The following is AIHA LAP Method Modification Task Force guidance on annotating FORM 2 method listings when a laboratory makes changes to established reference methods. Changes to established reference methods fall into two categories:

1. Changes to a reference method that ***does not materially*** affect method accuracy and precision
2. Changes to a reference method that **does materially** affect method precision and accuracy

The following applies for "ALL" modifications made to methodology regardless of the number of projects performed.

IMPORTANT NOTE: Changes in sampling methodology – media, flowrate, and duration – are not considered in this document. The laboratory management is solely responsible for any suggested changes to media, flowrate, and duration. The AIHA LAP considers any changes in sampling methodology to be a "Major Modification" subject to full documentation and validation. Laboratory must notify the sampler when they are aware that there are changes in media, flowrate, and duration that is not consistent with published methods.

Documentation requirements vary depending on the degree of modification made to the reference method. The laboratory is required to maintain a listing of all modifications made to the specific reference method along with rationale and data supporting the modifications. Modification documentation must be available to AIHA LAP staff and Site Assessor, upon request.

MINOR MODIFICATION – No Change in Method Citation

Any of the changes noted below are not considered material changes to the published method and **do not** require a "Method Modification Notation" to Form 2 listing. In all cases noted below, the laboratory must have a record of the change(s) and analytical data that supports the changes. Documentation must be maintained by method name.

1. General Labware, e.g., glassware, volume measuring device
2. Reagent brand with same purity is the same as reference method
3. Chromatographic column having similar or better performance characteristics
4. Sample preparation:
   Organic Solvents
   a. Desorption solvent and volume. NOTE: Any changes MUST be validated with documentation of performance.
   b. The number of desorption samples with each sample set provided that a Desorption Efficiency curve has been established with a minimum of 3

points, in duplicate, over the range of the method.

Metals

a. All changes to digestion acid(s) are considered a "Major Modification". See Major Modification section below.
b. Time of digestion may be considered a "Minor Modification" with method specified acid. Any difference in method digestion time must be supported and documented.

5. The number of calibration points including documentation of linear range has been established.
6. Addition of analytes in a scan of similar compounds providing method performance of the additional analytes is documented and include ensuring adequate separation of all analytes in the scan. The addition of analytes to a scan must be accompanied with a verification/documentation/scientific rationale that the **sampling method** is also appropriate.
7. Microbiology Specific
    a. Different media that perform the same function.
    b. Change in starting weight from the original reference method, but the ratio of sample to diluent is the same.
    c. Alternate biochemical confirmation methods (API vs. Enterotube or conventional biochemical)
    d. Commercially prepared media vs. laboratory prepared media.
    e. Alternative microorganisms for positive and negative controls exhibit the same characteristics as those stated in the published method.
    f. Kits (i.e. IDEXX for MPN, Total Coliform, Fecal Coliform, Enterococcus, HPC) when equivalency has been demonstrated by the manufacturer.
    g. Automated equipment such as plate readers and robots.

Important Note: The laboratory is required to maintain a listing of all modifications made to the specific reference method along with rationale and data supporting the modifications. This modification document must be updated as applicable and be available to AIHA LAP staff and Site Assessor, upon request.

MAJOR MODIFICATION – Requires Notation that the Method is Modified

Any other changes NOT shown above are considered a material change to the reference method. Modifications to the reference method that materially affect the methodology require adding the notation that the method has been modified by the laboratory.

The required documentation for all major modifications must be maintained in the laboratory records, filed by method, for ease of review by LAP AAB and/or Site Assessor.

The Accreditation process may be put on hold until requested documentation is received.

All material method changes require that the laboratory have documentation supporting the accuracy and precision of the "modifications." The documentation required includes all aspects of method validation and performance verification related to the changes made to the reference method including Method Uncertainty.

Sample Collection
Sample Collection, i.e., sampling media, flowrates, sampling duration, and collection efficiency is outside the prevue of AIHA LAP. It would be expected that a laboratory developing a sampling methodology for a new chemical agent would provide documentation of collection efficiency, stability, and recovery.

- Preparation reagents
    a. Except for desorption solvents (shown above under Minor Modification), changes in solvent type (polarity, acidity), solution concentration, volume used.
    b. For Metals -- Changes to digestion acid(s) are considered a "Major Modification
- Analytical technology – instrumentation
  Microbiology – Changes in incubation times and change in incubation temperatures
- Analytical technology – any change in detection system
- Linear range
- Method Precision
- Method Accuracy
- Quality control elements (Calibration points, ICV, CCV, LCS, Blanks)
- Reporting conventions

In-House Methods

When an analytical method is developed uniquely by the laboratory, i.e., there is no direct link to a published reference method, all the elements noted above under Major Method Modification must be documented and validated. This information must be available upon request by AIHA LAP or Site Assessor. Documentation required is consistent with NIOSH or OSHA method validation schemes. The method listing on FORM 2 must show "In-House Method" along with any specific laboratory identification number.

Report Documentation – Major Modifications and In-House Methods

The client report must include reference to modifications made and the availability of reviewing documentation with respect to those modifications.