



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
RESEARCH TRIANGLE PARK, NC 27711

OFFICE OF  
AIR QUALITY PLANNING  
AND STANDARDS

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

03/04/2021

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 320 (40 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 EPA has approved similar site-specific requests from a number of sterilization facilities subject to Subpart O for commercial sterilizers.

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.

1. *The zero and direct system calibration check shall be performed using ultra high purity nitrogen (N<sub>2</sub>) or equivalent.*
2. *The calibration transfer standard (CTS) direct and system calibration checks of Method 320 shall be performed using a cylinder gas standard containing 10 - 50 ppmv methane in a balance of N<sub>2</sub>.*
3. *Calibration direct and analyte spike recovery shall be conducted using a cylinder gas standard containing a blend of ethylene oxide and ethane in N<sub>2</sub>. It is recommended the concentration of ethylene oxide and ethane be approximately 2 ppmv and 500 ppmv, respectively.*
4. *Calibration checks shall consist of at least 10 independent scans and shall be performed both pre- and post- test.*
5. *Spectra representative of the optical filter (i.e., band pass filter) shall be collected for each test and included in the instrumental method.*
6. *The initial validation study conducted under Section 13.0 of Method 320 shall consist of at least 12 independent spiked and 12 independent unspiked samples. Dilution of the ethylene oxide standard by the stack gas must not exceed 10% of the total stack gas flow. Spiked sample concentrations in the stack gas should be approximately twice the native ethylene oxide concentration or 10 times the detection limit.<sup>1</sup> Statistical evaluation of the results of this validation study shall follow the procedures found in Method 301.*
7. *Dynamic spiking shall consist of 3 independent spiked and 3 independent unspiked samples. Dilution of the ethylene oxide standard in the stack gas must not exceed 10% of the total stack gas flow. Spiked sample concentrations in the stack gas should be approximately twice the native ethylene concentration or 10 times the detection limit.*

It is reasonable that this alternative test method approval be broadly applicable to conducting performance testing required under §63.365 ethylene oxide sterilization facilities subject to 40 CFR 63, Subpart O. For this reason, we will post this letter as ALT-142 on our website at [www.epa.gov/emc/broadly-applicable-approved-alternative-test-methods](http://www.epa.gov/emc/broadly-applicable-approved-alternative-test-methods) for use by other interested parties. This alternative test method approval is effective from the date of this letter until EPA either issues related rulemaking to Subpart O or Method 320.

If you should have any questions or require further information regarding this approval, please contact Ned Shappley of my staff at 919-541-7903 or email at [shappley.ned@epa.gov](mailto:shappley.ned@epa.gov).

Sincerely,

  
Steffan M. Johnson, Group Leader  
Measurement Technology Group

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<sup>1</sup> Detection Limit for this purpose is defined as the MAU as defined in EPA Method 320 (40 CFR Part 63, Appendix A); or the MDC#2 or MDC #3 as defined in ASTM D6348-12.

cc: Sara Ayres, EPA/OECA  
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