



STANDARD OPERATING PROCEDURE

QUALITY ASSURANCE PROGRAM MANAGER DESIGNEE TRAINING, RECORDS, & REPORTING

NEIW PCC

Effective January 11, 2023

Version 1.0

Approved by:

A handwritten signature in cursive script that reads "Emily Bialowas".

02/02/2023

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Date

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02/02/2023

Susan J. Sullivan
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Date

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DOCUMENT CONTROL INFORMATION

Revised By	Date	Version	Summary of Changes
Emily Bialowas, QAPM	1/11/23	1.0	Initial Version

This SOP will be reviewed annually.

I. SUMMARY

This SOP documents NEIWPCC’s procedures related to its Quality Assurance Program Manager designee program. The document includes the procedure for training employees to become designees, keeping of records related to designees, and periodic evaluation of the designee program and reporting to the Quality Management Steering Committee.

II. DEFINITIONS

QMP	Quality management plan. Overarching document that describes NEIWPCC’s quality program.
QMSC	Quality management steering committee. Provides internal oversight and guidance for NEIWPCC’s Quality Program.
QAPM	Quality assurance program manager (currently Emily Bialowas) is the point-of-contact for all quality assurance activities
Designee	Quality assurance program manager designee. An appropriately trained and certified staff person selected by the QAPM to review and approve a particular QAPP
QAPP	Quality assurance project plan (including all associated appendices, checklists, and forms)
HR	Human resources staff. Communicates staff milestones in periodic internal newsletters.
Designee records database	Database used to track information on training and status of QAPM designees
QAPP Tracker	Database used to track information and status of QAPP review and approval

III. DESIGNEE RECORDS DATABASE

Training records for designees are retained in an Access database, located on the Lowell headquarters office server ("I:\COMMON\Quality\Designee Records\QAPM Designee Records.accdb"). Details on the server, backup procedures, and file retention are available in the NEIWPCC QMP.

The database was initially developed in 2020 to consolidate information on all NEIWPCC designees. The primary structure of the database allows for the capture of information on the initial training of designees and their current status as well as a way to capture information on employees who are prospective candidates to become trained as designees. The database also provides the location for tracking ongoing training of current designees and pulls in information from the "QAPP Tracker" database to quickly understand designees' activity in reviewing QAPPs.

Details on how and when information is entered into the designee records database are contained in the individual steps for specific procedures, below. Note that information on prospective designees is generally entered during the new hire orientation process. The specific procedure for those cases is documented in NEIWPCC's "Quality Assurance Awareness Training" SOP.

IV. PROCEDURES

INITIAL TRAINING

Note that all steps included in this procedure are the responsibility of the QAPM. The QAPM may delegate individual steps as needed. At the end of the initial training process, designees shall be capable of being delegated review of a QAPP, as described in the NEIWPCC "Review and Approval Process For NEIWPCC Quality Assurance Project Plans" SOP.

Step 1

As needed and when opportune, identify prospective QAPM designees, referring first to the "currently eligible training leads" in the QAPM Designee Records database, where potential designees were identified at time of hire, and confirm suitability with staff supervisors.

Step 2

Verify each prospective designee meets the criteria to complete designee training, as outlined in the current version of the NEIWPCC designee policy¹.

Step 3

Meet with prospective designees to explain the expectations for training and ongoing responsibilities. Note that the QAPM has discretion on whether to proceed with training for any qualified prospective designee and can suspend or halt training at any time.

Step 4

Coordinate with prospective designee(s) to schedule Base Training Session 1 (see Appendix A for an overview of the current designee training program).

¹ At the time of approval, the current policy is detailed in, "NEIWPCC Quality Assurance Project Plan (QAPP) Evaluation Training And Designation of Review and Approval Authority," April 9, 2014

Step 5

Update training materials and designee training document package (summary available in Appendix A).

Step 6

Complete Base Training Session 1 (total of six hours). Note that at the end of this training the QAPM will assign example QAPPs for trainees to review, including completing relevant checklists and writing comment memos as preparation for Base Training Session 2.

Step 7

Enter trainee(s) information in QAPM Designee Records database, using training lead entries where available and applicable.

1. In the “Designee Summary” form, ensure that the following fields are complete:
 - a. Name
 - b. Indicate “Active Designee” = “No”
 - c. “Inactive Reason” = “In Training”
 - d. Base Training “Complete?” = “No”
 - e. Enter date training session was completed into the “Date of Session 1” field
2. In the “Training Records” table, enter a record for each trainee, capturing information about session 1.

Step 8

Schedule and complete Base Training Session 2. This session includes a discussion of each homework QAPP that was assigned at the end of Session 1 and a review of the materials generated by each trainee, in relation to the actual comment memos written during each QAPP’s review. One key objective of this training is to help trainees better align their understanding of the graded approach with that of the QAPM.

Step 9

Provide certificates of completion to new designee(s).

Step 10

Enter information on Session 2 into the QAPM Designee Records database:

1. In the “Designee Summary” form:
 - a. Update “Active Designee” = “Yes”
 - b. Remove value from “Inactive Reason”
 - c. Base Training “Complete” = “Yes”
 - d. Enter date training session was completed into the “Date of Session 2” field
2. In the “Training Records” table, enter a record for each trainee, capturing information about session 2.

Step 11

Notify EPA of current designees, including new designee(s).

Step 12

Notify HR of new designee(s) to include in HR newsletter

Step 13

Complete Practical Training for each new designee. For each new designee, at least three QAPP co-reviews should be completed, with one co-review covering each project type (i.e., primary data, secondary data, and modeling)².

Step 14

For each co-review that is completed, as part of the Practical Training process, enter relevant data into the QAPM Designee Records database³:

1. In the “Designee Summary” form:
 - a. In the next available “Co-Review” field, indicate the type of project followed by the QAPP unique ID and the short title of the project.
 - b. If this is the first co-review, enter, “No” into the “Complete?” field in the Practical Training section.
 - c. If this is the final co-review, enter, “Yes” into the “Complete?” field and fill in the “Date of Completion” field in the Practical Training section.
2. In the “Training Records” table, a record should be added for each co-review.

ONGOING TRAINING

Periodic and ongoing training of designees is necessary to ensure QAPP review standards are maintained, and designees are apprised of the most current processes and expectations in the organization. The QAPM collects information through a variety of means on when and how to provide ongoing training to designees, including through periodic conversations with designees, discussions with division directors, and at the time of updates to internal and/or external processes and standards.

The form and content of ongoing training for designees is at the discretion of the QAPM. The most common trainings are “refresher trainings,” which may be based on the same content as the most current new designee trainings or may simply be the attendance of a current designee at one or both Base Training sessions for new designees.

For any ongoing training, the QAPM should record each training session in the QAPM Designee Records database, in the “Training Records” table.

TERMINATION OF DESIGNEES

Generally, once an employee has received relevant training and been authorized as a designee, their status as such continues as long as they are in the employ of NEIWPCC. The QAPM is responsible for management of designees’ training and their effective utilization in QAPP

² The co-review process is completed opportunistically as draft QAPPs are received for review. The specific level of engagement and oversight for each designee and each review is at the discretion of the QAPM. To expedite this process, the QAPM can also use QAPPs that have already been approved, in a similar process as to what was completed for the homework QAPPs between Base Training Sessions 1 & 2. The objectives of the practical training are to ensure that the quality of the designee’s comment memo is up to the standard of the QAPM, that they are competent in managing the review process, and that they are capable of accurately producing and filing all relevant documents and records.

³ Note that the QAPM may determine that additional co-reviews are necessary for a given designee as part of their training. If this is the case, the records in the database should reflect that this portion of the training has not been completed until all necessary reviews have been completed. Any additional co-reviews shall be documented in the “Training Records” table for the designee.

reviews and in assuming other delegated QAPM duties. See the “Designee Program Evaluation and Reporting” section below for more information on the ongoing management of designees and the overall program.

If and when a designee ceases to be an employee of NEIWPC, their status as a designee also ends. At this time, the QAPM should update the QAPM Designee Records database to reflect this change: the “Active Designee” field should be updated to, “No”; the “Inactive Reason” field should be updated to, “Terminated”; and any pertinent details should be included in the “Comments” field, including the effective date of the change.

DESIGNEE PROGRAM EVALUATION AND REPORTING

The QAPM periodically and at their discretion, completes an evaluation of existing designee QAPP review readiness and report those results and intended designee program direction to the Quality Management Steering Committee. Typically, this is completed at or near the beginning of the NEIWPC fiscal year. The below processes can be modified as necessary if this is completed at a different time or the QAPM determines that the needs for the specific circumstances dictate it.

DESIGNEE COORDINATION GUIDELINES

The designee program is a key element in the overall Quality Program at NEIWPC. Designees have a high level of QA-related training and are engaged with QA-topics on a regular basis. Effective management of the designee program requires regular communication between the QAPM and their designees. In recent years, the foundation of communication has come from an annual meeting of the QAPM and their designees, typically near the end of the NEIWPC fiscal year in August or September.

This meeting has allowed the QAPM to provide updates on the Quality Program to designees, for designees to share ideas on systematic improvements, and for the group to reflect on specific challenges and resolutions that may have occurred during the past year. This has also been a chance for the QAPM to discuss upcoming expectations for QAPP reviews and request information on each designee’s capacity to assist with reviews in the coming year (see the “QAPP Review Readiness Determination” section below).

QAPP REVIEW READINESS DETERMINATION

The QAPM developed a more formal evaluation of designee QAPP review readiness in anticipation of reporting to the QMSC for FY21. The intent of this evaluation is to help guide training efforts and to help guide the QAPM in understanding the available resources when delegating QAPPs. The readiness determination is informational in nature and does not dictate or restrict the QAPM in how they approach their management of the designee program.

Designee readiness is determined using two factors: training and capacity.

- Training scores are determined by the training and QAPP review activities that each designee has undertaken over the previous fiscal year. There are three possible scores: Provisional, Current, and Required.
 - A “Provisional” score indicates that the designee has completed QAPM designee base training but needs to complete the practical training unit (i.e., QAPP co-reviews with the QAPM).

- A “Current” score indicates that the designee has completed at least one of the following within the previous fiscal year: QAPM designee base training, participated in an eligible training program⁴ (e.g., a “refresher”), or completed the review process of a QAPP delegated to them by the QAPM.
- A “Required” score indicates that the designee does not fit either the “Provisional” or “Current” criteria. A designee can move from a “Required” score to a “Current” score by either completing a refresher training or completing a QAPP co-review with the QAPM.
- Capacity scores are self-reported by designees and reflect the overall capacity that each designee anticipates having to review QAPPs in the upcoming fiscal year⁵. There are three possible scores: Yes, Maybe, and No.

Table 1, below, summarizes the nine possible readiness scores that result from the combination of each of the possible training and capacity scores. The flow chart included as Appendix B summarizes the data sources and criteria with which QAPP review readiness determinations are made.

Table 1. QAPP Review Readiness Scores

		<i>Provisional</i>	Training <i>Current</i>	<i>Required</i>
Capacity	Yes	Training Ongoing	Ready	Needs Training
	Maybe	Training Ongoing – 2 nd Priority	Ready – 2 nd Priority	Needs Training – 2 nd Priority
	No	Training Stalled	Lacks Capacity	Not Ready

PROCEDURE

Step 1

Copy the excel sheet that summarizes readiness from the previous iteration of the evaluation.

- Remove the data on capacity, training, and the review readiness determination.
- Update the list of designees in the sheet to reflect the current list of active designees, using the QAPM Designee Records database.

Step 2

Collect information on designee capacity for QAPP reviews in the coming period. Enter data into the updated excel sheet.

⁴ The QAPM determines eligibility of individual training opportunities on a case-by-case basis. All trainings that designees receive are recorded in the QAPM Designee Records database and each record contains an indication of whether that specific training is eligible to satisfy this requirement.

⁵ Note that the QAPM will generally contact individual designees during the process of delegating a given QAPP, to ensure that the designee has availability during that specific period.

Step 3

Using the information summarized in the “Designee Summary” form in the QAPM Designee Records database, determine the training status of each designee. Refer to the above criteria descriptions and the flow chart in Appendix B. Enter data into the updated excel sheet.

Step 4

Using Table 1, above, assign QAPP review readiness scores to each designee in the updated excel sheet.

REPORTING TO THE QMSC

Typically, once the QAPM has completed the process to make QAPP review readiness determinations for their designees, they will compile their results, add commentary, and submit a summary report to the QMSC. The QAPM will then meet with the QMSC to discuss the information in the report and seek input on any suggested changes to planned activities and the direction of the program. This reporting and subsequent discussions are intended to be internal to NEIWPCC and generally not shared with external entities, such as EPA.

APPENDIX A: QAPM DESIGNEE TRAINING PROGRAM OVERVIEW



NEIW PCC QAPM DESIGNEE TRAINING PROGRAM

TRAINING PROGRAM

BASE TRAINING

Session 1: Training Course (six hours total)

- Training Overview & QAPM Designee Role
- QAPP Introduction
- Performing QAPP Review
- QAPP Review & Approval Process

Homework: Independent Review of Draft QAPPs

Session 2: Discussion of QAPP Review Findings (1-2 hours)

NOTIFICATION TO EPA OF NEW DESIGNEE(S)

QAPM provides letter to EPA R1 & R2 with current roster of designees (includes those who completed base training) and summary of recently completed training.

PRACTICAL TRAINING

Co-Reviews: Typically one of each QAPP type, with additional reviews as needed.

REFERENCE DOCUMENTS

POLICY & GUIDANCE

1. Guide for Development and Approval of QAPPs
2. SOP for NEIW PCC QAPP Review & Approval
3. NEIW PCC Quality Management Plan

COURSE DOCUMENTS

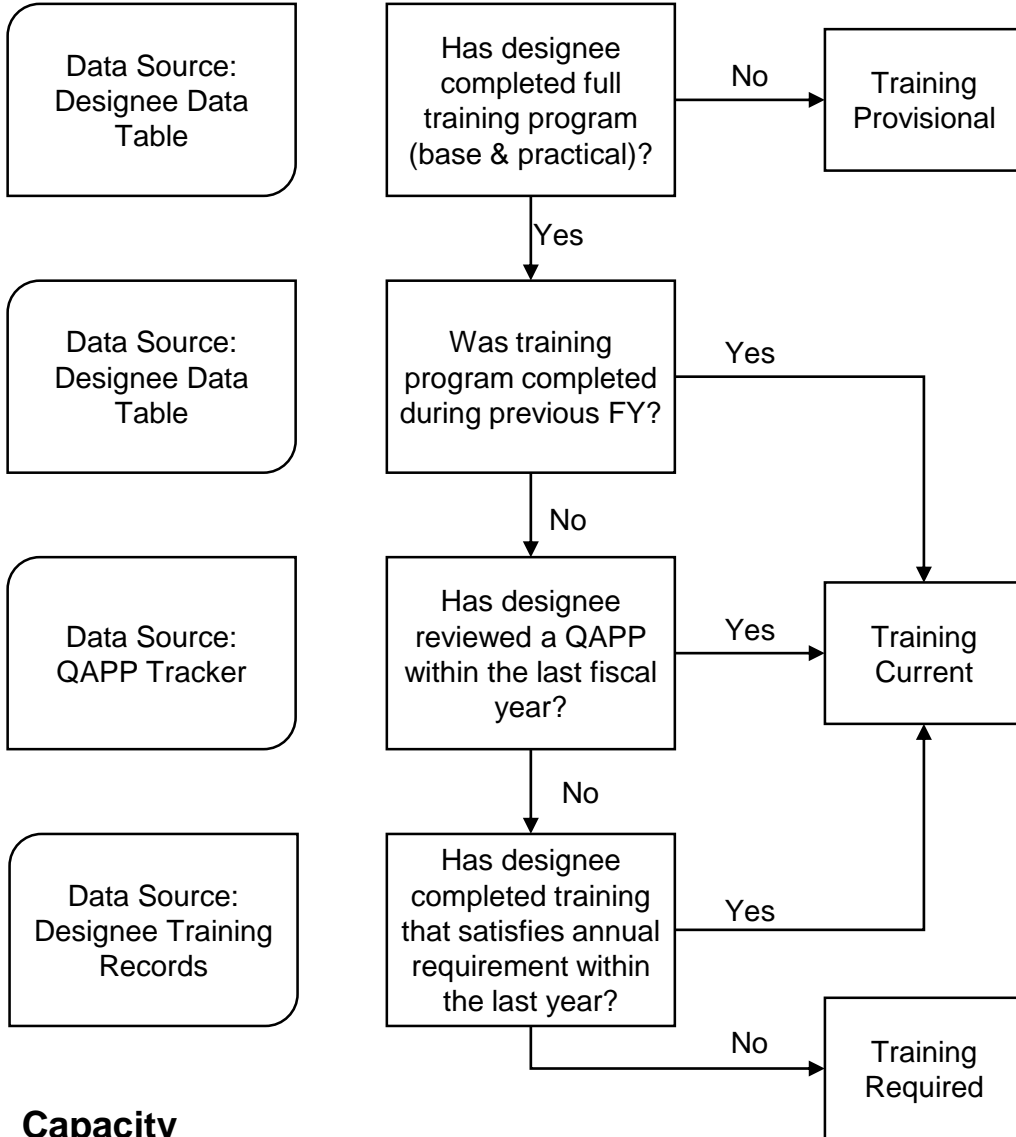
- Training course overview (this document)
- Course PowerPoint with notes
- QAPP or no QAPP examples
- Comment memo template
- Review checklists
- Sample QAPPs
- QAPP update docs
- Draft QAPPs for independent review
- Field assessment documents
- Readiness determination flow chart
- Offsite designee & delegated review process documents

All documents to be provided in electronic package to trainees.

APPENDIX B: DESIGNEE QAPP REVIEW READINESS DETERMINATION FLOW CHART

QA Designee QAPP Review Readiness Determination

Training



Capacity

