

NOTICE

To: Potential applicants for U.S. EPA designation of candidate Class II and III equivalent methods for PM_{2.5} and PM_{10-2.5} under the new (2006) EPA regulations at 40 CFR Part 53

New EPA regulations applicable to candidate Class II and Class III equivalent methods for PM_{2.5} and PM_{10-2.5} (amendments to 40 CFR Part 53) were recently promulgated and become effective on December 18, 2006 (*Federal Register*, Vol. 71, page 61236, October 17, 2006). These new rules set forth the specific field testing and other requirements that candidate methods for measuring concentrations of PM_{2.5} and PM_{10-2.5} in the ambient air must meet to be designated by EPA as Class II or Class III equivalent methods under Part 53. Organizations or entities wishing to have a particular PM_{2.5} and PM_{10-2.5} monitoring method considered by EPA for such designation are required to carry out the prescribed testing of the candidate method and submit an application containing the test results and other information to EPA in accordance with the provisions of Part 53.

In view of the complexity of the prescribed test requirements and the variety of possible candidate methods and testing venues, the EPA anticipates that questions are likely to arise in regard to specific method or testing situations. The EPA encourages potential applicants to seek timely answers from EPA for such questions so that candidate method testing is carried out properly and in accordance with the regulatory requirements. In response to such questions, the EPA will provide clarification of the requirements, decisions in regard to technical issues, and recommendations or guidance as may be appropriate.

In particular, applicants considering candidate method testing may wish to submit a proposed test plan to EPA in advance for review and comment by EPA in regard to its apparent conformance to the applicable test requirements. Such a test plan should include a description of the candidate method (make, model, PM size range, nature of the PM measurement so that its Class can be positively determined and any operational or aspiration characteristics can be considered, etc.), proposed test sites with rationale or justification for their selection, proposed sampling dates, identification of the FRM samplers to be used, the number of FRM and candidate methods to be included, and any other information that may have a bearing on the acceptability of the tests with regard to the Part 53 requirements. The more information that is included, the less chance there may be of overlooking some relevant aspect of the testing that could affect acceptability of the test results.

Also, it should be noted that the candidate method instruments tested must be representative of the final product to be manufactured and offered for sale as a designated equivalent method under Part 53 [§53.4(b)(6)]. That means that all method design and configuration details must remain unchanged throughout testing and commercial production. Significant changes to the method during or after the testing process (such as might be suggested from test data or test results) may render the test results inapplicable

to the equivalent method determination. Minor changes to the method after testing must be described in detail and accompanied by adequate justification that the change or changes result in no significant deterioration in the performance of the candidate method.

For purposes of documentation, all questions or information submitted to EPA in regard to Part 53 requirements should be in writing and sent to the address given in §53.4 of Part 53 or to the Reference and Equivalent Method Program (MD-D205-03), U.S. EPA, Research Triangle Park, NC 27711. EPA will provide a timely written response, which should be re-submitted to EPA as part of the content of an associated application under Part 53. Note that any information you submit to EPA that is claimed to be confidential or privileged information must be marked or identified as such (see §53.15 of Part 53), so that it will be treated in accordance with 40 CFR Part 2 concerning confidential business information (CBI). Non-CBI questions or information may also be submitted to EPA via e-mail to Hunike.Elizabeth@epa.gov.

Responses to questions or issues of a generic nature that are not deemed CBI and may be helpful to other potential applicants may be posted on EPA's AMTIC web site (www.epa.gov/ttn/amtic) or otherwise made available to other potential applicants or to the public. *This www site may also carry technical corrections, clarifications, general guidance, FYI announcements, spreadsheet templates for the required test data calculations, application templates, or other information concerning PM_{2.5} and PM_{10-2.5} FEM applications that may be of particular interest to potential Part 53 applicants.* Applicants are advised to check this web site frequently for new information prior to and during the testing and application process.

-- Reference and Equivalent Method Program, U.S. EPA. 11/14/06