



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 ATP 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% confidence level to the one it is intended to replace.

Procedures proposed for the 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://www.ecfr.gov/cgi-bin/text-idx?SID=7e9cdb69b430281f75d7c473a1e761dd&node=se40.23.136_16&rgn=div8.

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.