The Analytical Method Modification Program—How to Apply

The Texas Commission on Environmental Quality (TCEQ) has established a mechanism for obtaining approval to modify analytical reference methods used to generate data for regulatory purposes. This mechanism—called the analytical method modification (AMM) program—can be used for data provided to the TCEQ.

Objectives of the program are to:

- Provide greater regulatory flexibility.
- Reduce analytical costs.
- Minimize matrix interference problems.
- Potentially reduce the amount of hazardous materials either used or produced in laboratories.
- Enhance the utility of approved methods for regulatory monitoring.
- Ensure that modified methods produce data of equivalent or better quality than that of reference methods.
- Standardize and expedite the approval of method modifications by providing a single, defined application process for all TCEQ programs.

Who May Apply?

If you are responsible for producing regulatory data for the TCEQ, you may submit an application to modify an analytical method. You may also designate an individual or organization (for example, laboratory) to submit an application on your behalf.

At the end of this document, you will find the forms you need: TCEQ-10364, *Application for Analytical Method Modification*; and TCEQ-10365, *Initial Demonstration of Method Performance Checklist*. The forms are available separately on the TCEQ Web site, [www.tceq.state.tx.us](http://www.tceq.state.tx.us).
What Modifications May Be Proposed?

You may apply to modify front-end techniques for analytical methods. Front-end techniques include procedures, equipment, reagents, and solvents that are used to prepare a sample for analysis (for example, processes and devices for subsampling; sample extraction/digestion, cleanup, and introduction procedures; and sample apparatus changes).

Examples of method modifications that are within the scope of the AMM program are identified in Appendix 1, *Potentially Acceptable Front-End Method Modifications*.

What Modifications Will Be Approved?

We—the staff of the TCEQ—will approve front-end method modifications that generate data of equivalent or better quality than that of the reference method, unless the change is prohibited by law, rule, or method.

We cannot approve the following types of changes:

- Modifications that change the determinative technique of an analytical method. (The determinative step is the physical/chemical process by which the actual qualitative/quantitative measurement is made.) For most methods, the determinative step is an instrumental determination (for example, gas chromatography or inductively coupled plasma atomic emission spectroscopy).

- Modifications that change the analytical technique used to determine a method-defined parameter (one in which the analytical results are dependent upon how the entire procedure is performed). Such modifications may be defined, limited, or prohibited by method, rule, or regulation, as illustrated by the following examples:
  - Oil and grease/hexane extractable materials [U.S. Environmental Protection Agency (EPA) Method 1664A].
  - The Toxicity Characteristic Leaching Procedure (TCLP); flashpoint procedure, pH determination, paint filter liquids procedure, and corrosivity to identify hazardous waste [Resource Conservation and Recovery Act (RCRA)].
  - Tests used to measure airborne particulate matter (PM), such as PM$_{10}$ and PM$_{2.5}$ (Clean Air Act).
  - Alkalinity, asbestos, coliform (fecal), coliform (total), conductivity, E. Coli, heterotrophic plate count bacteria, and turbidity [Title 40, Code of Federal Regulations (40 CFR), Part 141].
Modifications* outside the scope of the AMM program may be approved according to:

- 40 CFR Sections 136.4 and 136.5 and Title 30 of the Texas Administrative Code (30 TAC), Section 319.12 for the Texas Pollution Discharge Elimination Systems (TPDES) program.
- 40 CFR 400-499 for other effluent monitoring programs.
- 40 CFR 141.27 for the drinking water program.
- 30 TAC Sections 335.509(a)–(b) for industrial nonhazardous waste classification purposes.
- 40 CFR Parts 52-76 and 30 TAC Chapters 111-122 for air programs.

* Please contact the Quality Assurance Section (512/239-0425) to determine the appropriate process for modifications beyond the scope of the AMM program.

How Do I Apply?

To request approval of a method modification:

1. Complete and sign the Application for Analytical Method Modification (Form TCEQ-10364, attached to this guide).
2. Complete and sign the Initial Demonstration of Method Performance Checklist (Form TCEQ-10365, attached to this guide).
3. Submit the application and attachments (checklist and supporting information) in triplicate (original and two copies) to the address indicated on the application.

Be sure your application package is complete. Incomplete applications will be returned.

How Long Does the Approval Process Take?

We usually approve or deny an application within 90 days. If we ask for more information, or if review by another state or federal agency such as the EPA is required, the review may take longer and you will be notified.

How Do I Get an Application?

You can get an application and checklist (Forms TCEQ-10364 and TCEQ-10365, attached) by asking for RG-380 in the following ways:

Write to: TCEQ Publications, MC 195
P.O. Box 13087
Austin, TX 78711-3087
What About Confidential Information?

We suggest that you not submit confidential information in your application. However, if it cannot be avoided, try to describe the information in nonconfidential terms throughout the application and include the information as an attachment. Clearly mark “CONFIDENTIAL” on each page of the attachment.

We are committed to upholding the policy of the Texas Public Information Act (Chapter 552, Texas Government Code) and to ensuring that the public’s access to information is protected. Under this law, disclosure of information is required, unless the material qualifies as confidential under an exemption in the Public Information Act or another law.

What Is Required for Method Validation?

You must validate and document that the proposed method modification generates data of a quality that is equal to or better than the approved reference method. At a minimum, the method validation documentation must include raw data for all samples, calibrations, verifications, blanks, matrix spikes and duplicates, and other quality control (QC) analyses required by the associated reference method and, if applicable, measurement quality objectives (MQOs) specific to a TCEQ program.

Raw data will vary per method specifications and may include, but are not limited to, any of the following:

- Sample preparation (extraction/digestion) dates.
- Analysis dates and times.
- Sequence of analyses or run logs.
- Sample volume.
- Extract volume prior to each cleanup step and after.
- Final extract volume.
- Digestion volume.
- Percent solids or percent moisture.
• Dilution data, differentiating between dilution of a sample and dilution of an extract or digestate.
• GC or GC/MS operation conditions, including detailed information on columns used, analysis conditions, and detectors.
• Chromatograms, ion current profiles, bar graph spectra, and library search results.
• Quantitation report, data system outputs, and other data to link the raw data to the results reported. (Note: If these data are edited manually, explanations of why manual intervention was necessary must be included.)
• Direct instrument readouts (for example, strip charts, printer tapes).
• Laboratory bench sheets and copies of all pertinent logbook pages for all sample preparation and cleanup steps, as well as for all other parts of the determination.

The *Initial Demonstration of Method Performance Checklist* (Form TCEQ-10365) identifies all of the criteria that must be addressed to document that the modified method meets or exceeds the performance criteria of the reference method and the MQOs, if applicable. The checklist also provides for a side-by-side comparison of results obtained during AMM demonstration of method performance with the performance criteria specified by the reference method and the MQOs, if applicable. In addition, the checklist identifies supporting data that must be attached to the checklist. **NOTE:** You must submit a completed checklist for each sample matrix in each medium to which your proposed AMM applies.

### Attachments to This Guide

- Appendix 1: *Potentially Acceptable Front-End Method Modifications*
- *Application for Analytical Method Modification* (Form TCEQ-10364)
- *Initial Demonstration of Method Performance Checklist* (Form TCEQ-10365) and Checklist Instructions
APPENDIX 1
Potentially Acceptable Front-End Method Modifications

Following are partial lists of example equipment, chemicals, and procedural specifications that may be considered acceptable front-end modifications to reference methods. Inclusion on these lists does not guarantee that a procedure will produce equivalent performance when used with a specified method.

**EQUIPMENT**

- AA or AE lamp type
- Absorption cell size
- Amperometer equipment
- Atomizer type
- Auto-analyzer equipment
  - Mixing technology
  - Measurement technology
  - Reaction procedure
- Automatic concentration equipment (for example, TurboVap)
- Beaker and/or flask size
- Centrifuge tube size
- Chromatographic cleanup/isolation column type/size
- Chromatography column and dimensions
  - (for example, GC, GPC, HPLC, ion exchange)
- Colorimetric apparatus
- Condenser glassware
- Connective tubing type
- Culture/fermentation tube size
- Dilution glassware type/size
- Dissolved oxygen analyzer
- Distillation apparatus
- Drying/desiccation apparatus
- Evaporating dish type/size
- Filter type/size
- Filtration apparatus
- Flame AA burner type
- Fume traps
- Furnace AA platform and tube type
- Glassware stopper type
- Gooch crucible/platinum dish size
- Graduated cylinder size
- Heating equipment
- Hydride generator
- Incubation bottle size
- Kuderna-Danish size
- Photometer type
- Pipet size
- Pressure reduction apparatus
- Proportionating or peristaltic pump
- Purge gas
- Reduction column composition/size
- Reflux apparatus
- Sample cooling and/or stirring devices
- Sample container type/size
- Sample digestion apparatus
  - Chemical oxidation
  - Microwave digestion
- Sample purge cell type/size
- Sample trap material/size
- Scrubber apparatus size
- Separatory funnel size
- Snyder column
- Solvent delivery system
- Syringe size
- Titration vessel size
- Vacuum apparatus
- Vial size

**CHEMICALS**

- Atomic absorption/emission fuels and oxidant
- Buffer solution
- Catalyst
- Cleanup column elution solvent
- Color developing reagent
- Dechlorinating reagents for residual chlorine
- Desiccant/drying chemical
- Materials for reference matrix
  - (for example, air/gas, effluent water, oil, sand, soil)
- Microbial activity reduction chemical
- Nitrification inhibitor
- Oxidizing and reducing chemicals
- Partitioning solvent
Dilution water composition  
Extraction solvent  
Fecal coliform culture source  
Fuel/oxidant ratio  
Glass cleaning chemical  
HPLC system/pump  
Indicator solution  
Inhibitor solution  
Internal standards  

Presence-absence broth medium  
Sample preservation chemical  
Sample digestion chemical  
Scrubber solution and concentration  
Standard solution concentration  
Stock solution concentration  
Surrogates  
Titrant

SPECIFICATIONS

Aeration time  
Calibration range  
Conductance measurements  
Dehydration techniques  
Desorption technique and time  
Fecal coliform preparation techniques  
Glassware cleaning techniques and sequences  
Heating time  
Hydride generation techniques  
Interference elimination techniques  
Metal- and organic-free water preparation  

Reflux time  
Sample aliquot size  
Sample cleanup techniques  
Sample cooling techniques and times  
Sample digestion/extraction techniques  
Sample holding time  
Sample mixing techniques  
Sample preservation conditions  
Sample transfer line temperature  
Solution standardization techniques  
Temperature specification
Texas Commission on Environmental Quality
Application for Analytical Method Modification (AMM)

Name of Applicant (Regulated Entity)

Mailing Address (City, State, Zip Code)

Area Code/Phone No.  Area Code/Fax No.

E-mail Address

Name of Laboratory Performing AMM:

AMM: (method title, number, and date/revision, as applicable)

Approved Reference Method: (method title, number, and date/revision, as applicable)

Analyte(s) or Class of Analyte(s): (for example, barium, trace metals, benzene, volatile organics; attach separate list, as needed)

Medium: (for example, wastewater, soil, air, solid waste, hazardous waste)

Is Information Proprietary?

Permit Information (If applicable)

ID Number of Existing or Pending Permit(s):

Issuing Agency (EPA/TCEQ):

Type of Permit:

Discharge Serial Number:

Attachments (Check each item below)

☐ Description of AMM (including benefits over reference method)

☐ AMM SOP (comparable to reference method format)

☐ Initial Demonstration of Method Performance Checklist

☐ AMM Supporting Data

☐ ☐ N/A Properly Labeled Confidential Information

☐ ☐ N/A Other ________________________________

Name and Signature of Applicant  Date

Title of Applicant/Name of Organization

Submit Application and Attachments in Triplicate (Original and Two Copies) to:
TCEQ; Quality Assurance Section, MC 176; Analytical Method Modification Program; P.O. Box 13087; Austin, TX 78711-3087
Initial Demonstration of Method Performance Checklist

Note: For the demonstration of equivalency, provide a checklist for each matrix in each medium.

Date: __________

Name of Laboratory

Laboratory Contact and Phone Number

Mailing Address (City, State, Zip Code)

Regulated Facility Name

Discharge Point ID (if applicable)

Permit No. (for existing or pending permits) or other Facility Identifier

EPA Program and Applicable Regulation

TCEQ Program and Applicable Regulation

Matrix Type: ____________________________
(for example, reagent water, sand, solvent waste, ambient air, stack gas)

Analyte or Class of Analytes: ____________________________
(for example, barium, trace metals, benzene, volatile organics; attach separate list, as needed)

The Initial Demonstration of Method Performance involves: (1) analysis of multiple spikes into the matrix of interest (for example, F024 waste, effluent from a specific wastewater plant) using the modified analytical method; (2) analysis of multiple spikes into analyte-free medium using the modified analytical method; and (3) analyses of the matrix of interest and of spikes into the matrix using the modified and reference methods.

The results for these analyses and the information you provide in the following checklist should provide side-by-side documentation that the modified analytical method meets or exceeds performance of the reference method, as well as applicable TCEQ program-specific Measurement Quality Objectives (MQOs).

Refer to the Checklist Instructions when providing the following information.

<table>
<thead>
<tr>
<th>Initial Demonstration of Method Performance</th>
<th>Performance Criteria(^1) Based on</th>
<th>Results Obtained (for AMM)</th>
<th>Checklist Category Item Achieved (Y or N)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Category</td>
<td>Reference Method</td>
<td>Measurement Quality Objectives</td>
<td></td>
</tr>
<tr>
<td>1. SOP for AMM (formatted as the reference method and attached)</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
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<tr>
<td>2. Title, number, and date/revision of reference method(^2)</td>
<td></td>
<td>N/A</td>
<td>N/A</td>
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</tbody>
</table>

TCEQ-10365 (08/28/03)
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<thead>
<tr>
<th>Category</th>
<th>Performance Criteria¹ Based on</th>
<th>Reference Method</th>
<th>Measurement Quality Objectives</th>
<th>Results Obtained (for AMM)</th>
<th>Checklist Category Item Achieved (Y or N)</th>
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<td>N/A</td>
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<td>3. Copy of reference method (attached)</td>
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<td>4. Itemized differences between the AMM and reference method (attached)</td>
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<td>5. Concentrations of calibration standards (calibration range)</td>
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<td>6. % RSD or slope/correlation coefficient of calibration regression line</td>
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<td>7. Performance range tested (with units)</td>
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<td>8. Sample(s) used in initial demonstration have recommended preservative</td>
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<td>9. Sample(s) used in initial demonstration met recommended holding times, where applicable</td>
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<td>10. Interferences (known or suspected)</td>
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<td>11. Qualitative identification criteria used</td>
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<td>12. Analysis of external reference material</td>
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<td>13. Source of external reference material</td>
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<td>14. Surrogates used, concentrations, and recoveries</td>
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<td>15. Sample preparation</td>
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<td>16. Cleanup procedures</td>
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<td>17. Spiking system, appropriate to method and application</td>
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<td>18. Spike levels (with units corresponding to final sample concentration)</td>
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<tr>
<td>Category</td>
<td>Performance Criteria&lt;sup&gt;1&lt;/sup&gt;</td>
<td>Results Obtained (for AMM)</td>
<td>Checklist Category Item Achieved (Y or N)</td>
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<td>Based on Reference Method Measurement Quality Objectives</td>
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<td>19.</td>
<td>(a) Number of replicate spikes in analyte-free medium [initial precision and recovery (IPR) test]; usually at least 4&lt;br&gt;(b) Precision for each analyte&lt;br&gt;(c) Bias for each analyte</td>
<td>N/A</td>
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<td>20.</td>
<td>(a) Number of replicate spikes in sample matrix of interest [Initial Demonstration of Laboratory Capability (IDC)]; usually at least 4&lt;br&gt;(b) Precision for each analyte&lt;br&gt;(c) Bias for each analyte</td>
<td>N/A</td>
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<tr>
<td>21.</td>
<td>(a) Results for sample matrix of interest using reference method and AMM&lt;br&gt;(b) Results for MS/MSD analyses during method comparison&lt;br&gt;(c) Method blanks for reference method and AMM</td>
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<td>22.</td>
<td>Detection limit (with units) for each analyte</td>
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<td>23.</td>
<td>Quantitation limit (with units) for each analyte</td>
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<td>24.</td>
<td>Qualitative confirmation</td>
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<td>25.</td>
<td>Frequency of the Initial Demonstration of Method Performance (specify frequency)</td>
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<td>26.</td>
<td>Ongoing demonstration of laboratory capability (specify frequency and criteria)</td>
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<td>27.</td>
<td>Matrix Spike/Matrix Spike Duplicate (MS/MSD) analyses (specify frequency and criteria)</td>
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<tr>
<td>28.</td>
<td>Other criteria (specify)</td>
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<tr>
<td>29.</td>
<td>Other criteria (additional)</td>
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</tbody>
</table>

<sup>1</sup>For multi-analyte methods, enter “See Attachment #” and attach a list or table containing the analyte-specific performance criteria from the reference method or those needed to satisfy applicable TCEQ program-specific measurement quality objectives.
If a reference method is the source of the performance criteria, the reference method should be appropriate to the required application, and the listed criteria should be fully consistent with that reference criteria.

Name and dated signature of each analyst involved in the Initial Demonstration of Method Performance (includes all steps in the method modification):

________________________  __________________________  __________
Name                      Signature                       Date

________________________  __________________________  __________
Name                      Signature                       Date

________________________  __________________________  __________
Name                      Signature                       Date

________________________  __________________________  __________
Name                      Signature                       Date
How to Complete the Checklist

In completing the Initial Demonstration of Method Performance Checklist, TCEQ-10365, follow these general guidelines. Specific instructions for corresponding numbered items 1 through 29 on the form are also listed.

- For each category on the checklist, provide the requested criteria or results from the reference method and/or program Measurement Quality Objectives (MQOs), in addition to the results or criteria for the AMM.
- If entries are lengthy: (1) refer in the checklist to a specific section of the reference or modified method; or (2) use a separate sheet to document the information, indicate “See Attachment #.” and attach the sheet to the checklist. Assign a number or other unique identifier to each attachment, and indicate the identifier in the space on the checklist.
- If a checklist item is not applicable, indicate “N/A” in the appropriate space, and provide an explanation for not completing the item.
- Place an “Y” or “N” in the column entitled “Checklist Category Item Achieved” to document completion of the Initial Demonstration of Method Performance requirement and attachment of any required documentation.

1. **Standard Operating Procedure (SOP) for AMM.** The format of the AMM must be comparable to the reference method format and must address, in detail, all reference method format elements.


3. **Copy of reference method.**

4. **Itemized differences between AMM and reference method attached.** Provide a summary of the differences.

5. **Concentrations of calibration standards (calibration range).** Include the ranges of concentrations of materials used in the reference and modified methods to establish the relationship between the response of the measurement systems and analyte concentrations. The ranges of the AMM calibration must bracket any appropriate action, decision, or regulatory limit. Additionally, the ranges must include the concentration range for which sample results are measured and reported (when samples are measured after sample dilution/concentration).

6. **% RSD or slope/correlation coefficient of calibration regression line.** List calibration criteria of the AMM and the reference methods. Include the slope of the calibration regression line, if a regression line is calculated, or the relative standard deviation (RSD) of the calibration factors, if this calculation is performed. A linear response is generally expected and is typically measured as either a linear regression for inorganic analytes, or as the RSD for organic analytes. However, the calibration relationship is not limited to a linear relationship (for example, quadratic fit). If applicable, a calibration curve (graphical representation of the instrument response versus the concentration of the calibration standards) should be attached.

7. **Performance range tested (with units).** List the actual range of sample concentrations that were tested and the concentration units.

8. **Sample(s) used in initial demonstration have recommended preservative, where applicable.** Unless alternative preservation has been specifically evaluated, these entries should reflect the reference method. If the preservation has been evaluated, list the requirements of the reference method, and describe the specifics of the study and its conclusions. Attach evaluation data.

9. **Sample(s) used in initial demonstration must be within recommended holding times, where applicable.** Unless holding time (time from when a sample is collected until analysis) has been specifically evaluated, these entries should be taken directly from the reference method/standard. If the holding time has been evaluated, include the study description and conclusions. Attach evaluation data.

10. **Interferences (known or suspected).** Enter information on any known interferences or suspected interferences with the modified method. Such interferences may be difficult to predict, but may be indicated by unacceptable spike recoveries in environmental matrices, especially when such recovery problems were not noted in testing a clean matrix in reagent water. The interferences associated with the reference method are to be indicated, as well as the effect of these interferences on the modified method. Note if the modified method eliminates or minimizes interferences associated with the reference method.

11. **Qualitative identification criteria used.** Enter all relevant criteria used for identification, including but not limited to such items as retention time, spectral wavelengths, and ion abundance ratios. List and use the requirements of the reference method as a guide when specifying identification criteria.

12. **Analysis of external reference material.** Enter the results of analysis on reference material from a source different from that used to prepare calibration standards (where applicable).
13. **Source of external reference material.** Enter criteria, if applicable, for traceability of materials used to verify the accuracy of the results, such as the National Institute of Standards and Technology (NIST).

14. **Surrogates used, concentrations, and recoveries.** Enter the name(s) of the surrogate compounds added to each sample prior to preparation, the concentration once spiked into the sample (i.e., final concentration), and the recovery limits for each surrogate in the sample(s). If no recovery limits are given in the reference method, they may be derived from specific performance tests, such as the Initial Demonstration of Capability (IDC) or Initial Precision and Recovery (IPR) analysis. A detailed listing may be attached, if more space is needed.

15. **Sample preparation.** Describe (or reference the section in the SOP) the sample preparation procedures used—for example, digestion, distillation, and/or extraction.

16. **Cleanup procedures.** Describe (or reference the section in the SOP) the intermediate steps prior to the determinative step (instrumental analysis)—for example, gel-permeation cleanup (GPC), copper sulfate, alumina/florisil treatment.

17. **Spiking system, appropriate to the method and application.** Enter the procedure by which a known amount of analyte(s) ("spike") was added to analyte-free medium and the sample matrix. This entry includes identification of the analyte, as well as the technique.

18. **Spike levels.** Enter the amount of the analyte(s) (spike) that was added to the analyte-free medium and to the matrix of interest in terms of the final concentration in the sample matrix analyzed. For wastewater samples, initial precision and accuracy spikes may be performed in reagent water in most cases. Since EPA-designated approved precision and recovery (accuracy) specifications are developed from reagent water spikes, IPR spike recoveries determined with the modified method may be compared with IPR criteria specified in the reference method.

19. (a) **Number of replicate spikes in analyte-free medium.** Enter the number of replicate spikes in aliquots of analyte-free medium analyzed during the initial demonstration of performance. In general, at least 4 replicates should be prepared and analyzed independently. All aliquots of analyte-free medium used in the test should be spiked with the same solution.

   (b) **Precision.** Enter the precision measure (standard deviation, relative standard deviation, or percent difference) and the numeric value obtained (with associated units) for each analyte spiked in the initial demonstration procedure.

   (c) **Bias.** Enter the bias measure (for example, % recovery, difference from true) and the numeric value obtained (with associated units) for each analyte spiked in the initial demonstration procedure.

20. (a) **Number of replicate spikes in sample matrix of interest.** Enter the matrix and number of replicate spikes analyzed during the initial demonstration of performance. In general, at least 4 replicates should be prepared and analyzed independently. All program-specific matrices used in the test should be spiked with the same solution.

   (b) **Precision.** Enter the precision measure (standard deviation, relative standard deviation, or percent difference) and the numeric value obtained (with associated units) for each analyte spiked in the initial demonstration procedure.

   (c) **Bias.** Enter the bias measure (for example, % recovery, difference from true) and the numeric value obtained (with associated units) for each analyte spiked in the initial demonstration procedure.

21. (a) **Results for sample matrix of interest using reference method and AMM.** Enter the results for aliquots from the same representative sample of the matrix of interest analyzed using the reference method and the AMM. Attach records for all sample preparation, cleanup, and analytical steps taken for both methods.

   (b) **Results for matrix spike/matrix spike duplicate (MS/MSD) analyses during method comparison.** Enter the results for MS/MSD analyses performed on the matrix of interest using the reference method and the AMM.

   (c) **Method blanks for reference method and AMM.** Enter the results for the method blanks associated with the analyses of the matrix of interest using the reference method and the AMM.

22. **Detection limit.** Enter the detection measure (for example, MDL) and the analytical result, with units for each analyte in the matrix. There are various measures of detection, which include Limit of Detection and Method Detection Limit. EPA's definition of MDL appears in 40 CFR 136, Appendix B. It should be noted that in some cases, it may not be important to achieve detection limits at low concentrations, if the purpose of the method is to sort or screen samples according to regulatory levels or action levels that are high, relative to MDLs. Attach all raw data for MDL studies.

23. **Quantitation limit.** List (or reference the section in the AMM SOP and the reference method) the lowest concentration at which the analyte can be reported with sufficient certainty that an unqualified numeric value is reportable. Measures of Quantitation limits include the Minimum Level (ML), Interim Minimum Level (IML), Practical Quantitation Level (PQL), and Limit of Quantitation (LOQ). Enter the measure of quantitation limit and the units for each analyte.

24. **Qualitative confirmation.** Enter all relevant criteria used for identification, including such items as retention time, use of second chromatographic column, use of second (different) analytical technique and spectral wavelengths. List and use the requirements of the reference method as a guide when specifying confirmation criteria.
25. **Frequency of Initial Demonstration of Method Performance.** Enter the frequency at which the initial demonstration must be repeated (for example, with each new instrument or analyte, or once a year, whichever is more frequent).

26. **Ongoing demonstration of laboratory capability.** Ongoing capability is demonstrated by analysis of a single reagent water sample spiked with the analyte(s) of interest [also called the laboratory control sample (LCS) and the laboratory-fortified blank]. Enter the frequency, spike concentration(s), and associated criteria for ongoing analysis of control samples.

27. **Matrix Spike/Matrix Spike Duplicate (MS/MSD) analyses.** Enter the frequency, spike concentration(s), and acceptance criteria for ongoing analysis of MS/MSD sets.

28. **Other criteria.** Enter other necessary program- or project-specific method performance categories.

29. **Other criteria.** Enter other performance data critical to evaluation of the AMM, and attach copies of relevant information.