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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

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 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