

SOP for NEIWPCC QAPP Approval Process

I. Summary

This document was prepared to assist NEIWPCC 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 scenario (section III) covers projects funded by EPA; the second scenario (section IV) covers projects funded by other organizations.

While this is intended to be a stand-alone document, it does not describe all aspects of the NEIWPCC 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 NEIWPCC's Quality Management website (neiwpc.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)
- QAPP writer:** Person responsible for writing and revising a QAPP (may be NEIWPCC employee or contractor)
- NEIWPCC project manager:** NEIWPCC 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 (currently Shelly Jenkins)
- QAPP Tracker:** Database used to track information and status of QAPP review and approval
- QAPM:** Quality assurance program manager (NEIWPCC's QAPM, currently Michael Jennings, 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:** NEIWPCC's primary point of contact at EPA for QA matters
- 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. Scenario 1: EPA Funded Project

Step 1: Project Manager Review for Completeness

1.1: Whether the QAPP writer is a NEIWPCCE employee or a contractor, the NEIWPCCE 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 neiwpcce.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: From this point forward, the PM should be cc'd on all emails regarding review and approval of the QAPP.

Step 3: Receipt of Draft QAPP

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

3.2: The receiver will create a new folder by project title in the designated location on the Common drive (for example, *I:\COMMON\QUALITY\QAPPS\QAPPS - PENDING\FY2015* for fiscal year 2015 projects) and will save both the electronic draft QAPP and corresponding QAPP submission form within this folder.

3.3: The receiver will email the draft QAPP to the quality assurance program manager (QAPM).

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 input the QA designee and assignment date into QAPP Tracker.

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 NEIWPCCE's EPA QA coordinator for Region 1. The message to EPA will request that the agency's staff review the draft QAPP and email any necessary modifications to the PM. The message to EPA will also request that the agency's staff not approve (sign) the QAPP until the NEIWPCCE review and approval process is complete. The process will then proceed as follows in steps 5

through 7. If, however, the QAPP requires approval through EPA Region 2, skip steps 5 through 7 below and follow the modified steps in the text box on page 5.

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 (for example, the project-specific folder in *I:\COMMON\QUALITY\QAPPS\QAPPS - PENDING\FY2015* for fiscal year 2015 projects). 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.

5.3: The QA designee will email the comment memo to the PM and EPA 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 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 box indicating that the electronic checklist has 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 EPA Region 1 review of the draft QAPP. (The PM is not required to save EPA's comments on the evaluation of the draft QAPP, but should this be desired, the PM may save EPA's comments to the QAPPS-PENDING folder (for example, the project-specific folder in *I:\COMMON\QUALITY\QAPPS\QAPPS - PENDING\FY2015* for fiscal year 2015 projects.) Files containing EPA's 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, EPA Region 1 project officer (if applicable), and EPA Region 1 QA reviewer (if applicable) 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 project officer, or EPA QA reviewer 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 the QA designee, EPA project officer, and/or EPA QA reviewer determine that the QAPP has been adequately revised.

7.4: Once it is determined 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. 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.

If the QAPP requires approval from EPA Region 2:

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 (for example, the project-specific folder in *I:\COMMON\QUALITY\QAPPS\QAPPS - PENDING\FY2015* for fiscal year 2015 projects). 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.

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 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 box indicating that the electronic checklist has been saved in the appropriate folder. If the QA designee is not located in the Lowell office, the designee will email 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.

Step 7: QAPP Revision Review

7.1: When revisions are complete, the PM will submit the revised QAPP to the QA designee 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 receiver, who will update QAPP Tracker.

7.3: If the QA designee determines that the revisions are inadequate, the PM will be notified so the QAPP can be further revised. Steps 6.1 and 7.1 will be repeated until the QA designee determines that the QAPP has been adequately revised.

7.4: Once the designee determines that the revisions are adequate, the QA designee will notify the PM that the QAPP meets NEIWPCC QA requirements 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 EPA Region 2 has indicated that the QAPP has been adequately revised, the signature process can be initiated.

7.8: 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.

7.9: The QA designee will send an email to the PM authorizing the signature process to begin. A copy of the email will be saved by the QA designee as a PDF and retained in the appropriate project folder. 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.

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: Once the PM (or assigned individual) receives all signatures, a PDF of the complete, approved QAPP will be emailed to the distribution list. The receiver will save a copy of the approved QAPP (with all signatures included) in the appropriate project folder. The receiver will also update the project record in QAPP Tracker to specify the date that the final QAPP was received.

Step 9: Electronically Filing the QAPP

9.1: Once the completed QAPP has been saved, the receiver will delete previous 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.

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 FY2015 QAPPS for fiscal year FY2015 projects) and update QAPP Tracker accordingly.

IV. Scenario 2: Project Funded By Other Organizations

Step 1: Project Manager Review for Completeness

1.1: Whether the QAPP writer is a NEIWPC employee or a contractor, the NEIWPC 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 neiwpc.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: From this point forward, the PM should be cc'd on all emails regarding review and approval of the QAPP.

Step 3: Receipt of Draft QAPP

3.1: Upon receipt of the draft QAPP and corresponding QAPP submission form, the receiver will create a new record in QAPP Tracker. (Additional details pertaining to QAPP Tracker are provided in section V of this document.)

3.2: The receiver will create a new folder by project title in the designated location on the Common drive (for example, *I:\COMMON\QUALITY\QAPPS\QAPPS - PENDING\FY2015* for fiscal year 2015 projects) and will save both the electronic draft QAPP and corresponding QAPP submission form within this folder.

3.3: Upon completion of **3.1** and **3.2**, the receiver will email the draft QAPP to the quality assurance program manager (QAPM).

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 input the QA designee and assignment date into QAPP Tracker.

4.2: Should the QAPP require approval from other organizations, the QAPM will email the draft QAPP to the appropriate reviewer. 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 not approve (sign) the QAPP until the NEIWPC 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 (for example, the project-specific folder in *I:\COMMON\QUALITY\QAPPS\QAPPS - PENDING\FY2015* for fiscal year 2015 projects). 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.

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 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 box indicating that the electronic checklist has 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 QAPPS-PENDING folder (for example, the project specific folder in I:\COMMON\QUALITY\QAPPS\QAPPS - PENDING\FY2015 for FY2015 projects). 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 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 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 determines that the QAPP has been adequately revised.

7.4: Once the QA designee determines 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. 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.

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.

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Step 9: Electronically Filing the QAPP

9.1: Once the completed QAPP has been saved, the receiver will delete previous 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.

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 FY2015 QAPPs for fiscal year 2015 projects) and update QAPP Tracker accordingly.

V. QAPP Tracker

- QAPP Tracker 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 navigation pane can be expanded and the QAPP Form opened. See Figure 1.
- When a new 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. The fields for inserting relevant dates for that record are located at the far right of the form.

Figure 1

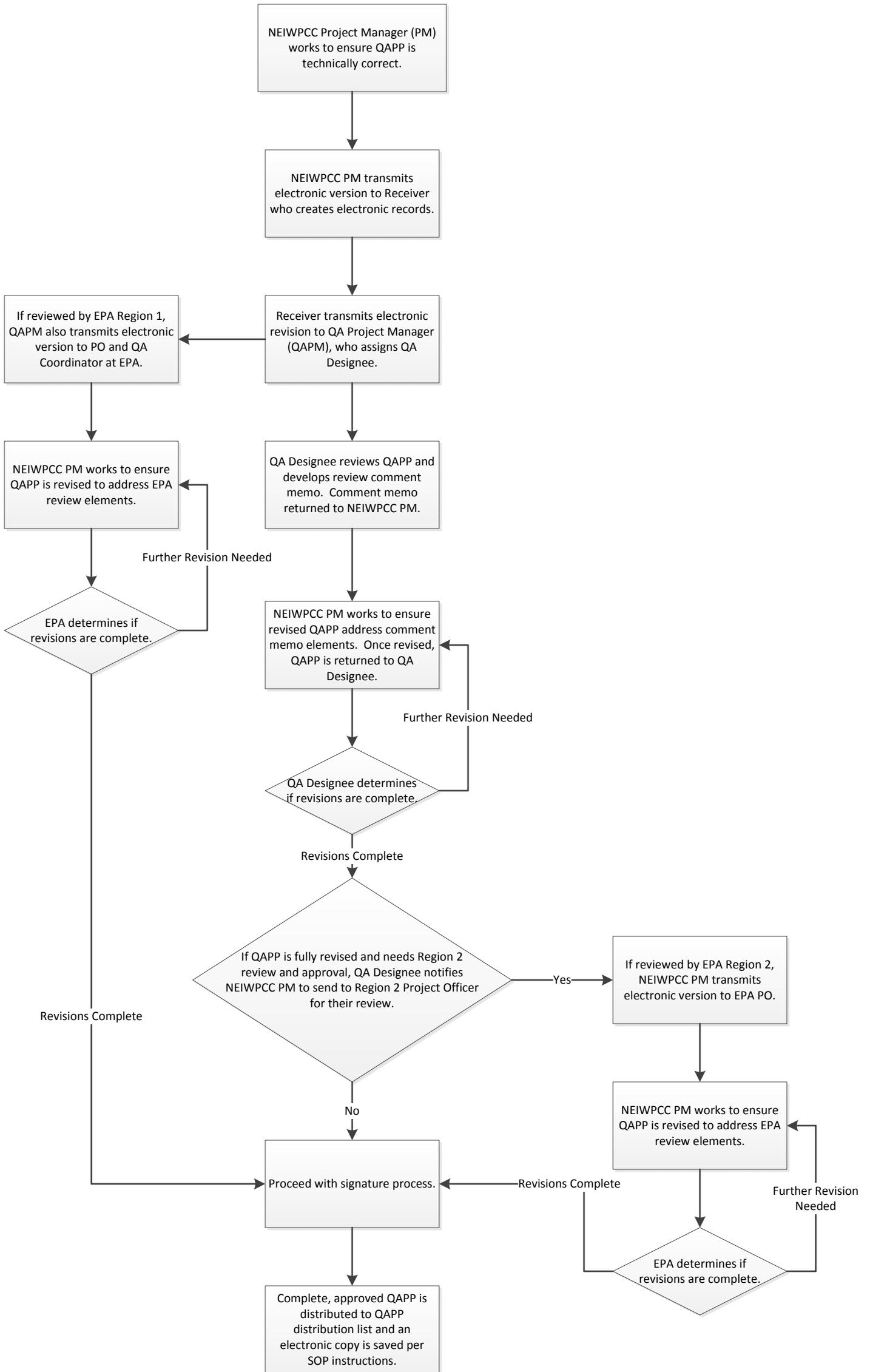
The screenshot shows the Microsoft Access interface for the QAPP Tracker database. The 'QAPP Table' is selected in the navigation pane. The main window displays the 'QAPP Form' with various fields and a 'QAPP Reviewer' section. Callouts provide instructions: 'Click here to open QAPP Form.' points to the 'QAPP Form' in the navigation pane; 'Scroll buttons for moving through records. Use * button to add new record.' points to the record navigation controls at the bottom; and 'QA designee inserts dates here.' points to the date fields in the 'QAPP Reviewer' section.

Click here to open QAPP Form.

Scroll buttons for moving through records. Use * button to add new record.

QA designee inserts dates here.

EPA Funded Project



Project Funded by Other Organizations

