

§ 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 cancella-

tion 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	✓	✓					
CO	Equivalent	Automated	✓	✓	✓				
		Manual	✓	✓					
		Automated	✓	✓					
O ₃	Equivalent	Automated	D	✓	✓				
		Manual	✓	✓					
		Automated	✓	✓					
NO ₂	Equivalent	Automated	F	✓	✓				
		Manual	✓	✓					
		Automated	✓	✓					
Pb	Reference	Manual	G						
	Equivalent	Manual	✓	✓					
PM ₁₀	Reference	Manual	J	✓	✓				
	Equivalent	Manual	✓	✓					
PM _{2.5}	Reference	Manual	L	✓	✓				
	Equivalent Class I	Manual	L	✓	✓				
PM _{10-2.5}	Equivalent Class II	Manual	L ¹	✓	✓ ²	✓	✓ ^{1,2}		
	Equivalent Class III	Automated	L ¹	✓	✓ ¹	✓ ¹	✓ ¹		
	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/pmqaainf.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 SO₂, CO, O₃, and NO₂

§ 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 spec-

ifications 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