



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
REGION 1
NEW ENGLAND REGIONAL LABORATORY
OFFICE OF ENVIRONMENTAL MEASUREMENT & EVALUATION
11 TECHNOLOGY DRIVE
NORTH CHELMSFORD, MASSACHUSETTS 01863-2431

November 14, 2018

Ms. Susan Sullivan, Executive Director
New England Interstate Water Pollution Control Commission
650 Suffolk Street, Suite 410
Lowell, MA 01854

Dear Ms. Sullivan:


The final report for the quality system assessment of the New England Interstate Water Pollution Control Commission conducted on October 17, 2018 is enclosed. We appreciate NEIWPCC's dedication to maintaining a strong quality system.

NEIWPCC's quality system continues to be fully integrated into the operation of all programs EPA reviewed. There were no non-conformances identified in any aspect of NEIWPCC's quality system that were reviewed. Therefore, no corrective actions are necessary.

Please extend our thanks to Mike Jennings, the exiting Quality Assurance Program Manager, and Peter Zaykoski, the new Quality Assurance Program Manager, as well as the rest of the staff that were available to be interviewed. We appreciate the time they took to meet with my staff and their good-natured cooperation.

We look forward to a continuing partnership with you and your staff in implementing quality systems to help achieve our mutual environmental goals. If you have any questions, feel free to contact me at 617-918-8312 or Nora Conlon of my staff at 617-918-8335.

Sincerely,


John Smaldone, Regional Quality Assurance Manager
U.S. EPA, Region 1

Attachment

cc: N. Conlon, (Region 1)
J. Butensky, (Region 1)
P. Zaykoski (NEIWPCC)
C. Lynes (Region 2)

Final Report – 11/14/2018
Quality System Assessment of New England Interstate Water Pollution Control
Commission (NEIWPCC)
October 17, 2018

Introduction

EPA Order CIO 2105.0, *Policy and Program Requirements for the Mandatory Agency-wide Quality System*, mandates that all organizations conducting environmental data and technology programs performed for EPA through EPA-funded extramural agreements shall have a quality system in operation to support these programs. Each quality system must be described in an approved Quality Management Plan (QMP) that details the policies and procedures, roles and responsibilities, and quality activities used to plan, implement and assess the effectiveness of the organization's quality system. EPA New England provides periodic oversight and assessment of the implementation of the quality systems financial assistance agreement recipients within New England.

Purpose, Background and Scope

To assess the status of the NEIWPCC Quality System, EPA NE performed a Quality System Assessment (QSA) on October 17, 2018. The last NEIWPCC QSA was performed in October and November 2013.

The primary purpose of the QSA was to evaluate the implementation and effectiveness of the NEIWPCC quality system. Criteria included:

- Quality requirements specified in EPA financial assistance regulations.
- The components of the NEIWPCC quality system, which were documented in its current QMP, Revision No. 6, January 2018.

NEIWPCC and EPA NE agreed, prior to this QSA, upon the schedule, agenda and general focus of the QSA. For this assessment, selected documents of the quality system were reviewed.

The specific issues addressed during the assessment included the following activities:

- General Quality System awareness
- Information collection for the annual Quality Assurance (QA) Status report
- Process for receipt, review, approval of Quality Assurance Project Plans (QAPPs)
- Training is up-to-date and transitions for new employees or positions is smooth

Executive Summary

NEIWPCC has fully integrated its quality system into the operation of its programs. Staff and managers are aware of the QMP and the quality system. The QMP is accurate. It is suggested that the Interstate Environmental Commission (IEC) parts of the plan be removed as soon as the separation of the two organizations is complete. The information collection for the annual QA Status report is efficient and timely. The system for QAPPs from receipt to storage is functioning well. The Annual QA training for all staff is effective. The inclusion of the Quality

Management System Overview for new employees is routine. The transition between the former QA Program Manager (QAPM) and the new QAPM is going well.

Assessment Process

Assessment procedures were developed by the EPA New England QA Unit. Candidate programs and personnel to be interviewed were jointly agreed upon by EPA and the NEIWPCC Quality Assurance Program Manager (QAPM). The specific procedures used to conduct this QSA are described below.

1. *Assessors.* The assessment team included the following members of the EPA New England QA Unit: Nora Conlon (team leader, NEIWPCC QA Contact) and Steve DiMattei
2. *Documents reviewed.* In preparation for the QSA the assessment team reviewed the following documents before the on-site assessment:
 - a. *NEIWPCC Quality Management Plan*, Revision No. 6, January 2018.
 - b. *NEIWPCC Guide for Development and Approval of Quality Assurance Project Plans (QA Project Plans)*, Version 2.0, March 2016.
 - c. NEIWPCC Annual Quality System Status Reports – FY2013 through FY2017
 - d. EPA Order CIO 2105.0
 - e. EPA QA/R-2, *EPA Requirements for Quality Management Plans*, March 2001
3. *Documents/electronic files reviewed on-site.* The following documents/files were reviewed during the on-site assessment:
 - QAPP Tracker computer system and electronic document storage
 - Overview of Quality Management System – two-page summary
 - Example Request for Proposal (to show standard QA language)
3. *Personnel interviewed.* The following NEIWPCC personnel were interviewed during the assessment.
 - Quality Assurance Program Manager (Peter Zaykoski)
 - Outgoing Quality Assurance Program Manager (Michael Jennings)
 - Division Directors (Jane Ceraso, Richard Friesner)
 - Staff (Heather Radcliffe, Staff Attorney; Drew Youngs, Environmental Analyst)
 - Opening Meeting: Susan Sullivan, Executive Director; Thomas Groves, Adam Auster, Richard Friesner, Selene Lehmann, Division Directors; Samantha James, Business Operations Manager; Linda Agostinelli, Comptroller; Michael Jennings, Senior Program Manager; Peter Zaykoski, Quality Assurance Program Manager.
 - Closing Meeting: Michael Jennings, Peter Zaykoski
4. *Criteria.* The criteria for this assessment were based on the following policies:
 - *EPA Guidance on Assessing Quality Systems*, EPA QA/G-3, March 2003.
 - *EPA Requirements for Quality Management Plans*, EPA QA/R-2, March 2001.
 - *EPA Requirements for Quality Assurance Project Plans*, EPA QA/R-5, March 2001.

- *Implementation of Quality Assurance Requirements for Organizations Receiving EPA Financial Assistance*
- *NEIWPCC Quality Management Plan*, Revision 6, January 2018.
- *Policy and Program Requirements for the Mandatory Agency-wide Quality System*, EPA CIO 2105.0 (formerly EPA Order 5360.1 A2) May 2000.

Assessment Results

Non-conformances: None

The non-conformances that were identified in the previous QSA have been rectified and fully incorporated into the Quality System.

Conformances:

1. NEIWPCC has successfully implemented its Quality System. Each interviewed person was aware of the Quality System and the QMP.
2. The information for the annual QA report is collected through appropriate channels. There are QA questions included in the annual performance appraisals.
3. QAPPs are consistently written, reviewed and approved prior to data collection activities. The training of QA designees for QAPP reviews has been completed and may be offered for some additional personnel. The file system is now wholly electronic in a shared server. The QAPP Tracker has been instituted to aid the process. The internal goal of 10 business days for QAPP reviews has been achievable for most QAPPs.
4. QMS Overview training is completed for all new employees. QA Awareness training is a standard topic at the All Staff annual meeting.

Recommendation:

1. The NEIWPCC and Interstate Environmental Commission (IEC) relationship is ending. It is suggested that IEC-specific information should be removed from the QMP, when appropriate.