the AOAC-RI's responses to the preliminary report,

and the 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 which 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 which 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 procedure. 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 AOAC-RI BOD. Any or all members of the 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 nonprofit corporation organized under the laws of the Commonwealth of Virginia. The AOAC-RI is an independent subsidiary of the AOAC INTERNATIONAL.

#### **11.2 AOAC Research Institute Staff and Reviewer Duties:**

The AOAC-RI staff consists of Managing Director, Program Manager, Technical Consultants, Project Managers, and administrative support. AOAC-RI Reviewers consist of General Referees, Topic Advisors, and Expert Reviewers.

##### **11.2.1 Managing 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) Oversee the issuance of PTM certificates as appropriate, based on final review of the expert reviewer reports and recommendations.

#### **11.2.2 Program 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 performance testing 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
- 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 Program Manager.

If the originally assigned Expert Reviewer cannot reach agreement on a recommendation to grant or deny PTM status, the AOAC-RI Project Manager may assign additional reviewer(s) to provide a deciding recommendation.

### **11.2.5 General Referees/Topic Advisors**

PTM reviews are coordinated with the appropriate General Referee or Topic Advisor from the AOAC OMA program to ensure consistency between programs.

General Referee/Topic Advisor duties include:

- 1) Replying to technical questions about the validation outline.
- 2) Reviewing the Validation Study Outline.
- 3) Reviewing the Methods 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:

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

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.

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 Managing 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; AOAC-RI Board members or officers; 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 Research Institute Board of Directors, who may

AOAC Research Institute Policies and Procedures decide to disclose confidential information for purposes of resolving AOAC-RI business that can not be resolved otherwise; or 2) with specific permission from the test kit manufacturer.

The test kit manufacturer will be consulted if the AOAC-RI 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 6.0.

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.

The AOAC RI Administrative Coordinator 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 Managing Director consulted.

**12. Flowcharts;**

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

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