Quality System Assessment

NJ Department of Environmental Protection

Trenton, New Jersey

Draft Final Report

Division of Environmental Science and Assessment
U.S. Environmental Protection Agency - Region 2
2890 Woodbridge Avenue
Edison, NJ 08837

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A. Executive Summary

In 2009, the U.S. Environmental Protection Agency (EPA), Region 2 performed a Quality System Assessment of the New Jersey Department of Environmental Protection's (NJDEP's) Quality System. The purposes of this assessment were to ascertain:

- whether the Department's Quality System was compliant with the requirements of USEPA Order CIO 2105.0 (formerly 5360.1 A2 (2000)), *Policy and Program Requirements for the Mandatory Agency-wide Quality System*, and
- was being implemented as described in NJDEP's Quality Management Plan (QMP), and
- whether the policies and procedures in this plan were adequate to ensure that the Department's monitoring projects produced data that were of sufficient quality, useful for their intended purposes and properly documented.

In CIO 2105.0, it is required that all environmental programs performed by EPA or directly for EPA through EPA-funded extramural agreements be supported by individual quality systems that comply fully with the American National Standard Institute, ANSI/ASQC E4-1994, *Specifications and Guidelines for Quality Systems for Environmental Data Collection and Environmental Technology Programs.*

In 2005, a Quality System Assessment of the New Jersey Department of Environmental Protection's Quality System was also performed by the Region 2 quality assurance staff and concentrated on many of the Department's Water Programs. The assessment found that many of the Water Programs, such as the Bureau of Freshwater and Biological Monitoring, the Bureau of Marine Water Monitoring and the Bureau of Nonpoint Pollution Control, had very successful, functioning quality systems. The assessment also identified areas where the Department needed improvements and these were delineated in a final report issued on March 14, 2006. A Corrective Action Plan was submitted by the Department on April 21, 2006.

This year, groups assessed included the Office of Quality Assurance (OQA), a cross section of bureaus within Site Remediation, the Bureau of Surface Water Permitting, the Bureau of Technical Services, the Office of Information Resources Management, the Bureau of Environmental Radiation, the Bureau of Geology and Topography and the Wetlands Program.

Some positive highlights were noted during EPA's closing meeting with Department's senior managers. Among the highlights were that the Office of Quality Assurance's Laboratory Certification Program has improved the frequency of laboratory audits since our last assessment of the program in 2005. Also, the Bureau of Surface Water Permitting, the Bureau of Technical Services, and the Bureau of Environmental Radiation were found to be in compliance with the NJDEP Quality Management Plan and have functioning quality systems.

However, some significant shortcomings were identified during the audit and include the following:

Many of the corrective actions identified in NJDEP's April 21, 2006 Corrective Action Plan were never completed by NJDEP.

The NJDEP Wetlands Program was operating outside of the NJDEP's Quality System. Since becoming aware of the QAPP requirements, the Wetlands Program is making positive steps while working with OQA.

The Site Remediation Program is operating outside of the NJDEP's Quality System. The Office of Quality Assurance is aware of this and has not performed any oversight. It is strongly recommended that NJDEP evaluate the offices and bureaus that have functioning quality systems, like those identified in the 2005 report (i.e. the Bureau of Freshwater and Biological Monitoring, the Bureau of Marine Water Monitoring and the Bureau of Nonpoint Pollution Control) and those identified in this report (i.e. the Bureau of Surface Water Permitting, the Bureau of Technical Services, and the Bureau of Environmental Radiation), and use them as models for implementing a functioning quality system for the entire Department.

The forthcoming Licensed Site Professional Program provides a unique opportunity for NJDEP to establish a new Quality System describing the roles and responsibilities of managers and staff at all levels. EPA Region 2 commits to assisting NJDEP's OQA and Site Remediation Bureaus in developing and implementing a well documented and transparent Quality System. We would be happy to provide QA training jointly with your program and QA Staff, and help craft appropriate QA language for your current technical regulations and emerging Licensed Site Professional program.

It is also highly recommended that NJDEP OQA discontinue the practice of including QA Work Commitments and Outputs in the Department's QMP. QA Work Commitments and Outputs are valuable tools, but should not be included in the Department's QMP. Instead, a detailed description of the QA Roles and Responsibilities of all bureaus, offices and programs should be developed. A separate yearly planning document similar to EPA's QA Annual Report and Workplan (copy provided to OQA) should be developed and used to identify QA commitments and outputs, which can then be used to generate the NJDEP QA Annual Report.

B. Purpose and Scope of the Assessment

. The purposes of this assessment were:

- To ascertain whether the Department's Quality System was compliant with the requirements of USEPA Order CIO 2105.0 (formerly 5360.1 A2 (2000)), *Policy and Program Requirements for the Mandatory Agency-wide Quality System*, and
- was being implemented as described in NJDEP's Quality Management Plan (QMP), and
- whether the policies and procedures in this plan were adequate to ensure that the Department's monitoring projects produced data that were of sufficient quality, useful for their intended purposes and properly documented.

In CIO 2105.0, it is required that all environmental programs performed by EPA or directly for EPA through EPA-funded extramural agreements be supported by individual quality systems that comply fully with the American National Standard Institute, ANSI/ASQC E4-1994,

Specifications and Guidelines for Quality Systems for Environmental Data Collection and Environmental Technology Programs.

The NJDEP Quality Management Plan, signed by the Commissioner, the Deputy Commissioners and all Assistant Commissioners, states in Section 2 that the Office of Quality Assurance (OQA) **"**has the responsibility for developing and administering the QMP and for overseeing the QA activities for all of the Department's environmental programs." Assistant QA Officers within OQA have been designated to provide oversight and assistance to the Department's environmental programs, and to ensure that technical and administrative policies are consistently applied across organizational boundaries. It also states in Section 3 that it is NJDEP policy "that no environmental data collection activities be performed by or for the Department until after a QAPP (QA Project Plan) covering those activities has been approved by OQA or the Designated QA Representative. A network of QA Representatives has been established to assist OQA in overseeing the Department's Quality System. Each QA Representative has an area of responsibility that may consist of a section, bureau, element, division, or program. Significant goals for this assessment included determining whether the Department:

- Assigns sufficient resources to QA activities,
- Assures that those resources are dedicated to QA activities,
- Sufficiently distinguishes QA Representative responsibilities and authorities, and
- Effectively implements those QA Representative responsibilities.

C. Review Team

Kevin Kubik, Assessment Team Leader, Region 2 QA Manager
Patricia Sheridan, Hazardous Waste Support Branch.
Sergio López-Luna, Hazardous Waste Support Branch
Jennifer Feranda, Hazardous Waste Support Branch
Donna Ringel, Monitoring and Assessment Branch
Esther Nelson, Monitoring and Assessment Branch
Reshma Punwasie, Monitoring and Assessment Branch
Paula Zevin, Monitoring and Assessment Branch

D. Findings and Recommendations

The following programs were reviewed. All Findings, Required Corrective Actions, Suggestions, and General Comments are detailed by program or bureau.

Office of Quality Assurance

NJDEP's April 21, 2006 Corrective Action Plan

I. GENERAL INFORMATION

Program Assessed: New Jersey Department of Environmental Protection
Environmental Regulation
Division of Environmental Safety and Health
Office of Quality Assurance

EPA Assessors: Kevin Kubik, Division of Environmental Science and Assessment
Donna Ringel, Monitoring and Assessment Branch

NJDEP Personnel Interviewed: Joseph Aiello - Office of Quality Assurance
Marc Ferko - Office of Quality Assurance

II. FINDINGS AND REQUIRED CORRECTIVE ACTIONS

Finding 1: Many of the corrective actions identified in NJDEP's April 21, 2006 Corrective Action Plan were never completed by NJDEP.

Citation: Corrective Action Plan, dated April 21, 2006 submitted to EPA Region 2 by Commissioner, Lisa P. Jackson, in response to the Quality System Assessment Report sent to NJDEP on March 14, 2006.

Required Corrective Action: The following corrective actions identified in NJDEP's Corrective Action Plan must be completed:

#1. – Conducting annual reviews of the Department's quality assurance program and the quality assurance work outputs.

Additionally, NJDEP OQA must complete the NJDEP QA Annual Report. This report must be distributed to all NJDEP senior managers, OQA staff, the program QA Representatives and to the EPA Region 2 QA Manager;

#2. – Developing an SOP for data collection audits based on EPA's QA/G-9R for distribution to all Quality Assurance Representatives;

#3. – Identifying and performing Program Management System Reviews (MSRs) and Technical System Audits (TSAs) (specifically CERCLA and RCRA which were identified to be completed during FY07/08);

#4 – Obtaining and reviewing the guidance for the Uniform Federal Policy QAPP's for Superfund and RCRA Projects and training will be provided to OQA staff and Department QA Representatives; (This guidance was provided to OQA in 2007.)

#5. – Revising OQA's SOP for conducting TSAs and providing training to OQA staff and Department QA Representatives;

#6. - Developing more meaningful QA Outputs and scheduling quarterly meetings with QA Representatives to discuss and track outputs.

III. SUGGESTIONS

None.

IV GENERAL COMMENTS

None.

V. CONCLUSIONS

It is highly recommended that NJDEP's OQA discontinue the practice of including QA Work Commitments and Outputs in the Department's QMP. QA Work Commitments and Outputs are a valuable tool, but should not be included in the Department's QMP. Instead a detailed description of the QA Roles and Responsibilities of all bureaus, offices and programs should be developed. A separate yearly planning document similar to EPA's QA Annual Report and Workplan (copy provided to OQA) should be developed, used to identify QA commitments and outputs, and used to generate the NJDEP QA Annual Report.

Laboratory Certification Program

I. GENERAL INFORMATION

Program Assessed:	New Jersey Department of Environmental Protection Environmental Regulation Division of Environmental Safety and Health Office of Quality Assurance
EPA Assessors:	Donna Ringel, Monitoring and Assessment Branch Kevin Kubik, Division of Environmental Science and Assessment
NJDEP Personnel Interviewed:	Rachel Ellis - Office of Quality Assurance Michael DiBalsi - Office of Quality Assurance

II. FINDINGS AND REQUIRED CORRECTIVE ACTIONS

Finding 1: There are no Standard Operating Procedures (SOPs) for the processes associated with the non-NELAP Laboratory Certification Program.

Citation: NJDEP QMP, FY07-10, Section 10.0 (B) 3 – Requires development of procedures and check-sheets for managing all administrative and technical aspects of laboratory certification.

Required Corrective Action: SOPs for non-NELAP Laboratory Certification processes must be developed by OQA. If NELAP and non-NELAP procedures are similar enough, perhaps the existing NELAP SOPs could just be amended to include the non-NELAC processes.

Finding 2: Results for proficiency evaluation (PE) samples for drinking water are currently only being tracked by technique and not by method.

Citation: 40 CFR 141.f (17)I A – Requires that laboratories successfully analyze PE samples for each method for which the laboratory desires certification.

Required Corrective Action: OQA must update their PE tracking system to allow drinking water PE sample results to be tracked by method. (Note: While this is a finding, it is not something that causes great concern since it seems there are not many laboratories that request certification for more than one method per technique.)

III. SUGGESTIONS

1. OQA should insure that evidence of successful completion of the EPA Drinking Water Certification Officer Training Course is documented in all assessor personnel files. A quick check of three assessor files found one (Nagourney) without a copy of the certificate.

2. OQA should consider sending staff that haven't had the EPA Drinking Water Certification Officer Training Course in greater than 10 years to audit the course as a refresher since analytical methodologies and technologies change over time.

IV. GENERAL COMMENTS

1. There has been improvement in the frequency of laboratory audits since our last assessment. Most non-NELAP laboratories are now being assessed within 3 years.

2. OQA laboratory assessors are very knowledgeable in both the regulations and the drinking water methods. This was evidenced by well documented assessment reports.

3. EPA assessors reviewed complete laboratory files for NJ Analytical Laboratories (11005) and Willingboro MUA (03112).

V. CONCLUSIONS

Overall, the NJDEP Laboratory Certification Program is being run in accordance with the NJDEP QMP and with EPA requirements (CFR and Drinking Water Laboratory Certification Manual). OQA must work on developing SOPs for their non-NELAP laboratory certification processes.

Site Remediation Program

I. GENERAL INFORMATION

Programs Assessed: New Jersey Department of Environmental Protection, Site

Remediation Program, CERCLA, Brownfields, UST, BUST and RCRA:

Office of Data Quality (ODQ)
Bureau of Case Management (BCM)
Bureau of Environmental Management and Site Assessment (BEMSA)
Bureau of Environmental Evaluation & Risk Assessment (BEERA)
Bureau of Investigation, Design & Construction (BIDC)
Bureau of Southern Field Operations (BSFO)
Bureau of Northern Field Operations (BNFO)
Bureau of Underground Storage Tanks (BUST)
Brownfields Remediation and Reuse Element – Office of Brownfields Reuse (OBR)

EPA Assessors: Sergio Lòpez-Luna, Hazardous Waste Support Section
Jennifer Feranda, Hazardous Waste Support Section
Patricia Sheridan, Hazardous Waste Support Branch
Kevin Kubik, Region 2 Quality Assurance Manager

NJDEP Personnel Interviewed: James DeNoble, Case Manager (BCM)
Steve Urbanik, Case Manager (BCM)
Greg Toffoli, Office Chief (ODQ)
Frank Sorce, Section Chief, Site Assessment Section (BEMSA)
William Lowery, Bureau Chief (BEMSA)
Ed Putman, Manager Publicly Funded Remediation
Brune Venner, Bureau Chief (BIDC)
Yacoub Yacoub, Bureau Chief (BNFO)
George King, Bureau Chief (BSFO)
Kevin Kratina, Bureau Chief (BUST)
Joseph Stefanoni, Case Manager (BUST)
Frank Camera (BEERA)
Ken Kloo, Administrator
Colleen Kokas, OBR Bureau Chief
Frank McLaughlin, OBR Case Manager

II. FINDINGS AND REQUIRED CORRECTIVE ACTIONS

All Programs Interviewed (Except Brownfields)

Finding 1: There are no documented procedures identifying the Quality System roles and responsibilities of any of the offices or bureaus within the Site Remediation Program as indicated by the associated managers and staff interviewed during this assessment.

Citation: ANSI/ASQ E-2004 5.3 Quality System and Description, 5.3.1 General Principles - A quality system shall be planned, established, documented, implemented,

and assessed as an integral part of a management system for environmental programs defined by this standard. The quality system shall include the organizational structure, policies and procedures, responsibilities, authorities, resources, requirements documents, and guidance documents necessary for implementing the quality management process.

Required Corrective Action: In previous assessments it was determined that some NJDEP programs have documented their processes and procedures; however, they are not identified in the NJDEP QMP. In the case of this assessment, the Site Remediation Program has no documented processes so they are obviously not identified in the NJDEP QMP. The Department must implement and document processes to assure that all Departmental organizations are implementing the established Quality System. The Office of Quality Assurance must take this opportunity to review ANSI/ASQ E-2004 (copy provided during Closing Meeting) and assure that all ANSI/ASQ E-2004 quality system requirements are integrated in the NJDEP QMP.

The Office of Quality Assurance must conduct a Department-wide Assessment to assure that all offices and bureaus are in compliance with the quality system requirements as described in ANSI/ASQ E-2004.

It is highly recommended that NJDEP's OQA discontinue the practice of including QA Work Commitments and Outputs in the Department's QMP. Instead a detailed description of the QA Roles and Responsibilities of all bureaus, offices and programs should be developed. A separate yearly planning document similar to EPA's QA Annual Report and Workplan (copy provided to OQA) should be developed, used to identify QA commitments and outputs, and used to generate the NJDEP QA Annual Report.

Finding 2: The Office of Quality Assurance is aware of the Site Remediation Program's failure to comply with the Department's Quality System but has not performed oversight of the Site Remediation Program to ensure compliance with the existing Quality System.

Citation: ANSI/ASQ E-2004 Section 5.2.2 Management Representative - Management shall designate a quality assurance manager with defined authority that includes: a) determining that the approved quality system is implemented and maintained in accordance with the requirements of this Standard.

Required Corrective Action: The Department must implement and document processes to assure that all Departmental organizations are implementing the established Quality System. The Office of Quality Assurance must take this opportunity to review ANSI/ASQ E-2004 (copy provided during Closing Meeting) and assure that all ANSI/ASQ E-2004 quality system requirements are integrated in the NJDEP QMP. The Office of Quality Assurance must conduct a Department-wide Assessment to assure that all offices and bureaus are in compliance with the quality system requirements as described in ANSI/ASQ E-2004.

Finding 3: Most staff and managers interviewed were unaware of the existence of the NJDEP QMP or its purpose.

Citation: ANSI/ASQ E-2004 Section 5.2 Management and Organization,

5.2.1 Management shall establish and implement a quality policy to ensure that environmental programs defined by this standard produce the type and quality of results needed and expected.

5.3.2 Quality Management Plan - The quality system and its operation shall be described and documented in a quality management plan. The quality management plan shall be reviewed and approved for implementation as policy or as a directive authorized by management.

B.3.3 Training Guidelines - In addition to technical training, management training should be considered that will provide managers with a working understanding of the quality system along with the tools and techniques (e.g., managerial, communication, and interpersonal skills) necessary to enable their full participation in planning, implementing, and assessing quality system aspects.

Management should also understand the criteria and tools available to assess the effectiveness of the quality system. Similarly, training should be provided to technical personnel and other staff to enhance their understanding of and contribution to the quality system, as appropriate.

Required Corrective Action: NJDEP must implement and document processes and procedures to assure that all affected Departmental staff are aware of the existence of the Department's QMP and their individual respective QA roles and responsibilities. The Office of Quality Assurance must implement and document processes to assure that all Departmental organizations are implementing the established Quality System. It is strongly recommended that the Office of Quality Assurance develop and implement a training course identifying the QA roles and responsibilities of all Departmental personnel.

Finding 4: Most staff and managers interviewed were unaware of the existence of their respective QA Representative and their own or their QA Representative's responsibilities.

Citation: NJDEP QMP, Section 10.0 C., Departmental Quality Assurance Representatives Duties:

1. Develop, track and document the progress of QMP work-outputs for their organizational area of responsibility;
2. Prepare annual written reports on the progress of their QMP work-outputs;
3. Attend semi-annual meetings;

4. QA Representatives may also be responsible for writing and approving SOPs and QAPPs;
5. Coordinating field sampling, laboratory analysis, data validation and data usability processes;
6. Attend all technical systems audits and management system reviews for their programs as requested by OQA;
7. QA Representatives work within their divisions and bureaus but obtain QA mandates and guidance from the Department QA Officer, and
8. Perform routine sample collection and/or data review audits.

Required Corrective Action: NJDEP must implement and document processes and procedures to assure that all affected Departmental staff are aware of the existence of the Department's QMP, their respective Designated QA Representative, and the QA roles and responsibilities of Designated QA Representatives and bureau staff. The Office of Quality Assurance must implement and document processes and procedures to assure that all Departmental organizations are implementing the established Quality System.

Finding 5: Very few managers and staff interviewed knew of the existence of NJDEP's Office of Quality Assurance and some confused it with the Site Remediation's Office of Data Quality.

Citations: ANSI/ASQ E-2004 Section 5.2.2 Management Representative - Management shall designate a quality assurance manager with defined authority that includes: a) determining that the approved quality system is implemented and maintained in accordance with the requirements of this Standard.

NJDEP Departmental Quality Management Plan, Section 2.0, Quality Assurance Program Management and Organization – The NJDEP Office of Quality Assurance (OQA) has the responsibility for developing and administering the Quality Management Plan and for overseeing QA activities associated with all of the Department's environmental programs.

Required Corrective Action: NJDEP must implement and document processes and procedures to assure that all affected Departmental staff are aware of the existence of the Office of Quality Assurance (OQA), the Department's QMP, and the QA roles and responsibilities of OQA, Designated QA Representatives and bureau staff. The Office of Quality Assurance must implement and document processes to continuously assure that all Departmental organizations are implementing the established Quality System. It is strongly recommended that the Office of Quality Assurance develop and implement a training program identifying QA roles and responsibilities for all affected Departmental personnel.

Finding 6: NJDEP Site Remediation Program personnel interviewed at all levels (management and staff) stated that an adequate quality assurance program is limited to using a certified laboratory followed by data validation.

Citation: ANSI/ASQ E-2004 Section 6, Collection and Evaluation of Environmental Data (Part B), 6.1 General - Environmental programs involving the collection, evaluation, and use of environmental data require additional quality system elements to plan, implement, and assess the application of QC and QA activities to such operations. These additional elements shall be used in conjunction with those in Clause 5, Management Systems, in order to provide a suitable and effective quality system to support environmental data collection and use.

The additional elements in Clause 6 also apply to the collection of environmental data that are used directly to design, construct, test, or operate environmental technology. Additional quality system elements applicable to environmental data include:

a) planning and scoping,
b) design of data collection operations,
c) implementation of planned operations,
d) assessment and response, and
e) assessment and verification of data usability.

Required Corrective Action: It is mandatory that NJDEP senior management commit to a Quality Assurance program that emphasizes all aspects of a quality system as described in ANSI/ASQ E-2004, not simply one that relies on use of a certified laboratory followed by data validation. The quality system must include, at a minimum, elements of planning and scoping, design of data collection operations, implementation of planned operations, assessment and response, and assessment and verification of data usability.

The Department must implement and document processes to assure that all Departmental organizations are implementing the established Quality System as described in ANSI/ASQ E-2004. The Office of Quality Assurance must take this opportunity to review ANSI/ASQ E-2004 (copy provided during Closing Meeting) and assure that all ANSI/ASQ E-2004 quality system requirements are integrated in the NJDEP QMP.

The Office of Quality Assurance must conduct a Department-wide Assessment to assure that all offices and bureau's are in compliance with the quality system requirements as described in ANSI/ASQ E-2004.

Finding 7: Very few of the Site Remediation Program's bureaus are performing "planning functions" (i.e. QAPP preparation and/or review) and those that are, are not documenting their processes.

Citation: ANSI/ASQ E-2004 Section 6.2, Planning and Scoping - All work involving the generation, acquisition, and use of environmental data shall be planned and documented. The type, quantity, and quality of environmental data needed for their intended use shall be identified and documented using a systematic planning process.

Project-specific planning shall involve the key users and clients as well as the technical staff responsible for obtaining, analyzing, and evaluating the data. Results of planning activities shall be subject to review for conformity to technical and quality expectations. Project planning shall be coordinated among participating organizations and shall include, as applicable, the:
a) definition of project/task scope and objectives and the desired action or result from the work;
b) identification of organizations (e.g., sampling groups and analytical laboratories) that need to participate in the project and their role in planning, implementation, and assessment activities;
c) identification of the environmental data required to achieve the desired action or result;
d) identification of QA and QC requirements to establish the quality of the data collected or produced;
e) identification of the documentation needed to adequately describe the quality of the results;
f) identification of necessary personnel, their needed skills, and required types of equipment;
g) identification of special applicable regulatory requirements and other constraints (e.g., time and budget);
h) identification of conditions under which suspension of work will be necessary;
i) determination of assessment tools needed (e.g., program technical reviews, peer reviews, surveillances, readiness reviews, and technical audits);
j) identification of methods/procedures for storing, retrieving, analyzing, and reporting the data produced (based on the intended use of the data); and
k) identification of possible methods/procedures (including waste minimization objectives) for characterization and disposal of contaminated sample material that may be accumulated during the project.

Required Corrective Action: The Department must implement and document processes to assure that all Departmental organizations are implementing the established Quality System as described in ANSI/ASQ E-2004. The Office of Quality Assurance must take this opportunity to review ANSI/ASQ E-2004 (copy provided during Closing Meeting) and assure that all ANSI/ASQ E-2004 quality system requirements are integrated in the NJDEP QMP. The Office of Quality Assurance must conduct a Department-wide Assessment to assure that all offices and bureaus are in compliance with the quality system requirements as described in ANSI/ASQ E-2004.

Finding 8: None of the Site Remediation Program's bureaus interviewed do any project assessment and/or process improvement beyond data validation, (i.e. no field audits, no split samples, no internal assessments, etc). The EPA assessment team was told that Responsible Party contractors and/or NJDEP contractors are "certified professionals and taken at their word."

Citation: ANSI/ASQ E-2004 Section 6.5, Assessment and Response - Activities performed during environmental data operations that affect the quality of the data shall

be assessed regularly and the findings reported to management to ensure that the requirements stated in approved and current planning documents are being implemented as prescribed. When warranted by findings of deficiency or nonconformity with requirements, appropriate corrective actions shall be taken in a timely manner. The adequacy and effectiveness of the corrective actions shall be confirmed, verified, and documented. Results obtained from nonconforming methods or instruments shall be evaluated to determine the impact of the nonconformity on the quality of the data. The adequacy and effectiveness of corrective actions taken shall be confirmed, verified, and documented.

Required Corrective Action: The Department must implement and document processes to assure that all Departmental organizations are implementing the established Quality System as described in ANSI/ASQ E-2004. The Office of Quality Assurance must establish processes and procedures to assure that all activities performed during environmental data operations that affect the quality of the data are assessed regularly and the findings reported to management to ensure that the requirements stated in approved and current planning documents are being implemented as prescribed.

Brownfields Program

Finding 1: The Office of Brownfields Reuse policies and procedures are not formally documented in Standard Operating Procedures (SOPs).

Citation: This is inconsistent with Department policy as defined in the Quality Management Plan (QMP), Section 3.0(a) Implementation of the Quality System, page 5 which states *"Documentation processes include Standard Operating Procedures (SOPs), Quality Assurance Project Plans (QAPPs), data validation, procedures and standardized report forms. These functions are generally carried out at the bureau level."*

Required Corrective Action: The Office of Brownfields Reuse must develop SOPs in order to describe both the technical and fundamental programmatic operational elements of the NJDEP Brownfields Program. This will facilitate consistent conformance to the Department's technical and quality system requirements as well as provide additional data quality support.

Finding 2: The Office of Brownfields Reuse does not require QAPPs, nor do they review QAPPs for EPA-funded and NJDEP-funded Brownfields projects. An example of this is the Harrison Avenue Landfill project which was completed under the EPA-funded Brownfields program in July 2006 for which no Quality Assurance Project Plan (QAPP)* was ever prepared.

*A subsequent copy of a QAPP for the Harrison Avenue Landfill Project was provided to EPA Region 2 during the NJDEP/EPA quarterly meeting on June 22, 2009. However, this QAPP was inappropriate and did not apply to the field investigation activities conducted by NJDEP under the EPA Brownfields grant received by NJDEP.

Citation : This action is inconsistent with Department policy as defined in the Quality Management Plan (QMP), Section 3.0, page 5 which states, *"The Department maintains a policy that no environmental data collection activities be performed by or for the Department until after a QAPP covering those activities has been approved by OQA or the Designated QA Representative."*

Required Corrective Action: The Office of Brownfields Reuse must prepare a QAPP when conducting environmental data collection activities for EPA-funded and NJDEP-funded Brownfields projects to be compliant with Departmental and EPA policies.

Finding 3: The Office of Brownfields Reuse has not specifically named the Quality Assurance (QA) Representative for their organization since Andrew Cyr no longer represents the Program. This action is inconsistent with Department and EPA policy.

Citation: NJDEP Quality Management Plan (QMP), Section 2.0, page 2 states "An organization of QA representatives has been established to assist OQA in overseeing the Department's QA program."

Required Corrective Action: The Office of Brownfields Reuse must provide the name to OQA of the individual selected as the Brownfields Program QA Representative to be in compliance with the Department's QMP.

III. SUGGESTIONS

None.

IV. GENERAL COMMENTS

The forthcoming Licensed Site Professional Program provides a unique opportunity for NJDEP to establish a new Quality System describing the roles and responsibilities of managers and staff at all levels. EPA Region 2 commits to assisting NJDEP's OQA and Site Remediation Bureau's in developing and implementing a well documented and transparent Quality System.

V. CONCLUSIONS

The Department must implement and document processes and procedures to assure that all Departmental organizations are implementing the established Quality System and to assure that all affected Departmental staff are aware of the existence of the Department's Quality System, the existence of the Office of Quality Assurance, the existence of QA Representatives, and the QA roles and responsibilities of each member of the Department.

Bureau of Surface Water Permitting

I. GENERAL INFORMATION

Program Assessed: New Jersey Department of Environmental Protection
Environmental Regulation
Division of Water Quality
Bureau of Surface Water Permitting

EPA Assessors: Donna Ringel, Monitoring and Assessment Branch

Reshma Punwasie, Monitoring and Assessment Branch
Esther Nelson, Monitoring and Assessment Branch

NJDEP Personnel Interviewed: Jason Lonardo – Principal Environmental Specialist
Bureau of Surface Water Permitting QA Representative
Marc Ferko - Office of Quality Assurance

II. FINDINGS AND REQUIRED CORRECTIVE ACTIONS

None.

III. SUGGESTIONS

1. Bureau staff are encouraged to conduct field audits to assess compliance with Quality Assurance Project Plans (QAPPs). Even a few such audits each year would give the program a sense of implementation effectiveness. OQA staff could train Bureau staff to conduct audits and assist in the development of an SOP for their conduct. It is recommended that the first few audits be a joint effort between OQA and Bureau staff.

2. We recommend a more formal process for the approval of the various guidance documents that are being developed by the Bureau. Approval by the Bureau chief must be documented. The documents must also include an effective date and version number. It is also recommended that such documents be reviewed on a regular basis (every 2-3 years) and updated, if deemed necessary. This review must be documented.

3. The Bureau must consider development of a data review/validation SOP or checklist. This would help insure consistency of data evaluations.

IV. GENERAL COMMENTS

1. The Bureau provided a copy of their regulation which includes the requirement for a Department-approved QAPP.

2. The Bureau has begun to develop a central filing system for water studies, and we encourage continued development of such a system.

3. The Bureau provided the following documents to the assessment team: 1) NJDEP regulation (7:14A-2.12) requiring QAPP development and Department approval for ambient water quality studies, 2) Guidance for preparation of Combined Work/ Quality Assurance Project Plans for Environmental Monitoring, 3) Internal Guidance

for the Development of a Site-Specific Harness and Metal Translator Values, and 4) General Guidance for the Development of a Site-Specific Harness and Translator Studies for Metals.

V. CONCLUSIONS

Overall, the Bureau is implementing its quality assurance program in accordance with the NJDEP QMP. There seems to be a very good working relationship between OQA staff and the Bureau's Quality Assurance Representative.

Bureau of Environmental Radiation (Radon Program)

I. GENERAL INFORMATION

Program Assessed: New Jersey Department of Environmental Protection
Environmental Regulation
Division of Environmental Safety and Health
Bureau of Environmental Radiation (Radon Program)

EPA Assessors: Donna Ringel, Monitoring and Assessment Branch

Reshma Punwasie, Monitoring and Assessment Branch

NJDEP Personnel Interviewed: Herbert Roy - Research Scientist
Bureau of Environmental Radiation QA Representative
Vas Komanduri - Office of Quality Assurance

II. FINDINGS AND REQUIRED CORRECTIVE ACTIONS

Finding 1: There is no Quality Assurance Project Plan (QAPP) for the radon data that are being collected and analyzed by the Bureau. There is a Standard Operating Procedure (SOP) which covers their Electret procedures, but this document does not include all of the information that is required in a QAPP.

Citation: NJDEP QMP Section 3.0 (a) 2 – The Department maintains a policy that no environmental data collection activities be performed by or for the Department until after a QAPP covering those activities has been approved by OQA or the Designated QA Representative.

Required Corrective Action: A generic QAPP must be developed for the Bureau's internal radon data collection and analysis activities. This QAPP must be reviewed and approved by OQA.

Finding 2: The QAPPs that are generated by outside radon testing firms are currently being reviewed and approved by the Radon Program staff. OQA is not involved in these QAPP reviews/approvals and the Bureau's QA Representative has not been delegated this authority.

Citation: NJDEP QMP Section 3.0 (a) 2 – The Department maintains a policy that no environmental data collection activities be performed by or for the Department until after a QAPP covering those activities has been approved by OQA or the Designated QA Representative

Required Corrective Action: OQA must review the process used by the program to review and approve QAPPs. If OQA is comfortable with the review and approval process, then they must formally delegate the Bureau the authority to approve these external QAPPs. This delegation of QAPP approval authority within the Bureau must be documented in the QMP.

Finding 3: The Bureau's SOP for their Electret Procedures has not been reviewed and approved by OQA.

Citation: Section 9.0 (item 8 on page 13 of the QMP) requires that OQA review/approve all new and/or revised Department Standard Operating Procedures

dealing with sample collection, analytical methodology, analytical data review/quality and analytical data use.

Recommendation: The Electret Procedures SOP deals with analytical methodology and it must be reviewed and approved by OQA.

III. SUGGESTIONS

1. The Bureau must have their internal radon analysis (Electret) certified by OQA. An SOP is already in place and proficiency testing is being done, however the Bureau is not currently certified for this analysis. This "laboratory" is not currently in compliance with the Department's requirements for laboratory certification.

IV. GENERAL COMMENTS

1. The Bureau provided copies of the following documents to the assessment team: 1) Electret Procedures SOP, 2) NJDEP regulation (7:28 -27.33) regarding QAPP requirements for radon services testing firms, 3) Routine Facility Inspection Procedure, 4) Radon Measurement Business Application Review Checklist, 5) Description of EXCEL Measurement Spreadsheet Program for Electronic Data Transfer, 6) QAPP Review Checklist, 7) Certified Radon Measurement Business Routine Facility Inspection Checklist, 8) Radiological Safety Plan Review Checklist, and 9) Sample letter sent to radon businesses regarding database quality requirements.

2. The Bureau has incorporated QAPP requirements directly into their regulations. QAPPs are submitted during the application process when firms apply for certification. The Program has developed program-specific QAPP checklists which are used by staff during QAPP review.

V. CONCLUSIONS

Overall, the Bureau is implementing its quality assurance program in accordance with most of the requirements of the NJDEP QMP. The Bureau's processes for using externally generated data seem to be very well controlled. The laboratories conducting radon analysis are certified by OQA. The mitigation firms are certified by the Program. The testing firms are certified by the Program. The testing and mitigation firms are inspected to ascertain compliance with the requirements. The program employs automated data review and data validation checks.

Wetlands Programs

I. GENERAL INFORMATION

Program Assessed: New Jersey Department of Environmental Protection
Natural & Historical Resources
Division of Parks and Forestry

New Jersey Department of Environmental Protection
Land Use Management
Division of Land Use Regulation
Bureau of Technical Services

Environmental Review Group

EPA Assessors: Donna Ringel, Monitoring and Assessment Branch
Reshma Punwasie, Monitoring and Assessment Branch

NJDEP Personnel Interviewed: Diane Dow – Section Chief, Environmental Review Group
Kathleen Waltz – Division of Parks and Forestry
Marc Ferko - Office of Quality Assurance

II. FINDINGS AND REQUIRED CORRECTIVE ACTIONS

Finding 1: These Divisions use data to generate wetlands maps and make determinations with regard to permits and certain land use designations (i.e., wetland of exceptional value). The NJ Natural Heritage program also maintains a database inventory of rare plants and animals. Both groups are operating outside of the Department's Quality System, as defined in the QMP. OQA has not been actively interacting with these programs, and thus the programs are currently operating outside of the QMP.

Citation: Section 2.0 of the QMP states that OQA has the responsibility for developing and administering the QMP and for overseeing QA activities associated with all of the Department's environmental programs. Section 3.0 of the QMP further requires that QAPPs be prepared and approved by OQA or the Designated QA Representative for all environmental data collection activities.

Required Corrective Action: OQA must assess the collection and use of environmental data by these organizations. OQA must then work with these groups, inventorying their existing QA policies and procedures to determine what gaps exist between what is being done and what is required by the QMP. Appropriate work outputs must be developed to bring these groups in line with the Department's QA requirements. A QA representative(s) needs to be designated to be the primary liaison with OQA. The QA representative will need to be trained. Once the program is in place, an audit schedule will need to be developed to assess implementation and effectiveness of the QA system as applied to these programs.

III. SUGGESTIONS

None.

IV. GENERAL COMMENTS

1. The Programs provided copies of the following documents: 1) Division of Land Use Regulation Vernal Habitat Certification Protocol, 2) Natural Heritage Methodology 3) EO Data Standard, 4) Information on the Biodiversity Data Model, 4) VegBank

data standards, 5) National Vegetation Classification System, 6) Ecological Integrity Assessment and Performance Measures for Wetland Mitigation, 7) Overview of Natural Heritage Methodology for Ecological Element Occurrence Ranking based on Ecological Integrity Assessment Methods, 8) Instruction Manual on Heritage Field Methodology: Documenting Ecological Communities, and 9) Protocols for the Establishment of Exceptional Resource Value Wetlands Pursuant to the Freshwater Wetlands Protection Act Based on Documentation of State or Federal Endangered or Threatened Species.

2. Since becoming aware of QAPP requirements for EPA-funded projects, these groups have prepared a QAPP for the work currently being conducted as part of an EPA funded NJDEP grant (No. 97267906). A copy of this draft QAPP was provided to EPA and to OQA for review and approval.

V. CONCLUSIONS

These wetlands programs are currently operating outside of the Department's Quality System. OQA and the programs need to work together to bring these wetlands programs into compliance with the requirements of the QMP.

Bureau of Technical Services

I. GENERAL INFORMATION

Program Assessed: New Jersey Department of Environmental Protection
Environmental Regulation
Division of Air Quality Permitting
Bureau of Technical Services

EPA Assessors: Reshma Punwasie, Monitoring and Assessment Branch
Esther Nelson, Monitoring and Assessment Branch
Donna Ringel, Monitoring and Assessment Branch

NJDEP Personnel Interviewed: Fred Ballay, Supervising Environmental Specialist, Bureau of Technical Services
Michael Klein, Section Chief, Bureau of Technical Services
Stuart Nagourney, Research Scientist, Office of Quality Assurance
Amy Bowman, Research Scientist, Office of Quality Assurance

II. FINDINGS AND REQUIRED CORRECTIVE ACTIONS

None.

III. SUGGESTIONS

1. Bureau staff are encouraged to continue updating SOPs such as Technical Manual 1004 (Guidelines for Compliance Stack Emission Test Programs), and Technical Manual 1005 (Guidelines for Continuous Emissions Monitoring Systems). At the time of this audit, these two documents are currently being updated. It is also recommended that such documents be reviewed on a regular basis (every 2-3 years) and updated, if deemed necessary. Such reviews must be documented.

2. The Bureau should continue to work with OQA to ensure that its voice is heard regarding the shift from EPA provision of stationary source audit samples to provision by a third party (e.g., The NELAC Institute). These changes were recently proposed by EPA.

3. Consider succession management planning, particularly with reduced resources. It was noted that John Jenks, BTS Chief is retiring and M. Klein, Section Chief will report directly to the Director (John Preczewski).

IV. GENERAL COMMENTS

1. The Bureau performs field oversight on more than 90% of the stack tests conducted in the state.

2. There seems to be a good working relationship between OQA staff and the Bureau. OQA is in the process of a conducting a technical audit of the Bureau. EPA requested a copy of the report upon completion. No findings were observed during OQA's audit of the Bureau.

3. The Bureau guidance states that new staff shadow experienced staff prior to performing field audits on their own. The complexity of stack tests observed by staff independently is appropriately incremental.

4. The Bureau provided the following example documents of stack test protocol or stack test data evaluations performed by the Bureau to the assessment team: 1) test indicated compliance (correspondence file for Wyeth Holding Corporation; APC ID No. 35001, PCP No. 070001, TST No. 070001); 2) test indicated non-compliance for one or more contaminants (correspondence file for Omni Baking Company; APC ID No. 75559, PCP No. 060001, TST No. 070001); 3) test indicated compliance, but operation inconsistent with the Permit (correspondence file for Raritan Valley Community College; APC ID No. 35482, PCP No. 050002, TST No. 070001); and 4) Retest recommended for one or more contaminants (correspondence file for Burlington County Resource Recovery Complex; APC ID No. 45949, BOP No. 070002, TST No. 070002).

V. CONCLUSIONS

Overall, the Bureau is implementing its quality assurance program in accordance with the NJDEP QMP. The Bureau's field presence and protocol reviews are clearly tracked and well documented. There seems to be a very good working relationship between OQA staff and the Bureau's Quality Assurance Representative.

Office of Information Resources Management (Database Management)

I. GENERAL INFORMATION

Program Assessed: New Jersey Department of Environmental Protection
Management and Budget
Division of Information Resources Management
Bureau of Database Management
Regulatory Program: NJEMS

EPA Assessors: Paula Zevin, Monitoring and Assessment Branch
Esther Nelson, Monitoring and Assessment Branch
Reshma Punwasie, Monitoring and Assessment Branch

NJDEP Personnel Interviewed: Joseph Feast, Jr. – Supervisory Environmental Engineer
Martin R. Hackman – Research Scientist, Office of Quality Assurance

II. FINDINGS AND REQUIRED CORRECTIVE ACTIONS

None.

III. SUGGESTIONS

1. A schedule for conducting internal technical audits to assess compliance with program SOPs must be prepared and implemented.

2. SOPs are dated; the newest one is from 2003/2005, the rest go back to the 1990s. The program needs to devise a more frequent schedule for review and revision/update of their SOPs.

IV. GENERAL COMMENTS

1. The Bureau provided copies of the following documents to the assessment team: 1) detailed current organizational charts (both OIRM and OQA), 2) list of SOPs (both OIRM and OQA), 3) back-up system layout, 4) SOP for the "Masterfile" data entry by DEP staff, 5) NJDEPDR Contingency Plan V2.

2. The Bureau has full-time staff dedicated to performing QA/QC measures on the key system of the "Masterfile" and a central return to service plan (contingency plan). OIRM has a "librarian," who keeps track of all records and documents. Internal NJDEP and other data received by OIRM are considered the property of the issuing programs and are expected to be validated by their owners. OIRM is managing both internal and external data and information exchanges and communication.

V. CONCLUSIONS

Overall, the Bureau is implementing its quality assurance program in accordance with the requirements of the NJDEP QMP. The Bureau has an open and mutually beneficial relationship with OQA. QA training is part of the Bureau's performance appraisals and is an on-going process, which is tracked and documented. Quality Assurance work outputs are updated each year and are subject to internal approval.

New Jersey Geological Survey, Bureau of Geology and Topography (Ground Water)

I. GENERAL INFORMATION

Program Assessed: New Jersey Department of Environmental Protection
Land Use Management
New Jersey Geological Survey (NJGS)
Bureau of Geology and Topography

EPA Assessors: Paula Zevin, Monitoring and Assessment Branch
Reshma Punwasie, Monitoring and Assessment Branch

NJDEP Personnel

Interviewed: John Dooley – Research Scientist
Martin R. Hackman – Research Scientist, Office of Quality Assurance (observer, for S. Nagourney)

II. FINDINGS AND REQUIRED CORRECTIVE ACTIONS

Finding 1: There are no existing SOPs covering the Bureau's activities. Staff use the NJDEP Sampling Manual and American Chemical Society and EPA methods for analyses, but it could not be ascertained which versions of the manual and methods were being used.

Citation: NJDEP QMP Section 3.0 (a) 1, Standard Operating Procedures (SOPs) – "SOPs are written for all routine and special work activities that impact the quality of environmental data. […] Examples of activities mandating the development of SOPs are: sample collection methods, laboratory analyses, audits/inspections, data review/validation, issuance of permits and modeling and data processing."

Required Corrective Action: SOPs must be developed for all appropriate activities, including sampling and analysis. They must be reviewed and approved by OQA, then revised or updated according to NJDEP's current QMP.

Finding 2: QAPPs for new projects are usually developed based on a previous or similar document or project. Established QAPP guidance or references do not appear to be readily available. Data validation and reconciliation procedures need to be included as an integral part of project planning and implementation. The Bureau has one new approved QAPP, developed in collaboration with USGS.

Citation: NJDEP QMP Section 3.0 (a) 2, Quality Assurance Project Plans (QAPPs) – "QAPPs are written in accordance with the following documents: 'Guidance for the Development of Quality Assurance Project Plans for Environmental Monitoring Projects,' April 2004, USEPA Region II; 'Uniform Federal Policy for Quality Assurance Project Plans,' EPA-505-B-04-900A, March 2005 (Used for CERCLA, RCRA and Brownfields projects)."

Required Corrective Action: The Bureau must ensure that the appropriate QAPP guidance document is used. If there is Bureau-specific QAPP guidance, it must be reviewed and approved by OQA prior to its use in QAPP development. Data validation and documentation must be incorporated into the process.

Finding 3: The Bureau does not have a formalized or even documented QA training program for its staff. Bureau staff keep current on their own.

Citation: NJDEP QMP Section 4.0, Personnel Qualifications and Training – "All Departmental personnel that perform quality assurance functions related to the generation of environmental data must obtain either formal or practical quality assurance training.

The Office of Quality Assurance or QA Representatives provide and/or coordinate arrangements for that training."

Recommendations: The Bureau and OQA must reconcile any existing documentation on staff QA training with current needs, ensure that staff take appropriate QA training, and that adequate records are kept.

III. SUGGESTIONS

1. The Bureau needs to formally document their QA processes: data validation, guidance used for QAPP development, and internal audit procedures.

2. Bureau outputs are usually peer-reviewed reports/articles. They need to be incorporated into NJDEP and Bureau QA guidelines and the process must be documented.

3. The Bureau's most recent assessment (ambient ground water) appears to have been conducted by OQA 3 to 5 years ago. It was unclear whether any deficiencies were identified and corrective actions implemented. The Bureau does not appear to have any corrective action plans. Auditing could be done on a more frequent and regular schedule. The Bureau must maintain its own documentation of these assessments and develop appropriate corrective action plans.

4. Work Outputs, although updated annually, need to be properly aligned with direct EPA funding. Activities 1, 2 and 5 on page 57 of the QMP are funded at least in part by EPA and thus must be noted as such.

IV. GENERAL COMMENTS

1. The assessment team asked for the following documents and information: 1) a current approved QAPP, 2) a list of the Bureau's SOPs (if they exist), 3) one example of an SOP (if applicable), 4) information on the guidance used to develop SOPs (if applicable), 5) examples of calibration and maintenance logs, 6) an updated copy of the QMP work outputs with the correctly asterisked EPA-funded projects (wholly or in part), 7) information on the Bureau's record-keeping system, and 8) what if any QA training staff has received and records of training. The Bureau provided only one of the requested documents – an approved current QAPP.

2. NJGS, Topography and Geology, is in charge of mapping surficial and bedrock geology, including ground water. The scientists perform field and analytical work in a non-regulatory framework, according to basic scientific principles. However, the Bureau does not have many of its procedures documented as part of their quality system.

V. CONCLUSIONS

Overall, the Bureau is not implementing its quality assurance program in accordance with the requirements of the NJDEP QMP. The Bureau has a relationship with OQA, but they must work together more closely to bring the Bureau within the requirements of the NJDEP QMP.

E. References

USEPA Order CIO 2105.0 (formerly 5360.1 A2 (2000)), Policy and Program Requirements for the Mandatory Agency-Wide Quality System, U.S. EPA, Washington, D.C. (May 2000).

ANSI/ASQ E4-2004, Quality systems for Environmental data and Technology Programs – Requirements with Guidance for Use, Milwaukee, WI.

FY=07-10 Departmental Quality Management Plan, NJDEP, Office of Quality Assurance, Trenton, N.J.