



Alternate Test Procedure Guidance

This guidance document describes the types of procedure modifications allowed and validation studies required for approval of an Alternate Test Procedure (ATP) by the state. Three categories of procedure modifications are available for laboratories: new procedures, alternate limited-use procedures, or alternate statewide-use procedures. Laboratories must demonstrate that the new or alternate procedure proposed is appropriate for use as related to the data quality objectives of the applicable program activity or project for which the proposed procedure will be used.

This guidance document clarifies the specific requirements for demonstrating appropriateness of use, provides guidance on conducting method validation studies, and assembling the required method validation documentation package. All method validation packages must be submitted to the appropriate agency regulating the program for review. For most programs in Minnesota, the Minnesota Pollution Control Agency (MPCA) will provide the review and make a recommendation to the U.S. Environmental Protection Agency (EPA) for acceptance or denial of the ATP. Guidance on the information that needs to be submitted is described in three documents:

1. Protocol for EPA Approval of New Methods for Organic and Inorganic Analytes in Wastewater and Drinking Water, March 1999
(http://water.epa.gov/scitech/methods/cwa/atp/upload/2007_02_06_methods_atp_EPA821B98003.pdf).
2. Protocol for EPA Approval of Alternate Test Procedures for Organic and Inorganic Analytes in Wastewater and Drinking Water, March 1999
(http://water.epa.gov/scitech/methods/cwa/atp/upload/2007_02_06_methods_atp_EPA821B98002.pdf).
3. EPA Microbiological Alternate Test Procedure Protocol for Drinking Water, Ambient Water and Wastewater Monitoring Methods, September 2010
(http://water.epa.gov/scitech/methods/cwa/atp/upload/micro_atp_protocol_sept2010.pdf).

A new procedure shall be considered appropriate for use if the State determines that:

1. The information contained in the method validation package supports the quality assurance targets of accuracy, precision, reliability and method detection limit(s) stated by the applicant.
2. The procedure quality assurance targets meet the stated data quality objectives of the contract, order, or permit for which the procedure will be used.

An alternate test procedure shall be considered appropriate for use if the State determines that the technical justification and other submitted information establish that the alternate procedure provides accuracy, precision, ruggedness, reliability and method detection limit(s) equivalent to, or better than, those of the procedure it is intended to replace. In addition, an alternate procedure must be shown to be equivalent at the 95 percent confidence level to the one it is intended to replace.

Procedures Proposed for National Pollutant Discharge Elimination

System National Pollutant Discharge Elimination System (Permits Program).

Laboratories have the flexibility to modify approved methods without an ATP as long as the modifications are documented per 40 CFR 136.6 at: <http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?c=ecfr&sid=586b36db46fcc2e447b23734e59a6d81&rgn=div5&view=text&node=40:22.0.1.1.1&idno=40>.

Another useful reference for deciding whether a modification falls within the allowed 40 CFR 136.6 definition can be found at: http://water.epa.gov/scitech/methods/cwa/update_questions.cfm.

However, if the method uses a determinative technique different from the approved method or the modification falls outside the flexibility described in 40 CFR 136.6, the laboratory must request a review of the documentation supplied. The laboratory must comply with provisions of 40 CFR 136.4 and 40 CFR 136.5. The information will be forwarded to the MPCA for review and acceptance. If accepted, the MPCA will forward the documents (along with their recommendation) to EPA, Region 5 for final approval. The determination for approval or rejection shall be made by the EPA.

Minor modifications to an approved method are allowed as long as the chemistry of the method is not changed and the modified method produces equivalent performance which is documented. Note that ATPs are specific to a matrix and therefore, must be proven to work on actual field samples, not simply clean water (i.e. be rugged to the matrix for which they are being used). If there are questions on what is considered an acceptable modification to a method, contact the MPCA QA Coordinator for the program area.