

§ 53.10

reference or equivalent method designation under § 53.11.

[71 FR 61276, Oct. 17, 2006]

§ 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

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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:

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(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 a notice of hearing in the FEDERAL REGISTER.

(3) For purposes of the hearing, the parties shall include EPA, the applicant or interested person(s) who requested the hearing, and any person permitted to intervene in accordance with paragraph (c) of this section.

(4) The Deputy General Counsel or the Deputy General Counsel's representative will represent EPA in any hearing under this section.

(5) Each party other than EPA may be represented by counsel or by any other duly authorized representative.

(b)(1) Upon appointment, the presiding officer will establish a hearing file. The file shall contain copies of the notices issued by the Administrator pursuant to § 53.11(b)(1), together with any accompanying material, the request for a hearing and supporting data submitted therewith, the notice of hearing published in accordance with paragraph (a)(2) of this section, and correspondence and other material data relevant to the hearing.

(2) The hearing file shall be available for inspection by the parties or their representatives at the office of the presiding officer, except to the extent that it contains information identified in accordance with § 53.15.

(c) The presiding officer may permit any interested person to intervene in the hearing upon such a showing of interest as the presiding officer may require; provided that permission to intervene may be denied in the interest of expediting the hearing where it appears that the interests of the person seeking to intervene will be adequately

represented by another party (or by other parties), including EPA.

(d)(1) The presiding officer, upon the request of any party or at the officer's discretion, may arrange for a pre-hearing conference at a time and place specified by the officer to consider the following:

(i) Simplification of the issues.

(ii) Stipulations, admissions of fact, and the introduction of documents.

(iii) Limitation of the number of expert witnesses.

(iv) Possibility of agreement on disposing of all or any of the issues in dispute.

(v) Such other matters as may aid in the disposition of the hearing, including such additional tests as may be agreed upon by the parties.

(2) The results of the conference shall be reduced to writing by the presiding officer and made part of the record.

(e)(1) Hearings shall be conducted by the presiding officer in an informal but orderly and expeditious manner. The parties may offer oral or written evidence, subject to exclusion by the presiding officer of irrelevant, immaterial, or repetitious evidence.

(2) Witnesses shall be placed under oath.

(3) Any witness may be examined or cross-examined by the presiding officer, the parties, or their representatives. The presiding officer may, at his/her discretion, limit cross-examination to relevant and material issues.

(4) Hearings shall be reported verbatim. Copies of transcripts of proceedings may be purchased from the reporter.

(5) All written statements, charts, tabulations, and data offered in evidence at the hearing shall, upon a showing satisfactory to the presiding officer of their authenticity, relevancy, and materiality, be received in evidence and shall constitute part of the record.

(6) Oral argument shall be permitted. The presiding officer may limit oral presentations to relevant and material issues and designate the amount of time allowed for oral argument.

(f)(1) The presiding officer shall make an initial decision which shall include written findings and conclusions and