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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, appendixes A–2 and G of part 50 of this chapter specify unique manual FRM for measuring those pollutants. Except as provided in § 53.16, other manual methods for lead will not be considered for a reference method determination 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 SO_2, 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 (appendix A–1 only for SO_2 methods) 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, as amended at 75 FR 35597, June 22, 2010]

§ 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