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$$P_j = \sqrt{\frac{\sum_{i=1}^{3} C^2_{(i)(j)} - \left(\sum_{i=1}^{3} C_{(i)(j)}\right)^{2/3}}{2}}$$

if $\overline{C}j$ is below 80 $\mu g / m^3$, or

$$RP_j = 100\% \times \sqrt{\frac{\sum_{i=1}^{3} C^2_{(i)(j)} - \left(\sum_{i=1}^{3} C_{(i)(j)}\right)^{2/3}}{2}} \quad \overline{C}_{(j)}$$

if $\overline{C}j$ is above 80 $\mu g / m^3$.

(v) The candidate method passes the precision test if all 10 P_j or RP_j values meet the specifications in table D–1.

(d) *Flow rate stability*—(1) *Technical definition.* Freedom from variation in the operating flow rate of the sampler under typical sampling conditions.

(2) *Test procedure.* (i) For each of the three test samplers and each of the 10 test days of the precision test, record each measured flow rate as $F_{(i)(j)(t)}$, where i is the sampler number, j is the test day, and t is the time of flow rate measurement (t = 0, 6, 12, 18, or 24 hours).

(ii) For each sampler and for each test day, calculate and record the average flow rate as:

$$\overline{F}_{(i)(j)} = \frac{\sum_{t=0}^{24} F_{(i)(j)(t)}}{n}$$

where n = number of flow rate measurements during the 24-hour test day.

(iii) For each sampler and for each test day, calculate and record the percent difference between the average flow rate and the initial flow rate as:

$$\Delta F_{(i)(j)} = \frac{\overline{F}_{(i)(j)} - F_{(i)(j)(0)}}{F_{(i)(j)(0)}} \times 100\%$$

where $F_{(i)(j)(0)}$ is the initial flow rate (t = 0).

(iv) For each sampler and for each of the 3 test days on which flow measurements were obtained at 6-hour intervals throughout the 24-hour sampling period, calculate and record the percent differences between each measured flow rate and the initial flow rate as:

$$\Delta F_{(i)(j)(t)} = \frac{F_{(i)(j)} - F_{(i)(j)(0)}}{F_{(i)(j)(0)}} \times 100\%$$

where t = 6, 12, 18, or 24 hours.

(v) The candidate method passes the flow rate stability test if all of the $\Delta F_{(i)(j)}$ and $\Delta F_{(i)(j)(t)}$ values meet the specifications in table D–1.

Subpart E—Procedures for Testing Physical (Design) and Performance Characteristics of Reference Methods and Class I and Class II Equivalent Methods for $PM_{2.5}$ or $PM_{10-2.5}$

SOURCE: 62 FR 38799, July 18, 1997, unless otherwise noted.

§ 53.50 General provisions.

(a) A candidate method for $PM_{2.5}$ or $PM_{10-2.5}$ described in an application for a FRM or FEM determination submitted under § 53.4 shall be determined by the EPA to be a FRM or a Class I, II, or III FEM on the basis of the definitions for such methods given in § 53.1. This subpart sets forth the specific tests that must be carried out and the test results, evidence, documentation,

and other materials that must be provided to EPA to demonstrate that a $PM_{2.5}$ or $PM_{10-2.5}$ sampler associated with a candidate reference method or Class I or Class II equivalent method meets all design and performance specifications set forth in appendix L or O, respectively, of part 50 of this chapter as well as additional requirements specified in this subpart E. Some or all of these tests may also be applicable to a candidate Class III equivalent method or analyzer, as may be determined under § 53.3(b)(3).

(b) *$PM_{2.5}$ methods*—(1) *Reference method.* A sampler associated with a candidate reference method for $PM_{2.5}$ shall be subject to the provisions, specifications, and test procedures prescribed in §§ 53.51 through 53.58.

(2) *Class I method.* A sampler associated with a candidate Class I equivalent method for $PM_{2.5}$ shall be subject to the provisions, specifications, and test procedures prescribed in all sections of this subpart.

(3) *Class II method.* A sampler associated with a candidate Class II equivalent method for $PM_{2.5}$ shall be subject to the provisions, specifications, and test procedures prescribed in all applicable sections of this subpart, as specified in subpart F of this part or as specified in § 53.3(a)(3).

(c) *$PM_{10-2.5}$ methods*—(1) *Reference method.* A sampler associated with a reference method for $PM_{10-2.5}$, as specified in appendix O to part 50 of this chapter, shall be subject to the requirements in this paragraph (c)(1).

(i) The $PM_{2.5}$ sampler of the $PM_{10-2.5}$ sampler pair shall be verified to be either currently designated under this part 53 as a FRM for $PM_{2.5}$, or shown to meet all requirements for designation as a FRM for $PM_{2.5}$, in accordance with this part 53.

(ii) The PM_{10C} sampler of the $PM_{10-2.5}$ sampler pair shall be verified to be of like manufacturer, design, configuration, and fabrication to the $PM_{2.5}$ sampler of the $PM_{10-2.5}$ sampler pair, except for replacement of the particle size separator specified in section 7.3.4 of appendix L to part 50 of this chapter with the downtube extension as specified in Figure O–1 of appendix O to part 50 of this chapter.

(iii) For samplers that meet the provisions of paragraphs (c)(1)(i) and (ii) of this section, the candidate $PM_{10-2.5}$ reference method may be determined to be a FRM without further testing.

(2) *Class I method.* A sampler associated with a Class I candidate equivalent method for $PM_{10-2.5}$ shall meet the requirements in this paragraph (c)(2).

(i) The $PM_{2.5}$ sampler of the $PM_{10-2.5}$ sampler pair shall be verified to be either currently designated under this part 53 as a FRM or Class I FEM for $PM_{2.5}$, or shown to meet all requirements for designation as a FRM or Class I FEM for $PM_{2.5}$, in accordance with this part 53.

(ii) The PM_{10c} sampler of the $PM_{10-2.5}$ sampler pair shall be verified to be of similar design to the $PM_{10-2.5}$ sampler and to meet all requirements for designation as a FRM or Class I FRM for $PM_{2.5}$, in accordance with this part 53, except for replacement of the particle size separator specified in section 7.3.4 of appendix L to part 50 of this chapter with the downtube extension as specified in Figure O–1 of appendix O to part 50 of this chapter.

(iii) For samplers that meet the provisions of paragraphs (c)(2)(i) and (ii) of this section, the candidate $PM_{10-2.5}$ method may be determined to be a Class I FEM without further testing.

(3) *Class II method.* A sampler associated with a Class II candidate equivalent method for $PM_{10-2.5}$ shall be subject to the applicable requirements of this subpart E, as described in § 53.3(a)(5).

(d) The provisions of § 53.51 pertain to test results and documentation required to demonstrate compliance of a candidate method sampler with the design specifications set forth in 40 CFR part 50, appendix L or O, as applicable. The test procedures prescribed in §§ 53.52 through 53.59 pertain to performance tests required to demonstrate compliance of a candidate method sampler with the performance specifications set forth in 40 CFR part 50, appendix L or O, as applicable, as well as additional requirements specified in this subpart E. These latter test procedures shall be used to test the performance of candidate samplers against the performance specifications and requirements specified in each procedure and

summarized in table E–1 of this subpart.

(e) Test procedures prescribed in § 53.59 do not apply to candidate reference method samplers. These procedures apply primarily to candidate Class I or Class II equivalent method samplers for $PM_{2.5}$ or $PM_{10-2.5}$ that have a sample air flow path configuration upstream of the sample filter that is modified from that specified for the FRM sampler, as set forth in 40 CFR part 50, appendix L, Figures L–1 to L–29 or 40 CFR part 50 appendix O, Figure O–1, if applicable, such as might be necessary to provide for sequential sample capability. The additional tests determine the adequacy of aerosol transport through any altered components or supplemental devices that are used in a candidate sampler upstream of the filter. In addition to the other test procedures in this subpart, these test procedures shall be used to further test the performance of such an equivalent method sampler against the performance specifications given in the procedure and summarized in table E–1 of this subpart.

(f) A 10-day operational field test of measurement precision is required under § 53.58 for both FRM and Class I FEM samplers for $PM_{2.5}$. This test requires collocated operation of three candidate method samplers at a field test site. For candidate FEM samplers, this test may be combined and carried out concurrently with the test for comparability to the FRM specified under § 53.34, which requires collocated operation of three FRM samplers and three candidate FEM samplers.

(g) All tests and collection of test data shall be performed in accordance with the requirements of reference 1, section 4.10.5 (ISO 9001) and reference 2, part B, (section 6) and Part C, (section 7) in appendix A of this subpart. All test data and other documentation obtained specifically from or pertinent to these tests shall be identified, dated, signed by the analyst performing the test, and submitted to EPA in accordance with subpart A of this part.

[71 FR 61289, Oct. 17, 2006]

§ 53.51 Demonstration of compliance with design specifications and manufacturing and test requirements.

(a) *Overview.* (1) Paragraphs (a) through (f) of this section specify certain documentation that must be submitted and tests that are required to demonstrate that samplers associated with a designated FRM or FEM for $PM_{2.5}$ or $PM_{10-2.5}$ are properly manufactured to meet all applicable design and performance specifications and have been properly tested according to all applicable test requirements for such designation. Documentation is required to show that instruments and components of a $PM_{2.5}$ or $PM_{10-2.5}$ sampler are manufactured in an ISO 9001-registered facility under a quality system that meets ISO–9001 requirements for manufacturing quality control and testing.

(2) In addition, specific tests are required by paragraph (d) of this section to verify that critical features of FRM samplers—the particle size separator and the surface finish of surfaces specified to be anodized—meet the specifications of 40 CFR part 50, appendix L or appendix O, as applicable. A checklist is required to provide certification by an ISO-certified auditor that all performance and other required tests have been properly and appropriately conducted, based on a reasonable and appropriate sample of the actual operations or their documented records. Following designation of the method, another checklist is required initially to provide an ISO-certified auditor's certification that the sampler manufacturing process is being implemented under an adequate and appropriate quality system.

(3) For the purposes of this section, the definitions of ISO 9001-registered facility and ISO-certified auditor are found in § 53.1. An exception to the reliance by EPA on ISO-certified auditors is the requirement for the submission of the operation or instruction manual associated with the candidate method to EPA as part of the application. This manual is required under § 53.4(b)(3). The EPA has determined that acceptable technical judgment for review of this manual may not be assured by ISO-certified auditors, and approval of this manual will therefore be performed by EPA.