§ 53.2 General requirements for a reference method determination.

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

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

(2) A reference method 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 subparts A and D of this part.

(3) A reference method 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 subparts A and E of this part. Further, reference method samplers must be manufactured in an ISO 9001-registered facility, as defined in §53.1 and as set forth in §53.51, and the Product Manufacturing Checklist set forth in subpart E of this part must be completed by an ISO-certified auditor, as defined in §53.1, and submitted to EPA annually to retain a $PM_{2.5}$ reference method designation.

(b) *Automated methods.* An automated reference method for measuring carbon monoxide (CO), ozone (O_3), and nitrogen dioxide (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 subpart B of this part.

§ 53.3 General requirements for an equivalent method determination.

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

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

(2) A $PM_{2.5}$ Class I equivalent method sampler must satisfy all requirements of subparts C and E of this part, which include appropriate demonstration that each and every deviation or modification from the reference method sampler specifications does not significantly alter the performance of the sampler.

(3) A $PM_{2.5}$ Class II equivalent method sampler must satisfy the applicable requirements of subparts C, E, and F of this part.

(4) Requirements for $PM_{2.5}$ Class III equivalent method samplers are not provided in this part because of the wide range of non-filter-based measurement technologies that could be applied and the likelihood that these requirements will have to be specifically adapted for each such type of technology. Specific requirements will be developed as needed and may include selected requirements from subparts C, E, or F of this part or other requirements not contained in this part.

(5) All designated equivalent methods for $PM_{2.5}$ must be manufactured in an ISO 9001-registered facility, as defined in §53.1 and as set forth in §53.51, and the Product Manufacturing Checklist set forth in subpart E of this part must be completed by an ISO-certified auditor, as defined in §53.1, and submitted to EPA annually to retain a $PM_{2.5}$ equivalent method designation.

(b) *Automated methods.* (1) Automated equivalent methods for pollutants other than $PM_{2.5}$ or PM_{10} must have been shown in accordance with this part to satisfy the requirements specified in subparts B and C of this part.

(2) Automated equivalent methods for PM_{10} must have been shown in accordance with this part to satisfy the requirements of subparts C and D of this part.

(3) Requirements for $PM_{2.5}$ Class III automated equivalent methods for

$PM_{2.5}$ are not provided in this part because of the wide range of non-filter-based measurement technologies that could be applied and the likelihood that these requirements will have to be specifically adapted for each such type of technology. Specific requirements will be developed as needed and may include selected requirements from subparts C, E, or F of this part or other requirements not contained in this part.

(4) All designated equivalent methods for $PM_{2.5}$ must be manufactured in an ISO 9001-registered facility, as set forth in subpart E of this part, and the Product Manufacturing Checklist set forth in subpart E of this part must be completed by an ISO-certified auditor and submitted to EPA annually to retain a $PM_{2.5}$ equivalent method designation.

[62 FR 38784, July 18, 1997; 63 FR 7714, Feb. 17, 1998]

§53.4 Applications for reference or equivalent method determinations.

(a) Applications for reference or equivalent method determinations shall be submitted in duplicate to: Director, National Exposure Research Laboratory, Department E (MD-77B), U.S. Environmental Protection Agency, Research Triangle Park, North Carolina 27711.

(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 $PM_{2.5}$ 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 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 appendix L 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