

March 26, 2013

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EPA Docket Center
Attention Docket ID Number EPA-HQ-OEI-2012-0774
EPA West Building
Mail code: 28221T
1200 Pennsylvania Avenue, NW
Washington, DC 20460

Dear Sir/Madam:

On behalf of the National Association of Clean Air Agencies (NACAA), thank you for this opportunity to comment on the Draft *Quality Standard For Environmental Data Collection, Production, and Use By Non-EPA (External) Organizations* (December 1, 2012, ID: EPA-HQ-OEI-2012-0774-0002), which was published in the *Federal Register* on December 26, 2012 (77 *Federal Register* 76035). Accompanying this document were two draft handbooks on which we are also commenting: *Draft Handbook for Preparing Quality Management Plans* (December 2012, ID: EPA-HQ-OEI-2012-0774-0004) and *Draft Handbook for Developing Quality Assurance Project Plans* (ID: EPA-HQ-OEI-2012-0774-0003). NACAA is a national, non-partisan, non-profit association of air pollution control agencies in 43 states, the District of Columbia, four territories and over 116 metropolitan areas. The air quality professionals in our member agencies have vast experience dedicated to improving air quality in the U.S. These comments are based upon that experience. The views expressed in these comments do not necessarily represent the positions of every state and local air pollution control agency in the country.

Introduction

The members of NACAA believe it is important that there be effective measures in place to ensure that the data we collect and use in our programs is of high quality. Accordingly, we agree that EPA should have appropriate and adequate quality management standards. However, we are concerned about some of the provisions in the standards and handbooks that EPA has proposed. We articulate these concerns below.

NACAA believes that a program of the magnitude outlined in the proposal, with such potentially significant changes and impacts on state and local air agencies, should have been discussed in greater detail with these agencies before being proposed. Such consultation could have helped EPA better understand the

ramifications of the proposed changes on the air program. It is not known whether EPA has noted significant problems with the quality of the data it has received from state and local agencies that would warrant such an overhaul of the quality management requirements. If so, we believe state and local air agencies should have been informed of these deficiencies and engaged in discussions about the best course of action to address them with EPA. Before EPA issues a final standard, we strongly recommend that the agency (1) discuss the proposed changes in detail with NACAA representatives who can provide insights into the workings of the air program and how they mesh with EPA's quality assurance concerns and goals and (2) make changes to the requirements that will ensure that the program provides the necessary quality assurance without undue and/or unintended burdens on state and local air agencies.

The Proposal Could Expand State and Local Quality Assurance Activities

While the proposal states that the standards would not impose any new requirements,¹ NACAA disagrees with this assessment and is concerned that it would, in fact, expand the obligations of state and local air agencies.

The document currently in effect states: "*The [Quality Assurance Project Plan] QAPP requirements in this chapter apply to all (intramural and extramural) environmental data operations that acquire, generate, or compile environmentally-related data and that are performed by or on behalf of EPA.*"² The new language in Annex B states "*The QAPP requirements in this Annex apply to all activities for EPA that acquire, generate, or analyze environmental data that are performed on behalf of EPA through external agreements.*"³ The addition of "*all activities for EPA*" and "*analyze*" could significantly broaden the scope of applicability for this program.

Further, the proposed standard includes an expanded list of data and activities covered by the requirements. The proposed standard states:

The QAPP or equivalent document shall document the project goals and objectives, and shall define the [quality assurance] procedures, [quality control] specifications, and other technical activities that must be implemented to ensure that the results of the project or task to be performed will meet project objectives. The organization shall prepare a QAPP, or equivalent quality document, for all applicable projects and tasks involving environmental data collection, production, and use as listed previously in Clause 2.1⁴

Clause 2.1 – states:

Environmental data may be:

- *collected from environment media directly in the form of physical samples or from existing electronic databases;*

¹ 77 Federal Register 77035

² EPA QA/R-5, *EPA Requirements for Quality Assurance Project Plans* (March 2001; Reissued May 2006), Section 2.3 – Applicability, page 7.

³ Draft *Quality Standard for Environmental Data Collection, Production and Use by Non-EPA (External) Organizations* (December 1, 2012), Clause B2.3 – Applicability of QAPPS, page 29.

⁴ Draft *Quality Standard*, Clause 7.5 Quality Assurance Project Plan (QAPP), page 9.

- *produced from analytical methods or instrumentation, and mathematical or electronic computational models or programs;*
- *collected from the literature or other existing data sources (e.g., web sites on the Internet); and*
- *used in a variety of analyses and evaluations to document environmental conditions and to support decisions pertaining to such conditions.*

Activities involving environmental data encompassed by this Standard include, but are not limited to:

- *direct and indirect field or laboratory measurements;*
- *evaluating the operation and performance of environmental technology (e.g., pollution control);*
- *inspections;*
- *survey development or application;*
- *enforcement and compliance monitoring or assessments;*
- *application of environmental management systems;*
- *environmental safety and health monitoring;*
- *scientific research;*
- *regulatory development;*
- *use of statistical or economic analyses using environmental data;*
- *use of information technology (e.g., the development and use of models such as pollutant transport and ground water migration, databases) supporting Agency programs;*
- *use of information sources outside of direct EPA management controls or authority (e.g., academic institutions); and*
- *use of data obtained from other sources (e.g., literature, Internet).⁵*

For state and local air agencies, this list of data and activities could represent an expansion of activities for which preparation of a QAPP will be required. This could require additional QAPPS for many activities, including those related to permitting and the development of State Implementation Plans (SIPs). Even if an agency employs a generic QAPP, as described in the draft QAPP handbook,⁶ this could be a very onerous change.

For example, state and local air agencies issue many permits each year, including many different permit types. The new standards could require these agencies to develop individual QAPPS in order to use the information submitted by permit applicants, thus elongating the permit process. Additionally, state and local air quality agencies develop SIPs, which is often a complex process involving the evaluation and analysis of emission inventories, various kinds of sources, control techniques and strategies and modeling, among other things. Under the proposed program, agencies would have to expand their efforts related to developing QAPPS and obtaining approvals from Quality Assurance Managers and EPA at various points in the process, thereby adding additional effort to an already complex and time-consuming process.

⁵ Draft *Quality Standard*, Clause 2.1 – Scope, page 2.

⁶ Draft *Handbook for Developing Quality Assurance Project Plans* (December 2012), Section 1.4 – Generic QAPPS, page 7.

Complying with an expanded quality management program as envisioned by the proposal would require additional state and local resources that are simply not available to agencies that are already financially strapped. That being the case, if this expansion is required, state and local air agencies could be placed in the position of having to divert already scarce resources from their core activities, the foundation of their air pollution control efforts, to satisfy the requirements of the quality standard.

It appears that the expansion of activities is not only on the part of state and local agencies. The proposed standards require all QAPPS and equivalent documents to be reviewed and approved by the EPA Quality Assurance Manager or an authorized representative.⁷ Currently, EPA reviews and approves only select QAPPS. EPA review of *all* QAPPS, particularly if the universe of QAPPS is expanded, would result in significant delays in the implementation of the activities in question.

The Proposal Advocates a Centralized Quality System that May be Different from Current State and Local Practice

It appears that EPA, through the proposal, is calling for state and local agencies to make organizational changes to result in a centralized quality system and to effectively ensure that there is staff dedicated to quality assurance (QA) oversight responsibilities. We are concerned that this is impractical and infeasible for many agencies. Among the provisions that contribute to the impression that EPA is seeking a centralized system are the following:

- Section 8.2 of the proposed standard (on Quality Management Personnel)⁸ states: “The functions of the quality management personnel may be totally related to quality management system activities or be in conjunction with other functions and responsibilities within the organization. If these personnel have other concurrent functions to perform, there must be no conflict of interest.” However, the proposed handbook for Quality Management Plans also states that it is critical that quality management personnel be “permitted functional independence from line management, as well as direct access to senior management as necessary to address quality issues.”⁹ If QA staff is independent from line management, it would be difficult for them to perform functions within the organization outside of their QA responsibilities.
- Annex A¹⁰ of the proposed standard calls for “an organization chart that identifies all of the components of the organization and, in particular, the organizational position and lines of reporting for the QA Manager (and any QA staff) that confirm and document the independence of the QA Manager from groups collecting, generating, using, and evaluating environmental data.” Again this seems to call for separate QA staff.
- The General Requirements Section of the proposed standard states “All QAPPS and equivalent documents shall be reviewed and approved by the organization’s QA Manager

⁷ Draft *Quality Standard*, Clause 7.5.1 – General Requirements, page 9.

⁸ Draft *Quality Standard*, Clause 8.2 – Quality Management Personnel, page 14.

⁹ Draft *Handbook for Preparing Quality Management Plans* (December 2012), Section 3.4.2 – Roles and Responsibilities, page 17.

¹⁰ Draft *Quality Standard*, Annex A, Clause A3.4, page 23.

and their management (as applicable) before submission to EPA.”¹¹ Having a central QA manager in the agency to review all the QAPPS is not ideal for some agencies because they prefer that the staff person reviewing QAPPS not be separated from the program-specific knowledge frequently needed to understand the contents.

State and local air agencies are structured in a variety of ways and some may have to reorganize in order to comply with the requirements in the proposed guidance calling for additional independence for QA staff. Currently, due to economic hardship, many state and local agencies are underfunded, understaffed and subject to hiring freezes and do not have the resources to hire additional QA staff or to take staff that currently perform a variety of functions and devote them to QA tasks.

Conclusion

The proposed quality standards and handbooks could have far-reaching consequences for state and local air agencies. The proposals could increase their burdens by requiring them to rewrite current QAPPS and prepare QAPPS for activities that have not necessitated them in the past. Additionally, state and local air agencies could be called upon to reorganize staff responsibilities to address the proposed quality management requirements. State and local air agencies are currently faced with inadequate and diminishing funds, as well as reduced staff levels, and would find it difficult to impossible to stretch their resources further.

NACAA does not believe that EPA has made a compelling case that the quality of the data it has received from state and local agencies is problematic enough to warrant such changes to the quality management requirements. In fact, EPA’s statement in the *Federal Register* that the changes will not impose any new requirements suggests that the agency believes that the level of effort in the current program is generally sufficient.

Whether EPA determines that some substantive changes are needed in the program or that the agency did not intend to add additional burdens, and the adverse consequences were inadvertent, we request that the agency repropose the standard and work collaboratively with state and local agencies to develop provisions that achieve their goals without any unintended negative ramifications. If NACAA can assist the agency in this, please do not hesitate to contact us.

Thank you for this opportunity to provide comments.

Sincerely,



David J. Shaw
New York
Co-President of NACAA



Barry R. Wallerstein
Los Angeles, CA
Co-President of NACAA

¹¹ Draft *Quality Standard*, Clause 7.5.1 – General Requirements, page 9.