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MOTION #1: GUIDELINES ON NEW POTENCY METHODS AND MODIFICATIONS TO POTENCY METHODS

Procedure for the adoption of a new method or to modify an existing method.

Step 1: A lab that wants to initiate a change, the “sponsor lab”, will create and document the new method or modification.

Step 2: The sponsor lab shall validate the method according to U.S. Food and Drug Administration document “Guidelines for the Validation of Chemical Methods in Food, Feed, Cosmetics, and Veterinary Products”, Level 4. The ICT will need to review the guidelines and make any needed adaptations.

Step 3: A collaborative study would then be conducted, using the AOAC Collaborative Study procedure as described in the FDA document for a “level 4” validation. The ICT would need to review the AOAC procedures and make appropriate adaptations. The ICT would need to adapt the procedure prior to use.

Step 4: A report would be created of the validation and study and sent to the ICT.

Step 5: The ICT would review the report and accept, reject, or request additional data and/or explanation, clarifications. As part of the review the ICT will review data that compares the results of the new method to previously approved methods (at the start this will just be the NY method but as new method are approved they will be include) to ensure that the new method has similar accuracy, bias, and measurement uncertainty.

Step 6: If approved, the new method or modification will be public and available to all labs to use.

In the event that the sponsor lab cannot obtain the number of labs needed for the AOAC guidelines (8 or 10) then the lab may contact the ICT and ask to be allowed to run the study with fewer labs. The ICT will evaluate the risk both of the lower method quality and the any risks of not validating the method. The ICT may approve the study to be done with fewer labs.

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MOTION #2 REGULATORY ABILITY TO PERFORM COLLABORATIVE STUDIES

To perform a collaborative study a laboratory or a PT provider must create and ship samples to laboratories for testing. This may involve direct payment or payment in kind (supplies, columns, or other items). A sponsor lab might wish to hire a PT provider to create the samples. The industry, potentially non-labs, may wish to commission a lab to create and sponsor a method. A lab may wish to specialize in method development and just do that and not test potency otherwise. Any changes to RCW, WAC or policy needed to allow this activity should be done.

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MOTION #3 COLLABORATION STUDY PARTICIPATION

When a sponsor lab plans a collaborative study, all labs that are authorized to perform potency testing must be asked if they wish to participate in the study and if the lab does want to participate, they must be included in the study.

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MOTION #4 STATE LAB PARTICIPATION

State Lab(s) testing for potency should be included in the list of labs invited to participate in collaborative studies and be allowed to be a sponsor laboratory. Any approved ISO compliant PT providers should be allowed to provide samples for validation studies and collaborative studies.