Appendix B

40 CFR Part 53.1-53.23

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AUTHORITY: Sec. 301(a) of the Clean Air Act (42 U.S.C. sec. 1857g(a)), as amended by sec. 15(c)(2) of Pub. L. 91–604, 84 Stat. 1713, unless otherwise noted.

SOURCE: 40 FR 7049, Feb. 18, 1975, unless otherwise noted.

Subpart A—General Provisions

SOURCE: 62 FR 38784, July 18, 1997, unless otherwise noted.

§ 53.1 Definitions.

Terms used but not defined in this part shall have the meaning given them by the Act.

Act means the Clean Air Act (42 U.S.C. 1857–18571), as amended.

Additive and multiplicative bias means the linear regression intercept and slope of a linear plot fitted to corresponding candidate and reference method mean measurement data pairs.

Administrator means the Administrator of the Environmental Protection Agency (EPA) or his or her authorized representative.

Agency means the Environmental Protection Agency.

Applicant means a person or entity who submits an application for a Federal reference method or Federal equivalent method determination under §53.4, or a person or entity who assumes the rights and obligations of an applicant under §53.7. Applicant may include a manufacturer, distributor, supplier, or vendor.

Automated method or analyzer means a method for measuring concentrations of an ambient air pollutant in which sample collection (if necessary), analysis, and measurement are performed automatically by an instrument.

Candidate method means a method for measuring the concentration of an air pollutant in the ambient air for which an application for a Federal reference method determination or a Federal equivalent method determination is submitted in accordance with §53.4, or a method tested at the initiative of the Administrator in accordance with §53.7.

Class I equivalent method means an equivalent method for $PM_{2.5}$ or $PM_{10-2.5}$ which is based on a sampler that is very similar to the sampler specified for reference methods in appendix L or appendix O (as applicable) of part 50 of this chapter, with only minor deviations or modifications, as determined by EPA.

Class II equivalent method means an equivalent method for $PM_{2.5}$ or $PM_{10-2.5}$ that utilizes a $PM_{2.5}$ sampler or

$PM_{10-2.5}$ sampler in which integrated $PM_{2.5}$ samples or $PM_{10-2.5}$ samples are obtained from the atmosphere by filtration and subjected to a subsequent filter conditioning process followed by a gravimetric mass determination, but which is not a Class I equivalent method because of substantial deviations from the design specifications of the sampler specified for reference methods in appendix L or appendix O (as applicable) of part 50 of this chapter, as determined by EPA.

Class III equivalent method means an equivalent method for $PM_{2.5}$ or $PM_{10-2.5}$ that is an analyzer capable of providing $PM_{2.5}$ or $PM_{10-2.5}$ ambient air measurements representative of one-hour or less integrated $PM_{2.5}$ or $PM_{10-2.5}$ concentrations as well as 24-hour measurements determined as, or equivalent to, the mean of 24 one-hour consecutive measurements.

CO means carbon monoxide.

Collocated means two or more air samplers, analyzers, or other instruments that are operated simultaneously while located side by side, separated by a distance that is large enough to preclude the air sampled by any of the devices from being affected by any of the other devices, but small enough so that all devices obtain identical or uniform ambient air samples that are equally representative of the general area in which the group of devices is located.

Federal equivalent method (FEM) means a method for measuring the concentration of an air pollutant in the ambient air that has been designated as an equivalent method in accordance with this part; it does not include a method for which an equivalent method designation has been canceled in accordance with §53.11 or §53.16.

Federal reference method (FRM) means a method of sampling and analyzing the ambient air for an air pollutant that is specified as a reference method in an appendix to part 50 of this chapter, or a method that has been designated as a reference method in accordance with this part; it does not include a method for which a reference method designation has been canceled in accordance with §53.11 or §53.16.

ISO 9001-registered facility means a manufacturing facility that is either:

(1) An International Organization for Standardization (ISO) 9001-registered manufacturing facility, registered to the ISO 9001 standard (by the Registrar Accreditation Board (RAB) of the American Society for Quality Control (ASQC) in the United States), with registration maintained continuously; or

(2) A facility that can be demonstrated, on the basis of information submitted to the EPA, to be operated according to an EPA-approved and periodically audited quality system which meets, to the extent appropriate, the same general requirements as an ISO 9001-registered facility for the design and manufacture of designated Federal reference method and Federal equivalent method samplers and monitors.

ISO-certified auditor means an auditor who is either certified by the Registrar Accreditation Board (in the United States) as being qualified to audit quality systems using the requirements of recognized standards such as ISO 9001, or who, based on information submitted to the EPA, meets the same general requirements as provided for ISO-certified auditors.

Manual method means a method for measuring concentrations of an ambient air pollutant in which sample collection, analysis, or measurement, or some combination thereof, is performed manually. A method for PM_{10} or $PM_{2.5}$ which utilizes a sampler that requires manual preparation, loading, and weighing of filter samples is considered a manual method even though the sampler may be capable of automatically collecting a series of sequential samples.

NO means nitrogen oxide.

NO_2 means nitrogen dioxide.

NO_X means oxides of nitrogen and is defined as the sum of the concentrations of NO_2 and NO.

O_3 means ozone.

Operated simultaneously means that two or more collocated samplers or analyzers are operated concurrently with no significant difference in the start time, stop time, and duration of the sampling or measurement period.

Pb means lead.

PM means PM_{10}, PM_{10C}, $PM_{2.5}$, $PM_{10-2.5}$, or particulate matter of unspecified size range.

$PM_{2.5}$ means particulate matter with an aerodynamic diameter less than or equal to a nominal 2.5 micrometers as measured by a reference method based on appendix L of part 50 of this chapter and designated in accordance with part 53 of this chapter, by an equivalent method designated in accordance with part 53 of this chapter, or by an approved regional method designated in accordance with appendix C to this part.

PM_{10} means particulate matter with an aerodynamic diameter less than or equal to a nominal 10 micrometers as measured by a reference method based on appendix J of part 50 of this chapter and designated in accordance with this part or by an equivalent method designated in accordance with this part.

PM_{10C} means particulate matter with an aerodynamic diameter less than or equal to a nominal 10 micrometers as measured by a reference method based on appendix O of part 50 of this chapter and designated in accordance with this part or by an equivalent method designated in accordance with this part.

$PM_{10-2.5}$ means particulate matter with an aerodynamic diameter less than or equal to a nominal 10 micrometers and greater than a nominal 2.5 micrometers as measured by a reference method based on appendix O to part 50 of this chapter and designated in accordance with this part or by an equivalent method designated in accordance with this part.

$PM_{2.5}$ sampler means a device, associated with a manual method for measuring $PM_{2.5}$, designed to collect $PM_{2.5}$ from an ambient air sample, but lacking the ability to automatically analyze or measure the collected sample to determine the mass concentrations of $PM_{2.5}$ in the sampled air.

PM_{10} sampler means a device, associated with a manual method for measuring PM_{10}, designed to collect PM_{10} from an ambient air sample, but lacking the ability to automatically analyze or measure the collected sample to determine the mass concentrations of PM_{10} in the sampled air.

PM_{10C} sampler means a PM_{10} sampler that meets the special requirements for a PM_{10C} sampler that is part of a $PM_{10-2.5}$ reference method sampler, as specified in appendix O to part 50 of this chapter, or a PM_{10} sampler that is part of a $PM_{10-2.5}$ sampler that has been designated as an equivalent method for $PM_{10-2.5}$.

$PM_{10-2.5}$ sampler means a sampler, or a collocated pair of samplers, associated with a manual method for measuring $PM_{10-2.5}$ and designed to collect either $PM_{10-2.5}$ directly or PM_{10C} and $PM_{2.5}$ separately and simultaneously from concurrent ambient air samples, but lacking the ability to automatically analyze or measure the collected sample(s) to determine the mass concentrations of $PM_{10-2.5}$ in the sampled air.

Sequential samples for PM samplers means two or more PM samples for sequential (but not necessarily contiguous) time periods that are collected automatically by the same sampler without the need for intervening operator service.

SO_2 means sulfur dioxide.

Test analyzer means an analyzer subjected to testing as part of a candidate method in accordance with subparts B, C, D, E, or F of this part, as applicable.

Test sampler means a PM_{10} sampler, $PM_{2.5}$ sampler, or $PM_{10-2.5}$ sampler subjected to testing as part of a candidate method in accordance with subparts C, D, E, or F of this part.

Ultimate purchaser means the first person or entity who purchases a Federal reference method or a Federal equivalent method for purposes other than resale.

[71 FR 61271, Oct. 17, 2006]

§ 53.2 General requirements for a reference method determination.

The following general requirements for a Federal reference method (FRM) determination are summarized in table A–1 of this subpart.

(a) *Manual methods*—(1) *Sulfur dioxide (SO_2) and lead.* For measuring SO_2 and lead, appendices A and G of part 50 of this chapter specify unique manual FRM for measuring these pollutants. Except as provided in §53.16, other manual methods for SO_2 and lead will not be considered for FRM determinations under this part.

(2) *PM_{10}.* A FRM for measuring PM_{10} must be a manual method that meets all requirements specified in appendix

$PM_{2.5}$ means particulate matter with an aerodynamic diameter less than or equal to a nominal 2.5 micrometers as measured by a reference method based on appendix L of part 50 of this chapter and designated in accordance with part 53 of this chapter, by an equivalent method designated in accordance with part 53 of this chapter, or by an approved regional method designated in accordance with appendix C to this part.

PM_{10} means particulate matter with an aerodynamic diameter less than or equal to a nominal 10 micrometers as measured by a reference method based on appendix J of part 50 of this chapter and designated in accordance with this part or by an equivalent method designated in accordance with this part.

PM_{10C} means particulate matter with an aerodynamic diameter less than or equal to a nominal 10 micrometers as measured by a reference method based on appendix O of part 50 of this chapter and designated in accordance with this part or by an equivalent method designated in accordance with this part.

$PM_{10-2.5}$ means particulate matter with an aerodynamic diameter less than or equal to a nominal 10 micrometers and greater than a nominal 2.5 micrometers as measured by a reference method based on appendix O to part 50 of this chapter and designated in accordance with this part or by an equivalent method designated in accordance with this part.

$PM_{2.5}$ sampler means a device, associated with a manual method for measuring $PM_{2.5}$, designed to collect $PM_{2.5}$ from an ambient air sample, but lacking the ability to automatically analyze or measure the collected sample to determine the mass concentrations of $PM_{2.5}$ in the sampled air.

PM_{10} sampler means a device, associated with a manual method for measuring PM_{10}, designed to collect PM_{10} from an ambient air sample, but lacking the ability to automatically analyze or measure the collected sample to determine the mass concentrations of PM_{10} in the sampled air.

PM_{10C} sampler means a PM_{10} sampler that meets the special requirements for a PM_{10C} sampler that is part of a $PM_{10-2.5}$ reference method sampler, as specified in appendix O to part 50 of this chapter, or a PM_{10} sampler that is part of a $PM_{10-2.5}$ sampler that has been designated as an equivalent method for $PM_{10-2.5}$.

$PM_{10-2.5}$ sampler means a sampler, or a collocated pair of samplers, associated with a manual method for measuring $PM_{10-2.5}$ and designed to collect either $PM_{10-2.5}$ directly or PM_{10C} and $PM_{2.5}$ separately and simultaneously from concurrent ambient air samples, but lacking the ability to automatically analyze or measure the collected sample(s) to determine the mass concentrations of $PM_{10-2.5}$ in the sampled air.

Sequential samples for PM samplers means two or more PM samples for sequential (but not necessarily contiguous) time periods that are collected automatically by the same sampler without the need for intervening operator service.

SO_2 means sulfur dioxide.

Test analyzer means an analyzer subjected to testing as part of a candidate method in accordance with subparts B, C, D, E, or F of this part, as applicable.

Test sampler means a PM_{10} sampler, $PM_{2.5}$ sampler, or $PM_{10-2.5}$ sampler subjected to testing as part of a candidate method in accordance with subparts C, D, E, or F of this part.

Ultimate purchaser means the first person or entity who purchases a Federal reference method or a Federal equivalent method for purposes other than resale.

[71 FR 61271, Oct. 17, 2006]

§ 53.2 General requirements for a reference method determination.

The following general requirements for a Federal reference method (FRM) determination are summarized in table A–1 of this subpart.

(a) *Manual methods*—(1) *Sulfur dioxide (SO_2) and lead.* For measuring SO_2 and lead, appendices A and G of part 50 of this chapter specify unique manual FRM for measuring these pollutants. Except as provided in §53.16, other manual methods for SO_2 and lead will not be considered for FRM determinations under this part.

(2) *PM_{10}.* A FRM for measuring PM_{10} must be a manual method that meets all requirements specified in appendix

J of part 50 of this chapter and must include a PM_{10} sampler that has been shown in accordance with this part to meet all requirements specified in this subpart A and subpart D of this part.

(3) *$PM_{2.5}$.* A FRM for measuring $PM_{2.5}$ must be a manual method that meets all requirements specified in appendix L of part 50 of this chapter and must include a $PM_{2.5}$ sampler that has been shown in accordance with this part to meet the applicable requirements specified in this subpart A and subpart E of this part. Further, FRM samplers must be manufactured in an ISO 9001-registered facility, as defined in § 53.1 and as set forth in § 53.51.

(4) *$PM_{10-2.5}$.* A FRM for measuring $PM_{10-2.5}$ must be a manual method that meets all requirements specified in appendix O of part 50 of this chapter and must include PM_{10C} and $PM_{2.5}$ samplers that have been shown in accordance with this part to meet the applicable requirements specified in this subpart A and subpart E of this part. Further, $PM_{10-2.5}$ FRM samplers must be manufactured in an ISO 9001-registered facility, as defined in § 53.1 and as set forth in § 53.51.

(b) *Automated methods.* An automated FRM for measuring CO, O_3, or NO_2 must utilize the measurement principle and calibration procedure specified in the appropriate appendix to part 50 of this chapter and must have been shown in accordance with this part to meet the requirements specified in this subpart A and subpart B of this part.

[71 FR 61271, Oct. 17, 2006]

§ 53.3 General requirements for an equivalent method determination.

(a) *Manual methods.* A manual Federal equivalent method (FEM) must have been shown in accordance with this part to satisfy the applicable requirements specified in this subpart A and subpart C of this part. In addition, a PM sampler associated with a manual method for PM_{10}, $PM_{2.5}$, or $PM_{10-2.5}$ must have been shown in accordance with this part to satisfy the following additional requirements, as applicable:

(1) *PM_{10}.* A PM_{10} sampler associated with a manual method for PM_{10} must satisfy the requirements of subpart D of this part.

(2) *$PM_{2.5}$ Class I.* A $PM_{2.5}$ Class I FEM sampler must also satisfy all requirements of subpart E of this part, which shall include appropriate demonstration that each and every deviation or modification from the FRM sampler specifications does not significantly alter the performance of the sampler.

(3) *$PM_{2.5}$ Class II.* (i) A $PM_{2.5}$ Class II FEM sampler must also satisfy the applicable requirements of subparts E and F of this part or the alternative requirements in paragraph (a)(3)(ii) of this section.

(ii) In lieu of the applicable requirements specified for Class II $PM_{2.5}$ methods in subparts C and F of this part, a Class II $PM_{2.5}$ FEM sampler may alternatively meet the applicable requirements in paragraphs (b)(3)(i) through (iii) of this section and the testing, performance, and comparability requirements specified for Class III equivalent methods for $PM_{2.5}$ in subpart C of this part.

(4) *$PM_{10-2.5}$ Class I.* A $PM_{10-2.5}$ Class I FEM sampler must also satisfy the applicable requirements of subpart E of this part (there are no additional requirements specifically for Class I $PM_{10-2.5}$ methods in subpart C of this part).

(5) *$PM_{10-2.5}$ Class II.* (i) A $PM_{10-2.5}$ Class II FEM sampler must also satisfy the applicable requirements of subpart C of this part and also the applicable requirements and provisions of paragraphs (b)(3)(i) through (iii) of this section, or the alternative requirements in paragraph (a)(5)(ii) of this section.

(ii) In lieu of the applicable requirements specified for Class II $PM_{10-2.5}$ methods in subpart C of this part and in paragraph (b)(3)(iii) of this section, a Class II $PM_{10-2.5}$ FEM sampler may alternatively meet the applicable requirements in paragraphs (b)(3)(i) and (ii) of this section and the testing, performance, and comparability requirements specified for Class III FEMs for $PM_{10-2.5}$ in subpart C of this part.

(6) *ISO 9001.* All designated FEMs for $PM_{2.5}$ or $PM_{10-2.5}$ must be manufactured in an ISO 9001-registered facility, as defined in § 53.1 and as set forth in § 53.51.

(b) *Automated methods.* All types of automated FEMs must have been shown in accordance with this part to

J of part 50 of this chapter and must include a PM_{10} sampler that has been shown in accordance with this part to meet all requirements specified in this subpart A and subpart D of this part.

(3) *$PM_{2.5}$.* A FRM for measuring $PM_{2.5}$ must be a manual method that meets all requirements specified in appendix L of part 50 of this chapter and must include a $PM_{2.5}$ sampler that has been shown in accordance with this part to meet the applicable requirements specified in this subpart A and subpart E of this part. Further, FRM samplers must be manufactured in an ISO 9001-registered facility, as defined in § 53.1 and as set forth in § 53.51.

(4) *$PM_{10-2.5}$.* A FRM for measuring $PM_{10-2.5}$ must be a manual method that meets all requirements specified in appendix O of part 50 of this chapter and must include PM_{10C} and $PM_{2.5}$ samplers that have been shown in accordance with this part to meet the applicable requirements specified in this subpart A and subpart E of this part. Further, $PM_{10-2.5}$ FRM samplers must be manufactured in an ISO 9001-registered facility, as defined in § 53.1 and as set forth in § 53.51.

(b) *Automated methods.* An automated FRM for measuring CO, O_3, or NO_2 must utilize the measurement principle and calibration procedure specified in the appropriate appendix to part 50 of this chapter and must have been shown in accordance with this part to meet the requirements specified in this subpart A and subpart B of this part.

[71 FR 61271, Oct. 17, 2006]

§ 53.3 General requirements for an equivalent method determination.

(a) *Manual methods.* A manual Federal equivalent method (FEM) must have been shown in accordance with this part to satisfy the applicable requirements specified in this subpart A and subpart C of this part. In addition, a PM sampler associated with a manual method for PM_{10}, $PM_{2.5}$, or $PM_{10-2.5}$ must have been shown in accordance with this part to satisfy the following additional requirements, as applicable:

(1) *PM_{10}.* A PM_{10} sampler associated with a manual method for PM_{10} must satisfy the requirements of subpart D of this part.

(2) *$PM_{2.5}$ Class I.* A $PM_{2.5}$ Class I FEM sampler must also satisfy all requirements of subpart E of this part, which shall include appropriate demonstration that each and every deviation or modification from the FRM sampler specifications does not significantly alter the performance of the sampler.

(3) *$PM_{2.5}$ Class II.* (i) A $PM_{2.5}$ Class II FEM sampler must also satisfy the applicable requirements of subparts E and F of this part or the alternative requirements in paragraph (a)(3)(ii) of this section.

(ii) In lieu of the applicable requirements specified for Class II $PM_{2.5}$ methods in subparts C and F of this part, a Class II $PM_{2.5}$ FEM sampler may alternatively meet the applicable requirements in paragraphs (b)(3)(i) through (iii) of this section and the testing, performance, and comparability requirements specified for Class III equivalent methods for $PM_{2.5}$ in subpart C of this part.

(4) *$PM_{10-2.5}$ Class I.* A $PM_{10-2.5}$ Class I FEM sampler must also satisfy the applicable requirements of subpart E of this part (there are no additional requirements specifically for Class I $PM_{10-2.5}$ methods in subpart C of this part).

(5) *$PM_{10-2.5}$ Class II.* (i) A $PM_{10-2.5}$ Class II FEM sampler must also satisfy the applicable requirements of subpart C of this part and also the applicable requirements and provisions of paragraphs (b)(3)(i) through (iii) of this section, or the alternative requirements in paragraph (a)(5)(ii) of this section.

(ii) In lieu of the applicable requirements specified for Class II $PM_{10-2.5}$ methods in subpart C of this part and in paragraph (b)(3)(iii) of this section, a Class II $PM_{10-2.5}$ FEM sampler may alternatively meet the applicable requirements in paragraphs (b)(3)(i) and (ii) of this section and the testing, performance, and comparability requirements specified for Class III FEMs for $PM_{10-2.5}$ in subpart C of this part.

(6) *ISO 9001.* All designated FEMs for $PM_{2.5}$ or $PM_{10-2.5}$ must be manufactured in an ISO 9001-registered facility, as defined in § 53.1 and as set forth in § 53.51.

(b) *Automated methods.* All types of automated FEMs must have been shown in accordance with this part to

satisfy the applicable requirements specified in this subpart A and subpart C of this part. In addition, an automated FEM must have been shown in accordance with this part to satisfy the following additional requirements, as applicable:

(1) An automated FEM for pollutants other than PM must be shown in accordance with this part to satisfy the applicable requirements specified in subpart B of this part.

(2) An automated FEM for PM_{10} must be shown in accordance with this part to satisfy the applicable requirements of subpart D of this part.

(3) A Class III automated FEM for $PM_{2.5}$ or $PM_{10-2.5}$ must be shown in accordance with this part to satisfy the requirements in paragraphs (b)(3)(i) through (iii) of this section, as applicable.

(i) All pertinent requirements of 40 CFR part 50, appendix L, including sampling height, range of operational conditions, ambient temperature and pressure sensors, outdoor enclosure, electrical power supply, control devices and operator interfaces, data output port, operation/instruction manual, data output and reporting requirements, and any other requirements that would be reasonably applicable to the method, unless adequate (as determined by the Administrator) rationale can be provided to support the contention that a particular requirement does not or should not be applicable to the particular candidate method.

(ii) All pertinent tests and requirements of subpart E of this part, such as instrument manufacturing quality control; final assembly and inspection; manufacturer's audit checklists; leak checks; flow rate accuracy, measurement accuracy, and flow rate cut-off; operation following power interruptions; effect of variations in power line voltage, ambient temperature and ambient pressure; and aerosol transport; unless adequate (as determined by the Administrator) rationale can be provided to support the contention that a particular test or requirement does not or should not be applicable to the particular candidate method.

(iii) Candidate methods shall be tested for and meet any performance requirements, such as inlet aspiration, particle size separation or selection characteristics, change in particle separation or selection characteristics due to loading or other operational conditions, or effects of surface exposure and particle volatility, determined by the Administrator to be necessary based on the nature, design, and specifics of the candidate method and the extent to which it deviates from the design and performance characteristics of the reference method. These performance requirements and the specific test(s) for them will be determined by Administrator for each specific candidate method or type of candidate method and may be similar to or based on corresponding tests and requirements set forth in subpart F of this part or may be special requirements and tests tailored by the Administrator to the specific nature, design, and operational characteristics of the candidate method. For example, a candidate method with an inlet design deviating substantially from the design of the reference method inlet would likely be subject to an inlet aspiration test similar to that set forth in § 53.63. Similarly, a candidate method having an inertial fractionation system substantially different from that of the reference method would likely be subject to a static fractionation test and a loading test similar to those set forth in §§ 53.64 and 53.65, respectively. A candidate method with more extensive or profound deviations from the design and function of the reference method may be subject to other tests, full wind-tunnel tests similar to those described in § 53.62, or to special tests adapted or developed individually to accommodate the specific type of measurement or operation of the candidate method.

(4) All designated FEM for $PM_{2.5}$ or $PM_{10-2.5}$ must be manufactured in an ISO 9001-registered facility, as defined in § 53.1 and as set forth in § 53.51.

[71 FR 61271, Oct. 17, 2006]

§ 53.4 Applications for reference or equivalent method determinations.

(a) Applications for FRM or FEM determinations shall be submitted in duplicate to: Director, National Exposure Research Laboratory, Reference and Equivalent Method Program (MD–D205–03), U.S. Environmental Protection

satisfy the applicable requirements specified in this subpart A and subpart C of this part. In addition, an automated FEM must have been shown in accordance with this part to satisfy the following additional requirements, as applicable:

(1) An automated FEM for pollutants other than PM must be shown in accordance with this part to satisfy the applicable requirements specified in subpart B of this part.

(2) An automated FEM for PM_{10} must be shown in accordance with this part to satisfy the applicable requirements of subpart D of this part.

(3) A Class III automated FEM for $PM_{2.5}$ or $PM_{10-2.5}$ must be shown in accordance with this part to satisfy the requirements in paragraphs (b)(3)(i) through (iii) of this section, as applicable.

(i) All pertinent requirements of 40 CFR part 50, appendix L, including sampling height, range of operational conditions, ambient temperature and pressure sensors, outdoor enclosure, electrical power supply, control devices and operator interfaces, data output port, operation/instruction manual, data output and reporting requirements, and any other requirements that would be reasonably applicable to the method, unless adequate (as determined by the Administrator) rationale can be provided to support the contention that a particular requirement does not or should not be applicable to the particular candidate method.

(ii) All pertinent tests and requirements of subpart E of this part, such as instrument manufacturing quality control; final assembly and inspection; manufacturer's audit checklists; leak checks; flow rate accuracy, measurement accuracy, and flow rate cut-off; operation following power interruptions; effect of variations in power line voltage, ambient temperature and ambient pressure; and aerosol transport; unless adequate (as determined by the Administrator) rationale can be provided to support the contention that a particular test or requirement does not or should not be applicable to the particular candidate method.

(iii) Candidate methods shall be tested for and meet any performance requirements, such as inlet aspiration, particle size separation or selection characteristics, change in particle separation or selection characteristics due to loading or other operational conditions, or effects of surface exposure and particle volatility, determined by the Administrator to be necessary based on the nature, design, and specifics of the candidate method and the extent to which it deviates from the design and performance characteristics of the reference method. These performance requirements and the specific test(s) for them will be determined by Administrator for each specific candidate method or type of candidate method and may be similar to or based on corresponding tests and requirements set forth in subpart F of this part or may be special requirements and tests tailored by the Administrator to the specific nature, design, and operational characteristics of the candidate method. For example, a candidate method with an inlet design deviating substantially from the design of the reference method inlet would likely be subject to an inlet aspiration test similar to that set forth in § 53.63. Similarly, a candidate method having an inertial fractionation system substantially different from that of the reference method would likely be subject to a static fractionation test and a loading test similar to those set forth in §§ 53.64 and 53.65, respectively. A candidate method with more extensive or profound deviations from the design and function of the reference method may be subject to other tests, full wind-tunnel tests similar to those described in § 53.62, or to special tests adapted or developed individually to accommodate the specific type of measurement or operation of the candidate method.

(4) All designated FEM for $PM_{2.5}$ or $PM_{10-2.5}$ must be manufactured in an ISO 9001-registered facility, as defined in § 53.1 and as set forth in § 53.51.

[71 FR 61271, Oct. 17, 2006]

§ 53.4 Applications for reference or equivalent method determinations.

(a) Applications for FRM or FEM determinations shall be submitted in duplicate to: Director, National Exposure Research Laboratory, Reference and Equivalent Method Program (MD–D205–03), U.S. Environmental Protection

Agency, Research Triangle Park, North Carolina 27711 (Commercial delivery address: 4930 Old Page Road, Durham, North Carolina 27703).

(b) Each application shall be signed by an authorized representative of the applicant, shall be marked in accordance with §53.15 (if applicable), and shall contain the following:

(1) A clear identification of the candidate method, which will distinguish it from all other methods such that the method may be referred to unambiguously. This identification must consist of a unique series of descriptors such as title, identification number, analyte, measurement principle, manufacturer, brand, model, etc., as necessary to distinguish the method from all other methods or method variations, both within and outside the applicant's organization.

(2) A detailed description of the candidate method, including but not limited to the following: The measurement principle, manufacturer, name, model number and other forms of identification, a list of the significant components, schematic diagrams, design drawings, and a detailed description of the apparatus and measurement procedures. Drawings and descriptions pertaining to candidate methods or samplers for $PM_{2.5}$ or $PM_{10-2.5}$ must meet all applicable requirements in reference 1 of appendix A of this subpart, using appropriate graphical, nomenclature, and mathematical conventions such as those specified in references 3 and 4 of appendix A of this subpart.

(3) A copy of a comprehensive operation or instruction manual providing a complete and detailed description of the operational, maintenance, and calibration procedures prescribed for field use of the candidate method and all instruments utilized as part of that method (under §53.9(a)).

(i) As a minimum this manual shall include:

(A) Description of the method and associated instruments.

(B) Explanation of all indicators, information displays, and controls.

(C) Complete setup and installation instructions, including any additional materials or supplies required.

(D) Details of all initial or startup checks or acceptance tests and any auxiliary equipment required.

(E) Complete operational instructions.

(F) Calibration procedures and descriptions of required calibration equipment and standards.

(G) Instructions for verification of correct or proper operation.

(H) Trouble-shooting guidance and suggested corrective actions for abnormal operation.

(I) Required or recommended routine, periodic, and preventative maintenance and maintenance schedules.

(J) Any calculations required to derive final concentration measurements.

(K) Appropriate references to any applicable appendix of part 50 of this chapter; reference 6 of appendix A of this subpart; and any other pertinent guidelines.

(ii) The manual shall also include adequate warning of potential safety hazards that may result from normal use and/or malfunction of the method and a description of necessary safety precautions. (See §53.9(b).) However, the previous requirement shall not be interpreted to constitute or imply any warranty of safety of the method by EPA. For samplers and automated methods, the manual shall include a clear description of all procedures pertaining to installation, operation, preventive maintenance, and trouble-shooting and shall also include parts identification diagrams. The manual may be used to satisfy the requirements of paragraphs (b)(1) and (2) of this section to the extent that it includes information necessary to meet those requirements.

(4) A statement that the candidate method has been tested in accordance with the procedures described in subparts B, C, D, E, and/or F of this part, as applicable.

(5) Descriptions of test facilities and test configurations, test data, records, calculations, and test results as specified in subparts B, C, D, E, and/or F of this part, as applicable. Data must be sufficiently detailed to meet appropriate principles described in part B, sections 3.3.1 (paragraph 1) and 3.5.1 and part C, section 4.6 of reference 2 of

appendix A of this subpart; and in paragraphs 1 through 3 of section 4.8 (Records) of reference 5 of appendix A of this subpart. Salient requirements from these references include the following:

(i) The applicant shall maintain and include records of all relevant measuring equipment, including the make, type, and serial number or other identification, and most recent calibration with identification of the measurement standard or standards used and their National Institute of Standards and Technology (NIST) traceability. These records shall demonstrate the measurement capability of each item of measuring equipment used for the application and include a description and justification (if needed) of the measurement setup or configuration in which it was used for the tests. The calibration results shall be recorded and identified in sufficient detail so that the traceability of all measurements can be determined and any measurement could be reproduced under conditions close to the original conditions, if necessary, to resolve any anomalies.

(ii) Test data shall be collected according to the standards of good practice and by qualified personnel. Test anomalies or irregularities shall be documented and explained or justified. The impact and significance of the deviation on test results and conclusions shall be determined. Data collected shall correspond directly to the specified test requirement and be labeled and identified clearly so that results can be verified and evaluated against the test requirement. Calculations or data manipulations must be explained in detail so that they can be verified.

(6) A statement that the method, analyzer, or sampler tested in accordance with this part is representative of the candidate method described in the application.

(c) For candidate automated methods and candidate manual methods for PM_{10}, $PM_{2.5}$, and $PM_{10-2.5}$ the application shall also contain the following:

(1) A detailed description of the quality system that will be utilized, if the candidate method is designated as a reference or equivalent method, to ensure that all analyzers or samplers offered for sale under that designation will have essentially the same performance characteristics as the analyzer(s) or samplers tested in accordance with this part. In addition, the quality system requirements for candidate methods for $PM_{2.5}$ and $PM_{10-2.5}$ must be described in sufficient detail, based on the elements described in section 4 of reference 1 (Quality System Requirements) of appendix A of this subpart. Further clarification is provided in the following sections of reference 2 of appendix A of this subpart: part A (Management Systems), sections 2.2 (Quality System and Description), 2.3 (Personnel Qualification and Training), 2.4 (Procurement of Items and Services), 2.5 (Documents and Records), and 2.7 (Planning); part B (Collection and Evaluation of Environmental Data), sections 3.1 (Planning and Scoping), 3.2 (Design of Data Collection Operations), and 3.5 (Assessment and Verification of Data Usability); and part C (Operation of Environmental Technology), sections 4.1 (Planning), 4.2 (Design of Systems), and 4.4 (Operation of Systems).

(2) A description of the durability characteristics of such analyzers or samplers (see § 53.9(c)). For methods for $PM_{2.5}$ and $PM_{10-2.5}$ the warranty program must ensure that the required specifications (see Table A–1 to this subpart) will be met throughout the warranty period and that the applicant accepts responsibility and liability for ensuring this conformance or for resolving any nonconformities, including all necessary components of the system, regardless of the original manufacturer. The warranty program must be described in sufficient detail to meet appropriate provisions of the ANSI/ASQC and ISO 9001 standards (references 1 and 2 in appendix A of this subpart) for controlling conformance and resolving nonconformance, particularly sections 4.12, 4.13, and 4.14 of reference 1 in appendix A of this subpart.

(i) Section 4.12 in reference 1 of appendix A of this subpart requires the manufacturer to establish and maintain a system of procedures for identifying and maintaining the identification of inspection and test status throughout all phases of manufacturing to ensure that only instruments

that have passed the required inspections and tests are released for sale.

(ii) Section 4.13 in reference 1 of appendix A of this subpart requires documented procedures for control of nonconforming product, including review and acceptable alternatives for disposition; section 4.14 in reference 1 of appendix A of this subpart requires documented procedures for implementing corrective (4.14.2) and preventive (4.14.3) action to eliminate the causes of actual or potential nonconformities. In particular, section 4.14.3 requires that potential causes of nonconformities be eliminated by using information such as service reports and customer complaints to eliminate potential causes of nonconformities.

(d) For candidate reference or equivalent methods for $PM_{2.5}$ and Class II or Class III equivalent methods for $PM_{10-2.5}$, the applicant, if requested by EPA, shall provide to EPA for test purposes one sampler or analyzer that is representative of the sampler or analyzer associated with the candidate method. The sampler or analyzer shall be shipped FOB destination to Director, National Exposure Research Laboratory, Reference and Equivalent Method Program (MD-D205–03), U.S. Environmental Protection Agency, 4930 Old Page Road, Durham, North Carolina 27703, scheduled to arrive concurrent with or within 30 days of the arrival of the other application materials. This analyzer or sampler may be subjected to various tests that EPA determines to be necessary or appropriate under § 53.5(f), and such tests may include special tests not described in this part. If the instrument submitted under this paragraph malfunctions, becomes inoperative, or fails to perform as represented in the application before the necessary EPA testing is completed, the applicant shall be afforded an opportunity to repair or replace the device at no cost to EPA. Upon completion of EPA testing, the analyzer or sampler submitted under this paragraph shall be repacked by EPA for return shipment to the applicant, using the same packing materials used for shipping the instrument to EPA unless alternative packing is provided by the applicant. Arrangements for, and the cost of, return shipment shall be the responsibility of the applicant. The EPA does not warrant or assume any liability for the condition of the analyzer or sampler upon return to the applicant.

[71 FR 61271, Oct. 17, 2006]

§ 53.5 Processing of applications.

After receiving an application for a FRM or FEM determination, the Administrator will, within 120 calendar days after receipt of the application, take one or more of the following actions:

(a) Send notice to the applicant, in accordance with § 53.8, that the candidate method has been determined to be a reference or equivalent method.

(b) Send notice to the applicant that the application has been rejected, including a statement of reasons for rejection.

(c) Send notice to the applicant that additional information must be submitted before a determination can be made and specify the additional information that is needed (in such cases, the 120-day period shall commence upon receipt of the additional information).

(d) Send notice to the applicant that additional test data must be submitted and specify what tests are necessary and how the tests shall be interpreted (in such cases, the 120-day period shall commence upon receipt of the additional test data).

(e) Send notice to the applicant that the application has been found to be substantially deficient or incomplete and cannot be processed until additional information is submitted to complete the application and specify the general areas of substantial deficiency.

(f) Send notice to the applicant that additional tests will be conducted by the Administrator, specifying the nature of and reasons for the additional tests and the estimated time required (in such cases, the 120-day period shall commence 1 calendar day after the additional tests have been completed).

[71 FR 61271, Oct. 17, 2006]

that have passed the required inspections and tests are released for sale.

(ii) Section 4.13 in reference 1 of appendix A of this subpart requires documented procedures for control of nonconforming product, including review and acceptable alternatives for disposition; section 4.14 in reference 1 of appendix A of this subpart requires documented procedures for implementing corrective (4.14.2) and preventive (4.14.3) action to eliminate the causes of actual or potential nonconformities. In particular, section 4.14.3 requires that potential causes of nonconformities be eliminated by using information such as service reports and customer complaints to eliminate potential causes of nonconformities.

(d) For candidate reference or equivalent methods for $PM_{2.5}$ and Class II or Class III equivalent methods for $PM_{10-2.5}$, the applicant, if requested by EPA, shall provide to EPA for test purposes one sampler or analyzer that is representative of the sampler or analyzer associated with the candidate method. The sampler or analyzer shall be shipped FOB destination to Director, National Exposure Research Laboratory, Reference and Equivalent Method Program (MD-D205–03), U.S. Environmental Protection Agency, 4930 Old Page Road, Durham, North Carolina 27703, scheduled to arrive concurrent with or within 30 days of the arrival of the other application materials. This analyzer or sampler may be subjected to various tests that EPA determines to be necessary or appropriate under § 53.5(f), and such tests may include special tests not described in this part. If the instrument submitted under this paragraph malfunctions, becomes inoperative, or fails to perform as represented in the application before the necessary EPA testing is completed, the applicant shall be afforded an opportunity to repair or replace the device at no cost to EPA. Upon completion of EPA testing, the analyzer or sampler submitted under this paragraph shall be repacked by EPA for return shipment to the applicant, using the same packing materials used for shipping the instrument to EPA unless alternative packing is provided by the applicant. Arrangements for, and the cost of, return shipment shall be the responsibility of the applicant. The EPA does not warrant or assume any liability for the condition of the analyzer or sampler upon return to the applicant.

[71 FR 61271, Oct. 17, 2006]

§ 53.5 Processing of applications.

After receiving an application for a FRM or FEM determination, the Administrator will, within 120 calendar days after receipt of the application, take one or more of the following actions:

(a) Send notice to the applicant, in accordance with § 53.8, that the candidate method has been determined to be a reference or equivalent method.

(b) Send notice to the applicant that the application has been rejected, including a statement of reasons for rejection.

(c) Send notice to the applicant that additional information must be submitted before a determination can be made and specify the additional information that is needed (in such cases, the 120-day period shall commence upon receipt of the additional information).

(d) Send notice to the applicant that additional test data must be submitted and specify what tests are necessary and how the tests shall be interpreted (in such cases, the 120-day period shall commence upon receipt of the additional test data).

(e) Send notice to the applicant that the application has been found to be substantially deficient or incomplete and cannot be processed until additional information is submitted to complete the application and specify the general areas of substantial deficiency.

(f) Send notice to the applicant that additional tests will be conducted by the Administrator, specifying the nature of and reasons for the additional tests and the estimated time required (in such cases, the 120-day period shall commence 1 calendar day after the additional tests have been completed).

[71 FR 61271, Oct. 17, 2006]

§ 53.6 Right to witness conduct of tests.

(a) Submission of an application for a reference or equivalent method determination shall constitute consent for the Administrator or the Administrator's authorized representative, upon presentation of appropriate credentials, to witness or observe any tests required by this part in connection with the application or in connection with any modification or intended modification of the method by the applicant.

(b) The applicant shall have the right to witness or observe any test conducted by the Administrator in connection with the application or in connection with any modification or intended modification of the method by the applicant.

(c) Any tests by either party that are to be witnessed or observed by the other party shall be conducted at a time and place mutually agreeable to both parties.

§ 53.7 Testing of methods at the initiative of the Administrator.

(a) In the absence of an application for a reference or equivalent method determination, the Administrator may conduct the tests required by this part for such a determination, may compile such other information as may be necessary in the judgment of the Administrator to make such a determination, and on the basis of the tests and information may determine that a method satisfies applicable requirements of this part.

(b) In the absence of an application requesting the Administrator to consider revising an appendix to part 50 of this chapter in accordance with § 53.16, the Administrator may conduct such tests and compile such information as may be necessary in the Administrator's judgment to make a determination under § 53.16(d) and on the basis of the tests and information make such a determination.

(c) If a method tested in accordance with this section is designated as a reference or equivalent method in accordance with § 53.8 or is specified or designated as a reference method in accordance with § 53.16, any person or entity who offers the method for sale as a reference or equivalent method thereafter shall assume the rights and obligations of an applicant for purposes of this part, with the exception of those pertaining to submission and processing of applications.

§ 53.8 Designation of reference and equivalent methods.

(a) A candidate method determined by the Administrator to satisfy the applicable requirements of this part shall be designated as a FRM or FEM (as applicable) by and upon publication of a notice of the designation in the FEDERAL REGISTER.

(b) Upon designation, a notice indicating that the method has been designated as a FRM or FEM shall be sent to the applicant.

(c) The Administrator will maintain a current list of methods designated as FRM or FEM in accordance with this part and will send a copy of the list to any person or group upon request. A copy of the list will be available for inspection or copying at EPA Regional Offices and may be available via the Internet or other sources.

[71 FR 61276, Oct. 17, 2006]

§ 53.9 Conditions of designation.

Designation of a candidate method as a FRM or FEM shall be conditioned to the applicant's compliance with the following requirements. Failure to comply with any of the requirements shall constitute a ground for cancellation of the designation in accordance with § 53.11.

(a) Any method offered for sale as a FRM or FEM shall be accompanied by a copy of the manual referred to in § 53.4(b)(3) when delivered to any ultimate purchaser, and an electronic copy of the manual suitable for incorporating into user-specific standard operating procedure documents shall be readily available to any users.

(b) Any method offered for sale as a FRM or FEM shall generate no unreasonable hazard to operators or to the environment during normal use or when malfunctioning.

(c) Any analyzer, PM_{10} sampler, $PM_{2.5}$ sampler, or $PM_{10-2.5}$ sampler offered for sale as part of a FRM or FEM shall function within the limits of the performance specifications referred to in

§ 53.6 Right to witness conduct of tests.

(a) Submission of an application for a reference or equivalent method determination shall constitute consent for the Administrator or the Administrator's authorized representative, upon presentation of appropriate credentials, to witness or observe any tests required by this part in connection with the application or in connection with any modification or intended modification of the method by the applicant.

(b) The applicant shall have the right to witness or observe any test conducted by the Administrator in connection with the application or in connection with any modification or intended modification of the method by the applicant.

(c) Any tests by either party that are to be witnessed or observed by the other party shall be conducted at a time and place mutually agreeable to both parties.

§ 53.7 Testing of methods at the initiative of the Administrator.

(a) In the absence of an application for a reference or equivalent method determination, the Administrator may conduct the tests required by this part for such a determination, may compile such other information as may be necessary in the judgment of the Administrator to make such a determination, and on the basis of the tests and information may determine that a method satisfies applicable requirements of this part.

(b) In the absence of an application requesting the Administrator to consider revising an appendix to part 50 of this chapter in accordance with § 53.16, the Administrator may conduct such tests and compile such information as may be necessary in the Administrator's judgment to make a determination under § 53.16(d) and on the basis of the tests and information make such a determination.

(c) If a method tested in accordance with this section is designated as a reference or equivalent method in accordance with § 53.8 or is specified or designated as a reference method in accordance with § 53.16, any person or entity who offers the method for sale as a reference or equivalent method thereafter shall assume the rights and obligations of an applicant for purposes of this part, with the exception of those pertaining to submission and processing of applications.

§ 53.8 Designation of reference and equivalent methods.

(a) A candidate method determined by the Administrator to satisfy the applicable requirements of this part shall be designated as a FRM or FEM (as applicable) by and upon publication of a notice of the designation in the FEDERAL REGISTER.

(b) Upon designation, a notice indicating that the method has been designated as a FRM or FEM shall be sent to the applicant.

(c) The Administrator will maintain a current list of methods designated as FRM or FEM in accordance with this part and will send a copy of the list to any person or group upon request. A copy of the list will be available for inspection or copying at EPA Regional Offices and may be available via the Internet or other sources.

[71 FR 61276, Oct. 17, 2006]

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(a) Any method offered for sale as a FRM or FEM shall be accompanied by a copy of the manual referred to in § 53.4(b)(3) when delivered to any ultimate purchaser, and an electronic copy of the manual suitable for incorporating into user-specific standard operating procedure documents shall be readily available to any users.

(b) Any method offered for sale as a FRM or FEM shall generate no unreasonable hazard to operators or to the environment during normal use or when malfunctioning.

(c) Any analyzer, PM_{10} sampler, $PM_{2.5}$ sampler, or $PM_{10-2.5}$ sampler offered for sale as part of a FRM or FEM shall function within the limits of the performance specifications referred to in

§ 53.6 Right to witness conduct of tests.

(a) Submission of an application for a reference or equivalent method determination shall constitute consent for the Administrator or the Administrator's authorized representative, upon presentation of appropriate credentials, to witness or observe any tests required by this part in connection with the application or in connection with any modification or intended modification of the method by the applicant.

(b) The applicant shall have the right to witness or observe any test conducted by the Administrator in connection with the application or in connection with any modification or intended modification of the method by the applicant.

(c) Any tests by either party that are to be witnessed or observed by the other party shall be conducted at a time and place mutually agreeable to both parties.

§ 53.7 Testing of methods at the initiative of the Administrator.

(a) In the absence of an application for a reference or equivalent method determination, the Administrator may conduct the tests required by this part for such a determination, may compile such other information as may be necessary in the judgment of the Administrator to make such a determination, and on the basis of the tests and information may determine that a method satisfies applicable requirements of this part.

(b) In the absence of an application requesting the Administrator to consider revising an appendix to part 50 of this chapter in accordance with § 53.16, the Administrator may conduct such tests and compile such information as may be necessary in the Administrator's judgment to make a determination under § 53.16(d) and on the basis of the tests and information make such a determination.

(c) If a method tested in accordance with this section is designated as a reference or equivalent method in accordance with § 53.8 or is specified or designated as a reference method in accordance with § 53.16, any person or entity who offers the method for sale as a reference or equivalent method thereafter shall assume the rights and obligations of an applicant for purposes of this part, with the exception of those pertaining to submission and processing of applications.

§ 53.8 Designation of reference and equivalent methods.

(a) A candidate method determined by the Administrator to satisfy the applicable requirements of this part shall be designated as a FRM or FEM (as applicable) by and upon publication of a notice of the designation in the FEDERAL REGISTER.

(b) Upon designation, a notice indicating that the method has been designated as a FRM or FEM shall be sent to the applicant.

(c) The Administrator will maintain a current list of methods designated as FRM or FEM in accordance with this part and will send a copy of the list to any person or group upon request. A copy of the list will be available for inspection or copying at EPA Regional Offices and may be available via the Internet or other sources.

[71 FR 61276, Oct. 17, 2006]

§ 53.9 Conditions of designation.

Designation of a candidate method as a FRM or FEM shall be conditioned to the applicant's compliance with the following requirements. Failure to comply with any of the requirements shall constitute a ground for cancellation of the designation in accordance with § 53.11.

(a) Any method offered for sale as a FRM or FEM shall be accompanied by a copy of the manual referred to in § 53.4(b)(3) when delivered to any ultimate purchaser, and an electronic copy of the manual suitable for incorporating into user-specific standard operating procedure documents shall be readily available to any users.

(b) Any method offered for sale as a FRM or FEM shall generate no unreasonable hazard to operators or to the environment during normal use or when malfunctioning.

(c) Any analyzer, PM_{10} sampler, $PM_{2.5}$ sampler, or $PM_{10-2.5}$ sampler offered for sale as part of a FRM or FEM shall function within the limits of the performance specifications referred to in

§ 53.6 Right to witness conduct of tests.

(a) Submission of an application for a reference or equivalent method determination shall constitute consent for the Administrator or the Administrator's authorized representative, upon presentation of appropriate credentials, to witness or observe any tests required by this part in connection with the application or in connection with any modification or intended modification of the method by the applicant.

(b) The applicant shall have the right to witness or observe any test conducted by the Administrator in connection with the application or in connection with any modification or intended modification of the method by the applicant.

(c) Any tests by either party that are to be witnessed or observed by the other party shall be conducted at a time and place mutually agreeable to both parties.

§ 53.7 Testing of methods at the initiative of the Administrator.

(a) In the absence of an application for a reference or equivalent method determination, the Administrator may conduct the tests required by this part for such a determination, may compile such other information as may be necessary in the judgment of the Administrator to make such a determination, and on the basis of the tests and information may determine that a method satisfies applicable requirements of this part.

(b) In the absence of an application requesting the Administrator to consider revising an appendix to part 50 of this chapter in accordance with § 53.16, the Administrator may conduct such tests and compile such information as may be necessary in the Administrator's judgment to make a determination under § 53.16(d) and on the basis of the tests and information make such a determination.

(c) If a method tested in accordance with this section is designated as a reference or equivalent method in accordance with § 53.8 or is specified or designated as a reference method in accordance with § 53.16, any person or entity who offers the method for sale as a reference or equivalent method thereafter shall assume the rights and obligations of an applicant for purposes of this part, with the exception of those pertaining to submission and processing of applications.

§ 53.8 Designation of reference and equivalent methods.

(a) A candidate method determined by the Administrator to satisfy the applicable requirements of this part shall be designated as a FRM or FEM (as applicable) by and upon publication of a notice of the designation in the FEDERAL REGISTER.

(b) Upon designation, a notice indicating that the method has been designated as a FRM or FEM shall be sent to the applicant.

(c) The Administrator will maintain a current list of methods designated as FRM or FEM in accordance with this part and will send a copy of the list to any person or group upon request. A copy of the list will be available for inspection or copying at EPA Regional Offices and may be available via the Internet or other sources.

[71 FR 61276, Oct. 17, 2006]

§ 53.9 Conditions of designation.

Designation of a candidate method as a FRM or FEM shall be conditioned to the applicant's compliance with the following requirements. Failure to comply with any of the requirements shall constitute a ground for cancellation of the designation in accordance with § 53.11.

(a) Any method offered for sale as a FRM or FEM shall be accompanied by a copy of the manual referred to in § 53.4(b)(3) when delivered to any ultimate purchaser, and an electronic copy of the manual suitable for incorporating into user-specific standard operating procedure documents shall be readily available to any users.

(b) Any method offered for sale as a FRM or FEM shall generate no unreasonable hazard to operators or to the environment during normal use or when malfunctioning.

(c) Any analyzer, PM_{10} sampler, $PM_{2.5}$ sampler, or $PM_{10-2.5}$ sampler offered for sale as part of a FRM or FEM shall function within the limits of the performance specifications referred to in

§ 53.20(a), § 53.30(a), § 53.50, or § 53.60, as applicable, for at least 1 year after delivery and acceptance when maintained and operated in accordance with the manual referred to in § 53.4(b)(3).

(d) Any analyzer, PM_{10} sampler, $PM_{2.5}$ sampler, or $PM_{10-2.5}$ sampler offered for sale as a FRM or FEM shall bear a prominent, permanently affixed label or sticker indicating that the analyzer or sampler has been designated by EPA as a FRM or FEM (as applicable) in accordance with this part and displaying any designated method identification number that may be assigned by EPA.

(e) If an analyzer is offered for sale as a FRM or FEM and has one or more selectable ranges, the label or sticker required by paragraph (d) of this section shall be placed in close proximity to the range selector and shall indicate clearly which range or ranges have been designated as parts of the FRM or FEM.

(f) An applicant who offers analyzers, PM_{10} samplers, $PM_{2.5}$ samplers, or $PM_{10-2.5}$ samplers for sale as FRM or FEMs shall maintain an accurate and current list of the names and mailing addresses of all ultimate purchasers of such analyzers or samplers. For a period of 7 years after publication of the FRM or FEM designation applicable to such an analyzer or sampler, the applicant shall notify all ultimate purchasers of the analyzer or sampler within 30 days if the designation has been canceled in accordance with § 53.11 or § 53.16 or if adjustment of the analyzer or sampler is necessary under § 53.11(b).

(g) If an applicant modifies an analyzer, PM_{10} sampler, $PM_{2.5}$ sampler, or $PM_{10-2.5}$ sampler that has been designated as a FRM or FEM, the applicant shall not sell the modified analyzer or sampler as a reference or equivalent method nor attach a label or sticker to the modified analyzer or sampler under paragraph (d) or (e) of this section until the applicant has received notice under § 53.14(c) that the existing designation or a new designation will apply to the modified analyzer or sampler or has applied for and received notice under § 53.8(b) of a new FRM or FEM determination for the modified analyzer or sampler.

(h) An applicant who has offered $PM_{2.5}$ or $PM_{10-2.5}$ samplers or analyzers for sale as part of a FRM or FEM may continue to do so only so long as the facility in which the samplers or analyzers are manufactured continues to be an ISO 9001-registered facility, as set forth in subpart E of this part. In the event that the ISO 9001 registration for the facility is withdrawn, suspended, or otherwise becomes inapplicable, either permanently or for some specified time interval, such that the facility is no longer an ISO 9001-registered facility, the applicant shall notify EPA within 30 days of the date the facility becomes other than an ISO 9001-registered facility, and upon such notification, EPA shall issue a preliminary finding and notification of possible cancellation of the FRM or FEM designation under § 53.11.

(i) An applicant who has offered $PM_{2.5}$ or $PM_{10-2.5}$ samplers or analyzers for sale as part of a FRM or FEM may continue to do so only so long as updates of the Product Manufacturing Checklist set forth in subpart E of this part are submitted annually. In the event that an annual Checklist update is not received by EPA within 12 months of the date of the last such submitted Checklist or Checklist update, EPA shall notify the applicant within 30 days that the Checklist update has not been received and shall, within 30 days from the issuance of such notification, issue a preliminary finding and notification of possible cancellation of the reference or equivalent method designation under § 53.11.

[71 FR 61276, Oct. 17, 2006]

§ 53.10 Appeal from rejection of application.

Any applicant whose application for a reference or equivalent method determination has been rejected may appeal the Administrator's decision by taking one or more of the following actions:

(a) The applicant may submit new or additional information in support of the application.

(b) The applicant may request that the Administrator reconsider the data and information already submitted.

(c) The applicant may request that any test conducted by the Administrator that was a material factor in the

§ 53.20(a), § 53.30(a), § 53.50, or § 53.60, as applicable, for at least 1 year after delivery and acceptance when maintained and operated in accordance with the manual referred to in § 53.4(b)(3).

(d) Any analyzer, PM_{10} sampler, $PM_{2.5}$ sampler, or $PM_{10-2.5}$ sampler offered for sale as a FRM or FEM shall bear a prominent, permanently affixed label or sticker indicating that the analyzer or sampler has been designated by EPA as a FRM or FEM (as applicable) in accordance with this part and displaying any designated method identification number that may be assigned by EPA.

(e) If an analyzer is offered for sale as a FRM or FEM and has one or more selectable ranges, the label or sticker required by paragraph (d) of this section shall be placed in close proximity to the range selector and shall indicate clearly which range or ranges have been designated as parts of the FRM or FEM.

(f) An applicant who offers analyzers, PM_{10} samplers, $PM_{2.5}$ samplers, or $PM_{10-2.5}$ samplers for sale as FRM or FEMs shall maintain an accurate and current list of the names and mailing addresses of all ultimate purchasers of such analyzers or samplers. For a period of 7 years after publication of the FRM or FEM designation applicable to such an analyzer or sampler, the applicant shall notify all ultimate purchasers of the analyzer or sampler within 30 days if the designation has been canceled in accordance with § 53.11 or § 53.16 or if adjustment of the analyzer or sampler is necessary under § 53.11(b).

(g) If an applicant modifies an analyzer, PM_{10} sampler, $PM_{2.5}$ sampler, or $PM_{10-2.5}$ sampler that has been designated as a FRM or FEM, the applicant shall not sell the modified analyzer or sampler as a reference or equivalent method nor attach a label or sticker to the modified analyzer or sampler under paragraph (d) or (e) of this section until the applicant has received notice under § 53.14(c) that the existing designation or a new designation will apply to the modified analyzer or sampler or has applied for and received notice under § 53.8(b) of a new FRM or FEM determination for the modified analyzer or sampler.

(h) An applicant who has offered $PM_{2.5}$ or $PM_{10-2.5}$ samplers or analyzers for sale as part of a FRM or FEM may continue to do so only so long as the facility in which the samplers or analyzers are manufactured continues to be an ISO 9001-registered facility, as set forth in subpart E of this part. In the event that the ISO 9001 registration for the facility is withdrawn, suspended, or otherwise becomes inapplicable, either permanently or for some specified time interval, such that the facility is no longer an ISO 9001-registered facility, the applicant shall notify EPA within 30 days of the date the facility becomes other than an ISO 9001-registered facility, and upon such notification, EPA shall issue a preliminary finding and notification of possible cancellation of the FRM or FEM designation under § 53.11.

(i) An applicant who has offered $PM_{2.5}$ or $PM_{10-2.5}$ samplers or analyzers for sale as part of a FRM or FEM may continue to do so only so long as updates of the Product Manufacturing Checklist set forth in subpart E of this part are submitted annually. In the event that an annual Checklist update is not received by EPA within 12 months of the date of the last such submitted Checklist or Checklist update, EPA shall notify the applicant within 30 days that the Checklist update has not been received and shall, within 30 days from the issuance of such notification, issue a preliminary finding and notification of possible cancellation of the reference or equivalent method designation under § 53.11.

[71 FR 61276, Oct. 17, 2006]

§ 53.10 Appeal from rejection of application.

Any applicant whose application for a reference or equivalent method determination has been rejected may appeal the Administrator's decision by taking one or more of the following actions:

(a) The applicant may submit new or additional information in support of the application.

(b) The applicant may request that the Administrator reconsider the data and information already submitted.

(c) The applicant may request that any test conducted by the Administrator that was a material factor in the

decision to reject the application be repeated.

§ 53.11 Cancellation of reference or equivalent method designation.

(a) *Preliminary finding.* If the Administrator makes a preliminary finding on the basis of any available information that a representative sample of a method designated as a reference or equivalent method and offered for sale as such does not fully satisfy the requirements of this part or that there is any violation of the requirements set forth in § 53.9, the Administrator may initiate proceedings to cancel the designation in accordance with the following procedures.

(b) *Notification and opportunity to demonstrate or achieve compliance.* (1) After making a preliminary finding in accordance with paragraph (a) of this section, the Administrator will send notice of the preliminary finding to the applicant, together with a statement of the facts and reasons on which the preliminary finding is based, and will publish notice of the preliminary finding in the FEDERAL REGISTER.

(2) The applicant will be afforded an opportunity to demonstrate or to achieve compliance with the requirements of this part within 60 days after publication of notice in accordance with paragraph (b)(1) of this section or within such further period as the Administrator may allow, by demonstrating to the satisfaction of the Administrator that the method in question satisfies the requirements of this part, by commencing a program to make any adjustments that are necessary to bring the method into compliance, or by taking such action as may be necessary to cure any violation of the requirements of § 53.9. If adjustments are necessary to bring the method into compliance, all such adjustments shall be made within a reasonable time as determined by the Administrator. If the applicant demonstrates or achieves compliance in accordance with this paragraph (b)(2), the Administrator will publish notice of such demonstration or achievement in the FEDERAL REGISTER.

(c) *Request for hearing.* Within 60 days after publication of a notice in accordance with paragraph (b)(1) of this section, the applicant or any interested person may request a hearing as provided in § 53.12.

(d) *Notice of cancellation.* If, at the end of the period referred to in paragraph (b)(2) of this section, the Administrator determines that the reference or equivalent method designation should be canceled, a notice of cancellation will be published in the FEDERAL REGISTER and the designation will be deleted from the list maintained under § 53.8(c). If a hearing has been requested and granted in accordance with § 53.12, action under this paragraph (d) will be taken only after completion of proceedings (including any administrative review) conducted in accordance with § 53.13 and only if the decision of the Administrator reached in such proceedings is that the designation in question should be canceled.

§ 53.12 Request for hearing on cancellation.

Within 60 days after publication of a notice in accordance with § 53.11(b)(1), the applicant or any interested person may request a hearing on the Administrator's action. If, after reviewing the request and supporting data, the Administrator finds that the request raises a substantial issue of fact, a hearing will be granted in accordance with § 53.13 with respect to such issue. The request shall be in writing, signed by an authorized representative of the applicant or interested person, and shall include a statement specifying:

(a) Any objections to the Administrator's action.

(b) Data or other information in support of such objections.

§ 53.13 Hearings.

(a)(1) After granting a request for a hearing under § 53.12, the Administrator will designate a presiding officer for the hearing.

(2) If a time and place for the hearing have not been fixed by the Administrator, the hearing will be held as soon as practicable at a time and place fixed by the presiding officer, except that the hearing shall in no case be held sooner than 30 days after publication of a notice of hearing in the FEDERAL REGISTER.

decision to reject the application be repeated.

§ 53.11 Cancellation of reference or equivalent method designation.

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(b) *Notification and opportunity to demonstrate or achieve compliance.* (1) After making a preliminary finding in accordance with paragraph (a) of this section, the Administrator will send notice of the preliminary finding to the applicant, together with a statement of the facts and reasons on which the preliminary finding is based, and will publish notice of the preliminary finding in the FEDERAL REGISTER.

(2) The applicant will be afforded an opportunity to demonstrate or to achieve compliance with the requirements of this part within 60 days after publication of notice in accordance with paragraph (b)(1) of this section or within such further period as the Administrator may allow, by demonstrating to the satisfaction of the Administrator that the method in question satisfies the requirements of this part, by commencing a program to make any adjustments that are necessary to bring the method into compliance, or by taking such action as may be necessary to cure any violation of the requirements of § 53.9. If adjustments are necessary to bring the method into compliance, all such adjustments shall be made within a reasonable time as determined by the Administrator. If the applicant demonstrates or achieves compliance in accordance with this paragraph (b)(2), the Administrator will publish notice of such demonstration or achievement in the FEDERAL REGISTER.

(c) *Request for hearing.* Within 60 days after publication of a notice in accordance with paragraph (b)(1) of this section, the applicant or any interested person may request a hearing as provided in § 53.12.

(d) *Notice of cancellation.* If, at the end of the period referred to in paragraph (b)(2) of this section, the Administrator determines that the reference or equivalent method designation should be canceled, a notice of cancellation will be published in the FEDERAL REGISTER and the designation will be deleted from the list maintained under § 53.8(c). If a hearing has been requested and granted in accordance with § 53.12, action under this paragraph (d) will be taken only after completion of proceedings (including any administrative review) conducted in accordance with § 53.13 and only if the decision of the Administrator reached in such proceedings is that the designation in question should be canceled.

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(a)(1) After granting a request for a hearing under § 53.12, the Administrator will designate a presiding officer for the hearing.

(2) If a time and place for the hearing have not been fixed by the Administrator, the hearing will be held as soon as practicable at a time and place fixed by the presiding officer, except that the hearing shall in no case be held sooner than 30 days after publication of a notice of hearing in the FEDERAL REGISTER.

decision to reject the application be repeated.

§ 53.11 Cancellation of reference or equivalent method designation.

(a) *Preliminary finding.* If the Administrator makes a preliminary finding on the basis of any available information that a representative sample of a method designated as a reference or equivalent method and offered for sale as such does not fully satisfy the requirements of this part or that there is any violation of the requirements set forth in § 53.9, the Administrator may initiate proceedings to cancel the designation in accordance with the following procedures.

(b) *Notification and opportunity to demonstrate or achieve compliance.* (1) After making a preliminary finding in accordance with paragraph (a) of this section, the Administrator will send notice of the preliminary finding to the applicant, together with a statement of the facts and reasons on which the preliminary finding is based, and will publish notice of the preliminary finding in the FEDERAL REGISTER.

(2) The applicant will be afforded an opportunity to demonstrate or to achieve compliance with the requirements of this part within 60 days after publication of notice in accordance with paragraph (b)(1) of this section or within such further period as the Administrator may allow, by demonstrating to the satisfaction of the Administrator that the method in question satisfies the requirements of this part, by commencing a program to make any adjustments that are necessary to bring the method into compliance, or by taking such action as may be necessary to cure any violation of the requirements of § 53.9. If adjustments are necessary to bring the method into compliance, all such adjustments shall be made within a reasonable time as determined by the Administrator. If the applicant demonstrates or achieves compliance in accordance with this paragraph (b)(2), the Administrator will publish notice of such demonstration or achievement in the FEDERAL REGISTER.

(c) *Request for hearing.* Within 60 days after publication of a notice in accordance with paragraph (b)(1) of this section, the applicant or any interested person may request a hearing as provided in § 53.12.

(d) *Notice of cancellation.* If, at the end of the period referred to in paragraph (b)(2) of this section, the Administrator determines that the reference or equivalent method designation should be canceled, a notice of cancellation will be published in the FEDERAL REGISTER and the designation will be deleted from the list maintained under § 53.8(c). If a hearing has been requested and granted in accordance with § 53.12, action under this paragraph (d) will be taken only after completion of proceedings (including any administrative review) conducted in accordance with § 53.13 and only if the decision of the Administrator reached in such proceedings is that the designation in question should be canceled.

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(a) Any objections to the Administrator's action.

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§ 53.13 Hearings.

(a)(1) After granting a request for a hearing under § 53.12, the Administrator will designate a presiding officer for the hearing.

(2) If a time and place for the hearing have not been fixed by the Administrator, the hearing will be held as soon as practicable at a time and place fixed by the presiding officer, except that the hearing shall in no case be held sooner than 30 days after publication of a notice of hearing in the FEDERAL REGISTER.

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§ 53.11 Cancellation of reference or equivalent method designation.

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(b) *Notification and opportunity to demonstrate or achieve compliance.* (1) After making a preliminary finding in accordance with paragraph (a) of this section, the Administrator will send notice of the preliminary finding to the applicant, together with a statement of the facts and reasons on which the preliminary finding is based, and will publish notice of the preliminary finding in the FEDERAL REGISTER.

(2) The applicant will be afforded an opportunity to demonstrate or to achieve compliance with the requirements of this part within 60 days after publication of notice in accordance with paragraph (b)(1) of this section or within such further period as the Administrator may allow, by demonstrating to the satisfaction of the Administrator that the method in question satisfies the requirements of this part, by commencing a program to make any adjustments that are necessary to bring the method into compliance, or by taking such action as may be necessary to cure any violation of the requirements of § 53.9. If adjustments are necessary to bring the method into compliance, all such adjustments shall be made within a reasonable time as determined by the Administrator. If the applicant demonstrates or achieves compliance in accordance with this paragraph (b)(2), the Administrator will publish notice of such demonstration or achievement in the FEDERAL REGISTER.

(c) *Request for hearing.* Within 60 days after publication of a notice in accordance with paragraph (b)(1) of this section, the applicant or any interested person may request a hearing as provided in § 53.12.

(d) *Notice of cancellation.* If, at the end of the period referred to in paragraph (b)(2) of this section, the Administrator determines that the reference or equivalent method designation should be canceled, a notice of cancellation will be published in the FEDERAL REGISTER and the designation will be deleted from the list maintained under § 53.8(c). If a hearing has been requested and granted in accordance with § 53.12, action under this paragraph (d) will be taken only after completion of proceedings (including any administrative review) conducted in accordance with § 53.13 and only if the decision of the Administrator reached in such proceedings is that the designation in question should be canceled.

§ 53.12 Request for hearing on cancellation.

Within 60 days after publication of a notice in accordance with § 53.11(b)(1), the applicant or any interested person may request a hearing on the Administrator's action. If, after reviewing the request and supporting data, the Administrator finds that the request raises a substantial issue of fact, a hearing will be granted in accordance with § 53.13 with respect to such issue. The request shall be in writing, signed by an authorized representative of the applicant or interested person, and shall include a statement specifying:

(a) Any objections to the Administrator's action.

(b) Data or other information in support of such objections.

§ 53.13 Hearings.

(a)(1) After granting a request for a hearing under § 53.12, the Administrator will designate a presiding officer for the hearing.

(2) If a time and place for the hearing have not been fixed by the Administrator, the hearing will be held as soon as practicable at a time and place fixed by the presiding officer, except that the hearing shall in no case be held sooner than 30 days after publication of a notice of hearing in the FEDERAL REGISTER.

(3) For purposes of the hearing, the parties shall include EPA, the applicant or interested person(s) who requested the hearing, and any person permitted to intervene in accordance with paragraph (c) of this section.

(4) The Deputy General Counsel or the Deputy General Counsel's representative will represent EPA in any hearing under this section.

(5) Each party other than EPA may be represented by counsel or by any other duly authorized representative.

(b)(1) Upon appointment, the presiding officer will establish a hearing file. The file shall contain copies of the notices issued by the Administrator pursuant to § 53.11(b)(1), together with any accompanying material, the request for a hearing and supporting data submitted therewith, the notice of hearing published in accordance with paragraph (a)(2) of this section, and correspondence and other material data relevant to the hearing.

(2) The hearing file shall be available for inspection by the parties or their representatives at the office of the presiding officer, except to the extent that it contains information identified in accordance with § 53.15.

(c) The presiding officer may permit any interested person to intervene in the hearing upon such a showing of interest as the presiding officer may require; provided that permission to intervene may be denied in the interest of expediting the hearing where it appears that the interests of the person seeking to intervene will be adequately represented by another party (or by other parties), including EPA.

(d)(1) The presiding officer, upon the request of any party or at the officer's discretion, may arrange for a prehearing conference at a time and place specified by the officer to consider the following:

(i) Simplification of the issues.

(ii) Stipulations, admissions of fact, and the introduction of documents.

(iii) Limitation of the number of expert witnesses.

(iv) Possibility of agreement on disposing of all or any of the issues in dispute.

(v) Such other matters as may aid in the disposition of the hearing, including such additional tests as may be agreed upon by the parties.

(2) The results of the conference shall be reduced to writing by the presiding officer and made part of the record.

(e)(1) Hearings shall be conducted by the presiding officer in an informal but orderly and expeditious manner. The parties may offer oral or written evidence, subject to exclusion by the presiding officer of irrelevant, immaterial, or repetitious evidence.

(2) Witnesses shall be placed under oath.

(3) Any witness may be examined or cross-examined by the presiding officer, the parties, or their representatives. The presiding officer may, at his/her discretion, limit cross-examination to relevant and material issues.

(4) Hearings shall be reported verbatim. Copies of transcripts of proceedings may be purchased from the reporter.

(5) All written statements, charts, tabulations, and data offered in evidence at the hearing shall, upon a showing satisfactory to the presiding officer of their authenticity, relevancy, and materiality, be received in evidence and shall constitute part of the record.

(6) Oral argument shall be permitted. The presiding officer may limit oral presentations to relevant and material issues and designate the amount of time allowed for oral argument.

(f)(1) The presiding officer shall make an initial decision which shall include written findings and conclusions and the reasons therefore on all the material issues of fact, law, or discretion presented on the record. The findings, conclusions, and written decision shall be provided to the parties and made part of the record. The initial decision shall become the decision of the Administrator without further proceedings unless there is an appeal to, or review on motion of, the Administrator within 30 calendar days after the initial decision is filed.

(2) On appeal from or review of the initial decision, the Administrator will have all the powers consistent with making the initial decision, including the discretion to require or allow briefs, oral argument, the taking of additional evidence or the remanding to

the presiding officer for additional proceedings. The decision by the Administrator will include written findings and conclusions and the reasons or basis therefore on all the material issues of fact, law, or discretion presented on the appeal or considered in the review.

§ 53.14 Modification of a reference or equivalent method.

(a) An applicant who offers a method for sale as a reference or equivalent method shall report to the EPA Administrator prior to implementation any intended modification of the method, including but not limited to modifications of design or construction or of operational and maintenance procedures specified in the operation manual (see § 53.9(g)). The report shall be signed by an authorized representative of the applicant, marked in accordance with § 53.15 (if applicable), and addressed as specified in § 53.4(a).

(b) A report submitted under paragraph (a) of this section shall include:

(1) A description, in such detail as may be appropriate, of the intended modification.

(2) A brief statement of the applicant's belief that the modification will, will not, or may affect the performance characteristics of the method.

(3) A brief statement of the probable effect if the applicant believes the modification will or may affect the performance characteristics of the method.

(4) Such further information, including test data, as may be necessary to explain and support any statement required by paragraphs (b)(2) and (b)(3) of this section.

(c) Within 30 calendar days after receiving a report under paragraph (a) of this section, the Administrator will take one or more of the following actions:

(1) Notify the applicant that the designation will continue to apply to the method if the modification is implemented.

(2) Send notice to the applicant that a new designation will apply to the method (as modified) if the modification is implemented, submit notice of the determination for publication in the FEDERAL REGISTER, and revise or supplement the list referred to in § 53.8(c) to reflect the determination.

(3) Send notice to the applicant that the designation will not apply to the method (as modified) if the modification is implemented and submit notice of the determination for publication in the FEDERAL REGISTER.

(4) Send notice to the applicant that additional information must be submitted before a determination can be made and specify the additional information that is needed (in such cases, the 30-day period shall commence upon receipt of the additional information).

(5) Send notice to the applicant that additional tests are necessary and specify what tests are necessary and how they shall be interpreted (in such cases, the 30-day period shall commence upon receipt of the additional test data).

(6) Send notice to the applicant that additional tests will be conducted by the Administrator and specify the reasons for and the nature of the additional tests (in such cases, the 30-day period shall commence 1 calendar day after the additional tests are completed).

(d) An applicant who has received a notice under paragraph (c)(3) of this section may appeal the Administrator's action as follows:

(1) The applicant may submit new or additional information pertinent to the intended modification.

(2) The applicant may request the Administrator to reconsider data and information already submitted.

(3) The applicant may request that the Administrator repeat any test conducted that was a material factor in the Administrator's determination. A representative of the applicant may be present during the performance of any such retest.

§ 53.15 Trade secrets and confidential or privileged information.

Any information submitted under this part that is claimed to be a trade secret or confidential or privileged information shall be marked or otherwise clearly identified as such in the submittal. Information so identified will be treated in accordance with part 2 of this chapter (concerning public information).

the presiding officer for additional proceedings. The decision by the Administrator will include written findings and conclusions and the reasons or basis therefore on all the material issues of fact, law, or discretion presented on the appeal or considered in the review.

§ 53.14 Modification of a reference or equivalent method.

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(b) A report submitted under paragraph (a) of this section shall include:

(1) A description, in such detail as may be appropriate, of the intended modification.

(2) A brief statement of the applicant's belief that the modification will, will not, or may affect the performance characteristics of the method.

(3) A brief statement of the probable effect if the applicant believes the modification will or may affect the performance characteristics of the method.

(4) Such further information, including test data, as may be necessary to explain and support any statement required by paragraphs (b)(2) and (b)(3) of this section.

(c) Within 30 calendar days after receiving a report under paragraph (a) of this section, the Administrator will take one or more of the following actions:

(1) Notify the applicant that the designation will continue to apply to the method if the modification is implemented.

(2) Send notice to the applicant that a new designation will apply to the method (as modified) if the modification is implemented, submit notice of the determination for publication in the FEDERAL REGISTER, and revise or supplement the list referred to in § 53.8(c) to reflect the determination.

(3) Send notice to the applicant that the designation will not apply to the method (as modified) if the modification is implemented and submit notice of the determination for publication in the FEDERAL REGISTER.

(4) Send notice to the applicant that additional information must be submitted before a determination can be made and specify the additional information that is needed (in such cases, the 30-day period shall commence upon receipt of the additional information).

(5) Send notice to the applicant that additional tests are necessary and specify what tests are necessary and how they shall be interpreted (in such cases, the 30-day period shall commence upon receipt of the additional test data).

(6) Send notice to the applicant that additional tests will be conducted by the Administrator and specify the reasons for and the nature of the additional tests (in such cases, the 30-day period shall commence 1 calendar day after the additional tests are completed).

(d) An applicant who has received a notice under paragraph (c)(3) of this section may appeal the Administrator's action as follows:

(1) The applicant may submit new or additional information pertinent to the intended modification.

(2) The applicant may request the Administrator to reconsider data and information already submitted.

(3) The applicant may request that the Administrator repeat any test conducted that was a material factor in the Administrator's determination. A representative of the applicant may be present during the performance of any such retest.

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Any information submitted under this part that is claimed to be a trade secret or confidential or privileged information shall be marked or otherwise clearly identified as such in the submittal. Information so identified will be treated in accordance with part 2 of this chapter (concerning public information).

the presiding officer for additional proceedings. The decision by the Administrator will include written findings and conclusions and the reasons or basis therefore on all the material issues of fact, law, or discretion presented on the appeal or considered in the review.

§ 53.14 Modification of a reference or equivalent method.

(a) An applicant who offers a method for sale as a reference or equivalent method shall report to the EPA Administrator prior to implementation any intended modification of the method, including but not limited to modifications of design or construction or of operational and maintenance procedures specified in the operation manual (see § 53.9(g)). The report shall be signed by an authorized representative of the applicant, marked in accordance with § 53.15 (if applicable), and addressed as specified in § 53.4(a).

(b) A report submitted under paragraph (a) of this section shall include:

(1) A description, in such detail as may be appropriate, of the intended modification.

(2) A brief statement of the applicant's belief that the modification will, will not, or may affect the performance characteristics of the method.

(3) A brief statement of the probable effect if the applicant believes the modification will or may affect the performance characteristics of the method.

(4) Such further information, including test data, as may be necessary to explain and support any statement required by paragraphs (b)(2) and (b)(3) of this section.

(c) Within 30 calendar days after receiving a report under paragraph (a) of this section, the Administrator will take one or more of the following actions:

(1) Notify the applicant that the designation will continue to apply to the method if the modification is implemented.

(2) Send notice to the applicant that a new designation will apply to the method (as modified) if the modification is implemented, submit notice of the determination for publication in the FEDERAL REGISTER, and revise or supplement the list referred to in § 53.8(c) to reflect the determination.

(3) Send notice to the applicant that the designation will not apply to the method (as modified) if the modification is implemented and submit notice of the determination for publication in the FEDERAL REGISTER.

(4) Send notice to the applicant that additional information must be submitted before a determination can be made and specify the additional information that is needed (in such cases, the 30-day period shall commence upon receipt of the additional information).

(5) Send notice to the applicant that additional tests are necessary and specify what tests are necessary and how they shall be interpreted (in such cases, the 30-day period shall commence upon receipt of the additional test data).

(6) Send notice to the applicant that additional tests will be conducted by the Administrator and specify the reasons for and the nature of the additional tests (in such cases, the 30-day period shall commence 1 calendar day after the additional tests are completed).

(d) An applicant who has received a notice under paragraph (c)(3) of this section may appeal the Administrator's action as follows:

(1) The applicant may submit new or additional information pertinent to the intended modification.

(2) The applicant may request the Administrator to reconsider data and information already submitted.

(3) The applicant may request that the Administrator repeat any test conducted that was a material factor in the Administrator's determination. A representative of the applicant may be present during the performance of any such retest.

§ 53.15 Trade secrets and confidential or privileged information.

Any information submitted under this part that is claimed to be a trade secret or confidential or privileged information shall be marked or otherwise clearly identified as such in the submittal. Information so identified will be treated in accordance with part 2 of this chapter (concerning public information).

§ 53.16 Supersession of reference methods.

(a) This section prescribes procedures and criteria applicable to requests that the Administrator specify a new reference method, or a new measurement principle and calibration procedure on which reference methods shall be based, by revision of the appropriate appendix to part 50 of this chapter. Such action will ordinarily be taken only if the Administrator determines that a candidate method or a variation thereof is substantially superior to the existing reference method(s).

(b) In exercising discretion under this section, the Administrator will consider:

(1) The benefits, in terms of the requirements and purposes of the Act, that would result from specifying a new reference method or a new measurement principle and calibration procedure.

(2) The potential economic consequences of such action for State and local control agencies.

(3) Any disruption of State and local air quality monitoring programs that might result from such action.

(c) An applicant who wishes the Administrator to consider revising an appendix to part 50 of this chapter on the ground that the applicant's candidate method is substantially superior to the existing reference method(s) shall submit an application for a reference or equivalent method determination in accordance with § 53.4 and shall indicate therein that such consideration is desired. The application shall include, in addition to the information required by § 53.4, data and any other information supporting the applicant's claim that the candidate method is substantially superior to the existing reference method(s).

(d) After receiving an application under paragraph (c) of this section, the Administrator will publish notice of its receipt in the FEDERAL REGISTER and, within 120 calendar days after receipt of the application, take one of the following actions:

(1) Determine that it is appropriate to propose a revision of the appendix to part 50 of this chapter in question and send notice of the determination to the applicant.

(2) Determine that it is inappropriate to propose a revision of the appendix to part 50 of this chapter in question, determine whether the candidate method is a reference or equivalent method, and send notice of the determinations, including a statement of reasons for the determination not to propose a revision, to the applicant.

(3) Send notice to the applicant that additional information must be submitted before a determination can be made and specify the additional information that is needed (in such cases, the 120-day period shall commence upon receipt of the additional information).

(4) Send notice to the applicant that additional tests are necessary, specifying what tests are necessary and how the test shall be interpreted (in such cases, the 120-day period shall commence upon receipt of the additional test data).

(5) Send notice to the applicant that additional tests will be conducted by the Administrator, specifying the nature of and reasons for the additional tests and the estimated time required (in such cases, the 120-day period shall commence 1 calendar day after the additional tests have been completed).

(e)(1)(i) After making a determination under paragraph (d)(1) of this section, the Administrator will publish a notice of proposed rulemaking in the FEDERAL REGISTER. The notice of proposed rulemaking will indicate that the Administrator proposes:

(A) To revise the appendix to part 50 of this chapter in question.

(B) Where the appendix specifies a measurement principle and calibration procedure, to cancel reference method designations based on the appendix.

(C) To cancel equivalent method designations based on the existing reference method(s).

(ii) The notice of proposed rulemaking will include the terms or substance of the proposed revision, will indicate what period(s) of time the Administrator proposes to allow for replacement of existing methods under section 2.3 of appendix C to part 58 of this chapter, and will solicit public comments on the proposal with particular reference to the considerations

set forth in paragraphs (a) and (b) of this section.

(2)(i) If, after consideration of comments received, the Administrator determines that the appendix to part 50 in question should be revised, the Administrator will, by publication in the FEDERAL REGISTER:

(A) Promulgate the proposed revision, with such modifications as may be appropriate in view of comments received.

(B) Where the appendix to part 50 (prior to revision) specifies a measurement principle and calibration procedure, cancel reference method designations based on the appendix.

(C) Cancel equivalent method designations based on the existing reference method(s).

(D) Specify the period(s) that will be allowed for replacement of existing methods under section 2.3 of appendix C to part 58 of this chapter, with such modifications from the proposed period(s) as may be appropriate in view of comments received.

(3) Canceled designations will be deleted from the list maintained under §53.8(c). The requirements and procedures for cancellation set forth in §53.11 shall be inapplicable to cancellation of reference or equivalent method designations under this section.

(4) If the appendix to part 50 of this chapter in question is revised to specify a new measurement principle and calibration procedure on which the applicant's candidate method is based, the Administrator will take appropriate action under §53.5 to determine whether the candidate method is a reference method.

(5) Upon taking action under paragraph (e)(2) of this section, the Administrator will send notice of the action to all applicants for whose methods reference and equivalent method designations are canceled by such action.

(f) An applicant who has received notice of a determination under paragraph (d)(2) of this section may appeal the determination by taking one or more of the following actions:

(1) The applicant may submit new or additional information in support of the application.

(2) The applicant may request that the Administrator reconsider the data and information already submitted.

(3) The applicant may request that any test conducted by the Administrator that was a material factor in making the determination be repeated.

TABLE A–1 TO SUBPART A OF PART 53—SUMMARY OF APPLICABLE REQUIREMENTS FOR REFERENCE AND EQUIVALENT METHODS FOR AIR MONITORING OF CRITERIA POLLUTANTS

Pollutant	Ref. or equivalent	Manual or automated	Applicable part 50 appendix	Applicable subparts of part 53					
				A	B	C	D	E	F
SO_2	Reference	Manual	A						
	Equivalent	Manual	✓	✓					
		Automated	✓	✓	✓				
CO	Reference	Automated	C	✓	✓				
	Equivalent	Manual	✓	✓					
		Automated	✓	✓	✓				
O_3	Reference	Automated	D	✓	✓				
	Equivalent	Manual	✓	✓					
		Automated	✓	✓	✓				
NO_2	Reference	Automated	F	✓	✓				
	Equivalent	Manual	✓	✓					
		Automated	✓	✓	✓				
Pb	Reference	Manual	G						
	Equivalent	Manual	✓	✓					
PM_{10}	Reference	Manual	J	✓	✓				
	Equivalent	Manual	✓	✓	✓				
		Automated	✓	✓	✓				
$PM_{2.5}$	Reference	Manual	L	✓	✓				
	Equivalent Class I	Manual	L	✓	✓	✓			
	Equivalent Class II	Manual	L[1]	✓	✓[2]	✓	✓[1,2]		
	Equivalent Class III	Automated	L[1]	✓	✓	✓[1]	✓[1]		
$PM_{10-2.5}$	Reference	Manual	O[2]	✓	✓				
	Equivalent Class I	Manual	O_2	✓	✓				
	Equivalent Class II	Manual	O[2]	✓	✓[2]	✓[1]	✓[1,2]		

Pollutant	Ref. or equivalent	Manual or automated	Applicable part 50 appendix	Applicable subparts of part 53					
				A	B	C	D	E	F
	Equivalent Class III	Automated	L[1],O[1,2]	✓	✓	✓[1]	✓[1]		

[1] Some requirements may apply, based on the nature of each particular candidate method, as determined by the Administrator.
[2] Alternative Class III requirements may be substituted.

[71 FR 61276, Oct. 17, 2006]

APPENDIX A TO SUBPART A OF PART 53—REFERENCES

(1) American National Standard Quality Systems—Model for Quality Assurance in Design, Development, Production, Installation, and Servicing, ANSI/ISO/ASQC Q9001–1994. Available from American Society for Quality, P.O. Box 3005, Milwaukee, WI 53202 (*http://qualitypress.asq.org*).

(2) American National Standard Quality Systems for Environmental Data and Technology Programs—Requirements with guidance for use, ANSI/ASQC E4–2004. Available from American Society for Quality P.O. Box 3005, Milwaukee, WI 53202 (*http://qualitypress.asq.org*).

(3) Dimensioning and Tolerancing, ASME Y14.5M-1994. Available from the American Society of Mechanical Engineers, 345 East 47th Street, New York, NY 10017.

(4) Mathematical Definition of Dimensioning and Tolerancing Principles, ASME Y14.5.1M-1994. Available from the American Society of Mechanical Engineers, 345 East 47th Street, New York, NY 10017.

(5) ISO 10012, Quality Assurance Requirements for Measuring Equipment-Part 1: Meteorological confirmation system for measuring equipment):1992(E). Available from American Society for Quality Control, 611 East Wisconsin Avenue, Milwaukee, WI 53202.

(6) Quality Assurance Guidance Document 2.12. Monitoring $PM_{2.5}$ in Ambient Air Using Designated Reference or Class I Equivalent Methods. U.S. EPA, National Exposure Research Laboratory, Research Triangle Park, NC, November 1998 or later edition. Currently available at *http://www.epa.gov/ttn/amtic/pmqainf.html*.

[62 FR 38784, July 18, 1997, as amended at 71 FR 61278, Oct. 17, 2006]

Subpart B—Procedures for Testing Performance Characteristics of Automated Methods SO_2, CO, O_3, and NO_2

§ 53.20 General provisions.

(a) The test procedures given in this subpart shall be used to test the performance of candidate automated methods against the performance specifications given in table B–1. A test analyzer representative of the candidate automated method must exhibit performance better than, or equal to, the specified value for each such specification (except Range) to satisfy the requirements of this subpart. Except as provided in paragraph (b) of this section, the range of the candidate method must be the range specified in table B–1 to satisfy the requirements of this subpart.

(b) For a candidate method having more than one selectable range, one range must be that specified in table B–1 and a test analyzer representative of the method must pass the tests required by this subpart while operated in that range. The tests may be repeated for a broader range (i.e., one extending to higher concentrations) than that specified in table B–1 provided that the range does not extend to concentrations more than two times the upper range limit specified in table B–1. If the application is for a reference method determination, the tests may be repeated for a narrower range (one extending to lower concentrations) than that specified in table B–1.

If the tests are conducted or passed only for the specified range, any reference or equivalent method determination with respect to the method will be limited to that range. If the tests are passed for both the specified range and a broader range (or ranges), any such determination will include the broader range(s) as well as the specified range, provided that the tests required by subpart C of this part (if applicable) are met for the broader range(s). If the tests are passed for both the specified range and a narrower range, a reference method determination for the method will include the narrower range as well as the specified range. Appropriate test data shall be submitted for each range sought to be included in a reference or equivalent

method determination under this paragraph (b).

(c) For each performance specification (except Range), the test procedure shall be initially repeated seven (7) times to yield 7 test results. Each result shall be compared with the corresponding specification in table B–1; a value higher than or outside that specified constitutes a failure. These 7 results for each parameter shall be interpreted as follows:

(1) Zero (0) failures: Candidate method passes the performance parameter.

(2) Three (3) or more failures: Candidate method fails the performance parameter.

(3) One (1) or two (2) failures: Repeat the test procedures for the parameter eight (8) additional times yielding a total of fifteen (15) test results. The combined total of 15 test results shall then be interpreted as follows:

(i) One (1) or two (2) failures: Candidate method passes the performance parameter.

(ii) Three (3) or more failures: Candidate method fails the performance parameter.

TABLE B–1—PERFORMANCE SPECIFICATIONS FOR AUTOMATED METHODS

Performance parameter	Units [1]	Sulfur dioxide	Photochemical oxidants	Carbon monoxide	Nitrogen dioxide	Definitions and test procedures
1. Range	Parts per million	0–0.5	0–0.5	0–50	0–0.5	Sec. 53.23(a).
2. Noise	do	.005	.005	.50	.005	Sec. 53.23(b).
3. Lower detectable limit	Parts per million	.01	.01	1.0	.01	Sec. 53.23(c).
4. Interference equivalent						Sec. 53.23(d).
Each interferant	Parts per million	±.02	±.02	±1.0	±0.02	
Total interferant	do	.06	.06	1.5	.04	
5. Zero drift, 12 and 24 hour	do	±.02	±.02	±1.0	±.02	Sec. 52.23(e).
6. Span drift, 24 hour						Do.
20 percent of upper range limit	Percent	±20.0	±20.0	±10.0	±20.0	
80 percent of upper range limit	do	±5.0	±5.0	±2.5	±5.0	
7. Lag time	Minutes	20	20	10	20	Do.
8. Rise time	do	15	15	5	15	Do.
9. Fall time	do	15	15	5	15	Do.
10. Precision						Do.
20 percent of upper range limit	Parts per million	.01	.01	.5	.02	
80 percent of upper range limit	do	.015	.01	.5	.03	

[1] To convert from parts per million to $\mu g/m^3$ at 25 °C and 760 mm Hg, multiply by M/0.02447, where *M* is the molecular weight of the gas.

(d) The tests for *zero drift*, *span drift*, *lag time*, *rise time*, *fall time*, and *precision* shall be combined into a single sequential procedure to be conducted at various line voltages and ambient temperatures specified in §53.23(e). The tests for *noise*, *lower detectable limit*, and *interference equivalents* shall be made at any temperature between 20 °C. and 30 °C. and at any normal line voltage between 105 and 125 volts, and shall be conducted such that not more than three (3) test results for each parameter are obtained per 24 hours.

(e) All response readings to be recorded shall first be converted to concentration units according to the calibration curve constructed in accordance with §53.21(b).

(f) All recorder chart tracings, records, test data and other documentation obtained from or pertinent to these tests shall be identified, dated, signed by the analyst performing the test, and submitted.

NOTE: Suggested formats for reporting the test results and calculations are provided in Figures B–2, B–3, B–4, B–5, and B–6 in appendix A. Symbols and abbreviations used in this subpart are listed in table B–5, appendix A.

[40 FR 7049, Feb. 18, 1975, as amended at 40 FR 18168, Apr. 25, 1975; 41 FR 52694, Dec. 1, 1976]

§ 53.21 Test conditions.

(a) *Set-up and start-up* of the test analyzer shall be in strict accordance with the operating instructions specified in the manual referred to in §53.4(b)(3). Allow adequate warm-up or stabilization time as indicated in the operating instructions before beginning the tests.

method determination under this paragraph (b).

(c) For each performance specification (except Range), the test procedure shall be initially repeated seven (7) times to yield 7 test results. Each result shall be compared with the corresponding specification in table B–1; a value higher than or outside that specified constitutes a failure. These 7 results for each parameter shall be interpreted as follows:

(1) Zero (0) failures: Candidate method passes the performance parameter.

(2) Three (3) or more failures: Candidate method fails the performance parameter.

(3) One (1) or two (2) failures: Repeat the test procedures for the parameter eight (8) additional times yielding a total of fifteen (15) test results. The combined total of 15 test results shall then be interpreted as follows:

(i) One (1) or two (2) failures: Candidate method passes the performance parameter.

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TABLE B–1—PERFORMANCE SPECIFICATIONS FOR AUTOMATED METHODS

Performance parameter	Units [1]	Sulfur dioxide	Photochemical oxidants	Carbon monoxide	Nitrogen dioxide	Definitions and test procedures
1. Range	Parts per million	0–0.5	0–0.5	0–50	0–0.5	Sec. 53.23(a).
2. Noise	do	.005	.005	.50	.005	Sec. 53.23(b).
3. Lower detectable limit	Parts per million	.01	.01	1.0	.01	Sec. 53.23(c).
4. Interference equivalent						Sec. 53.23(d).
Each interferant	Parts per million	±.02	±.02	±1.0	±0.02	
Total interferant	do	.06	.06	1.5	.04	
5. Zero drift, 12 and 24 hour	do	±.02	±.02	±1.0	±.02	Sec. 52.23(e).
6. Span drift, 24 hour						Do.
20 percent of upper range limit	Percent	±20.0	±20.0	±10.0	±20.0	
80 percent of upper range limit	do	±5.0	±5.0	±2.5	±5.0	
7. Lag time	Minutes	20	20	10	20	Do.
8. Rise time	do	15	15	5	15	Do.
9. Fall time	do	15	15	5	15	Do.
10. Precision						Do.
20 percent of upper range limit	Parts per million	.01	.01	.5	.02	
80 percent of upper range limit	do	.015	.01	.5	.03	

[1] To convert from parts per million to $\mu g/m^3$ at 25 °C and 760 mm Hg, multiply by M/0.02447, where *M* is the molecular weight of the gas.

(d) The tests for *zero drift*, *span drift*, *lag time*, *rise time*, *fall time*, and *precision* shall be combined into a single sequential procedure to be conducted at various line voltages and ambient temperatures specified in §53.23(e). The tests for *noise*, *lower detectable limit*, and *interference equivalents* shall be made at any temperature between 20 °C. and 30 °C. and at any normal line voltage between 105 and 125 volts, and shall be conducted such that not more than three (3) test results for each parameter are obtained per 24 hours.

(e) All response readings to be recorded shall first be converted to concentration units according to the calibration curve constructed in accordance with §53.21(b).

(f) All recorder chart tracings, records, test data and other documentation obtained from or pertinent to these tests shall be identified, dated, signed by the analyst performing the test, and submitted.

NOTE: Suggested formats for reporting the test results and calculations are provided in Figures B–2, B–3, B–4, B–5, and B–6 in appendix A. Symbols and abbreviations used in this subpart are listed in table B–5, appendix A.

[40 FR 7049, Feb. 18, 1975, as amended at 40 FR 18168, Apr. 25, 1975; 41 FR 52694, Dec. 1, 1976]

§ 53.21 Test conditions.

(a) *Set-up and start-up* of the test analyzer shall be in strict accordance with the operating instructions specified in the manual referred to in §53.4(b)(3). Allow adequate warm-up or stabilization time as indicated in the operating instructions before beginning the tests.

If the candidate method does not include an integral strip chart recorder, connect the output signal of the test analyzer to a suitable strip chart recorder of the servo, null-balance type. This recorder shall have a chart width of at least 25 centimeters, chart speeds up to 10 cm per hour, a response time of 1 second or less, a deadband of not more than 0.25 percent of full scale, and capability either of reading measurements at least 5 percent below zero or of offsetting the zero by at least 5 percent.

NOTE: Other data acquisition components may be used along with the chart recorder during conduct of these tests. Use of the chart recorder is intended only to facilitate evaluation of data submitted.

(b) *Calibration* of the test analyzer shall be as indicated in the manual referred to in § 53.4(b)(3) and as follows: If the chart recorder does not have below zero capability, adjust either the controls of the test analyzer or the chart recorder to obtain a +5% offset zero reading on the recorder chart to facilitate observing negative response or drift. If the candidate method is not capable of negative response, the test analyzer (not recorder) shall be operated with an offset zero. Construct and submit a calibration curve showing a plot of recorder scale readings (ordinate) against pollutant concentrations (abscissa). A plot of output units (volts, millivolts, milliamps, etc.) against pollutant concentrations shall also be shown for methods not including an integral chart recorder. All such plots shall consist of at least seven (7) approximately equally spaced, identifiable points, including 0 and 90±5 percent of full scale.

(c) Once the test analyzer has been set up and calibrated and the tests started, manual adjustment or normal periodic maintenance is permitted only every 3 days. Automatic adjustments which the test analyzer performs by itself are permitted at any time. The submitted records shall show clearly when any manual adjustment or periodic maintenance was made and describe the operations performed.

(d) If the test analyzer should malfunction during any of the performance tests, the tests for that parameter shall be repeated. A detailed explanation of the malfunction, remedial action taken, and whether recalibration was necessary (along with all pertinent records and charts) shall be submitted. If more than one malfunction occurs, all performance test procedures for all parameters shall be repeated.

(e) Tests for all performance parameters shall be completed on the same test analyzer, except that use of multiple test analyzers to accelerate testing will be permitted when alternate ranges of a multi-range candidate method are being tested.

§ 53.22 Generation of test atmospheres.

(a) Table B–2 specifies preferred methods for generating test atmospheres and suggested methods of verifying the concentrations. Only one means of establishing the concentration of a test atmosphere is normally required. If the method of generation can produce reproducible concentrations, verification is optional. If the method of generation is not reproducible, then establishment of the concentration by some verification method is required. However, when a method of generation other than that given in table B–2 is used, the test concentration shall be verified.

(b) The test atmosphere delivery system shall be designed and constructed so as not to significantly alter the test atmosphere composition or concentration during the period of the test. The delivery system shall be fabricated from borosilicate glass or FEP Teflon.

(c) The output of the test atmosphere generation system shall be sufficiently stable to obtain stable response during the required tests. If a permeation device is used for generation of a test atmosphere, the device, as well as the air passing over it, shall be controlled to ±0.1 °C.

(d) All diluent air shall be zero air free of contaminants likely to cause a detectable response on the test analyzer.

If the candidate method does not include an integral strip chart recorder, connect the output signal of the test analyzer to a suitable strip chart recorder of the servo, null-balance type. This recorder shall have a chart width of at least 25 centimeters, chart speeds up to 10 cm per hour, a response time of 1 second or less, a deadband of not more than 0.25 percent of full scale, and capability either of reading measurements at least 5 percent below zero or of offsetting the zero by at least 5 percent.

NOTE: Other data acquisition components may be used along with the chart recorder during conduct of these tests. Use of the chart recorder is intended only to facilitate evaluation of data submitted.

(b) *Calibration* of the test analyzer shall be as indicated in the manual referred to in § 53.4(b)(3) and as follows: If the chart recorder does not have below zero capability, adjust either the controls of the test analyzer or the chart recorder to obtain a +5% offset zero reading on the recorder chart to facilitate observing negative response or drift. If the candidate method is not capable of negative response, the test analyzer (not recorder) shall be operated with an offset zero. Construct and submit a calibration curve showing a plot of recorder scale readings (ordinate) against pollutant concentrations (abscissa). A plot of output units (volts, millivolts, milliamps, etc.) against pollutant concentrations shall also be shown for methods not including an integral chart recorder. All such plots shall consist of at least seven (7) approximately equally spaced, identifiable points, including 0 and 90±5 percent of full scale.

(c) Once the test analyzer has been set up and calibrated and the tests started, manual adjustment or normal periodic maintenance is permitted only every 3 days. Automatic adjustments which the test analyzer performs by itself are permitted at any time. The submitted records shall show clearly when any manual adjustment or periodic maintenance was made and describe the operations performed.

(d) If the test analyzer should malfunction during any of the performance tests, the tests for that parameter shall be repeated. A detailed explanation of the malfunction, remedial action taken, and whether recalibration was necessary (along with all pertinent records and charts) shall be submitted. If more than one malfunction occurs, all performance test procedures for all parameters shall be repeated.

(e) Tests for all performance parameters shall be completed on the same test analyzer, except that use of multiple test analyzers to accelerate testing will be permitted when alternate ranges of a multi-range candidate method are being tested.

§ 53.22 Generation of test atmospheres.

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(b) The test atmosphere delivery system shall be designed and constructed so as not to significantly alter the test atmosphere composition or concentration during the period of the test. The delivery system shall be fabricated from borosilicate glass or FEP Teflon.

(c) The output of the test atmosphere generation system shall be sufficiently stable to obtain stable response during the required tests. If a permeation device is used for generation of a test atmosphere, the device, as well as the air passing over it, shall be controlled to ±0.1 °C.

(d) All diluent air shall be zero air free of contaminants likely to cause a detectable response on the test analyzer.

TABLE B–2—TEST ATMOSPHERES

Test gas	Generation	Verification
Ammonia	Permeation device. Similar to system described in references 1 and 2.	Indophenol method, reference 3.
Carbon dioxide	Cylinder of zero air or nitrogen containing CO_2 as required to obtain the concentration specified in table B–3.	Use NBS-certified standards whenever possible. If NBS standards are not available, obtain 2 standards from independent sources which agree within 2 percent; or obtain one standard and submit it to an independent laboratory for analysis which must agree within 2 percent of the supplier's nominal analysis.
Carbon monoxide.	Cylinder of zero air or nitrogen containing CO as required to obtain the concentration specified in table B–3.	Do.
Ethane	Cylinder of zero air or nitrogen containing ethane as required to obtain the concentration specified in table B–3.	Do.
Ethylene	Cylinder of prepurified nitrogen containing ethylene as required to obtain the concentration specified in table B–3.	Do.
Hydrogen chloride.	Cylinder[1] of prepurified nitrogen containing approximately 100 p/m of gaseous HCl. Dilute with zero air to concentration specified in table B–3.	Collect samples in bubbler containing distilled water and analyze by the mercuric thiocyanate method, ASTM (D512), p. 29, reference 4.
Hydrogen sulfide.	Permeation device system described in references 1 and 2.	Tentative method of analysis for H_2 S content of the atmosphere, p. 426, reference 5.
Methane	Cylinder of zero air containing methane as required to obtain the concentration specified in table B–3.	Use NBS-certified standards whenever possible. If NBS standards are not available, obtain 2 standards from independent sources which agree within 2 percent; or obtain one standard and submit it to an independent laboratory for an analysis which must agree within 2 percent of the supplier's nominal analysis.
Nitric oxide	Cylinder[1] of prepurified nitrogen containing approximately 100 p/m NO. Dilute with zero air to required concentration.	Gas-phase titration as described in reference 6, section 7.1.
Nitrogen dioxide.	1. Gas phase titration as described in reference 6 2. Permeation device, similar to system described in references 1 and 2.	1. Use an NO_2 analyzer calibrated with a gravimetrically calibrated permeation device. 2. Use an NO_2 analyzer calibrated by gas-phase titration as described in reference 6.
Ozone	Calibrated ozone generator as described in reference 7, appendix D.	Use an ozone analyzer calibrated by gas-phase titration as described in reference 6.
Sulfur dioxide ..	Permeation device Similar to system described in reference method for SO_2, reference 7, appendix A.	P-rosaniline method. Reference 7, appendix A.
Water	Pass zero air through distilled water at a fixed known temperature between 20° and 30 °C. such that the air stream becomes saturated. Dilute with zero air to concentration specified in table B–3.	Measure relative humidity by means of a dew-point indicator, calibrated electrolytic or piezo electric hygrometer, or wet/dry bulb thermometer.
Xylene	Cylinder of prepurified nitrogen containing 100 p/m xylene. Dilute with zero air to concentration specified in table B–3.	Use NBS-certified standards whenever possible. If NBS standards are not available, obtain 2 standards from independent sources which agree within 2 percent; or obtain one standard and submit it to an independent laboratory for an analysis which must agree within 2 percent of the supplier's nominal analysis.
Zero air	1. Ambient air purified by appropriate scrubbers or other devices such that it is free of contaminants likely to cause a detectable response on the analyzer. 2. Cylinder of compressed zero air certified by the supplier or an independent laboratory to be free of contaminants likely to cause a detectable response on the analyzer.	

[1] Use stainless steel pressure regulator dedicated to the pollutant measured.

Reference 1. O'Keeffe, A. E., and Ortaman, G. C. ''Primary Standards for Trace Gas Analysis,'' *Anal. Chem.* 38, 760 (1966).
Reference 2. Scaringelli, F. P., A. E., Rosenberg, E., and Bell, J. P., ''Primary Standards for Trace Gas Analysis.'' *Anal. Chem.* 42, 871 (1970).
Reference 3. ''Tentative Method of Analysis for Ammonia in the Atmosphere (Indophenol Method)'', *Health Lab Sciences,* vol. 10, No. 2, 115–118, April 1973.
Reference 4. *1973 Annual Book of ASTM Standards,* American Society for Testing and Materials, 1916 Race St., Philadelphia, PA.
Reference 5. *Methods for Air Sampling and Analysis,* Intersociety Committee, 1972, American Public Health Association, 1015.
Reference 6. *Federal Register,* vol. 38, No. 110, Tentative Method for the Continuous Measurement of Nitrogen Dioxide (Chemiluminescent) addenda C. (June 8, 1973).
Reference 7. *Federal Register,* vol. 36, No. 228, National Primary and Secondary Ambient Air Quality Standards, Nov. 25, 1971.

(e) The concentration of each test atmosphere shall be established and/or verified before or during each series of tests. Samples for verifying test concentrations shall be collected from the test atmosphere delivery system as close as possible to the sample intake port of the test analyzer.

(f) The accuracy of all flow measurements used to calculate test atmosphere concentrations shall be documented and referenced to a primary standard (such as a spirometer, bubble meter, etc.). Any corrections shall be clearly shown. All flow measurements given in volume units shall be standardized to 25 °C. and 760 mm Hg.

(g) Schematic drawings and other information showing complete procedural details of the test atmosphere generation, verification, and delivery system shall be provided. All pertinent calculations shall be clearly indicated.

[40 FR 7049, Feb. 18, 1975, as amended at 40 FR 18168, Apr. 25, 1975]

§ 53.23 Test procedures.

(a) *Range*—(1) *Technical definition.* Nominal minimum and maximum concentrations which a method is capable of measuring.

NOTE: The nominal range is specified at the lower and upper range limits in concentration units, for example, 0–0.5 p/m.

(2) *Test procedure.* Submit a suitable calibration curve, as specified in § 53.21(b), showing the test analyzer's response over at least 95 percent of the required range.

NOTE: A single calibration curve will normally suffice.

(b) *Noise*—(1) *Technical definition.* Spontaneous, short duration deviations in output, about the mean output, which are not caused by input concentration changes. Noise is determined as the standard deviation about the mean and is expressed in concentration units.

(2) *Test procedure.* (i) Allow sufficient time for the test analyzer to warm up and stabilize. Determine at two concentrations, first using zero air and then a pollutant test gas concentration as indicated below. The noise specification in table B–1 shall apply to both of these tests.

(ii) Connect an integrating-type digital meter (DM) suitable for the test analyzer's output and accurate to three significant digits, to measure the analyzer's output signal.

NOTE: Use of a chart recorder in addition to the DM is optional.

(iii) Measure zero air for 60 minutes. During this 60-minute interval, record twenty-five (25) readings at 2-minute intervals. (See Figure B–2 in appendix A.)

(iv) Convert each DM reading to concentration units (p/m) by reference to the test analyzer's calibration curve as determined in § 53.21(b). Label the converted DM readings r_1, r_2, r_3 . . . r_i . . . r_{25}.

(v) Calculate the standard deviation, S, as follows:

$$S = \sqrt{\frac{\sum_{i=1}^{25}(r_i)^2 - \frac{1}{25}\left(\sum_{i=1}^{25} r_i\right)^2}{24}} \; (p/m)$$

where i indicates the i-th DM reading in ppm.

(vi) Let S at 0 ppm be identified as S_o; compare S_o to the noise specification given in table B–1.

(vii) Repeat steps (iii) through (vi) of this section using a pollutant test atmosphere concentration of 80±5 percent of the upper range limit (URL) instead of zero gas, and let S at 80 percent of the URL be identified as S_{80}. Compare S_{80} to the noise specification given in table B–1.

(viii) Both S_0 and S_{80} must be less than or equal to the specification for noise to pass the test for the noise parameter.

(c) *Lower detectable limit*—(1) *Technical definition.* The minimum pollutant concentration which produces a signal of twice the noise level.

(2) *Test procedure.* (i) Allow sufficient time for the test analyzer to warm up and stabilize. Measure zero air and record the stable reading in ppm as B_Z. (See Figure B–3 in appendix A.)

(ii) Generate and measure a pollutant test atmosphere concentration equal to the value for the lower detectable limit specified in table B–1.

NOTE: If necessary, the test atmosphere concentration may be generated or verified at a higher concentration, then accurately

(e) The concentration of each test atmosphere shall be established and/or verified before or during each series of tests. Samples for verifying test concentrations shall be collected from the test atmosphere delivery system as close as possible to the sample intake port of the test analyzer.

(f) The accuracy of all flow measurements used to calculate test atmosphere concentrations shall be documented and referenced to a primary standard (such as a spirometer, bubble meter, etc.). Any corrections shall be clearly shown. All flow measurements given in volume units shall be standardized to 25 °C. and 760 mm Hg.

(g) Schematic drawings and other information showing complete procedural details of the test atmosphere generation, verification, and delivery system shall be provided. All pertinent calculations shall be clearly indicated.

[40 FR 7049, Feb. 18, 1975, as amended at 40 FR 18168, Apr. 25, 1975]

§ 53.23 Test procedures.

(a) *Range*—(1) *Technical definition.* Nominal minimum and maximum concentrations which a method is capable of measuring.

NOTE: The nominal range is specified at the lower and upper range limits in concentration units, for example, 0–0.5 p/m.

(2) *Test procedure.* Submit a suitable calibration curve, as specified in § 53.21(b), showing the test analyzer's response over at least 95 percent of the required range.

NOTE: A single calibration curve will normally suffice.

(b) *Noise*—(1) *Technical definition.* Spontaneous, short duration deviations in output, about the mean output, which are not caused by input concentration changes. Noise is determined as the standard deviation about the mean and is expressed in concentration units.

(2) *Test procedure.* (i) Allow sufficient time for the test analyzer to warm up and stabilize. Determine at two concentrations, first using zero air and then a pollutant test gas concentration as indicated below. The noise specification in table B–1 shall apply to both of these tests.

(ii) Connect an integrating-type digital meter (DM) suitable for the test analyzer's output and accurate to three significant digits, to measure the analyzer's output signal.

NOTE: Use of a chart recorder in addition to the DM is optional.

(iii) Measure zero air for 60 minutes. During this 60-minute interval, record twenty-five (25) readings at 2-minute intervals. (See Figure B–2 in appendix A.)

(iv) Convert each DM reading to concentration units (p/m) by reference to the test analyzer's calibration curve as determined in § 53.21(b). Label the converted DM readings r_1, r_2, r_3 . . . r_i . . . r_{25}.

(v) Calculate the standard deviation, S, as follows:

$$S = \sqrt{\frac{\sum_{i=1}^{25}(r_i)^2 - \frac{1}{25}\left(\sum_{i=1}^{25} r_i\right)^2}{24}} \; (p/m)$$

where i indicates the i-th DM reading in ppm.

(vi) Let S at 0 ppm be identified as S_o; compare S_o to the noise specification given in table B–1.

(vii) Repeat steps (iii) through (vi) of this section using a pollutant test atmosphere concentration of 80±5 percent of the upper range limit (URL) instead of zero gas, and let S at 80 percent of the URL be identified as S_{80}. Compare S_{80} to the noise specification given in table B–1.

(viii) Both S_0 and S_{80} must be less than or equal to the specification for noise to pass the test for the noise parameter.

(c) *Lower detectable limit*—(1) *Technical definition.* The minimum pollutant concentration which produces a signal of twice the noise level.

(2) *Test procedure.* (i) Allow sufficient time for the test analyzer to warm up and stabilize. Measure zero air and record the stable reading in ppm as B_Z. (See Figure B–3 in appendix A.)

(ii) Generate and measure a pollutant test atmosphere concentration equal to the value for the lower detectable limit specified in table B–1.

NOTE: If necessary, the test atmosphere concentration may be generated or verified at a higher concentration, then accurately

diluted with zero air to the final required concentration.

(iii) Record the test analyzer's stable indicated reading, in ppm, as B_L.

(iv) Determine the Lower Detectable Limit (LDL) as LDL = $B_L - B_Z$. Compare this LDL value with the noise level, S_0, determined in §53.23(b), for 0 concentration test atmosphere. LDL must be equal to or higher than $2S_0$ to pass this test.

(d) *Interference equivalent*—(1) *Technical definition.* Positive or negative response caused by a substance other than the one being measured.

(2) *Test procedure.* The test analyzer shall be tested for all substances likely to cause a detectable response. The test analyzer shall be challenged, in turn, with each interfering agent specified in table B–3. In the event that there are substances likely to cause a significant interference which have not been specified in table B–3, these substances shall be tested at a concentration substantially higher than that normally found in the ambient air. The interference may be either positive or negative, depending on whether the test analyzer's response is increased or decreased by the presence of the interferent. Interference equivalents shall be determined by mixing each interferent, one at a time, with the pollutant at the concentrations specified in table B–3, and comparing the test analyzer's response to the response caused by the pollutant alone. Known gas-phase reactions that might occur between an interferent and the pollutant are designated by footnote 3 in table B–3. In these cases, the interference equivalent shall be determined in the absence of the pollutant.

(i) Allow sufficient time for warm-up and stabilization of the test analyzer.

(ii) For a candidate method using a prefilter or scrubber based upon a chemical reaction to derive part of its specificity, and which requires periodic service or maintenance, the test analyzer shall be ''conditioned'' prior to each interference test as follows:

TABLE B–3—INTERFERANT TEST CONCENTRATION,[1] PARTS PER MILLION

Pollutant	Analyzer type[2]	Hydrochloric acid	Ammonia	Hydrogen sulfide	Sulfur dioxide	Nitrogen dioxide	Nitric oxide	Carbon dioxide	Ethylene	Ozone	M-xylene	Water vapor	Carbon monoxide	Methane	Ethane
SO_2	Flame photometric (FPD)			0.1	[1] 0.14			750				[3] 20,000	50		
SO_2	Gas chromatography (FPD).			.1	[4].14			750				[3] 20,000	50		
SO_2	Spectrophotometric-wet chemical (pararosaniline reaction).	0.2	[3] 0.1	.1	[4].14	0.5		750		0.5					
SO_2	Electrochemical	.2	[3].1	.1	[4].14	.5	0.5		0.2	.5		[3] 20,000			
SO_2	Conductivity	.2	[3].1		[4].14	.5		750							
SO_2	Spectrophotometric-gas phase.				[4].14	.5	.5			.5	0.2				
O_3	Chemiluminescent			[3].1				750		[4].08		[3] 20,000			
O_3	Electrochemical		[3].1		.5	.5				[4].08		[3] 20,000			
O_3	Spectrophotometric-wet chemical (potassium iodide reaction).		[3].1		.5	.5	[3].5			[4].08					
O_3	Spectrophotometric-gas phase.				.5	.5	[3].5			[4].08					
CO	Infrared							750				20,000	[4] 10		
CO	Gas chromatography with flame ionization detector.											20,000	[4] 10		0.5
CO	Electrochemical						.5		.2			20,000	[4] 10		
CO	Catalytic combustion-thermal detection.		.1					750	.2			20,000	[4] 10	5.0	.5
CO	IR fluorescence							750				20,000	[4] 10		.5
CO	Mercury replacement UV photometric.								.2				[4] 10		.5
NO_2	Chemiluminescent		[3].1		.5	[4].1	.5					20,000			
NO_2	Spectrophotometric-wet chemical (azo-dye reaction).				.5	[4].1	.5	750		.5					
NO_2	Electrochemical	0.2	[3].1		.5	[4].1	.5	750		.5		20,000	50		
NO_2	Spectrophotometric-gas phase.		[3].1		.5	[4].1	.5			.5		20,000	50		

[1] Concentrations of interferant listed must be prepared and controlled to ±10 percent of the state value.
[2] Analyzer types not listed will be considered by the administrator as special cases.
[3] Do not mix with pollutant.
[4] Concentration of pollutant used for test. These pollutant concentrations must be prepared to ±10 percent of the stated value.

(A) Service or perform the indicated maintenance on the scrubber or prefilter as directed in the manual referred to in § 53.4(b)(3).

(B) Before testing for each interferent, allow the test analyzer to sample through the scrubber a test atmosphere containing the interferent at a concentration equal to the value specified in table B–3. Sampling shall be at the normal flow rate and shall be continued for 6 continuous hours prior to testing.

(iii) Generate three test atmosphere streams as follows:

(A) Test atmosphere *P:* Pollutant concentration.

(B) Test atmosphere *I:* Interference concentration.

(C) Test atmosphere *Z:* Zero air.

(iv) Adjust the individual flow rates and the pollutant or interferent generators for the three test atmospheres as follows:

(A) The flow rates of test atmospheres *I* and *Z* shall be identical.

(B) The concentration of pollutant in test atmosphere *P* shall be adjusted such that when *P* is mixed (diluted) with either test atmosphere *I* or *Z*, the resulting concentration of pollutant shall be as specified in table B–3.

(C) The concentration of interferent in test atmosphere *I* shall be adjusted such that when *I* is mixed (diluted) with test atmosphere *P*, the resulting concentration of interferent shall be equal to the value specified in table B–3.

(D) To minimize concentration errors due to flow rate differences between *I* and *Z*, it is recommended that, when possible, the flow rate of *P* be from 10 to 20 times larger than the flow rates of *I* and *Z*.

(v) Mix test atmospheres *P* and *Z* by passing the total flow of both atmospheres through a mixing flask.

(vi) Sample and measure the mixture of test atmospheres *P* and *Z* with the test analyzer. Allow for a stable reading, and record the reading, in concentration units, as *R* (see Figure B–3).

(vii) Mix test atmospheres *P* and *I* by passing the total flow of both atmospheres through a mixing flask.

(viii) Sample and measure this mixture. Record the stable reading, in concentration units, as R_I.

(ix) Calculate the interference equivalent (*IE*) as:

$$IE = R_I - R$$

IE must be equal to or less than the specification given in table B–1 for each interferent to pass the test.

(x) Follow steps (iii) through (ix) of this section, in turn, to determine the interference equivalent for each interferent.

(xi) For those interferents which cannot be mixed with the pollutant, as indicated by footnote (3) in table B–3, adjust the concentration of test atmosphere *I* to the specified value without being mixed or diluted by the pollutant test atmosphere. Determine *IE* as follows:

(A) Sample and measure test atmosphere *Z* (zero air). Allow for a stable reading and record the reading, in concentration units, as *R*.

(B) Sample and measure the interferent test atmosphere *I*. If the test analyzer is not capable of negative readings, adjust the analyzer (not the recorder) to give an offset zero. Record the stable reading in concentration units as R_I, extrapolating the calibration curve, if necessary, to represent negative readings.

(C) Calculate $IE = R_I - R$. *IE* must be equal to or less than the specification in table B–1 to pass the test.

(xii) Sum the absolute value of all the individual interference equivalents. This sum must be equal to or less than the total interferent specification given in table B–1 to pass the test.

(e) *Zero drift, span drift, lag time, rise time, fall time, and precision*—(1) *Technical definitions*—(i) *Zero drift:* The change in response to zero pollutant concentration, over 12- and 24-hour periods of continuous unadjusted operation.

(ii) *Span drift:* The percent change in response to an up-scale pollutant concentration over a 24-hour period of continuous unadjusted operation.

(iii) *Lag time:* The time interval between a step change in input concentration and the first observable corresponding change in response.

(iv) *Rise time:* The time interval between initial response and 95 percent of final response after a step increase in input concentration.

(v) *Fall time:* The time interval between initial response and 95 percent of final response after a step decrease in input concentration.

(vi) *Precision:* Variation about the mean of repeated measurements of the same pollutant concentration, expressed as one standard deviation about the mean.

(2) Tests for these performance parameters shall be accomplished over a period of seven (7) or more days. During this time, the line voltage supplied to the test analyzer and the ambient temperature surrounding the analyzer shall be varied from day to day. One test result for each performance parameter shall be obtained each test day, for seven (7) or fifteen (15) test days as necessary. The tests are performed sequentially in a single procedure.

(3) The 24-hour test day may begin at any clock hour. The first 12 hours out of each test day are required for testing 12-hour zero drift. Tests for the other parameters shall be conducted during the remaining 12 hours.

(4) Table B–4 specifies the line voltage and room temperature to be used for each test day. The line voltage and temperature shall be changed to the specified values at the start of each test day (i.e., at the start of the 12-hour zero test). Initial adjustments (day zero) shall be made at a line voltage of 115 volts (rms) and a room temperature of 25 °C.

(5) The tests shall be conducted in blocks consisting of 3 test days each until 7 or 15 test results have been obtained. (The final block may contain fewer than three test days.) If a test is interrupted by an occurrence other than a malfunction of the test analyzer, only the block during which the interruption occurred shall be repeated.

(6) During each block, manual adjustments to the electronics, gas, or reagent flows or periodic maintenance shall not be permitted. Automatic adjustments which the test analyzer performs by itself are permitted at any time.

(7) At least 4 hours prior to the start of the first test day of each block, the test analyzer may be adjusted and/or serviced according to the periodic maintenance procedures specified in the manual referred to in § 53.4(b)(3). If a new block is to immediately follow a previous block, such adjustments or servicing may be done immediately after completion of the day's tests for the last day of the previous block and at the voltage and temperature specified for that day, but only on test days 3, 6, 9, and 12.

NOTE: If necessary, the beginning of the test days succeeding such maintenance or adjustment may be delayed as necessary to complete the service or adjustment operation.

(8) All response readings to be recorded shall first be converted to concentration units according to the calibration curve. Whenever a test atmosphere is to be measured but a stable reading is not required, the test atmosphere shall be measured long enough to cause a change in response of at least 10% of full scale. Identify all readings and other pertinent data on the strip chart. (See Figure B–1 illustrating the pattern of the required readings.)

TABLE B–4—LINE VOLTAGE AND ROOM TEMPERATURE TEST CONDITIONS

Test day	Line voltage,[1] rms	Room temperature,[2] °C	Comments
0	115	25	Initial set-up and adjustments.
1	125	20	
2	105	20	
3	125	30	Adjustments and/or periodic maintenance permitted at end of tests.
4	105	30	
5	125	20	
6	105	20	Adjustments and/or periodic maintenance permitted at end of tests.
7	125	30	Examine test results to ascertain if further testing is required.
8	105	30	
9	125	20	Adjustments and/or periodic maintenance permitted at end of tests.
10	105	20	
11	125	30	
12	105	30	Adjustments and/or periodic maintenance permitted at end of tests.

TABLE B–4—LINE VOLTAGE AND ROOM TEMPERATURE TEST CONDITIONS—Continued

Test day	Line voltage,[1] rms	Room temperature,[2] °C	Comments
13	125	20	
14	105	20	
15	125	30	

[1] Voltage specified shall be controlled to ±1 volt.
[2] Temperature specified shall be controlled to ±1 °C.

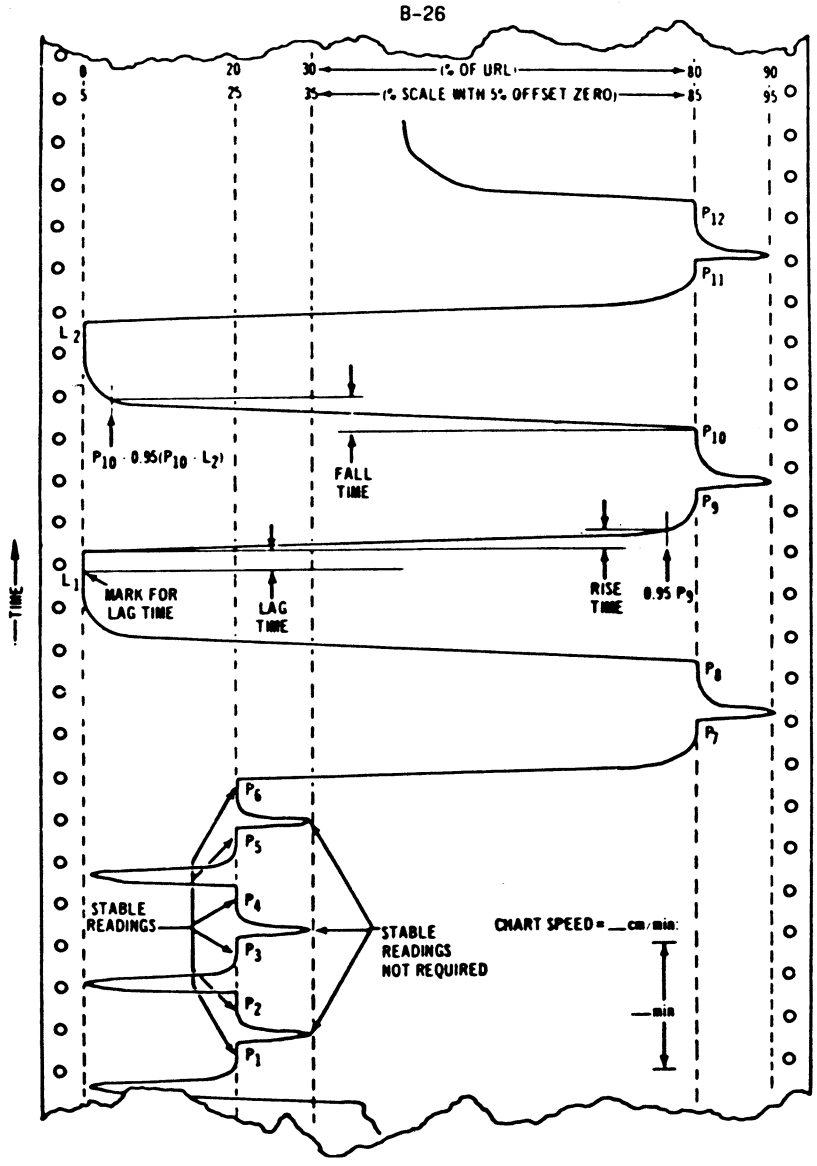

Figure B-1. Example showing the nature of the tracing obtained during the test for drift, lag time, rise time, fall time, and precision. The time scale has been greatly compressed.

(9) *Test procedure.* (i) Arrange to generate pollutant test atmospheres as follows:

Test atmosphere	Pollutant concentration (percent)
A_0	Zero air.
A_{20}	20±5 of the upper range limit.
A_{30}	30±5 of the upper range limit.

Test atmosphere	Pollutant concentration (percent)
A_{80}	80±5 of the upper range limit.
A_{90}	90±5 of the upper range limit.

Test atmospheres A_0, A_{20}, and A_{80} shall be consistent during the tests and from day to day.

(ii) For steps (xxv) through (xxxi) of this section, a chart speed of at least 10 centimeters per hour shall be used. The actual chart speed, chart speed changes, and time checks shall be clearly marked on the chart.

(iii) Allow sufficient time for test analyzer to warm up and stabilize at a line voltage of 115 volts and a room temperature of 25 °C. Recalibrate, if necessary, and adjust the zero baseline to 5 percent of chart. No further adjustments shall be made to the analyzer until the end of the tests on the third day.

(iv) Measure test atmosphere A_0 until a stable reading is obtained, and record this reading (in ppm) as Z'_n, where n = 0 (see Figure B–4 in appendix A).

(v) Measure test atmosphere A_{20}. Allow for a stable reading and record it as M'_n, where n = 0.

(vi) Measure test atmosphere A_{80}. Allow for a stable reading and record it as S'_n, where n = 0.

(vii) The above readings for Z'_0, M'_0, and S'_0 should be taken at least four (4) hours prior to the beginning of test day 1.

(viii) At the beginning of each test day, adjust the line voltage and room temperature to the values given in table B–4.

(ix) Measure test atmosphere A_0 continuously for at least twelve (12) continuous hours during each test day.

(x) After the 12-hour zero drift test (step ix), sample test atmosphere A_0. A stable reading is not required.

(xi) Measure test atmosphere A_{20} and record the stable reading (in ppm) as P_1. (See Figure B–4 in appendix A.)

(xii) Sample test atmosphere A_{30}; a stable reading is not required.

(xiii) Measure test atmosphere A_{20} and record the stable reading as P_2.

(xiv) Sample test atmosphere A_0; a stable reading is not required.

(xv) Measure test atmosphere A_{20} and record the stable reading as P_3.

(xvi) Sample test atmosphere A_{30}; a stable reading is not required.

(xvii) Measure test atmosphere A_{20} and record the stable reading as P_4.

(xviii) Sample test atmosphere A_0; a stable reading is not required.

(xix) Measure test atmosphere A_{20} and record the stable reading as P_5.

(xx) Sample test atmosphere A_{30}; a stable reading is not required.

(xxi) Measure test atmosphere A_{20} and record the stable reading as P_6.

(xxii) Measure test atmosphere A_{30} and record the stable reading as P_7.

(xxiii) Sample test atmosphere A_{90}; a stable reading is not required.

(xxiv) Measure test atmosphere A_{80} and record the stable reading as P_8. Increase chart speed to at least 10 centimeters per hour.

(xxv) Measure test atmosphere A_0. Record the stable reading as L_1.

(xxvi) Quickly switch the test analyzer to measure test atmosphere A_{80} and mark the recorder chart to show the exact time when the switch occurred.

(xxvii) Measure test atmosphere A_{90} and record the stable reading as P_{80}.

(xxviii) Sample test atmosphere A_{90}; a stable reading is not required.

(xxix) Measure test atmosphere A_{80} and record the stable reading as P_{10}.

(xxx) Measure test atmosphere A_0 and record the stable reading as L_2.

(xxxi) Measure test atmosphere A_{80} and record the stable reading as P_{11}.

(xxxii) Sample test atmosphere A_{90}; a stable reading is not required.

(xxxiii) Measure test atmosphere A_{80} and record the stable reading as P_{12}.

(xxxiv) Repeat steps (viii) through (xxxiii) of this section, each test day.

(xxxv) If zero and span adjustments are made after the readings are taken on test days 3, 6, 9, or 12, complete all adjustments; then measure test atmospheres A_0, A_{80}, and A_{20}. Allow for a stable reading on each, and record the readings as $Z'_nS'_n$, and M_n respectively, where n = the test day number.

(10) Determine the results of each day's tests as follows. Mark the recorder chart to show readings and determinations.

(i) *Zero drift.* (A) 12-hour. Examine the strip chart pertaining to the 12-

hour continuous zero air test. Determine the minimum (Cmin.) and maximum (Cmax.) readings (in p/m) during this period of 12 consecutive hours, extrapolating the calibration curve to negative concentration units if necessary. Determine the 12-hour zero drift (12*ZD*) as $12ZD = C^{max.} - C^{min.}$. (See Figure B–5 in appendix A.)

(B) Calculate the 24-hour zero drift (24*ZD*) for the *n*-th test day as $24ZD_n = Z_n - Z_{n-1}$, or $24ZD_n = Z_n - Z'_{n-1}$ if zero adjustment was made on the previous day, where $Z_n = \frac{1}{2}(L_1+L_2)$ for L_1 and L_2 taken on the *n*-th test day.

(C) Compare 12*ZD* and 24*ZD* to the zero drift specification in table B–1. Both 12*ZD* and 24*ZD* must be equal to or less than the specified value to pass the test for zero drift.

(ii) *Span drift.* (A) Span drift at 20 percent of URL (MSD)

$$MSD_n = \frac{M_n - M_{n-1}}{M_{n-1}} \times 100\%$$

$$MSD_n = \frac{M_n - M'_{n-1}}{M'_{n-1}} \times 100\%$$

If span adjustment was made on the previous day, where

$$M_n = \frac{1}{6}\sum_{i=1}^{6} P_i$$

n indicates the *n*-th test day, and *i* indicates the *i*-th reading on the *n*-th day.

(B) Span drift at 80 percent of URL (USD):

$$USD_n = \frac{S_n - S_{n-1}}{S_{n-1}} \times 100\%$$

or

$$USD_n = \frac{S_n - S'_{n-1}}{S'_{n-1}} \times 100\%$$

If span adjustment was made on the previous day, where

$$S_n = \frac{1}{6}\sum_{i=7}^{12} P_i$$

n indicates the *n*-th test day, and *i* indicates the *i*-th reading on the *n*-th test day.

(C) Both USD and MSD must be equal to or less than the respective specifications given in table B–1 to pass the test for span draft.

(iii) *Lag time.* Determine, from the strip chart, the elapsed time in minutes between the mark made in step (xxvi) and the first observable (two times the noise level) response. This time must be equal to or less than the time specified in table B–1 to pass the test for lag time.

(iv) *Rise time.* Calculate 95 percent of reading P_9 and determine from the recorder chart, the elapsed time between the first observable (two times noise level) response and a response equal to 95 percent of the P_9 reading. This time must be equal to or less than the rise time specified in table B–1 to pass the test for rise time.

(v) *Fall time.* Calculate five percent of $(P_{10} - L_2)$ and determine, from the strip chart, the elapsed time in minutes between the first observable decrease in response following reading P_{10} and a response equal to five percent of $(P_{10} - L_2)$. This time must be equal to or less than the fall time specification in table B–1 to pass the test for fall time.

(vi) *Precision.* Calculate precision (P_{20} and P_{80}) for each day's test as follows:

(A)

$$P_{30} = \sqrt{\frac{1}{5}\left[\sum_{i=1}^{6} P_i^2 - \frac{1}{6}\left(\sum_{i=1}^{6} P_i\right)^2\right]}$$

(B)

$$P_{30} = \sqrt{\frac{1}{5}\left[\sum_{i=7}^{12} P_i^2 - \frac{1}{6}\left(\sum_{i=7}^{12} P_i\right)^2\right]}$$

(C) Both P_{20} and P_{80} must be equal to or less than the specification given in table B–1 to pass the test for precision.

[40 FR 7049, Feb. 18, 1975, as amended at 41 FR 52694, Dec. 1, 1976]

APPENDIX A TO SUBPART B OF PART 53—OPTIONAL FORMS FOR REPORTING TEST RESULTS

TABLE B–5—SYMBOLS AND ABBREVIATIONS

B_L	Analyzer reading at specified *LDL* concentration.
B_z	Analyzer reading at 0 concentration for *LDL* test.
DM	Digital meter.
C_{max}	Maximum analyzer reading during 12*ZD* test.
C_{min}	Minimum analyzer reading during 12*ZD* test.
i	Subscript indicating the *i*-th quantity in a series.
IE	Interference equivalent.
L_1	First analyzer zero reading for 24*ZD* test.
L_2	Second analyzer zero reading for 24*ZD* test.
M_n	Average of $P_1 \ldots P_6$ for the *n*-th test day.
M'_n	Adjusted span reading at 20 percent of *URL* on the *n*-th test day.
MSD	Span drift at 20 percent of *URL*.
n	Subscript indicating the test day number.
P	Analyzer reading for precision test.
P_i	The *i*-th analyzer reading for precision test.
P_{20}	Precision at 20 percent of *URL*.
P_{80}	Precision at 80 percent of *URL*.
R	Analyzer reading of pollutant alone for *IE* test.
R_I	Analyzer reading with interferent added for *IE* test.
r_i	The *i*-th *DM* reading for noise test.
S	Standard deviation of noise readings.
S_0	Noise value (*S*) measured at 0 concentration.
S_{80}	Noise value (*S*) measured at 80 percent of *URL*.
S_n	Average of $P_7 \ldots P_{12}$ for the *n*-th test day.
S'_n	Adjusted span reading at 80 percent of *URL* on the *n*-th test day.
URL	Upper range limit.
USD	Span drift at 80 percent o
Z	Average of L_1 and L_2.
Z_n	Average of L_1 and L_2 on the *n*-th test day.
Z'_n	Adjusted zero reading on the *n*-th test day.
ZD	Zero drift.
12*ZD*	12-hour zero drift.
24*ZD*	24-hour zero drift.

Applicant _____ Date _____

Test No. _____

Analyzer _____ Range _____

READING NUMBER (i)	TIME	0% of URL		80% of URL	
		DM READING	r_i, ppm	DM READING	r_i, ppm
1					
2					
3					
4					
5					
6					
7					
8					
9					
10					
11					
12					
13					
14					
15					
16					
17					
18					
19					
20					
21					
22					
23					
24					
25					
$\sum_{i=1}^{25} r_i$					
$\sum_{i=1}^{25} r_i^2$					
S			S_0 =		S_{80} =

Figure B-2. Form for noise data.

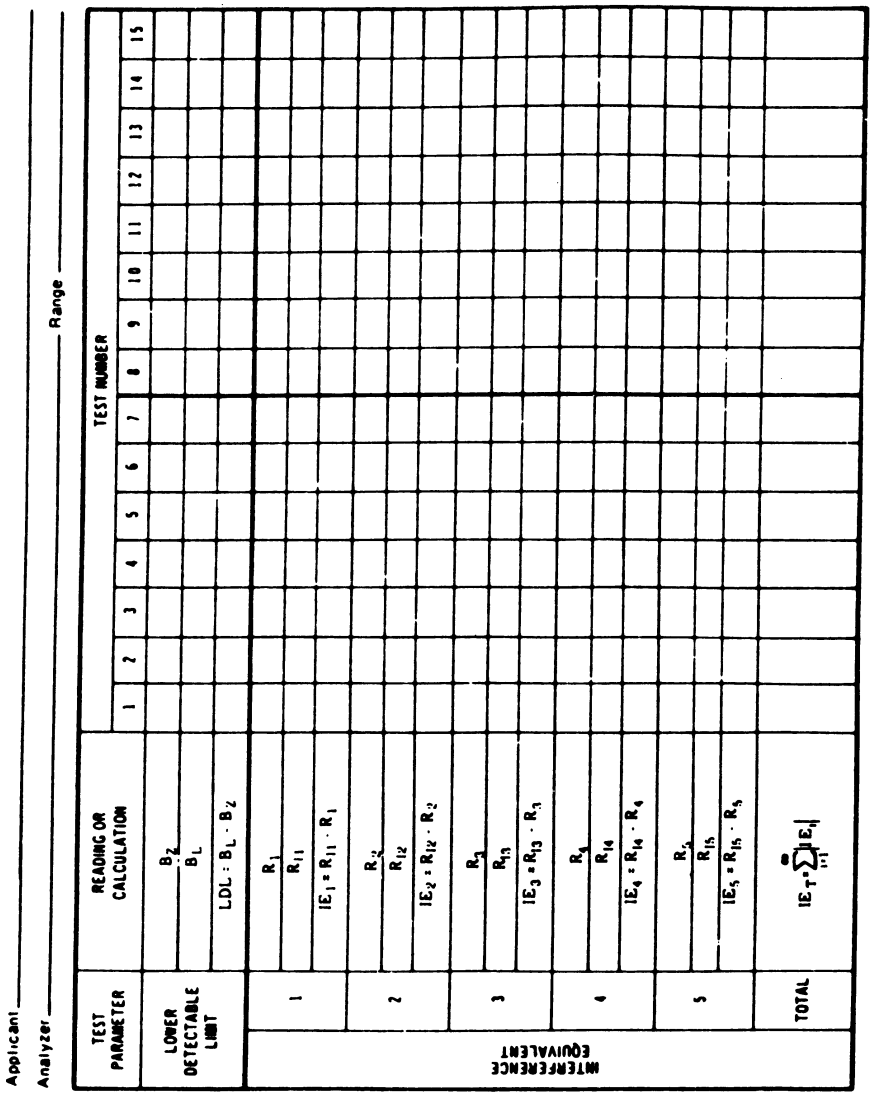

Figure B-3. Form for data and calculations for lower detectable limit and interference equivalent.

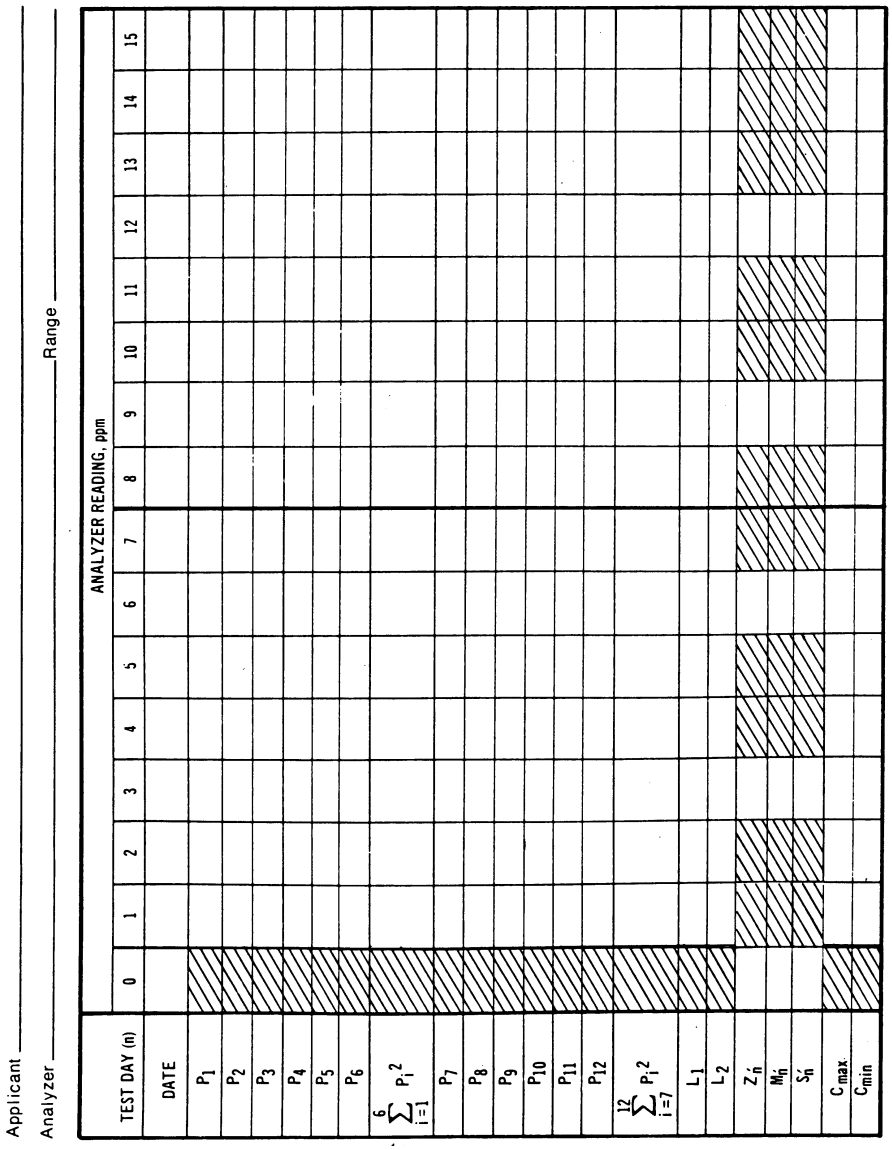

Figure B-4. Form recording data for drift and precision.

Applicant _____ Range _____

Analyzer _____

TEST PARAMETER		CALCULATION	n - th TEST DAY														
			1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Zero drift	12 hour	$12ZD = C_{max} - C_{min}$															
	24 hour	$Z = \frac{1}{4}(L_1 + L_2)$															
		$24ZD_n = Z_n - Z_{n-1}$															
		$24ZD_n = Z_n - Z'_{n-1}$															
Span drift	20% URL	$M_n = \frac{1}{6}\sum_{i=1}^{6} P_i$															
		$MSD_n = \frac{M_n - M_{n-1}}{M_n - 1} \times 100\%$															
		$MSD_n = \frac{M_n - M'_{n-1}}{M'_n - 1} \times 100\%$															
	80% URL	$S_n = \frac{1}{6}\sum_{i=7}^{12} P_i$															
		$USD_n = \frac{S_n - S_{n-1}}{S_{n-1}} \times 100\%$															
		$USD_n = \frac{S_n - S'_{n-1}}{S'_{n-1}} \times 100\%$															
Precision	20% URL	$P_{20} = \sqrt{\frac{1}{5}\left[\sum_{i=1}^{6} P_i^2 - \frac{1}{6}\left(\sum_{i=1}^{6} P_i\right)^2\right]}$															
	80% URL	$P_{80} = \sqrt{\frac{1}{5}\left[\sum_{i=7}^{12} P_i^2 - \frac{1}{6}\left(\sum_{i=7}^{12} P_i\right)^2\right]}$															

Figure B-5. Form for calculating zero drift, span drift and precision.

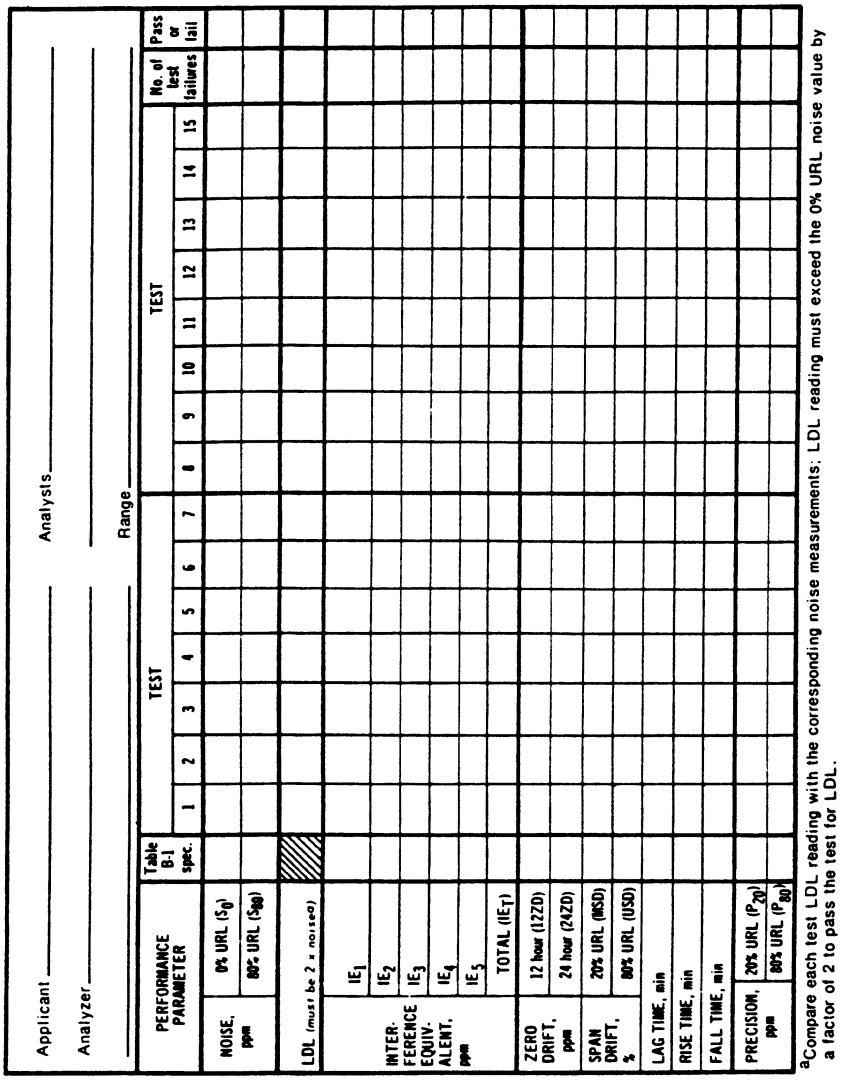

Figure B-6. Form for summary of test results.

[40 FR 7049, Feb. 18, 1975, as amended at 40 FR 18169, Apr. 25, 1975]

Subpart C—Procedures for Determining Comparability Between Candidate Methods and Reference Methods

SOURCE: 71 FR 61278, Oct. 17, 2006, unless otherwise noted.

§ 53.30 General provisions.

(a) *Determination of comparability.* The test procedures prescribed in this subpart shall be used to determine if a candidate method is comparable to a reference method when both methods measure pollutant concentrations in