

EPA's Alternative Test Method Approval Procedures – Stationary Source Program

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Ned Shappley Office of Air Quality Planning and Standards



Topics

Background and Approval Authority

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Alternative Test Method/Monitoring Approval Authority

- 40 CFR Parts 59, 60, 61, 63, and 65 all include authority for EPA Administrator to approve alternatives to test methods or monitoring procedures required under these parts
 - Test Methods: § 60.8(b), 61.18(h), 63.7(f), 59.104, 59.208, 65.158(a)(2)
 - Monitoring: § 60.13(l), 61.14(g), 63.8(f)
- Alternative methods must be ".....adequate for... determination of compliance...."

Why?

- A way to integrate innovative measurement techniques into the existing air rules for compliance purposes.
- Provide flexibility to use methods not incorporated into a given New Source Performance Standard (NSPS) or National Emission Standard for Hazardous Air Pollutant Standard (NESHAP).
- Provide an alternative to methods which may be biased due to interferences from a given source matrix.



Alternative Method Approval Authority Delegation

Who can approve alternatives?

- Administrator authority to approve major changes to <u>test methods</u> is delegated to OAQPS (MTG Group Leader)
- Administrator authority to approve major changes to <u>monitoring</u> is delegated to EPA Regional Offices
- Administrator authority to approve minor changes to test methods/monitoring is delegated to EPA Regional Offices
- Most states delegated authority for approval of minor changes (and sometimes intermediate)

§ 63.2 - Test Method vs. Monitoring

- A test method as a "validated procedure for sampling, preparing, and analyzing for an air pollutant specified in a relevant standard as the performance test procedure."
- Monitoring is comprehensive term that may include, but is not limited to Continuous Emission Monitoring Systems (CEMS), Opacity monitoring systems, CPMS or automatic continuing monitoring that is used for demonstrating compliance with an applicable regulation
- In actuality, the test procedure used to determine compliance could be a test method or a monitoring procedure



Minor/Intermediate/Major Alternative Test Method

Minor Change	Intermediate Change	Major Change
 Site-specific No national significance No effect on stringency of standard Made to accommodate site-specific constraints 	 Modification involves proven technology Site-specific but could have national significance Potential effect on stringency of standard, but demonstrated that will not 	 Modification is an entirely new method and/or involves unproven technology May be site-specific, but will usually set a national precedent Potentially broadly applicable
• Example: minor sampling changes within an existing test method	Example: changes within a prescribed analytical approach	Example: Replacement of a method used for a compliance test
Delegation: State/Region	Delegation: Region/OAQPS	• Delegation: Region/OAQPS

Approval Process for Major or Intermediate Change to Test Method

- Written request to OAQPS from an affected source or their agent
 - Name/Facility Location/Testing Requirements
 - Propose alternative with detailed procedure
 - Justification and Supporting Information
 - Appropriate cc:s
- EPA will acknowledge request
 - Review request, justification, and supporting information
 - Request additional info, if needed
- Issue approval/disapproval as official letter



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY RESEARCH TRIANGLE PARK, NC 27711

03/04/2021

OFFICE OF AIR QUALITY PLANNING AND STANDARDS

Mr. Mark Meyer Plant Manager Baxter Healthcare Corporation 1900 Highway 201 North Mountain Home, Arkansas 72653

Dear Mr. Meyer:

We are writing in response to your letter dated January 27, 2021, in which you request the approval of alternative testing procedures. The EPA's Office of Air Quality Planning and Standards (OAQPS) is the delegated authority for consideration of major alternatives to test methods and procedures as set forth in 40 CFR 63.7(f) under which your request must be addressed. Baxter Healthcare is requesting approval of the use of Method 20, 640 CFR Part 63, Appendix A), a Fourier Transform Infrared (FTIR) spectroscopy method, in lieu of Method 18 or Method 25A (40 CFR Part 60, Appendix A) for emission testing for ethylene oxide at your sterilization facility located in Mountain Home, Arkansas. Use of Method 18 or Method 25A is required to demonstrate compliance with the applicable emission limits under the National Emissions Standards for Hazardous Air Pollutants (NESHAP): Ethylene Oxide Emission Standards for Sterilization Facilities (40 CFR Part 63, Subpart O).

In your request, you state that Method 320 offers real-time quantification of ethylene oxide emissions and that the quality assurance and quality control (QA/QC) incorporated into Method 320, and the associated validation protocols, will ensure the quality of the ethylene oxide results. Furthermore, you explain that the modified Method 320 approach using the band-pass FTIR will allow for much more sensitive measurements than Method 18 or Method 25A, and adherence to the additional QA/QC recommended by the band-pass FTIR manufacturer would further ensure the data quality. Additionally, you note that EFA has approved similar site-specific requests from a number of sterilization facilities subject to Subpart O for commercial sterilizars.

Based on our understanding of FTIR principles, and recognition that the FTIR technique will offer better sensitivity and better time-resolution than the current measurement requirements in Subpart O, we are approving the Method 320 approaches described above as an alternative test method in lieu of Method 18 and Method 25A.

This approval is contingent on meeting the Method 320 QA/QC requirements and objectives, which include performing validation studies and dynamically spiking the compound of interest (i.e., ethylene oxide). Also, the following provisions must be met when the band-pass FTIR instrument modifications are applied. These provisions and this approval are specific to the Max Analytical StarBoost™ System.



Criteria for Approval of Major/Intermediate Changes to Test Methods

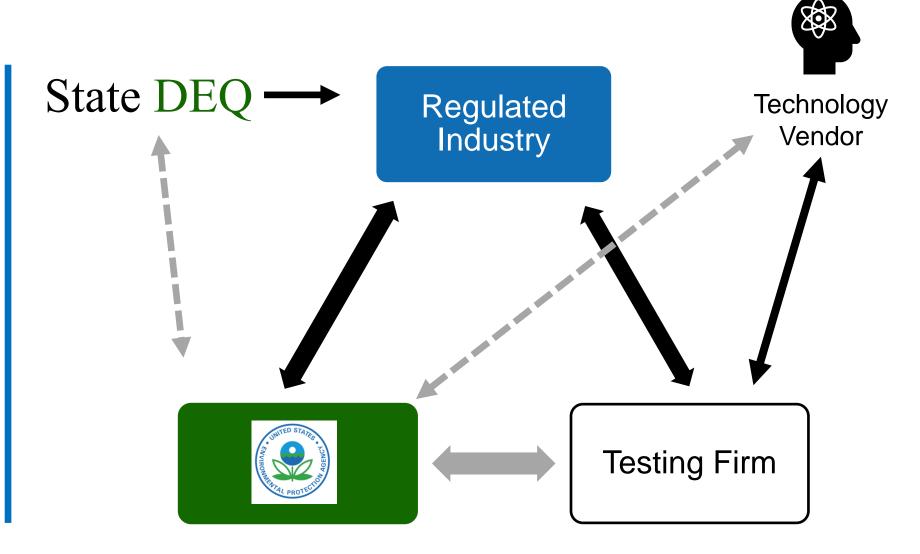
- Produce results adequate for the Administrator's determination of compliance
 - Any approved alternative test method will produce results adequate for the Administrator's determination of compliance (see 40 CFR Parts 60 and 63, Sections 60.2 and 63.2)
 - The change in the testing method or procedure will not affect the stringency of the applicable regulation.



Criteria for Approval of Major/Intermediate Changes to Test Methods

- Acceptance of an alternative test method shall be based on substantive technical support information
 - Detailed and documented test procedures
 - Direct comparisons (e.g., Method 301) with existing reference or compliance test methods
 - Precision and bias determinations (e.g., duplicate test trains and multiple test runs under a range of test conditions)
 - Chemical, engineering, and economical evaluations are also a consideration

Case Study 1
Commercial Sterilizers
and Emerging
Technology

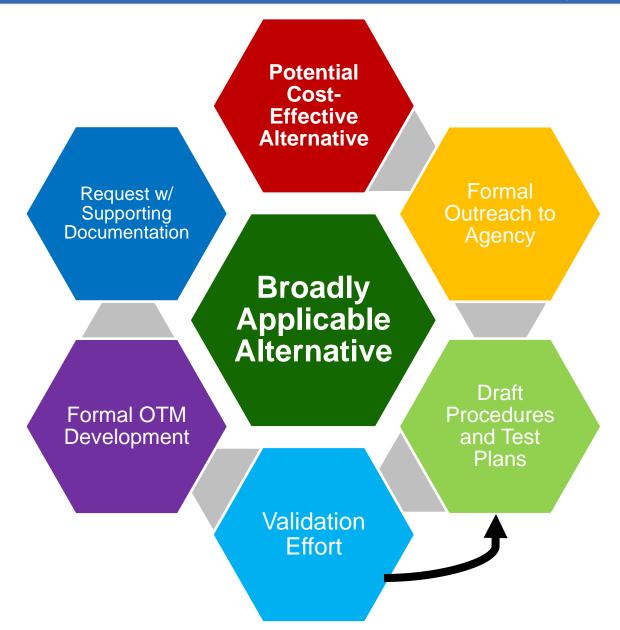




Broadly Applicable Alternative Test Method Approvals

- All alternative monitoring approvals and most alternative method approvals are site-specific
- In 2007, EPA clarified process to issue test method approvals that are broadly applicable
- Federal Register Notice lays out authority and procedures for approval (72 FR 4257, 1/30/2007)
- Over 140 Broad Approval Decisions
- Only OAQPS can issue broad approvals

Case Study 2 –
Other Test Method
Development and
Broadly Applicable
Alternatives





Resources

- Definitions of major/intermediate/minor changes to test methods and monitoring § 63.90(a)
- Delegation of approval authority to states § 63.91(g)
- Delegation of approval authority to Regions Directive 7-121
 http://intranet.epa.gov/ohr/rmpolicy/ads/delegat.htm (EPA Internal site)
- Guideline for alternative test method requests on EMC website: https://www.epa.gov/sites/production/files/2020-08/documents/gd-022.pdf
- Broad approvals for test method changes on EMC website: https://www.epa.gov/emc/broadly-applicable-approved-alternative-test-methods
- Federal Register Notice on alternative test method process and broad approvals on EMC website: https://www.epa.gov/emc/emc-recent-additions





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Air Emission Measurement Center (EMC)



February 2021: <u>GD 54 - EPA</u>
<u>Source Test Observation and</u>
Report Review Checklists

January 2021: Other Test
Method 45 (OTM-45)
Measurement of Selected
Per- and Polyfluorinated
Alkyl Substances from
Stationary Sources

October 2020: <u>Revisions</u>
to Test Methods and
Performance Specifications
for Air Emission Sources;
Final Rule - FR Notice
10/7/2020.

NOTICE: It has come to our attention that one of the two providers of audit samples has ceased manufacturing samples for the stationary source audit program. The general provisions to 40 CFR Parts 60 and 63 (see §60.8(g)(1) and §63.7(c)(2)(iii)(A)) require that the owner or operator obtain audit samples if the audit samples are "commercially available" and have defined "commercially available" as two or more independent accredited audit sample providers (AASP) to have blind audit samples available for purchase. Since there are no longer two providers, the requirement to obtain these audit samples is no longer in effect until such time as another independent AASP has audit samples available for purchase.

When there are two or more AASP with audit samples available for purchase, we will update this webpage with the name or names of the providers and audit sample(s) available for purchase. At that time, this information must be listed on the EMC website for 60 days before audits are required again.

The Air Emission Measurement Center (EMC) provides information on test methods for measuring pollutants from smokestacks and other industrial sources. This website compiles the test methods available for emission measurement. Contact EMC staff for technical assistance in the use and application of the methods.

Test Methods

- Promulgated Test Methods
- Proposed Test Methods
- Approved Alternative Methods
- Conditional Test Methods
- Other Test Methods

Monitoring

- Promulgated and Proposed
 Performance Specifications
- Quality Assurance Procedures
- Compliance Assurance Monitoring
- Continuous Emission Monitoring
- Metals and Mercury Emissions
 Monitoring

Technical Support

- <u>Technical Support for Quality</u>
 <u>Assurance</u>, <u>Audit Program</u>, <u>etc.</u>
- EMC Methods Support Directory

www.epa.gov/emc



Questions?

Ned Shappley
US EPA
919.541.7903
Shappley.ned@epa.gov