

**ENVIRONMENTAL LABORATORY APPROVAL PROGRAM
CERTIFICATION MANUAL**

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The Program will accept applications for the approval of alternate testing procedures. The protocol requires the applicant to produce data demonstrating that the proposed alternate testing procedure is comparable to an approved method. This is done by analyzing replicate samples by both the approved and alternate procedures.

Alternate testing procedure approval may be limited or broad in nature. The amount of comparison data required depends on the nature of approval sought.

Limited Approval

Limited approval may be granted only to facility laboratories wishing to use an alternate testing procedure for samples originating within the facility's operation. For each sample source three samples should be collected. Each sample should be divided into eight aliquots. Four aliquots should be analyzed by the approved method and four by the proposed alternate, thus producing 24 data points per sample source. Analyte concentrations should range from the required detection limit (if applicable) to 20% greater than the regulatory limit. Samples may be spiked if necessary.

Broad Approval

Commercial, fee-for-service, or large central laboratories may seek broad approval for an alternate testing procedure. Required comparison data are gathered as follows. For each category matrix (Public Drinking Water, Environmental Analyses/Water, etc.), five representative sample sources should be selected. Collect three samples from each selected source, in which the concentration ranges from the required detection limit (if applicable) to a level 20% greater than the regulatory limit. Samples may be spiked, if required. Divide each sample into eight aliquots. Analyze four aliquots by an approved method and four by the alternate method, thus producing 24 data points per sample source and 120 data points per category matrix.

Application and Approval Procedure

Applications for alternate testing procedures should include the following:

Name and address of requesting laboratory

ELAP ID number

Category and analyte of interest

Approved method used to produce comparison data

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Description of alternate test method, including

- Summary of method
- Applicable matrices
- Working range
- Reagents and their preparation
- Equipment specifications
- Procedure
- Calculations
- Precision
- Literature citations

Required comparative data including:

- Sample source(s)
- Dates and times collected
- Matrix
- Whether sample was spiked and how
- Analytical results of both the approved and proposed alternate method

Applications will be reviewed on technical merit and the data submitted will be statistically evaluated. If the proposed alternate testing procedure appears acceptable, arrangements will be made for an on-site demonstration of the method.

For the on-site demonstration, the laboratory will use the proposed alternate testing procedure to analyze one or more artificial samples supplied by a Program Laboratory Consultant. The artificial sample(s) will have a known concentration verified by a DOH laboratory and will be designed to challenge the alternate test procedure. An acceptable analytical result for the demonstration is one that lies within the interval formed by the known concentration plus or minus two times the published standard deviation for the approved method used to generate the comparison data.

After successful completion of the demonstration analysis, the Program will issue a letter granting approval for the alternate testing procedure.

The Program will consider other protocols to demonstrate that a proposed alternate test procedure is equivalent to an approved method in both precision and accuracy. Alternate protocols may be submitted to the Program office for evaluation.

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US EPA, Clean Water Act and Safe Drinking Water Act, Alternate Testing Procedures (ATP)

1. Waste Water / Non-Potable Water (40 CFR 136.4-136.6):

Per 40 CFR 136.4, any person may apply to the Regional Administrator in the Region where the discharge occurs for approval of an alternative test procedure. EPA Region 2 (Edison, NJ) is responsible for environmental protection of New York, New Jersey, Puerto Rico, and US Virgin Islands.

When the discharge for which an alternative test procedure is proposed and occurs within a State having a permit program approved pursuant to section 402 of the Act, the applicant shall submit his application to the Regional Administrator through the Director of the State agency having responsibility for issuance of NPDES permits within such State. NYS Department of Environmental Conservation, Division of Water, Bureau of Water Permits, administers the SPDES permit program.

In the case of “acceptable versions” of methods, (minor modifications to approved methods), a letter of approval will be issued by that office. This approval is regional.

Links to helpful sites:

<http://water.epa.gov/scitech/methods/cwa/atp/questions.cfm>
<http://www.dec.ny.gov/about/661.html>

2. Drinking Water (40 CFR 141.27):

EPA promulgates analytical methods for all regulated drinking water contaminants. A regulation for a particular contaminant will include one or more methods that must be used to determine that contaminant. Subsequently, the Agency may approve additional methods or modifications of EPA approved methods in another rule. EPA may also authorize the use of alternate analytical methods as provided in 40 CFR 141.27, "With the written permission of the State, concurred by the Administrator of the EPA, an alternate analytical technique may be employed. An alternate technique may be accepted only if it is substantially equivalent to the prescribed test in both precision and accuracy as it relates to the determination of compliance with any MCL."

Anyone can request that EPA approve a new method or modification of a method already approved by EPA, by submitting EPA-specified data and other information to EPA Office of Groundwater and Drinking Water (Cincinnati, OH). EPA

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will evaluate the material to determine whether the method or method modification meets EPA criteria. In the case of “acceptable versions” of methods, (minor modifications to approved methods), a letter of approval will be issued by that office. This approval is nationwide.