1.0 Revision History

1.1 Revision 1 – 1994: "Appendix 18 Definitions & Modification Guideline"

1.2 Revision 2 – 2023: "AOAC Research Institute Modification Guideline Policy"

2.0 Revision Requirements

2.1 The Modification Guidance Policy and Modification Guidance Table will be reviewed at a minimum every five years.

3.0 Purpose

This policy document provides guidance on the process and requirements for modifications to *Performance Tested Methods*SM (PTM) certified methods, *Reviewed and Recognized*SM (R^2) certified methods. The guideline aims to ensure that modifications to test methods do not violate the conditions of the certification. The guidance provides a standardized approach for a wide range of scenarios; however, it is not all-inclusive. For any modification not covered by the Modification Guidance Table, contact AOAC RI for appropriate actions. The Modification Guidance Table can be found on the AOAC RI website under Research Institute Resources and Forms.

4.0 Definitions

4.1 Modification – Changes to certified methods that generally fall into categories described on the Modification Guidance Table.

4.2 Extension – Addition of a new claim to a certified method including new matrix(es), new reference method(s) and/or new method protocol. Extensions can be initiated by the Method Sponsor or as part of an AOAC RI managed Targeted Matrix Extension or Emergency Response Validation.

4.3 Method – A particular process for determining the presence/absence or amount of a target analyte(s). Components of a method includes applicability, reagents and equipment, sample preparation, analysis procedure, interpretation of results, and warnings, limitations, and precautions.

4.4 Manufacturer – The company responsible for manufacturing a test kit or instrumentation.

4.5 Submitting company – The original company responsible for submitting the appropriate AOAC RI program application. They are the default Method Sponsor, in the absence of any new/additional Sponsor. For example, in cases of company acquisitions.

4.6 Method Sponsor – Company responsible for ensuring compliance to AOAC RI policies and procedures. This is the current Certification Mark licensee.

4.7 Distributor – Company that rebrands method instructions for use, packaging, and/or labeling of AOAC RI certified PTMs. Responsible for participating in and compliance of the AOAC RI Certification Mark License Agreement policies including yearly renewal procedures.

4.8 Matrix – A single and specific food/environmental/cannabis item validated and claimed in the scope of a method. Examples include raw ground beef (80% lean), dried cannabis flower (≥ 0.3% delta-9 THC), and stainless-steel surface (sponge, 4" x 4").

4.9 Matrix Group – AOAC RI recognizes three matrix groups of foods (including cannabis food products), environmental samples, and cannabis (non-food products).

4.10 Performance Claims – Summary of certified method claims, which can be found on the AOAC RI program certificate.

4.11 AOAC RI Volunteer Expert – Subject matter expert (with respect to analyte, scientific methodology, matrixes). One is assigned per level 3 modification and may be assigned to level 2 modifications. Has in-depth knowledge of AOAC RI process and ensures continuity for technical requirements from study to study. Typically, the Volunteer Expert reviews the validation protocol and report.

4.12 AOAC RI Expert Reviewer – Subject matter expert (with respect to analyte, scientific methodology, matrixes). Two are assigned per level 3 modification. Typically, the Expert Reviewer reviews the validation report. Method Sponsors or Technical Consultants may request the validation protocol is reviewed by the Expert Reviewers as well.

5.0 Policy Note (Administration)

5.1 It is the responsibility of the Method Sponsor to notify the AOAC RI when changes are made to a certified method. See the Modification Guidance Table for additional information. Level 1, 2 and 3 changes are required to be reported prior to implementation of modification.

5.2 Failure to appropriately notify the AOAC RI of changes may result in cancellation of the certificate.

5.3 Method Sponsors are contractually obligated to provide documentation to the AOAC RI if reportable changes are made to a certified method. The AOAC RI will determine the extent of the documentation required (e.g., updated Instructions for use, and report including appropriate data).

5.4 Following the Modification Guidance Table, some changes do not require notification to the AOAC RI (e.g., changes to non-critical physical materials, kit production, quality control procedures). In these instances, there are expectations for internal data collection by the Method Sponsor. Any changes to performance claims must be reported.

5.5 When documentation is required, the Method Sponsor must submit a modification application with the corresponding fee. Fees to review modifications are based on the level of modification (Section 6.0). Consulting applications are highly recommended.

5.5.1 Consulting applications are required for testing protocol review and approval by the AOAC RI Volunteer Expert regardless of whether the Technical Consultant or Method Sponsor drafted the protocol.

5.6 A method that is modified and re-approved by the AOAC RI is considered an extension of the original certificate. The modification record is included on the certificate.

6.0 Levels of Modifications

6.1 Check the modification guidance table to determine whether the modification is internal information, level 1 editorial review, level 1 with data review, level 2 or level 3. If the change is not listed in the modification guidance table, contact AOAC RI.

6.2 Internal Information – A modification that typically does not require AOAC RI review. Internal study design suggestions can be found within the modification guidance table. If the new process falls outside of the performance claims (within Method Sponsors quality

management system tolerance), change must be reported to AOAC RI as a level 2 modification.

6.3 Level 1 modification editorial review – These changes are typically editorial. Notification is not required prior to implementation. These can be submitted at any time during the year OR during annual renewals. Level 1 rebranding modifications must be approved prior to implementation.

6.4 Level 1 modification with data review – For manufacturers that are not ISO 9001 or 13485 certified, there are some level 1 changes that require data submission. Discuss with AOAC RI Technical Consultant for data requirements. Changes with required data must be approved prior to implementation.

6.5 Level 2 modification reviews – These changes require data submission and review. Protocol review by AOAC RI is strongly recommended. Review timelines can be requested. The Method Sponsor must use the AOAC RI PTM/R^2 report template to submit a properly formatted report with appropriate data, revised instructions for use, and new labeling if warranted. The most current AOAC RI PTM/R^2 report template can be obtained by contacting AOAC RI. The modification must be approved by the AOAC RI before a Method Sponsor may use the certification mark on a modified test method.

6.6 Level 3 modification reviews – These changes require data submission, an independent laboratory study and review. Protocol review by AOAC RI is strongly recommended. Review timelines can be requested. An AOAC RI Technical Consultant prepares the independent laboratory protocol. The Method Sponsor must use the AOAC RI PTM/R^2 report template to submit a properly formatted report with appropriate data, revised instructions for use, and new labeling if warranted. The most current AOAC RI PTM/R^2 report template can be obtained by contacting AOAC RI. The modification must be approved by the AOAC RI before a Method Sponsor may use the certification mark on a modified test method.

7.0 How To Use

7.1 The guidelines in the Modification Guidance Table provide a standardized approach for a wide range of scenarios, however it is not all-inclusive. For any modification not covered by the Modification Guidance Table, contact AOAC RI for appropriate actions. The Modification Guidance Table can be found on the AOAC RI website.

7.2 Navigate to the appropriate method type tab (e.g., Immunodiagnostics).

7.3 The method type tabs will describe potential changes and provide details on the modification level and the study design for each.

7.4 The study design tab will detail the testing requirements.

7.5 Method Sponsors are advised to discuss modifications requiring data submission with an AOAC RI Technical Consultant prior to conducting any of the work in the Modification Guidance Table.

7.6 For changes listed as internal information, Method Sponsors should follow their internal quality management system. Method Sponsors can contact their AOAC RI Technical Consultant for assistance if needed.

8.0 Urgent Need Modification

8.1 An urgent need modification may be warranted if there are raw material shortages, raw material regulatory changes, equipment failures, unexpected performance issues or other circumstances which require an urgent modification to keep certified methods available to end users.

8.2 Urgent need modifications are only relevant to level 1 and level 2 modifications.

8.3 When an urgent need modification is desired, the following steps should be followed:

8.3.1 The Method Sponsor reaches out to the Sr. Director of the AOAC RI and an AOAC RI Technical Consultant requesting an urgent need modification. The following information must be provided:

8.3.1.1 Kit name, part number and PTM/R^2 number

8.3.1.2 Description of the change

8.3.1.3 Justification for urgent need modification rather than standard timeline

8.3.1.4 Preliminary data

8.3.2 AOAC RI will review the information and decide whether the urgent need modification will be granted. If it is granted, the Method Sponsor must fill out the standard PTM/R^2 modification application noting that this has been approved as an urgent need modification.

8.3.3 The Technical Consultant will set a timeline for the project, including agreed upon dates and party responsibilities. The Method Sponsor will approve the timeline.

8.3.4 The Method Sponsor may implement the change before the study and review are completed.

8.3.5 The Method Sponsor and AOAC RI then work together to complete the project on the agreed upon timeline.

8.3.5.1 If the timeline falls behind due to AOAC RI Technical Consultants, staff or experts, there is no effect on the project.

8.3.5.2 If the timeline falls behind due to the Method Sponsor, the Method Sponsor can request a timeline extension from AOAC RI. Failure to meet agreed upon timelines or timeline extensions, could result in loss of the PTM/R^2 certificate.

9.0 Group Modifications

9.1 Group Modifications or modifications to related methods may be submitted as one modification, provided the following:

9.1.1 The modification requested applies to all methods (e.g., a reagent used by all methods is modified from liquid lyophilized form).

9.1.2 All methods share a common methodology (e.g., PCR, lateral flow, ELISA) and instrumentation.

9.2 If the criteria above are satisfied, the Method Sponsor can submit one modification application. The fee schedule for group modifications can be found on the AOAC RI website.

9.3 Method Sponsors should contact an AOAC RI Technical Consultant to determine modification level and if method modifications can be grouped.

10.0 Approval of Modifications or Extensions

Method Sponsors will be notified in writing when their modification(s) are approved. The AOAC RI website "List of Certified Methods" will be updated to reflect any new claims and the certificate will be updated to include the modification information.