

STANDARD OPERATING PROCEDURE

**Review and Approval Process for NEIWPC Quality Assurance Project Plans
(QAPPs)**

New England Interstate Water Pollution Control Commission
(NEIWPC)

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I. SUMMARY

This document was prepared to assist NEIWPCQ staff in understanding the Commission's process for the review and approval of quality assurance project plans. It outlines roles, responsibilities, and procedures for two scenarios: the first covers projects funded by EPA; the second scenario covers projects funded by other organizations.

While this is intended to be a stand-alone document, it does not describe all aspects of the NEIWPCQ Quality Management System, the process for determining when a QAPP is needed, or specific components and requirements of a quality assurance project plan. For additional guidance on these topics, go to NEIWPCQ's Quality Management website (neiwpcq.org/quality).

Note that the procedures described below do not apply to a program that has QAPP-approval authority, in which case the program would have its own approval procedure.

II. DEFINITIONS

QAPP	Quality assurance project plan (including all associated appendices, checklists, and forms)
Unique identifier	Alphanumeric label assigned to each QAPP submitted for NEIWPCQ review and approval
QAPP writer	Person responsible for writing and revising a QAPP (may be NEIWPCQ employee or contractor)
NEIWPCQ project manager (PM)	NEIWPCQ staff person responsible for oversight of project in need of an approved QAPP
Checklist	Any of several review templates used to assess completeness of a QAPP (The checklist used is based on type of project (primary data, secondary data, or modeling).
Receiver	Designated administrative contact for QAPP tracking at the Lowell office (email: gapps@neiwpcq.org)
QAPP Tracker	Database used to track information and status of QAPP review and approval
QAPM	Quality assurance program manager (currently Peter Zaykoski) is the point-of-contact for all quality assurance activities
QA designee	An appropriately trained and certified staff person selected by the QAPM to review and approve a particular QAPP
EPA QA coordinator	NEIWPCQ's primary point of contact at EPA for QA matters (currently Nora Conlon for EPA Region 1 and Carol Lynes for EPA Region 2)
EPA project officer	EPA staff person responsible for project oversight
EPA QA reviewer	EPA staff person responsible for reviewing and approving QAPP once it complies with EPA QAPP requirements

III. PROCEDURE

The process for review and approval of all NEIWPCQ QAPPS consists of nine steps in three phases:

Phase 1: Preparation and Initialization

- Step 1. Project Manager Review for Completeness
- Step 2. Initial Submission of Draft QAPP
- Step 3. Receipt of Draft QAPP

Phase 2: Review and Revision

- Step 4. QAPP Review Assignment
- Step 5. Reviewing Draft QAPP
- Step 6. Draft QAPP Revision
- Step 7. QAPP Revision Review

Phase 3: Finalization and Filing

- Step 8. Finalization of QAPP
- Step 9. Electronically Filing the QAPP

All QAPP review and approval processes share the same detailed process instructions for phases one and three; the specific process for phase two is dependent on the funding source of the project. Details for each step in the process are presented below and flow charts showing summarizing the steps for each scenario are provided in Appendix A.

Phase 1: Preparation and Initialization

Step 1: Project Manager Review for Completeness

1.1: Whether the QAPP writer is a NEIWPCQ employee or a contractor, the NEIWPCQ project manager (PM) will review the draft QAPP by comparing it to the appropriate checklist, project scope of work, and advisory committee guidance to ensure that the QAPP adequately describes the project activities to be conducted and that all necessary QAPP elements are included. In addition, the PM will ensure that all applicable aspects of the project are detailed in the QAPP. If the QAPP is found to be inadequate, the PM will provide specific directions to the QAPP writer, who will make the necessary modifications. The PM must verify that all issues have been adequately addressed before proceeding to step 2.

Step 2: Initial Submission of Draft QAPP

2.1: Once the PM has reviewed the draft QAPP and assessed it as complete, the PM will complete the electronic QAPP submission form (available at neiwpcq.org/quality).

2.2: The PM will email both an electronic version of the draft QAPP and the completed electronic QAPP submission form to the receiver.

NOTE: The PM is responsible for identifying all necessary reviewers (EPA, state agency, or other) before submitting the draft QAPP for review. The QAPM will assist in this process as necessary.

Step 3: Receipt of Draft QAPP

3.1: Upon receipt of the draft QAPP and corresponding QAPP submission form, the receiver will assign a unique identifier to the QAPP (see Appendix B) and create a new record in QAPP Tracker. (Additional details pertaining to QAPP Tracker are provided in Section IV of this document.)

3.2: The receiver will create a new folder by project title in the designated location on the Common drive (I:\COMMON\QUALITY\QAPPS\QAPPS - PENDING) and will save both the electronic draft QAPP and corresponding QAPP submission form within this folder, in accordance with the QAPP File Naming Convention (see Appendix C).

3.3: The receiver will email the draft QAPP to the quality assurance program manager (QAPM), copying the PM, including a screenshot of the QAPP Tracker record for reference in the body of the email.

NOTE: Once assigned by the receiver, the unique identifier should be included in all correspondence related to the QAPP. Similarly, if an EPA RFA (Request for Applications) number was available and provided by the PM, it should be included in all correspondence during QAPP review.

NOTE: From this point forward, the PM should be copied on all emails regarding review and approval of the QAPP.

Phase 2: Review and Revision

Two scenarios are presented below covering: 1) projects with EPA funding, and 2) projects with funding from other organizations. Each describes the specific actions for steps 4-7 of the overall process.

Scenario 1: EPA Funded Project

The key difference between review processes involving EPA Region 1 and Region 2 is in the order of review: the Region 1 review process occurs concurrently with NEIWPCQ review, while Region 2 review occurs subsequent to NEIWPCQ review. If approval of both EPA Region 1 and Region 2 is required, the concurrent NEIWPCQ and EPA Region 1 review should occur before Region 2 review is initiated.

Step 4: QAPP Review Assignment

4.1: Once the QAPM receives the draft QAPP, the QAPM will assign a QA designee to conduct the review, and the draft QAPP will be emailed to that individual. (The QA designee will typically be selected, in consultation with appropriate supervisory staff, based on availability and areas of technical expertise.) The QAPM will update QAPP Tracker to reflect the QA designee as the reviewer.

4.2: Should the QAPP require approval from EPA Region 1, the QAPM will email it to the appropriate EPA Region 1 project officer and NEIWPCQ's EPA QA coordinator for Region 1. Any additional reviewers identified as necessary by the PM, save for EPA Region 2 if applicable, will be included on this message. The message will request that the agency's staff review the draft QAPP and email any necessary modifications to the PM. The message will also communicate who the QAPM has assigned as QA designee and request that the agency's staff not approve (sign) the QAPP until the NEIWPCQ review and approval process is complete. If the QAPP requires approval through EPA Region 2, that review will

occur after NEIWPCQ review and concurrent Region 1 review (if necessary). The Region 2 review process is described in steps 7.4 - 7.6 below.

Step 5: Reviewing Draft QAPP

5.1: The QA designee will review the draft QAPP, using (and completing) the appropriate review checklist.

5.2: Upon completion of the checklist, the QA designee will generate a comment memo that details any needed modifications. The QA designee will save the completed checklist and comment memo in the appropriate electronic project file (the project-specific folder in I:\COMMON\QUALITY\QAPPS\QAPPS - PENDING). If the QA designee is not located in the Lowell office, the designee will email the comment memo and checklist to the receiver, who will save the files to the appropriate location.

NOTE: All files saved in a project-specific QAPP folder should be named in accordance with the QAPP File Naming Convention contained in Appendix C of this document.

5.3: The QA designee will email the comment memo to the PM and EPA Region 1 reviewers to initiate the revision process. Under most circumstances, the PM should receive the comment memo from the QA designee within 10 business days from the time the QA designee received the draft QAPP.

5.4: The QA designee will update the project record in QAPP Tracker to specify the date the comment memo was sent and will check the boxes indicating that the electronic checklist and comment memo have been saved in the appropriate folder. If the QA designee is not located in the Lowell office, the designee will email the necessary information to the receiver, who will update QAPP Tracker.

Step 6: Draft QAPP Revision

6.1: The PM will email the QA designee's comment memo to the QAPP writer so that the writer can revise the draft QAPP to address issues identified in the memo.

6.2: The QAPP writer will also incorporate any modifications identified during the concurrent review of the draft QAPP from EPA Region 1 or any other applicable reviewers. (The PM is not required to save EPA or other reviewers' comments on the evaluation of the draft QAPP, but should this be desired, the PM may save additional comments to the project-specific QAPPS-PENDING folder. Files containing additional comments should indicate Do Not Delete in the file name. If the PM is not located in the Lowell office, the PM can email the necessary information to the receiver, who will save the file(s).)

Step 7: QAPP Revision Review

7.1: When revisions are complete, the PM will submit the revised QAPP to the QA designee, EPA Region 1 project officer (if applicable), EPA Region 1 QA reviewer (if applicable) and any additional applicable reviewers to determine if revisions are adequate.

7.2: The QA designee will update QAPP Tracker to specify the date the revised QAPP was received. If the QA designee is not located in the Lowell office, the designee will email the necessary information to the receiver, who will update QAPP Tracker.

7.3: If the QA designee, EPA Region 1 project officer, EPA Region 1 QA reviewer, or other reviewer(s) (as applicable) determine that the revisions are inadequate, the PM will be notified so the QAPP can be further revised. Steps 6.1, 6.2, and 7.1 will be repeated until all applicable reviewers determine that the QAPP has been adequately revised.

NOTE: If the QAPP does not require approval from EPA Region 2, skip steps 7.4, 7.5, and 7.6 and proceed to step 7.7. If the QAPP requires approval from EPA Region 2, continue to step 7.4.

7.4: Once the QA designee, EPA Region 1 project officer (if applicable), EPA Region 1 QA reviewer (if applicable) and any additional reviewers determine that the revisions are adequate, the QA designee will notify the PM that the QAPP meets NEIWPCQ and EPA Region 1 QA requirements (if applicable) and can be sent to the appropriate EPA Region 2 project officer, who will coordinate the Region 2 review and approval process.

7.5: The PM will email a Word version of the QAPP to EPA Region 2, so that modifications can be identified via the Track Changes feature.

7.6: As the PM receives feedback on the draft QAPP from EPA Region 2, the PM will work to ensure that the QAPP is adequately revised to address identified issues.

7.7: Once all applicable reviewers have indicated to the PM that the QAPP has been adequately revised, the signature process can be initiated. The QA designee will update QAPP Tracker to specify the date that the revisions were approved. If the QA designee is not located in the Lowell office, the designee will email the receiver, who will update QAPP Tracker.

7.8: The QA designee will send an email to the PM authorizing the signature process to begin. A copy of the email will be saved as a PDF by the QA designee and retained in the appropriate project folder. The QA designee will check the box in QAPP Tracker to indicate that the OK to proceed message has been filed. If the QA designee is not located in the Lowell office, the designee will email the necessary information to the receiver, who will save the PDF in the appropriate project folder and update QAPP Tracker.

NOTE: Upon completion of step 7.8, continue to Phase 3 of the process, which begins on page 9.

Scenario 2: Project Funded By Other Organizations

Step 4: QAPP Review Assignment

4.1: Once the QAPM receives the draft QAPP, the QAPM will assign a QA designee to conduct the review, and the draft QAPP will be emailed to that individual. (The QA designee will typically be selected, in consultation with appropriate supervisory staff, based on availability and areas of technical expertise.) The QAPM will update QAPP Tracker to reflect the QA designee as the reviewer.

4.2: Should the QAPP require approval from other organizations, the QAPM will email the draft QAPP to the appropriate reviewer(s). The message will request a review of the draft QAPP with any necessary modifications emailed to the PM. The message will also request that the other organization(s) not approve (sign) the QAPP until the NEIWPCQ review and approval process is complete.

Step 5: Reviewing Draft QAPP

5.1: The QA designee will review the draft QAPP, using (and completing) the appropriate review checklist.

5.2: Upon completion of the checklist, the QA designee will generate a comment memo that details any needed modifications. The QA designee will save the completed checklist and comment memo in the appropriate electronic project file (the project-specific folder in *I:\COMMON\QUALITY\QAPPS\QAPPS - PENDING*). If the QA designee is not located in the Lowell office, the designee will email the comment memo and checklist to the receiver, who will save the files to the appropriate location.

NOTE: All files saved in a project-specific QAPP folder should be named in accordance with the QAPP File Naming Convention contained in Appendix C of this document.

5.3: The QA designee will email the comment memo to the PM to initiate the revision process. Under most circumstances, the PM should receive the comment memo from the QA designee within 10 business days from the time the QA designee received the draft QAPP.

5.4: The QA designee will update the project record in QAPP Tracker to specify the date the comment memo was sent and will check the boxes indicating that the electronic checklist and comment memo have been saved in the appropriate folder. If the QA designee is not located in the Lowell office, the designee will email the necessary information to the receiver, who will update QAPP Tracker.

Step 6: Draft QAPP Revision

6.1: The PM will email the QA designee's comment memo to the QAPP writer so that the writer can revise the draft QAPP to address issues identified in the memo.

6.2: The QAPP writer will also incorporate any necessary modifications identified during the concurrent review of the draft QAPP by other approving organizations (if applicable). If the PM would like to save any comments (optional) on the evaluation of the draft QAPP, the PM can save them to the project specific QAPPS-PENDING folder. Files containing comments should indicate Do Not Delete in the file name. If the PM is not located in the Lowell office, the PM can email the necessary information to the receiver, who will save the file.

Step 7: QAPP Revision Review

7.1: When revisions are complete, the PM will submit the revised QAPP to the QA designee and any other reviewers (if applicable) who will determine if revisions are adequate.

7.2: The QA designee will update QAPP Tracker to specify the date the revised QAPP was received. If the QA designee is not located in the Lowell office, the designee will email the necessary information to the receiver, who will update QAPP Tracker.

7.3: If the QA designee or other reviewer determines that the revisions are inadequate, the PM will be notified so the QAPP can be further revised. Steps 6.1, 6.2, and 7.1 will be repeated until the QA designee and all applicable reviewers determine that the QAPP has been adequately revised.

7.4: Once all reviewers determine that the revisions are adequate, the signature process may be initiated. The QA designee will update QAPP Tracker to specify the date that the revisions were approved. If the QA designee is not located in the Lowell office, the designee will email the receiver, who will update QAPP Tracker.

7.5: The QA designee will send an email to the PM authorizing the signature process to begin. A copy of the email will be saved as a PDF by the QA designee and retained in the appropriate project folder. The QA designee will check the box in QAPP Tracker to indicate that the OK to proceed message has been filed. If the QA designee is not located in the Lowell office, the designee will email the necessary information to the receiver, who will save the PDF in the appropriate project folder and update QAPP Tracker.

Phase 3: Finalization and Filing

Step 8: Finalization of QAPP

8.1: The PM (or person assigned finalization responsibility within the QAPP) will circulate the complete, final QAPP to the appropriate individuals to obtain signatures. The QAPP should be circulated via email, with signatures added electronically, unless hard copies with original signatures are required.

8.2: Upon receipt of the signature page, the QA designee will check the box in QAPP Tracker indicating that the signature page was received, when the final QAPP is circulated. If the QA designee is not located in the Lowell office, the designee will email the necessary information to the receiver, who will update QAPP Tracker.

8.3: Once the PM (or assigned individual) receives all signatures, the PM (or assigned individual) will email a PDF of the complete, approved QAPP to the distribution list.

8.4: Upon receipt of the complete, approved QAPP, the QA designee will forward a copy of the approved QAPP to the receiver with finalization instructions. The QA designee will instruct the receiver to save a copy of the approved QAPP (with all signatures included) in the appropriate project folder, update the project record in QAPP Tracker to specify the date that the final QAPP was received and fiscal year of completion for the review process, and move the project folder from the "QAPPS - PENDING" directory to the appropriate fiscal year folder in the "QAPPS - COMPLETE" directory.

NOTE: The QA designee must confirm that all fields in the QAPP Tracker for which s/he is responsible, have been completed before providing finalization instructions to the receiver.

Step 9: Electronically Filing the QAPP

9.1: Upon receiving finalization instructions from the QA designee, the receiver will save a copy of the complete, approved QAPP (with all signatures included) in the appropriate project folder. Once the complete QAPP has been saved, the receiver will delete intermediate drafts of the QAPP and ensure that the folder also contains the checklist, comment memo, submission form, and the email authorizing initiation of the signature process. The receiver will retain any files designated Do Not Delete and the initial draft QAPP, which will be retained for training purposes.

9.2: With the aforementioned documents included, the receiver will relocate the project folder to the “QAPPS - COMPLETE” folder on the Common drive (for example, I:\COMMON\QUALITY\QAPPS\QAPPS - COMPLETE\Completed FY2020 QAPPS for fiscal year FY2020 projects) and update QAPP Tracker accordingly.

IV. QAPP TRACKER

QAPP Tracker (Figure 1) is an Access database used to compile project-specific information pertaining to the QAPP review and approval process. It can be found at I:\COMMON\QUALITY.

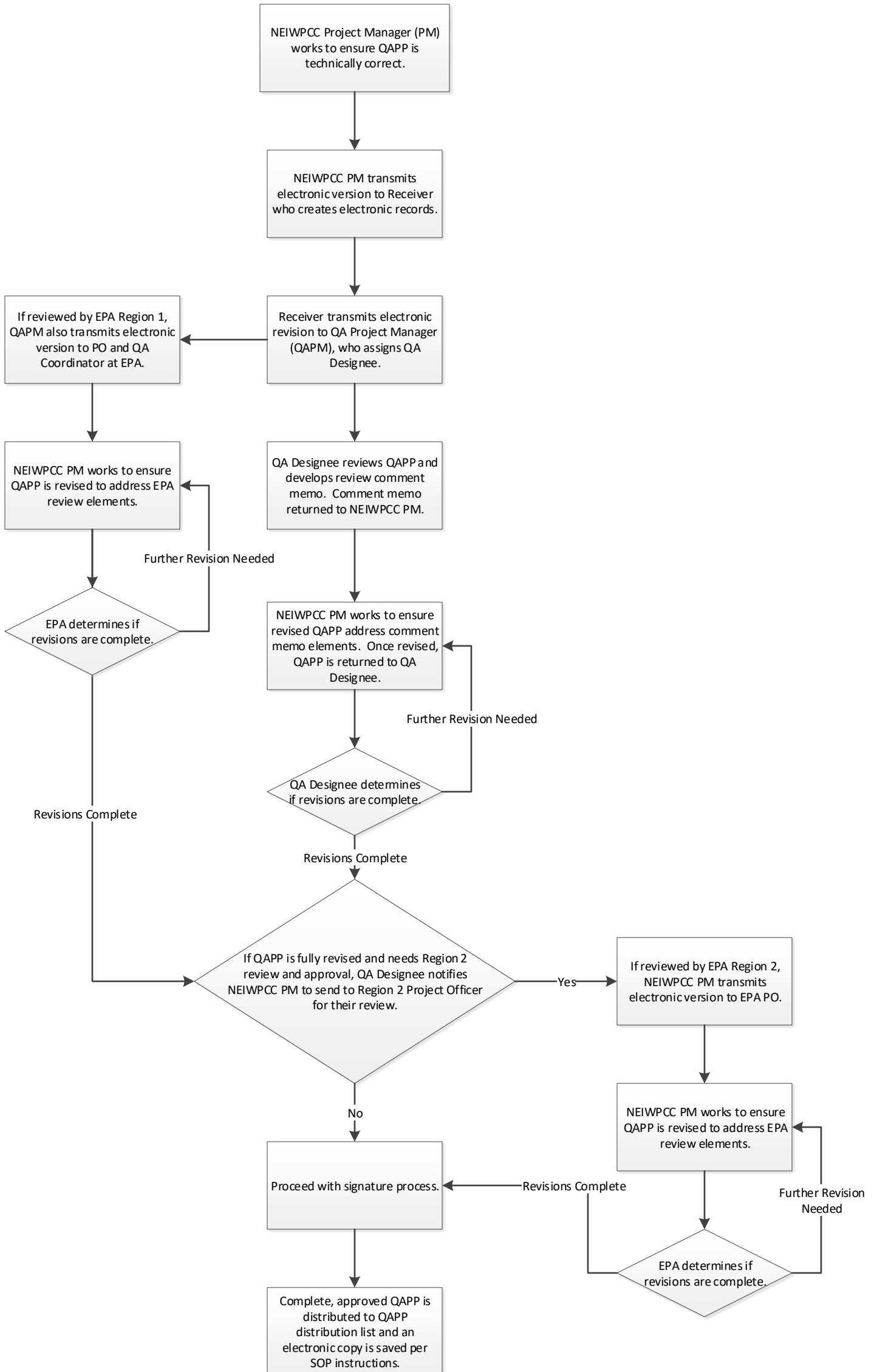
- Once QAPP Tracker is opened, the QAPP Form can be opened from the navigation pane.
- When a QAPP is submitted for review, the receiver will create a new record for the project and populate the fields within the record using information provided on the QAPP Submission Form.
- When the QA designee (or receiver) updates the project-specific record within QAPP Tracker, the appropriate record is first found using the scroll buttons or search function. The fields for inserting relevant dates for that record are located at the far right of the form.

Figure 1

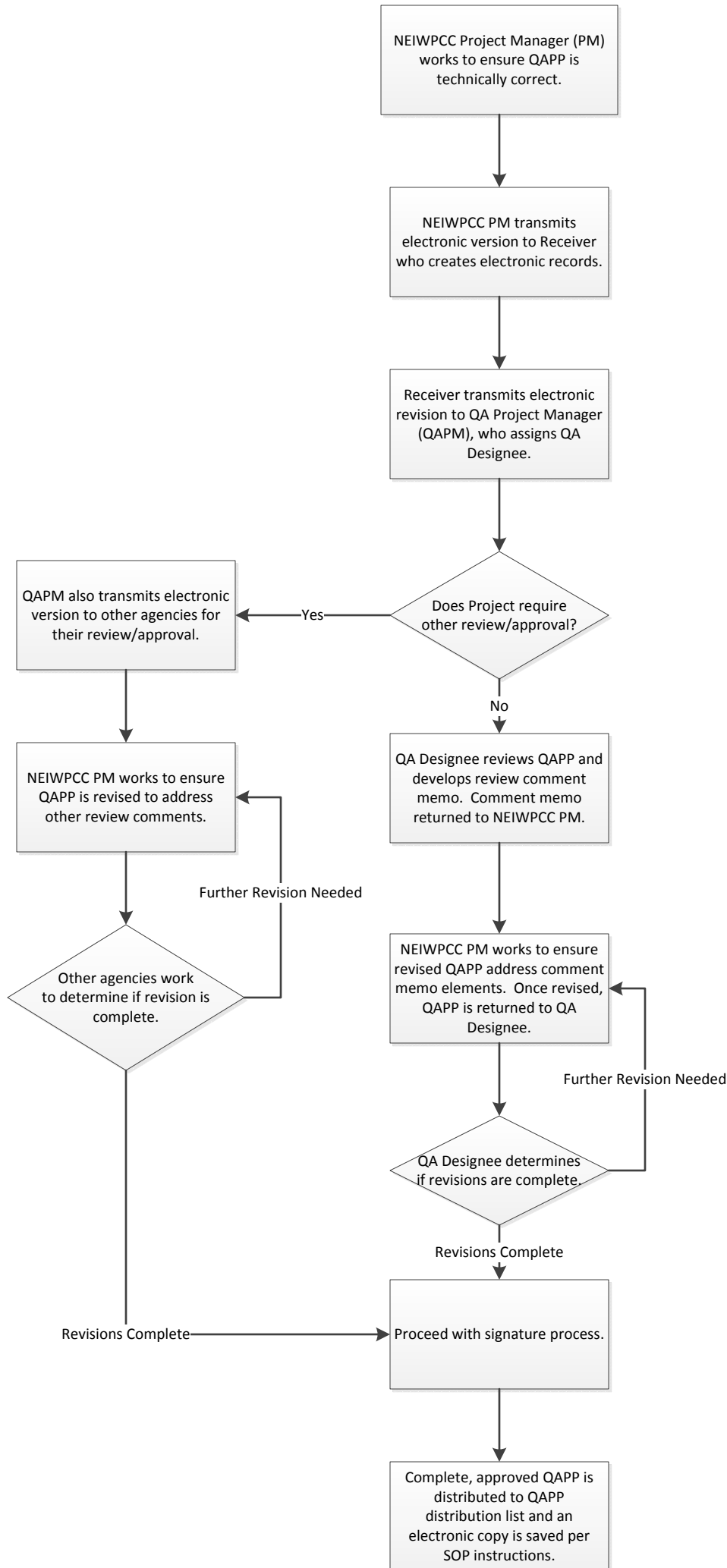
The screenshot shows the Microsoft Access interface for the QAPP Form. On the left, the 'All Tables' pane lists various tables and queries, with 'QAPP Form' circled in blue. A callout box points to this circle with the text: 'Click here to open QAPP Form.' The main window displays the 'QAPP Form' with several input fields: 'QAPP Title', 'Short Title', 'Description', 'QAPP ID', 'NEIWPCQ PM', 'NEIWPCQ Project Code', 'Grant/Contract Number', 'JCC (Project)', 'JCC (Reviewer)', 'Start Date', and 'End Date'. Below these are 'Categories' with checkboxes for various environmental topics like Agriculture, Fish, Modeling, Sediment Loading, etc. At the bottom, there are checkboxes for 'Electronic Checklist Saved', 'Electronic Final QAPP Saved', 'Comment Memo Saved', 'OK to Proceed Message Saved', and 'Signature Page Received'. A 'Comments' text area is also present. On the right side of the form, there are date fields for 'QAPP Reviewer', 'Delegated Program Review', 'Date Draft QAPP Received', 'Date Review Completed', 'Date Revisions Received', 'Date Revisions Approved', and 'Date Final QAPP Received'. A legend below these fields indicates: Green=QAPP Initially Reviewed, Purple=During QAPP Review Process, and Blue=QAPP Complete. A callout box points to the date fields with the text: 'QA designee inserts dates here.' At the bottom of the form, there are record navigation buttons (back, forward, search, etc.) and a search box. A callout box points to these buttons with the text: 'Scroll buttons or search for moving through records. Use * button to add new record.'

APPENDIX A: PROCESS FLOWCHARTS

EPA Funded Project



Project Funded by Other Organizations



APPENDIX B: QAPP UNIQUE ID SYSTEM

In order to better track quality assurance project plans (QAPPS) through the NEIWPCQ review and approval process, a system of unique identifiers has been instituted for all QAPPS entering the review process, beginning in fiscal year 2020. This will allow clear correspondence, accurate records, and better quality control of our QAPP review and approval process data.

Definitions

Table 1. Identification System Elements

ID Element	Description
FY	The fiscal year when the QAPP was submitted for review
QAPP #	The number of the QAPP as it was received in a given fiscal year
Amendment #	The number of the amendment

Format

The format of unique identifier for each QAPP is built from the elements in Table 1, above, as follows:

Q[FY]-[QAPP #]-A[Amendment #]

With the following rules:

- FY is preceded by "Q" to differentiate these identifiers from other unique identifiers used in NEIWPCQ systems (e.g. agreement numbers).
- FY is specified by two digits
- QAPP # is sequentially defined by the Receiver at the time of receipt. It is specified by a three digit number (e.g. 012) and resets to 001 at the beginning of each fiscal year.
- Amendment # is only used if the QAPP that is submitted is an amendment to an existing QAPP. The number of the amendment should be preceded by "A" and the FY and QAPP # should be the same as the original QAPP.

Examples

- QAPP submitted on 10/27/19 and is the second QAPP received during fiscal year 2020: **Q20-002**
- Amendment 1 to Q20-002 submitted on 1/20/21: **Q20-002-A1**

APPENDIX C: FILE NAMING CONVENTION

This file naming convention applies to those files and folders created during the NEIWPCQ quality assurance project plan (QAPP) review and approval process as well as final, approved QAPPS. This convention was developed to be consistent with the NEIWPCQ Filename Convention Rules.

This convention is in effect beginning October 1, 2019.

Definitions

Table 1. File & Folder Name Elements

File Name Element	Description
QAPP ID	The unique identifier assigned to each QAPP by the Receiver at the initialization of the review process
Short Title	A brief title assigned to each QAPP and provided by the Project Manager on the Submission Form
Document Type	The short name for each type of document created during the review process (e.g. review checklists or comment memos). Specific shorthand names are defined in Table 2 below
Additional Detail	In some cases another element is necessary to capture the content of the file. This element is flexible.
Date	The date of creation of the file, most recent edit, or approval as appropriate

Table 2. QAPP Review Documents

Document Type	File Name Shorthand	Description
Submission Form	submission form	Form provided by NEIWPCQ Project Manager during initial submission of QAPP for review
Draft QAPP	QAPP DRAFT	Initial QAPP as submitted to the Receiver for review
Final, Approved QAPP	QAPP FINAL	Approved and signed QAPP used during project implementation
Appendices	APPX	Any appendices that are not included within the body of the QAPP and provided as separate files
Review Checklist	checklist	Any of several review templates used to assess completeness of a QAPP (The checklist used is based on type of project (primary data, secondary data, or modeling).
Review Comment Memo	memo	Document used to communicate revisions requested by the QA Designee to the NEIWPCQ Project Manager
Authorization Message	ok to proceed	A copy of the email sent to the Project Manager indicating that all revisions requested have been made and the NEIWPCQ QA Designee is ready to proceed to signature

Format

For both QAPP folders and the documents contained within those folders, a combination of the elements above are used to create consistency using the following formats. Note that underscores should be used between elements as delimiters.

For each **QAPP folder**, the unique identifier and the short title are used as follows:

[QAPP ID]_[short title]

For each **review document** the format is as follows:

[QAPP ID]_[document type]_[additional detail]_[date]

With consideration of the following rules:

- Document type descriptors should use the shorthand names as defined in Table 2, above.
- For any appendices filed, the document type element in the file name should correspond to the version of the QAPP with which they belong (“QAPP DRAFT” or “QAPP FINAL”) and the appendix number or letter should be appended to the abbreviation, “APPX”, and included in the “additional detail” element.
- All dates should conform to the rules of the NEIWPCQ file naming convention, which specify that they should be ordered by MONTH, DAY, YEAR, using two digits each and separated by periods.
- Additional information can be coded into the “additional detail” element as necessary. It is important that the length of this element is minimized and only included when necessary.
- If there are any additional documents that need to be filed in the QAPP folder, they should generally follow the above format using logical names in the “document type” element. If these additional files should be retained beyond the duration of the review process, they should be labeled “Do Not Delete” in the “additional detail” element.

Example

A finalized QAPP with the following details:

- QAPP ID: Q20-023
- Short Title: Hudson Invasive Species Survey
- Two appendices submitted: A & B

Would be filed in the following folder: “Q20-023_Hudson Invasive Species Survey” listed in the appropriate fiscal year folder in the “QAPPS - COMPLETE” directory. The following files would be included in the folder (dates represent arbitrary timeline):

- Q20-023_submission form_05.20.20
- Q20-023_QAPP DRAFT_05.20.20
- Q20-023_QAPP DRAFT_APPX A_05.20.20
- Q20-023_QAPP DRAFT_APPX B_05.20.20
- Q20-023_checklist_05.22.20
- Q20-023_memo_05.22.20
- Q20-023_ok to proceed_05.26.20
- Q20-023_QAPP FINAL_05.29.20
- Q20-023_QAPP FINAL_APPX A_05.29.20
- Q20-023_QAPP FINAL_APPX B_05.29.20