occur has final responsibility for approval of any alternate test procedure proposed by the responsible person or firm making the discharge.

(b) Within thirty days of receipt of an application, the Director will forward such application proposed by the responsible person or firm making the discharge, together with his recommendations, to the Regional Administrator. Where the Director recommends rejection of the application for scientific and technical reasons which he provides, the Regional Administrator shall deny the application and shall forward this decision to the Director of the State Permit Program and to the Alternate Test Procedure Program Coordinator, Office of Science and Technology (4303), Office of Water, U.S. Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460.

(c) Before approving any application for an alternate test procedure proposed by the responsible person or firm making the discharge, the Regional Administrator shall forward a copy of the application to the Alternate Test Procedure Program Coordinator, Office of Science and Technology (4303), Office of Water, U.S. Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460.

(d) Within ninety days of receipt by the Regional Administrator of an application for an alternate test procedure, proposed by the responsible person or firm making the discharge, the Regional Administrator shall notify the applicant and the appropriate State agency of approval or rejection, or shall specify the additional information which is required to determine whether to approve the proposed test procedure. Prior to the expiration of such ninety day period, a recommendation providing the scientific and other technical basis for acceptance or rejection will be forwarded to the Regional Administrator by the Alternate Test Procedure Program Coordinator, Washington, DC. A copy of all approval and rejection notifications will be forwarded to the Alternate Test Procedure Program Coordinator, Office of Science and Technology (4303), Office of Water, U.S. Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460, for the purposes of national coordination.

(e) *Approval for nationwide use.* (1) As expeditiously as is practicable after receipt by the Alternate Test Procedure Program Coordinator, Washington, DC, of an application for an alternate test procedure for nationwide use, the Alternate Test Procedure Program Coordinator, Washington, DC, shall notify the applicant in writing whether the application is complete. If the application is incomplete, the applicant shall be informed of the information necessary to make the application complete.

(2) As expeditiously as is practicable after receipt of a complete package, the Alternate Test Procedure Program Coordinator shall perform any analysis necessary to determine whether the alternate test procedure satisfies the applicable requirements of this part, and the Alternate Test Procedure Program Coordinator shall recommend to the Administrator that he/she approve or reject the application and shall also notify the application of the recommendation.

(3) As expeditiously as practicable, an alternate method determined by the Administrator to satisfy the applicable requirements of this part shall be proposed by EPA for incorporation in subsection 136.3 of 40 CFR part 136. EPA shall make available for review all the factual bases for its proposal, including any performance data submitted by the applicant and any available EPA analysis of those data.

(4) Following a period of public comment, EPA shall, as expeditiously as practicable, publish in the FEDERAL REGISTER a final decision to approve or reject the alternate method.

[38 FR 28760, Oct. 16, 1973, as amended at 41 FR 52785, Dec. 1, 1976; 55 FR 33440, Aug. 15, 1990; 62 FR 30763, June 5, 1997; 72 FR 11239, Mar. 12, 2007]

§ 136.6 Method modifications and analytical requirements.

(a) *Definitions of terms used in this section.*

(1) *Analyst* means the person or laboratory using a test procedure (analytical method) in this Part.

(2) *Chemistry of the method* means the reagents and reactions used in a test

procedure that allow determination of the analyte(s) of interest in an environmental sample.

(3) *Determinative technique* means the way in which an analyte is identified and quantified (e.g., colorimetry, mass spectrometry).

(4) *Equivalent Performance* means that the modified method produces results that meet the QC acceptance criteria of the approved method at this part.

(5) *Method-defined analyte* means an analyte defined solely by the method used to determine the analyte. Such an analyte may be a physical parameter, a parameter that is not a specific chemical, or a parameter that may be comprised of a number of substances. Examples of such analytes include temperature, oil and grease, total suspended solids, total phenolics, turbidity, chemical oxygen demand, and biochemical oxygen demand.

(6) *QC* means ''quality control.''

(b) *Method modifications*—(1) *Allowable changes.* Except as set forth in paragraph (b)(3) of this section, an analyst may modify an approved test procedure (analytical method) provided that the chemistry of the method or the determinative technique is not changed, and provided that the requirements of paragraph (b)(2) of this section are met.

(i) Potentially acceptable modifications regardless of current method performance include changes between automated and manual discrete instrumentation; changes in the calibration range (provided that the modified range covers any relevant regulatory limit); changes in equipment such as using similar equipment from a vendor other than that mentioned in the method (e.g., a purge-and-trap device from OIA rather than Tekmar), changes in equipment operating parameters such as changing the monitoring wavelength of a colorimeter or modifying the temperature program for a specific GC column; changes to chromatographic columns (treated in greater detail in paragraph (d) of this section); and increases in purge-and-trap sample volumes (provided specifications in paragraph (e) of this section are met). The changes are only allowed provided that all the requirements of paragraph (b)(2) of this section are met.

(ii) If the characteristics of a wastewater matrix prevent efficient recovery of organic pollutants and prevent the method from meeting QC requirements, the analyst may attempt to resolve the issue by using salts as specified in *Guidance on Evaluation, Resolution, and Documentation of Analytical Problems Associated with Compliance Monitoring* (EPA 821–B–93–001, June 1993), provided that such salts do not react with or introduce the target pollutant into the sample (as evidenced by the analysis of method blanks, laboratory control samples, and spiked samples that also contain such salts) and that all requirements of paragraph (b)(2) of this section are met. Chlorinated samples must be dechlorinated prior to the addition of such salts.

(iii) If the characteristics of a wastewater matrix result in poor sample dispersion or reagent deposition on equipment and prevents the analyst from meeting QC requirements, the analysts may attempt to resolve the issue by adding an inert surfactant (*i.e.* a surfactant that will not affect the chemistry of the method), which may include Brij-35 or sodium dodecyl sulfate (SDS), provided that such surfactant does not react with or introduce the target pollutant into the sample (as evidenced by the analysis of method blanks, laboratory control samples, and spiked samples that also contain such surfactant) and that all requirements of paragraph (b)(2) of this section are met. Chlorinated samples must be dechlorinated prior to the addition of such surfactant.

(2) *Requirements.* A modified method must produce equivalent performance to the approved methods for the analyte(s) of interest, and the equivalent performance must be documented.

(i) *Requirements for establishing equivalent performance*

(A) If the approved method contains QC tests and QC acceptance criteria, the modified method must use these QC tests and the modified method must meet the QC acceptance criteria. The Analyst may only rely on QC tests and QC acceptance criteria in a method if it includes wastewater matrix QC tests and QC acceptance criteria (e.g., as matrix spikes) and both initial (start-up)

and ongoing QC tests and QC acceptance criteria.

(B) If the approved method does not contain QC tests and QC acceptance criteria, or if the QC tests and QC acceptance criteria in the method do not meet the requirements of paragraph (b)(2)(i)(A) of this section, the analyst must employ QC tests specified in *Protocol for EPA Approval of Alternate Test Procedures for Organic and Inorganic Analytes in Wastewater and Drinking Water* (EPA–821–B–98–002, March 1999) and meet the QC provisions specified therein. In addition, the Analyst must perform on-going QC tests, including assessment of performance of the modified method on the sample matrix (e.g., analysis of a matrix spike/matrix spike duplicate pair for every twenty samples of a discharge analyzed), and analysis of an ongoing precision and recovery sample and a blank with each batch of 20 or fewer samples.

(C) Calibration must be performed using the modified method and the modified method must be tested with every wastewater matrix to which it will be applied (up to nine distinct matrices; as described in the ATP Protocol, after validation in nine distinct matrices, the method may be applied to all wastewater matrices), in addition to any and all reagent water tests. If the performance in the wastewater matrix or reagent water does not meet the QC acceptance criteria the method modification may not be used.

(D) Analysts must test representative effluents with the modified method, and demonstrate that the results are equivalent or superior to results with the unmodified method.

(ii) *Requirements for documentation*. The modified method must be documented in a method write-up or an addendum that describes the modification(s) to the approved method. The write-up or addendum must include a reference number (e.g., method number), revision number, and revision date so that it may be referenced accurately. In addition, the organization that uses the modified method must document the results of QC tests and keep these records, along with a copy of the method write-up or addendum, for review by an auditor.

(3) *Restrictions*. An analyst may not modify an approved analytical method for a method-defined analyte. In addition, an analyst may not modify an approved method if the modification would result in measurement of a different form or species of an analyte (e.g., a change to a metals digestion or total cyanide distillation). An analyst may also may not modify any sample preservation and/or holding time requirements of an approved method.

(c) *Analytical requirements for multi-analyte methods (Target Analytes)*. For the purpose of NPDES reporting, the discharger or permittee must meet QC requirements only for the analyte(s) being measured and reported under the NPDES permit.

(d) The following modifications to approved methods are authorized in the circumstances described below:

(1) *Capillary column*. Use of a capillary (open tubular) GC column rather than a packed column is allowed with EPA Methods 601–613, 624, 625, and 1624B in Appendix A to this part, provided that all QC tests for the approved method are performed and all QC acceptance criteria are met. When changing from a packed column to a capillary column, retention times will change. Analysts are not required to meet retention time specified in the approved method when this change is made. Instead, analysts must generate new retention time tables with capillary columns to be kept on file along with other startup test and ongoing QC data, for review by auditors.

(2) *Increased sample volume in purge and trap methodology*. Use of increased sample volumes, up to a maximum of 25 mL, is allowed for an approved method, provided that the height of the water column in the purge vessel is at least 5 cm. The analyst should also use one or more surrogate analytes that are chemically similar to the analytes of interest in order to demonstrate that the increased sample volume does not adversely affect the analytical results.

[72 FR 11239, Mar. 12, 2007]