



New Hampshire Department of Environmental Services

Guidance on How to Complete Program-Level Quality Assurance Self-Audits for Calendar Year 2018

DECEMBER 2018

This document is intended to help program managers to fulfill the annual self-audit requirements in the NHDES Quality Management Plan - <http://www.des.nh.gov/organization/commissioner/p2au/pis/qap/documents/r-co-16-02.pdf>.

Table of Contents

1. Introduction to the NHDES Quality Assurance System.....	3
2. Basic Instructions.....	3
3. Reporting Relief Criteria.....	3
4. Definitions	4
5. First-Party Auditing in the NHDES QA System – the Condensed Version.....	5
6. NHDES QA System Self-Audit Forms.....	6

QA System Self-Audit Forms:

<u>Program QA Self-Audit Form A</u>	A-1
<u>Program QA Self-Audit Form B</u>	B-1

1. Introduction to the NHDES Quality Assurance System

In carrying out its mission, the New Hampshire Department of Environmental Services (NHDES) relies upon many different types of data to evaluate and measure existing environmental conditions, to identify and understand areas of concern, to assign responsibility for these areas, and to communicate credibly on environmental issues to a wide variety of audiences.

The data NHDES uses must be credible, and the quality of that data must be appropriate for its intended uses. The Department, through its Quality Assurance (QA) System, uses a systematic approach to the management of data and overall quality assurance issues across NHDES. A key element of NHDES's overarching QA System is a requirement that all programs managing environmental data (see definition below) assess their data quality systems and associated documentation at least annually.

Implementation of the NHDES QA System is the responsibility of staff throughout the Department, with the guidance and support of the NHDES Senior Leadership Team, the QA Manager, Assistant QA Manager, and the QA Team, as well as Program Managers.

2. Basic Instructions

All NHDES programs which generate, use, compile, or communicate environmental data (see definitions below) are required by NHDES policy to annually file QA self-audit forms with the NHDES QA Manager. Two different forms are used. See Sec. 6, below, for details on which form to use for a given program.

A supplemental work instruction has been created for staff to complete the self-audit reports and is located at the [self-audit procedure](#).

3. Reporting Relief Criteria

Generally, all programs within NHDES that are involved in environmental data operations conduct an annual QA self-audit to verify that their operations continue to comply with the requirements of the NHDES QMP, any required QAPPs or similar program-specific quality documents, SOPs, technical or professional standards, or other requirements set prior to work being performed.

There is an important exception to the above scenario -- When a given program has effectively submitted its QA self-audit reports for four consecutive years, and where there are no instances of non-reporting for any two consecutive years (both conditions being met during the preceding six years), the NHDES QA Manager has the authority to allow such programs to submit their QA Self-Audit reports every other year, until such time that the aforementioned criteria are no longer met. In all cases, and for whatever reason, the minimum program reporting rate is every two years.

Note: As part of the Form A, QA self-audit report package, program managers must still provide a copy of the QAPP (or QA Manual) cover page, along with a summary of any needed or recommended changes to the QAPP. The entire submittal is to be forwarded to the QA Manager by the deadline set by the QA Manager (typically in February of each year).

4. Definitions

Area for Improvement/Non-Conformance

The most important aspect of the Annual QA self-audit process is to evaluate program operations to determine areas that are in need of improvement, as well as instances where aspects of the program did not happen as outlined in the program's QA Manual or Quality Assurance Project Plan (QAPP). These instances are typically referred to as a system non-conformance (see definition below). Program Managers must provide a listing of current year and prior year Areas for Improvement and Non-Conformances as part of completing the annual self-audit process. Examples include:

- 1) needing to repair/replace a piece of equipment that will no longer hold its calibration;
- 2) finding that a data point which did not meet quality standards escaped review and was used inappropriately;
- 3) needing to develop a new or updated SOP for a new or existing process/activity; or
- 4) needing to improve or develop a new volunteer training program, etc.

Audit

A systematic examination to determine whether activities and related results comply with planned arrangements and whether the arrangements are implemented effectively and are suitable to achieve objectives.

Audit, First-Party

An audit conducted by members of the organizational unit being audited or a self-assessment. The annual QA Self-Audits required in the NHDES QA System are first-party audits.

Audit, Second-Party

An audit conducted by individuals from within the same corporate body as the organization being audited, but who are not entirely independent. These are generally considered superior to first-party audits. An audit of a program's quality system by the NHDES QA Team is an example of a second-party audit.

Audit, Third-Party

An audit conducted by individuals from an organization that is entirely independent from the organization being audited. ISO 9000 and 14001 registration audits, and audits of NHDES by EPA are examples of third-party audits.

Document

Any written, recorded information that is subject to change over time. Procedures, plans, policies, and records are documents. Documents may be controlled. See Record.

Documented Procedure

A written document that details the method for an operation, analysis, or action with thoroughly prescribed techniques and steps, and that is officially approved as the method of performing certain routine or repetitive tasks. This may be text (*e.g.*, a memo), but also may be a graphic, as seen in the

floor-layout charts in the 29 Hazen Drive conference rooms. This memo may simply document reliance on a standard reference, such as *Standard Methods for the Examination of Water and Wastewater*.

Environmental Data

Any measurements or information that describe environmental processes, location, or conditions; ecological or health effects and consequences; environmental modeling; or the performance of environmental technology. *Administrative* data, such as number of permits issued, is not *environmental* data. However, the number of acres of wetlands allowed to be disturbed via these permits is *environmental* data.

Program

A functional unit within NHDES conducting activities as defined in statute(s) or otherwise. A program will often be found at the Bureau level, but this varies across NHDES. An example would be the Volunteer Lake Assessment Program within the Watershed Management Bureau of the Water Division.

Program Manager

The person responsible for conducting a specific NHDES program. This program management function is vested in people at different administrative levels within NHDES.

Project Manager

The person that has direct knowledge and/or responsibility at the project or site-specific level.

Record

A completed document that provides objective evidence of an item or process. Records may include text, photographs, drawings, magnetic tape, or other data recording media. Records are not generally subject to modification after they are created. See Document.

Secondary Data

Data generated by others that are used in the program under consideration. Plans and reports submitted by consultants are a typical example. In the NHDES QA System, use of secondary data must be managed, mainly by having effective data review procedures.

5. First-Party Auditing in the NHDES QA System – the Condensed Version

Program Managers are responsible for auditing and verifying, at least annually, whether their programs' work went as expected, what problems were encountered, whether procedures still meet program QA needs, and where improvements can be made. This step must address the *root cause* of deficiencies, wherever this is possible, so that the program procedures can be improved. Most importantly, this audit must be documented.

An audit form is an essential tool for this purpose. Using a form helps to ensure that all points are sufficiently covered, and the form itself can be used to record and communicate the results. The forms required for use in the NHDES QA Self-Audit process are discussed and presented below.

The QA System Self-Audit forms are typically due to the NHDES QA Manager by a date set by the QA Manager in the e-mail kicking off each round of QA Self-Audits. **The due date for the Calendar Year 2018 QA Self-Audits is Wednesday, 2/20/2019.**

6. NHDES QA System Self-Audit Forms

The following pages include forms that program managers can use to help them audit their programs' quality system. These forms will be signed and submitted to the NHDES QA Manager by the date indicated in the e-mail kicking off this round of self-audits. Forms are signed by the program manager, but may be prepared by staff, as the program manager decides. A response needs to be entered for all questions, especially the "Special Question of the Year," and inclusion of current and prior-year Areas for Improvement/Non-Conformances (See Definition Section) – however, "N/A" is often the appropriate response. A traceable reference to a guidance document, often a regulation, may also be an appropriate response. The completed form can serve as documentation that the program has completed its audit and to communicate the results of the audit. Two options are available:

1. **Form A** is for those NHDES programs whose environmental data operations are described in one or more EPA-approved QAPPs, a master or programmatic QAPP, or which have completed NHDES-approved QA Manuals (see [template](#)).
2. **Form B** is for programs that are in earlier stages of building a quality system and have not yet developed formal program QAPPs or QA Manuals, or more mature programs that have opted to not develop Program QAPPs or QA Manuals. Form B consists of several sets of questions, each of which are specific to individual topics within the NHDES QA System. Each of them refers to a chapter or section of the [NHDES Quality Management Plan](#). All sections must be addressed, although as noted above, "N/A" or writing in a reference to another document (often a regulation), can be used, as appropriate. For many programs, Sec. 7, in which you describe how you handle data generated by others, is very important.

QA Manual: Using the [template](#). After several QA Self-Audit cycles, programs should seriously consider compiling their previous Form B responses and other QA System documentation into a **QA Manual**. Multiple Form B responses that are largely the same year-to-year will be reviewed closely. For instance, repeated responses of "no non-conformances found" or "no areas for improvement identified" over a period of two to three reporting cycles will raise a red flag for the self-audit reviewers. No system is perfect. "Things" happen, and every program and system can be improved, even if only slightly from year-to-year.

The NHDES QA Team requires the use of one of these two forms, as opposed to other forms that program managers may have or produce. If you have questions, or would like to see examples of program QAPPs and QA Manuals, please contact the NHDES QA Manager, Assistant QA Manager, or any member of the NHDES QA Team.

Calendar Year 2018 Program-Level QA Self-Audit - Form A

Please fill out one Self-Audit Form per program in accordance with the [self-audit procedure](#)

1. Program Information:

NHDES Program:	
Bureau:	
Division:	
Name/Title of Reviewer:	

1a. Do you have a **Master / Program QAPP** or **Multi-Year Project QAPP**? Yes No

1b. Does this program operate under a **Program QA Manual**? Yes No

STOP *e Form B instead.*
 If you answered “No” to both questions, **STOP** *e Form B instead.*
 If you answered “Yes” to one or both questions, proceed to **Questions 2 - 4 below**.

2. Master/ Program QAPP / Major Project QAPP / QA Manual Information

QAPP or QA Manual Title:			
Status:	Approved <input type="checkbox"/>	Under Review <input type="checkbox"/>	Not Yet Submitted <input type="checkbox"/>
Approved by:	EPA <input type="checkbox"/>	DES <input type="checkbox"/>	Other <input type="checkbox"/>
Approval date:		Expiration Date	EPA RFA No
Date you updated your QAPP in the QAPP Inventory (live link)	Note: This should be no later than 2/20/19 and the link is to the left		

3. You MUST attach the following items (use the check box!) as part of the REQUIRED annual review process:

- A copy of the cover and signature pages of the QAPP/QA Manual;
- A bulleted list of suggested changes to the QAPP/QA Manual;
- A list of the **past** areas for improvements/non-conformances found in the **CY2017** review (or earlier), and how they were resolved (or not); and
- A list of the **new** areas for improvements/non-conformances found in the **CY2018** review, and a schedule describing how they will be addressed.

NOTE: Use the following convention to list areas for improvements/non-conformances: YYYY-Consecutive number = (e.g., 2018-01, 2018-02, etc.)

4. Special Question: Which of the following (pick two) in-house EPA-led trainings would you be interested in attending?

- QAPP Review – What is EPA looking for?
- Sampling design and rationale – Filling in data gaps
- QC samples – Why do we need them?
- Data quality objectives vs. data quality indicators
- Reporting limits, method detection limits and regulatory criteria
- Other (please describe) _____

I certify that the NHDES program under my supervision is participating in the NHDES Quality Assurance System, and that the above accurately reflects the annual self-audit of this program’s quality system.

Program Manager Signature: _____

Printed Name: _____ Date: _____

Calendar Year 2018 Program-Level QA Self-Audit - Form B

Please fill out one Self-Audit Form per program in accordance with the [self-audit procedure](#)

Note: Were you aware that you could be filling out the shorter Form A if you compiled your QA-related decisions and standard operating procedures under a Program [QA Manual Template](#) or drafted a Master / Program QAPP? The QA Team can guide you in this process or you can do it yourself following the template. Some examples are available upon request.

1. Program Information:

NHDES Program:	
Bureau:	
Division:	
Name/Title of Reviewer:	

- 1a. Do you have a Master / Program QAPP or Multi-Year Project QAPP? Yes No
- 1b. Does this program operate under a Program QA Manual? Yes No
- 1c. Do you generate Project-Specific QAPPs of one year or less in duration? Yes No

*If you answered “Yes” to questions 1a or 1b, Use **Form A** instead.
If you answered “No” to both questions, proceed to **Questions 2 & 3 below**.
Also, if you answered “Yes” to 1c, proceed to **Questions 2 & 3 below**.*

2. You MUST attach the following items (use the check box!) as part of the REQUIRED annual review process:

- A list of the past areas for improvements/non-conformances found in the **CY2017** review (or earlier), and how they were resolved (or not); and
- A list of the new areas for improvements/non-conformances found in the **CY2018** review, and a schedule describing how they will be addressed.

3. Special Question: Which of the following (pick 2) in-house EPA-led trainings would you be interested in attending?

- QAPP Review – What is EPA looking for?
- Sampling design and rationale – Filling in data gaps
- QC samples – Why do we need them?
- Data quality objectives vs. data quality indicators
- Reporting limits, method detection limits and regulatory criteria
- Other (please describe) _____

Note: When asked to “show/provide” documentation, a copy should be attached, or a link accessible to DES QA staff may be provided in the [CY 2018 Program Submittals](#) folder. Incorporation by reference is encouraged, but the document being referred to must be made accessible to reviewers. Do not hesitate to write “N/A” for any question or category that doesn’t apply to your program. If the QA Team has questions about this, you will be contacted.

I certify that the NHDES program under my supervision is participating in the NHDES Quality Assurance System, and that the above accurately reflects the annual self-audit of this program’s quality system.

Program Manager Signature: _____

Printed Name: _____ Date: _____

NOTE: If you switched over to a QA Manual, you would only have to fill out this form once, and just check it over. See the [QA Manual Template](#) for more details.

1. Background Information:

a. What environmental data do you gather/use/compile? Be as specific as possible. Describe data sources.
Enter response here
b. What decisions are made using these data?
Enter response here
c. Do you assess fees, build enforcement actions, develop public health standards, or similar actions based on the data? If yes, please specify.
Enter response here
d. Who is the audience for the data?
Enter response here

2. How Do You Decide When Data Is Good Enough?

Ref: NHDES QMP Sec 8.3

a. What are your data quality needs, referred to as “Data Quality Objectives (DQOs)”? That is, how do you determine what data you need and how good (accuracy, precision, etc.) it must be in order to be useful for decision-making? Is there a regulatory standard which has to be met? There is an assumption that you don’t simply accept any and all data. Please attach documentation of your policy or decision on this. If you have no documentation, please use this form to describe what your objectives on this issue are.
Enter response here
b. How are these DQOs communicated to staff?
Enter response here
c. Do your DQOs change when there are enforcement or similar concerns?
Enter response here

3. Field Sampling (If your program does no field sampling, write “N/A” under a.) Ref: NHDES QMP Sec 8.4

a. What are your written sampling procedures? If none documented, describe them.
Enter response here
b. How do you field-modify sampling procedures? Show/provide approval procedures.
Enter response here
c. How is staff trained in procedures? Show/provide documentation.
Enter response here
d. How are training records kept? Show/provide documentation.
Enter response here
e. Question: What QA training did staff complete this year?
Enter response here
f. How is equipment calibrated? Show/provide documentation.
Enter response here
g. How are calibration records kept? Show/provide documentation.
Enter response here
h. How do you ensure that your sampling methods and procedures meet your data needs? Show/provide documentation.
Enter response here

4. Field Testing (If your program does no field testing, write “N/A” under a.) Ref: NHDES QMP Sec. 8.5

a. What are your written field testing procedures? If none documented, describe them.
Enter response here
b. How do you field-modify testing procedures? Show/provide approval procedures.
Enter response here
c. How is staff trained in procedures? Show/provide documentation.
Enter response here
d. How do you check sample or test material? Show/provide documentation.
Enter response here
e. How is equipment calibrated?
Enter response here
f. How are calibration records kept? Show/provide documentation.
Enter response here
g. What field records are generated? Show/provide copy of guidance/procedure.
Enter response here
h. How are records kept in the office? Show/provide a copy of procedure/guidance.
Enter response here
i. How do you ensure that your testing methods and procedures meet your data needs?
Enter response here

5. In-House Testing

Ref: NHDES QMP Sec. 8.6

Note: This is intended for NHDES programs that do at least some of their own testing. It is not for programs or persons who take water or other samples and bring them to the State Laboratory, which has its own extensive QA system, for testing. Otherwise, write “N/A” under a.

a. What type of in-house testing do you perform?
Enter response here
b. What methods are used? Show/provide documentation.
Enter response here
c. How do you ensure that protocols are up to date? Show/provide documentation.
Enter response here
d. How are data handled when a test is not run per specification?
Enter response here
e. Show/provide copy of procedure for recording test results.
Enter response here
f. Show/provide copy of procedure for communicating results to the data user.
Enter response here
g. How is staff trained?
Enter response here
h. How are training records kept? Show/provide documentation.
Enter response here

6. Environmental Conditions Descriptions & Data

Ref: NHDES QMP Sec. 8.7

Note: This is a broad category and considers, roughly, all data which is not chemical in nature: geological or ecological data, presence/non-presence information, GIS data, analysis of aerial photography, how models are chosen and used, and many other issues. See the definition of “Environmental Data.”

a. How do you decide what information to record? Provide documentation of decision
Enter response here
b. How is the information recorded? If forms, provide copies.
Enter response here
c. Show/provide copy of procedures for taking field notes. If none documented, describe them.
Enter response here
d. Show/provide copy of procedures or guidance for photo-documentation. If none documented, describe them.
Enter response here
e. How is staff trained? How are training records kept? Show/provide documentation.
Enter response here
f. How are (ad-hoc) deviations from procedures handled? Before the fact? After the fact? If before, who approves the deviations?
Enter response here
g. How are (permanent) changes to procedures made? Who approves? How are they communicated to staff? Show/provide example document. Is there a procedure for this process?
Enter response here

7. Review & Validation of Data

Ref: NHDES QMP Sec. 9.2

a. Show/provide any written guidance you have to describe how you check data before it is transmitted outside your program or used for making decisions, whether this is data generated by your program, or data you receive from others (“secondary data”). If none documented, describe them.
Enter response here
b. Show/provide any written guidance you have to describe how you address data that does not meet your program’s needs. If none documented, describe them.
Enter response here
c. Show/provide copy of procedures for taking field notes. If none documented, describe them.
Enter response here
d. Show/provide copy of procedures or guidance for photo-documentation. If none documented, describe them.
Enter response here
e. How is staff trained? How are training records kept?
Enter response here
f. How are deviations from procedures handled? Before the fact? After the fact?
Enter response here
g. How are changes to procedures made? Who approves? How are they communicated to staff? Show/provide example document. Is there a procedure for this process?
Enter response here

8. *Retention of Data*

Ref: NHDES QMP Chap. 6, Sec 6.2

a. Show/provide filing procedures. If none documented, describing them using this form.
Enter response here
b. Do you keep back-up copies of any data? How do you decide what to back up? Show/provide copy of procedure.
Enter response here
c. Show/provide procedures for securing files. If none documented, describe them.
Enter response here
d. How long do you retain data? Show/provide copy of data retention decision. Include data removal/destruction decision.
Enter response here

9. *Reporting Results – includes outgoing correspondence and other communications from NHDES*
Ref: NHDES QMP Sec. 8.8

a. To whom do you send data? Note: “Send” refers to anyone outside of the program, whether elsewhere in NHDES or external to NHDES.
Enter response here
b. Show/provide written guidance on reporting formats. If none documented, describe them.
Enter response here
c. How do you decide who is responsible for signing the data reports? Show documentation of decision.
Enter response here
d. When reporting to different audiences, do you vary the form or type of report? How is this decision made?
Enter response here
e. How is staff informed of proper reporting methods? Provide example documentation.
Enter response here

10. *System Reviews & Assessments*

Ref: NHDES QMP Chapters 9 & 10

a. If you do other system assessments (apart from completing this Form B), such as management reviews, field audits, audits of contractors, etc., please describe here. Also include any such reviews of your program that may have been done by others. Show/provide documentation for the last review. Note: This does not refer to ad hoc adjustments. This DOES, however, include any work you do, whether in the field or otherwise, to check that your staff, contractors or other data providers are producing information in a way that meets your expectations.
Enter response here
b. How do you document and correct areas for improvements/non-conformances – (<i>i.e.</i> , times when your system did not work as expected or as well as it could have)?
Enter response here

