Attachment 1

$PM_{2.5}$ PEP Adequacy and Independence Criteria: Monitoring Rule Requirements and Supplemental Guidance July 2009

The underlying document is an Attachment to the most current revision to the annual Memorandum from the Director of the Air Quality Assessment Division to Regional Air Program Managers for Ambient Monitoring Air Monitoring Quality Assurance Contacts, entitled "Guidance on Self-Implementation of the Performance Evaluation Program (PEP) for $PM_{2.5}$ Monitoring Lead (Pb) monitoring and the National Performance Audit Program (NPAP) for NAAQS Gases." This memorandum is posted on AMTIC at <http://www.epa.gov/ttn/amtic/npepqa.html>.

This attachment is a living document which will be reviewed annually and revised as needed. Subsequent revisions will be posted as separate documents on AMTIC at <http://www.epa.gov/ttn/amtic/pmpep.html>. A revision may not be necessary every year. Each subsequent memo that announce the opportunity for State, Local and Tribal programs to assume their Performance evaluation programs will reference the most current revision to the PEP Adequacy Document. Questions and Comments on this Document may be sent to Dennis Crumpler, OAQPS lead for the $PM_{2.5}$ Performance Evaluation Program. crumpler.dennis@epa.gov . Please send a courtesy copy of your communication to your respective EPA Regional PEP lead or Quality Assurance Manager.

PEP Program Adequacy and Independence Criteria: Monitoring Rule Requirements and Supplemental Guidance

Glossary (taken from the Current Field and Laboratory Operating Procedures)

AQS	Air Quality System (EPA data base for ambient monitoring data)
COC	Chain of Custody form
COR	For EPA, the Contracting Officer's Representative on a given contract; he or she could be a Work Assignment Manager (WAM), Task Order Delivery Officer (TOPO), or Delivery Order Project Officer (DOPO)
ESAT	Environmental Services Assistance Team
FS	A field scientist is a person certified by the U.S. Environmental Protection Agency (EPA) as completing a required training program as being capable and responsible for conducting FRM PEs. That person would have a 2- or 4- year college degree in a physical or life science or scientific instrumentation or have equivalent training or work experience.
FRM	Federal Reference Method
NIST	National Institute of Standards and Technology
OAQPS	Office of Air Quality Planning and Standards
PEP	$PM_{2.5}$ Federal Reference Method *Performance Evaluation Program*
PQAO	Primary Quality Assurance Organization
QAPP	Quality Assurance Project Plan
SOP	Standard Operating Procedures
SLT	State, local or Tribal (refers to environmental agencies and in particular those that conduct ambient air monitoring and related quality assurance activities

Overview of Monitoring Rule Requirements

- Monitoring plans or the QAPP shall provide for the implementation of a program of independent and adequate audits of all monitors providing data for SLAMS and PSD, including provisions of adequate resources for such audit programs. (40 CFR 58 Appendix A section 2.4). Starting January 1, 2009, this requirement also applies to SPM monitors using FRM, FEM, or ARM methods which also meet the requirements of Appendix E of 40 CFR 58, unless alternative QA procedures are approved by the Regional Administrator. (Appendix A, section 1; 40 CFR 58.20; and 40 CFR 58.11(a)(2)) EPA interprets this requirement to apply only to SLAMS, PSD, and SPM monitors that measure NAAQS pollutants.)
- Primary quality assurance organizations with 5 or fewer $PM_{2.5}$ monitoring sites are required to have 5 valid independent audits per year; primary quality assurance organizations with greater than 5 sites are required to have 8 valid audits per year. Each method designation must be evaluated each year, within the required 5 or 8 audits. (40 CFR part 58 Appendix A section 3.2.7)
- The regulation requires100 percent completeness (meaning whatever it takes to get 5 or 8 valid samples).
- All FRM samplers at within each SLAMS network will be subject to a PEP audit within 6 years.

Guidance – General

- The general requirement for a program of independent and adequate audits means that any SLT implementing a PEP program must provide for independence and adequacy for both field and lab implementation elements of the $PM_{2.5}$ PEP program.
- QAPP and SOPs for implementation will be reviewed and approved by Region.
- SLT PEPs should have an adequate number of audit samplers, including back-ups.
- If equipment is borrowed from the Regional PEP program, there must be some formal agreement that the SLT agency will repair or replace damaged equipment in a timely manner.
- While the old and revised monitoring rules are silent on the scheduling of the required audits, the 1998 PEP Implementing Guidance, the1999 PEP QAPP, and the "Redbook" both refer to quarterly audits. We still believe the seasonal representation achieved by auditing one or two monitoring sites in each quarter is the best practice. When there were many more audits to complete, the schedules sometimes were strained and audits may have fallen a week or two into following quarters. With the number of audits shrinking and the number of organizations, upon which PEP numbers are determined, the new PQAOs, are shrinking, the scheduling should be more manageable.
- The implementation of the PEP program by SLTs requires an enhanced QA system for the PEP. Comparability between Federally-conducted and SLT PEPs is essential. Biannual collocations of all PEP samplers in each Region are one of the critical QC activities in the PEP. These "parking lot studies" provide
    - First, a comparison of sampler performance;
    - Second, a comparison of the technical performances of the SLT and the Region's personnel, and
    - Third, a comparison of all Regions at the National level.

  In addition to the collocations, annual TSAs of the SLT programs will be necessary, just as TSAs are necessary for EPA's ESAT-run PEP in each Region.

  The EPA, via contractor support, will compile a nationwide PEP QA summary report each year and will compile a 3-year report in the third year. These reports will include comparisons of the collocations and TSAs Regionally and nationally as well as results of the audits of the FRM network. The frequency of these reports will be re-evaluated annually.

Independence of the SLT PEP Program

40 CRF part 58 Appendix Section 2.2 states: "The monitoring organization must provide for a quality assurance management function -- that aspect of the overall management system of the organization that determines and implements the quality policy defined in a monitoring organization's QMP…The quality assurance management function must have sufficient technical expertise and management authority to conduct independent oversight and assure the implementation of the organization's quality system relative to the ambient air quality monitoring program and should be organizationally independent of environmental data generation activities." (EPA has a good example of a QMP for OAQPS

http://www.epa.gov/oar/oaqps/qa/qmp.pdf. In the preamble to the October 17, 2006, Federal Register that promulgated the recent revisions of the aforementioned monitoring regulations, EPA explained that "An independent organization could be another unit of the same agency that is sufficiently separated in terms of organizational reporting and which can provide for independent filter weighing and performance evaluation auditing." In the PEP QAPP and implementing guidance, EPA elaborates "An organization can conduct the Performance Evaluation Program (PEP) if it can meet the above definition and has a management/supervision structure that, at a minimum, will allow for the separation of its routine sampling personnel from its auditing personnel by two levels of management. In addition, the pre- and post-sample weighing of audit filters must be performed by separate laboratory facility using separate laboratory equipment. Field and laboratory personnel would be required to meet the PEP field and laboratory training and certification requirements. The State and local organizations are also asked to consider participating in the centralized field and laboratory standards certification process.

Adequacy of the SLT PEP Program

PEP Field Operations -- Critical Steps and Activities

The current PEP Field SOP January 2009, contains all the following requirements. (The SOP may be revised each year beginning with a discussion of operational issues during the certification and recertification courses, which are typically held in the fall. Necessary revisions are drafted and then vetted again through a semi-formal review process including public comment period. Consequently, the STLs that conduct PEP are encouraged to participate in the training and SOP review process.)

1. Initial training and certification of audit personnel through EPA's federally-implemented PEP Field scientist course prior to an Agency's implementation of the program.

    a. The PEP is the "Gold Standard" for network bias (and relative accuracy on a local basis); therefore, uniform and consistent implementation remains a primary objective. Operator and sampler performance are held to high standards. Comprehensive record keeping, the quality control of the filter exposure and handling, and careful data validation are critical activities. EPA will provide the initial training in a timely manner for every State that needs to get certified to take their program. We will tailor the course to the specific roles that the States are assuming—field operations, gravimetric lab operations, or both. The course may be as much a forum for a given agency to fine tune their PEP QAPPs as it is for training. SLT Field Lab Scientist may also attend EPA national training and recertification courses.
2. Annual recertification of audit personnel either by
    a. Attending an annual PEP certification or recertification course;
    b. Attending a Regionally implemented recertification course conducted by a certified, EPA regional or OAQPS trainer;

c. Local Recertification conducted by an independent organization (contractor) that has been certified by OAQPS and commissioned by the respective EPA Regional Office; see alternative during collocation events—element 16 below.

3. Existence of a back-up sampler, for the circumstance of having a sampler failure near the end of a quarter or year; which would otherwise jeopardize completeness (5 or 8 valid audits). These may be made available from the federally run PEP program.
4. Performance leak check, pressure, temperature, time and flow rate check at <u>every audit</u>. Data recorded and available upon request.
5. For a new SLT program (i.e., less than 2 years old), the frequency for field blanks is one per FRM/FEM audit. For all others, one field blank should be performed per Field Scientist (FS) per trip. A trip may include audits for more than one FRM/FEM sampler.
6. Generation of trip blanks for at least one-half of the Field Blanks, i.e., 3 for the SLTs that conduct five PEP events and 4 for those that conduct 8 PEP events. The trip blank would be valid only if it is associated with a valid PEP audit and a field blank associated with that Audit. (Programs using the Federal PEP support lab will get these automatically.)
7. PEP sampler should be positioned horizontally within 1-4 meters of the target FRM sampler and any other low volume sampler within the same distance to the FRM; or, 2-4 m from any high volume sampler that is located with the same distance from the FRM. The primary sampler's (monitor's) inlet and the PEP sampler inlet can vary by no more than 1 meter vertically.
8. Use of pre-weighed filters within 30 days of stable pre-PEP-event tare weight.
9. Use of filter caps and antistatic bags, which isolate samples from dust and moisture contamination during storage and shipping.
10. Sample placed on cold packs (ice substitute) upon retrieval and maintained at 4^{o}C.
    a. The October 17, 2006, regulatory changes Part 50 Appendix L section 8.36 actually states routine FRM filter samples are to be shipped at temperatures no greater than experienced during sampling and weighed within 10 days except that 30 days for post-sampling conditioning and weighing be allowed if the routine sample should is shipped on cold packs. That is the only way a sample can remain below the ambient monitoring temperature it must be cold-packed. Again, since the PEP is the "Gold Standard,' we should retain the more stringent quality control measures.
11. The sample should be transported/shipped to the gravimetric service lab at 4^{o}C with an accompanying max/min thermometer.
    a. EPA will provide "max-min" thermometers if the SLT agencies do not have them.
12. The exposed filter shipment and delivery goal is to recover it within 8 hours of the end of the sampling event, get it cold-packed and shipped the same day via Fedex or other service, delivery to gravimetric service laboratory with next day "morning" delivery. A more rapid recovery and delivery is always acceptable. Only in crucial scheduling situations should the PEP event occur such that Friday filter recovery is necessary. If it occurs, samples must be refrigerated over the week-end at 4^{o}C and then shipped with 24-hour delivery on the following Monday morning. A 48-hour collection is permissible if the site is inaccessible on holidays and weekends; however, Friday audits or Thursdays before Friday Holidays should be avoided if at all possible. If 48-hour collection is unavoidable, the filters get a 48-hour collection flag. Only in the case of an emergency, up to 96-hour collection is permissible, and then the resulting data is still carefully scrutinized. If the collection time

13. SLT-operated PEPs will implement a chain of custody protocol and require completed field data sheets for each PEP event. EPA will furnish COCs and FDSs to those agencies that utilize the Federal PEP lab service. Chain of Custody Forms (COCs) and Field Data Sheets (FDSs) and all QA/QC data should be filed and made available upon request. As a general rule, PEP files should be held for 4 years plus the current calendar year in order to address any FRM data-driven decision appeals. Electronic files of the blank forms will be available to fully self implementing programs upon request and are encouraged for the sake of consistency in reporting.
14. Audit samplers must be inspected and cleaned, if necessary, on quarterly basis or more frequently if circumstances dictate—PEP equipment must be pristine. An example would be an audit conducted during a period when a dust storm occurred
15. If the PEP sampler is something other than a BGI PQ200, a multi-point verification and /or calibration for all parameters (pressure, temperature, flow) using an NIST traceable standard that is independent from the routine operational verification standard, is required annually. The PQ200 requires multipoint calibration only for temperature.
16. To accommodate SLT PEP programs which may be limited by travel budgets or policies of their agencies, the EPA has modified several QA oversight activities called for in the original PEP Implementation Plan and QAPP: (a) Periodic Sampling events using collocated PEP Samplers; (b) Technical Systems Audits of PEP field scientists and supporting gravimetric laboratories, and (c) on-site recertification for SLT Field Scientists.
    a. ***Collocations:*** In those Regions where SLTs assume the responsibilities associated with the PEP, collocations will serve as an assessment of the comparability of Federal/State/Tribal/Local programs and the resulting PEP data.
        i. Each SLT-run PEP shall conduct semi-annual collocation of all audit instruments, each at a single location for three sampling events to identify calibration drift and malfunctions among the PEP samplers. (Quarterly collocations were historically required).
        ii. At least one collocation shall be a joint activity of the PEP-implementing STL agencies and the respective Region's ESAT-run PEP field operations. The schedule will be worked out through the EPA Regional Office and the federal PEP support lab in EPA Region 4.
        iii. Each Regional and SLT program needs to set-up and operate the collocation through all measurement phases as if it were performing a routine audit. After considerable deliberation among the SLT agencies and EPA Regions who have been participating in collocations, it was determined that SLT employees are required to conduct all the necessary procedures in joint collocation studies. (This is the only way one would capture all potential sources of measurement error that might cause a program to be dissimilar to the federally implemented PEP.)
        iv. It is important that the SLT have a back-up operator in case the primary operator cannot perform all the requisite functions during the collocation, e.g., due to an unforeseen emergency the SLT employees must return to home or office.
        v. If an SLT agency chooses to participate in only one collocation event with its respective EPA Region in a year, then it must conduct one other collocation event that involves at least four samplers and meets all other collocation criteria such as

b. ***Technical Systems Audits***--SLT- implemented PEPs will be subject to one annual technical systems audit of the field activities and support laboratories. These audits will typically be conducted by the Regional PEP Lead and will involve an on-site review of field and or lab activities, a review of data acquisition, management and record keeping and relevant QA/QC procedures.
   i. The EPA Regional PEP Lead may use one or both of the collocation events to conduct audits.
   ii. The EPA Regional PEP Lead will specify that paperwork for at least one quarter of PEP activity, be submitted by the SLT PEP for a TSA review.
   iii. The Regional ESAT Contractor, if holding a current PEP field scientist certification, is qualified to coordinate the collocation sampling event and also conduct a technical review of the SLT PEP field procedures and sample handling. *This may occur only if the Region agrees and has provided for this activity with the ESAT contractor through the appropriate contract instrument*. If the Regional PEP LEAD or QA official is present, the review would qualify as a recertification of the SLT field scientist(s). The EPA Regional PEP Lead or QA official will be present for at least one of the collocation events and observe the operational procedures, as part of the Region's responsibility.

c. ***Recertifications of Field scientists—***The EPA Regional PEP Lead may, at their discretion, utilize the field activity reviews and TSAs to recertify SLT PEP field personnel.
   i. The TSA and evaluation forms will be reported to OAQPS for compiling in a national oversight record. OAQPS will compile an annual summary and include the summaries in a detailed Triennial PEP QA Report.
   ii. These forms are in the currently approved QAPP, which is available on AMTIC at http://www.epa.gov/ttn/amtic/pmpep.html, or they can be requested from the National PEP Lead at OAQPS.

PEP Laboratory (Lab) -- Critical Steps and Activities

Due to the intricacies of data handling and consistency of results for the participating programs it is recommended that SLTs utilize EPA's PEP service laboratory. An independent laboratory will be required to adhere to the following:

1. The PEP Lab's QAPP and SOPs should be available, reviewed, and approved by the respective Regional PEP Lead or QA manager prior to implementation; then subsequently, made available upon request. Their elements, specifications and QA/QA criteria should be equivalent to those of the federally implemented PEP.
2. Initial training through Federal PEP sanctioned course prior to implementation.
   a. Substantial differences in the theoretically could exist between FRM gravimetric lab procedures and the federally-run PEP, due to the QA/QC requirements in the PEP LAB SOP, the data validation procedures, and posting to AQS. EPA will require PEP labs to retain the same levels of QA/QC.

3. The PEP Lab must be independent of the SLT's laboratory performing routine FRM sample weighing for the sampler(s) being audited.
4. The PEP Lab and analyst will be audited annually by the EPA Region or OAQPS; recertification of lab technicians is part of the process.
5. The PEP Lab must meet the Temperature/Humidity control conditions for a 24-hour period in order to allow weighing of samples.
6. All PEP Labs must meet QC requirements as described in PEP lab SOPs and include
    a. Lab Blanks - 10% or 1 per weighing session,
    b. Duplicate Filter weighing - 1 per weighing session,
    c. Balance check - beginning and end of weighing session,
    d. Previous session's duplicate at end of each weigh session - +/- 15 ug.
7. Every balance used for PEP gravimetric analyses must be internally audited annually against an NIST certified set of standards that are independent from the routine operating standards. An annual recalibration will satisfy this requirement if it is conducted by an independent party and the results before and after recertification are documented.
8. Reference Standards will be checked or certified as follows:
    a. Working mass standard check against primary on a quarterly and monthly basis.
    b. Primary standards and working standards certified annually as NIST traceable. Documentation sent to OAQPS.
    c. Lab temp and humidity standards certified annually as NIST traceable. Documentation sent to OAQPS.
9. The PEP Field and Lab SOPs discuss the time requirements for weighing exposed filters. Generally, weighing is expected within 10 days from filter exposure end date/time, see the discussion in the September 2006 field SOP which will be incorporated into the Lab SOP revisions in 2007.
10. Filters must be equilibrated a minimum of 24 hours for pre **and** post weighing. Documentation must be available that demonstrates stable mass is achieved consistently in the lab with 24 hour equilibration periods; if not, 48 hours is required.
11. The PEP Lab will employ filter equilibration blanks.
    a. Lot blanks used to determine general equilibration time.
    b. Lot exposure blanks – used to establish equilibrium of a specific batch of filters.
12. The PEP Lab will initiate and complete chain of custody (COC) procedures. COCs and Field Data Sheets should be recorded and stored and made available upon request, according to the schedule laid out in the Field and Lab SOPs. Digital versions are available on the AMTIC website.
13. The PEP lab will archive filters for current year plus last calendar year in cold storage and 3 preceding years at ambient.
14. The PEP Lab will follow AQS format for reporting QA data to appropriate fields in AQS.
15. The PEP Lab will load data into AQS within AQS's schedule—every 90 days, which is no later than deadline for SLT/PQAO submission of the $PM_{2.5}$ FRM data obtained in the same quarter as the audit.

16. The PEP Lab will participate in an annual gravimetric round-robin performance evaluation administered by EPA's Office of Radiation and Indoor Air-National Air and Radiation Environmental Laboratory, in Montgomery, Alabama.
17. The PEP Lab (or in the case of an SLT PEP program, it might be the client PQAO) submits annual report of results to EPA in format specified by EPA.