

Clarification to Method Modifications

1. Modifications during Annual Renewals

- 1.1 Level 1 modifications may be included in the Annual Review at no cost if:
 - 1.1.1 The Method Modification Review Form is included with the Annual Review form; and
 - 1.1.2 All of the relevant information, data, and documentation are received with the Annual Review form; and
 - 1.1.3 The Annual Review Application fee is received with the Annual Review form.
- 1.2 Level 2 and Level 3 modifications are subject to the usual fees as prescribed in the AOAC Research Institute Fee Schedule.
- 1.3 It is incumbent on the method sponsor to work with their project manager to ensure that all of the relevant information, data, and documentation are submitted with the Annual Review Application. Incomplete method modification packages will not be accepted.
- 1.4 It is incumbent on the method sponsor to work with their project manager and the relevant General Referee to determine that the proposed method modification is truly a level 1 modification. Level 2 and 3 modifications will be assessed the normal fees.

2. Shared Method Modifications

- 2.1 A modification that is proposed for a series of related methods can be submitted under one Method Modification Application Review Form and will be assessed one method modification fee.
 - 2.1.1 For example, if a company has developed and has PTM approval for a series of methods for *Salmonella*, *E.coli*, and *Listeria* using the same analytical platform, but differing in specific reagents (antibodies, PCR probes), and the company proposes to change a part of the procedure that is common to all of the methods, for example, a change in the heating block, then the modification for all of the related methods can be reviewed at one time under one Method Modification Review Form.
- 2.2 All of the relevant information, data, and documentation for all the methods under consideration must be received with the Method Modification Review Form.
- 2.3 Level 1, 2, and 3 modifications are subject to the usual fees as prescribed in the AOAC Research Institute Fee Schedule.

- 2.4 It is incumbent on the method sponsor to work with their project manager to ensure that all of the relevant information, data, and documentation are submitted with the Method Modification Review Form. Incomplete method modification packages will not be accepted.
- 2.5 It is incumbent on the method sponsor to work with their project manager and the relevant General Referee to determine the correct method modification level

Version 2
10/22/2009