

**ENVIRONMENTAL LABORATORY APPROVAL PROGRAM
CERTIFICATION MANUAL**

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The Program (ELAP) 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.

Limited Approval

Limited approval may be granted only to a single facility or laboratory wishing to use an alternate testing procedure for samples originating within the facility's operation. The Program will work with the laboratory on its proposed study.

Chemistry

In general, ELAP requires the validation study to include samples run by the approved prep, if applicable, and determinative method and samples run by the lab-developed or user-defined prep, if applicable, and determinative method. Thirty (30) samples must be run per each method. Ten (10) at the low, 10 at mid and 10 at high end of calibration. This equates to sixty (60) samples in total, not including quality control samples, where applicable. The lab will compare the recoveries, QC limits, etc. for each of the methods.

The lab will also complete an initial demonstration of capability (DOC), as well as, a limit of detection (LOD) or method detection limit (MDL) study for the lab-developed prep, if applicable, and determinative method. The initial DOC and MDL study are matrix specific.

The initial DOC and MDL study criteria can be found in the latest version of the TNI Standard and 40 CFR 136, Appendix B to Part 136, respectively.

Microbiology

The laboratory will submit a Lab-Developed Standard Operating Procedure or Method (SOPM), including any extraction and/or prep methods utilized. The SOPM must include appropriate controls including a negative and positive control, a testing algorithm, and all expected reporting and reflex testing scenarios. Specimen reports for each scenario must be included. If any alterations from the manufacturer's instructions or reporting guidelines (including acceptable score) are instituted, submission of additional validation data supporting this change would be required.

All extraction methods that will be used in the laboratory must be included in the validation. At least thirty (30) isolates for each extraction method must be included as part of the total number of representative isolates required in the validation.

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If lab-developed or acquired databases will be used in addition to the library databases provided by the manufacturer, submit the criteria for isolate selection (how isolates will be selected for library addition), confirmation method (how the organism was identified), spectral quality and number of spectra required for library creation.

The information in this section was adopted from the Department's Clinical Laboratory Evaluation Program (CLEP).

Broad Approval

Commercial, fee-for-service, or large laboratories may seek broad approval for an alternate testing procedure. This alternate laboratory developed method would be approved regionally or nationally by the US EPA. See additional information related to wastewater and drinking water alternate testing procedures below.

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

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

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- 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 is acceptable, the Program will issue a letter granting approval for the alternate testing procedure. If it is not, the Program will request additional information.

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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 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.