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that have passed the required inspections and tests are released for sale.

(ii) Section 4.13 in reference 1 of appendix A of this subpart requires documented procedures for control of nonconforming product, including review and acceptable alternatives for disposition; section 4.14 in reference 1 of appendix A of this subpart requires documented procedures for implementing corrective (4.14.2) and preventive (4.14.3) action to eliminate the causes of actual or potential nonconformities. In particular, section 4.14.3 requires that potential causes of nonconformities be eliminated by using information such as service reports and customer complaints to eliminate potential causes of nonconformities.

(d) For candidate reference or equivalent methods for $PM_{2.5}$ and Class II or Class III equivalent methods for $PM_{10-2.5}$, the applicant, if requested by EPA, shall provide to EPA for test purposes one sampler or analyzer that is representative of the sampler or analyzer associated with the candidate method. The sampler or analyzer shall be shipped FOB destination to Director, National Exposure Research Laboratory, Reference and Equivalent Method Program (MD-D205–03), U.S. Environmental Protection Agency, 4930 Old Page Road, Durham, North Carolina 27703, scheduled to arrive concurrent with or within 30 days of the arrival of the other application materials. This analyzer or sampler may be subjected to various tests that EPA determines to be necessary or appropriate under § 53.5(f), and such tests may include special tests not described in this part. If the instrument submitted under this paragraph malfunctions, becomes inoperative, or fails to perform as represented in the application before the necessary EPA testing is completed, the applicant shall be afforded an opportunity to repair or replace the device at no cost to EPA. Upon completion of EPA testing, the analyzer or sampler submitted under this paragraph shall be repacked by EPA for return shipment to the applicant, using the same packing materials used for shipping the instrument to EPA unless alternative packing is provided by the applicant. Arrangements for, and the cost of, return shipment shall be the responsibility of the applicant. The EPA does not warrant or assume any liability for the condition of the analyzer or sampler upon return to the applicant.

[71 FR 61271, Oct. 17, 2006]

§ 53.5 Processing of applications.

After receiving an application for a FRM or FEM determination, the Administrator will, within 120 calendar days after receipt of the application, take one or more of the following actions:

(a) Send notice to the applicant, in accordance with § 53.8, that the candidate method has been determined to be a reference or equivalent method.

(b) Send notice to the applicant that the application has been rejected, including a statement of reasons for rejection.

(c) 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).

(d) Send notice to the applicant that additional test data must be submitted and specify what tests are necessary and how the tests shall be interpreted (in such cases, the 120-day period shall commence upon receipt of the additional test data).

(e) Send notice to the applicant that the application has been found to be substantially deficient or incomplete and cannot be processed until additional information is submitted to complete the application and specify the general areas of substantial deficiency.

(f) 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).

[71 FR 61271, Oct. 17, 2006]