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(a) Any method offered for sale as a FRM or FEM shall be accompanied by a copy of the manual referred to in § 53.4(b)(3) when delivered to any ultimate purchaser, and an electronic copy of the manual suitable for incorporating into user-specific standard operating procedure documents shall be readily available to any users.

(b) Any method offered for sale as a FRM or FEM shall generate no unreasonable hazard to operators or to the environment during normal use or when malfunctioning.

(c) Any analyzer, PM_{10} sampler, $PM_{2.5}$ sampler, or $PM_{10-2.5}$ sampler offered for sale as part of an FRM or FEM shall function within the limits of the performance specifications referred to in § 53.20(a), § 53.30(a), § 53.35, § 53.50, or § 53.60, as applicable, for at least 1 year after delivery and acceptance when maintained and operated in accordance with the manual referred to in § 53.4(b)(3).

(d) Any analyzer, PM_{10} sampler, $PM_{2.5}$ sampler, or $PM_{10-2.5}$ sampler offered for sale as a FRM or FEM shall bear a prominent, permanently affixed label or sticker indicating that the analyzer or sampler has been designated by EPA as a FRM or FEM (as applicable) in accordance with this part and displaying any designated method identification number that may be assigned by EPA.

(e) If an analyzer is offered for sale as a FRM or FEM and has one or more selectable ranges, the label or sticker required by paragraph (d) of this section shall be placed in close proximity to the range selector and shall indicate clearly which range or ranges have been designated as parts of the FRM or FEM.

(f) An applicant who offers analyzers, PM_{10} samplers, $PM_{2.5}$ samplers, or $PM_{10-2.5}$ samplers for sale as FRM or FEMs shall maintain an accurate and current list of the names and mailing addresses of all ultimate purchasers of such analyzers or samplers. For a period of 7 years after publication of the FRM or FEM designation applicable to such an analyzer or sampler, the applicant shall notify all ultimate purchasers of the analyzer or sampler within 30 days if the designation has been canceled in accordance with § 53.11 or § 53.16 or if adjustment of the analyzer or sampler is necessary under § 53.11(b).

(g) If an applicant modifies an analyzer, PM_{10} sampler, $PM_{2.5}$ sampler, or $PM_{10-2.5}$ sampler that has been designated as a FRM or FEM, the applicant shall not sell the modified analyzer or sampler as a reference or equivalent method nor attach a label or sticker to the modified analyzer or sampler under paragraph (d) or (e) of this section until the applicant has received notice under § 53.14(c) that the existing designation or a new designation will apply to the modified analyzer or sampler or has applied for and received notice under § 53.8(b) of a new FRM or FEM determination for the modified analyzer or sampler.

(h) An applicant who has offered $PM_{2.5}$ or $PM_{10-2.5}$ samplers or analyzers for sale as part of a FRM or FEM may continue to do so only so long as the facility in which the samplers or analyzers are manufactured continues to be an ISO 9001-registered facility, as set forth in subpart E of this part. In the event that the ISO 9001 registration for the facility is withdrawn, suspended, or otherwise becomes inapplicable, either permanently or for some specified time interval, such that the facility is no longer an ISO 9001-registered facility, the applicant shall notify EPA within 30 days of the date the facility becomes other than an ISO 9001-registered facility, and upon such notification, EPA shall issue a preliminary finding and notification of possible cancellation of the FRM or FEM designation under § 53.11.

[71 FR 61276, Oct. 17, 2006, as amended at 78 FR 3281, Jan. 15, 2013; 80 FR 65460, Oct. 26, 2015]

§ 53.10 Appeal from rejection of application.

Any applicant whose application for a reference or equivalent method determination has been rejected may appeal the Administrator's decision by taking one or more of the following actions:

(a) The applicant may submit new or additional information in support of the application.

(b) The applicant may request that the Administrator reconsider the data and information already submitted.

(c) The applicant may request that any test conducted by the Administrator that was a material factor in the decision to reject the application be repeated.

§ 53.11 Cancellation of reference or equivalent method designation.

(a) *Preliminary finding.* If the Administrator makes a preliminary finding on the basis of any available information that a representative sample of a method designated as a reference or equivalent method and offered for sale as such does not fully satisfy the requirements of this part or that there is any violation of the requirements set forth in § 53.9, the Administrator may initiate proceedings to cancel the designation in accordance with the following procedures.

(b) *Notification and opportunity to demonstrate or achieve compliance.* (1) After making a preliminary finding in accordance with paragraph (a) of this section, the Administrator will send notice of the preliminary finding to the applicant, together with a statement of the facts and reasons on which the preliminary finding is based, and will publish notice of the preliminary finding in the FEDERAL REGISTER.

(2) The applicant will be afforded an opportunity to demonstrate or to achieve compliance with the requirements of this part within 60 days after publication of notice in accordance with paragraph (b)(1) of this section or within such further period as the Administrator may allow, by demonstrating to the satisfaction of the Administrator that the method in question satisfies the requirements of this part, by commencing a program to make any adjustments that are necessary to bring the method into compliance, or by taking such action as may be necessary to cure any violation of the requirements of § 53.9. If adjustments are necessary to bring the method into compliance, all such adjustments shall be made within a reasonable time as determined by the Administrator. If the applicant demonstrates or achieves compliance in accordance with this paragraph (b)(2), the Administrator will publish notice of such demonstration or achievement in the FEDERAL REGISTER.

(c) *Request for hearing.* Within 60 days after publication of a notice in accordance with paragraph (b)(1) of this section, the applicant or any interested person may request a hearing as provided in § 53.12.

(d) *Notice of cancellation.* If, at the end of the period referred to in paragraph (b)(2) of this section, the Administrator determines that the reference or equivalent method designation should be canceled, a notice of cancellation will be published in the FEDERAL REGISTER and the designation will be deleted from the list maintained under § 53.8(c). If a hearing has been requested and granted in accordance with § 53.12, action under this paragraph (d) will be taken only after completion of proceedings (including any administrative review) conducted in accordance with § 53.13 and only if the decision of the Administrator reached in such proceedings is that the designation in question should be canceled.

§ 53.12 Request for hearing on cancellation.

Within 60 days after publication of a notice in accordance with § 53.11(b)(1), the applicant or any interested person may request a hearing on the Administrator's action. If, after reviewing the request and supporting data, the Administrator finds that the request raises a substantial issue of fact, a hearing will be granted in accordance with § 53.13 with respect to such issue. The request shall be in writing, signed by an authorized representative of the applicant or interested person, and shall include a statement specifying:

(a) Any objections to the Administrator's action.

(b) Data or other information in support of such objections.

§ 53.13 Hearings.

(a)(1) After granting a request for a hearing under § 53.12, the Administrator will designate a presiding officer for the hearing.

(2) If a time and place for the hearing have not been fixed by the Administrator, the hearing will be held as soon as practicable at a time and place fixed by the presiding officer, except that the hearing shall in no case be held sooner than 30 days after publication of