

# NRMRL QAPP REQUIREMENTS FOR METHOD DEVELOPMENT PROJECTS

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**GENERAL REQUIREMENTS:** Include cover page, distribution list, approvals, and page numbers.

## 0. COVER PAGE

Include the Division/Branch, project title, revision number, EPA technical lead, QA category, organization responsible for QAPP preparation, and date.

## 1. PROJECT DESCRIPTION AND OBJECTIVES

- 1.1 Provide a description of the situation that requires the generation of a new or modified method.
- 1.2 State the purpose of the project and list specific project objective(s).

## 2. ORGANIZATION AND RESPONSIBILITIES

- 2.1 Identify all project personnel, including QA, and related responsibilities for each participating organization, as well as their relationship to other project participants.
- 2.2 Include a project schedule that includes key milestones.

## 3. SCIENTIFIC APPROACH

- 3.1 Identify the specific analyte(s) of interest and the matrix/matrices under study.
- 3.2 Identify the analytical approach that will be used and how it will be optimized for this study. Also describe any tests of interference and analyte stability.
- 3.2 Identify the method performance metrics (QA/QC checks) that will be used to evaluate the method, including the procedures used. These metrics could include (but are not limited to) positive and negative controls, sensitivity, precision, accuracy, recovery, linearity, specificity, robustness, and range.

## 4. SAMPLING PROCEDURES

- 4.1 Provide the requirements for samples that will be used to test the method (including matrix and presence/concentration of analytes).
- 4.2 If synthetic (i.e., laboratory-prepared) samples are used, describe the preparation of these samples.
- 4.3 If non-synthetic (i.e., real-world sample) samples are used, address the following:
  - describe the sampling design that will be used and the steps taken to assure that representative samples are collected
  - discuss or reference each sampling procedure
  - provide a list of sample containers, sample quantities to be collected, and the sample amount required for each analysis, including QC sample analysis

- describe procedures for packing and shipping samples, and provisions for maintaining chain-of-custody, as applicable
- 4.4 Specify sample preservation requirements (e.g., refrigeration, acidification, etc.) and holding times.
- 4.5 Describe the method for uniquely numbering each sample.

## 5. MEASUREMENT PROCEDURES

- 5.1 Describe in detail or reference each preparation or analytical procedure to be used, if known. Include steps for preparation, calibration, measurement, quality control, and reporting.
- 5.2 If not provided in Section 5.1 or the referenced method, include specific calibration procedures, including linearity checks and initial and continuing calibration checks.

## 6. METHOD PERFORMANCE METRICS

For each method performance metric (QA/QC check) identified in Section 3.2, specify the frequencies for performing these checks, associated acceptance criteria, and corrective actions to be performed if acceptance criteria are not met.

## 7. DATA ANALYSIS, INTERPRETATION, AND MANAGEMENT

- 7.1 Identify the data reporting requirements, including data reduction procedures specific to the project and applicable calculations and equations.
- 7.2 Describe data validation procedures used to ensure the reporting of accurate project data.
- 7.3 Describe how the data will be summarized or analyzed (e.g., qualitative analysis, descriptive or inferential statistics) to meet the project objective(s).
- 7.3.1 If descriptive statistics are proposed, state what tables, plots, and/or statistics (e.g., mean, median, standard error, minimum and maximum values) will be used to summarize the data.
- 7.3.2 If an inferential method is proposed, indicate whether the method will be a hypothesis test, confidence interval, or confidence limit and describe how the method will be performed.
- 7.4 Describe data storage requirements for both hard copy and electronic data.

## 8. REPORTING

- 8.1 List and describe the deliverables expected from each project participant.
- 8.2 Specify the expected final product(s) that will be prepared for the project (e.g., journal article, final report, etc.). If a method/SOP will be developed, specify the required format.

## 9. REFERENCES

Provide references either in the body of the text as footnotes or in a separate section.