Quality Planning Handbook

NARSTO Quality Systems Science Center

ORNL/CDIAC-111

NARSTO Quality Planning Handbook

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ABBREVIATIONS

AQAR	Annual Quality Assessment Report
DQOs	Data Quality Objectives
GIS	Geographic Information System
MSR	Management Systems Review
NARSTO	[formerly North American Research Strategy for Tropospheric Ozone]
PDA	Permanent Data Archive
PE	Performance Evaluation
QA	Quality Assurance
QC	Quality Control
QSMP	Quality Systems Management Plan
PQMP	Program Quality Management Plans
QIWP	Quality Integrated Work Plan
QSSC	Quality Systems Science Center
R&D	Research and Development
RPs	Research Protocols
SOPs	Standard Operating Procedures
TSA	Technical Systems Audit
U.S. EPA	United States Environmental Protection Agency

SUMMARY OF CHANGES BETWEEN EDITIONS

This is a “living” document; it will be changed and updated from time to time. Minor changes will be issued as updates to the major revisions. Users should ensure that they have the current edition of this document. Major changes will be issued as new whole revision numbers as needed.

First Edition 1.0, April 21, 1998

The original NARSTO Quality Planning Handbook was released.

Revised Edition 1.0, November 22, 1999

Minor changes were made including adding a new cover and incorporating other editorial changes.

1.0 INTRODUCTION

This ***Quality Planning Handbook***, prepared by the NARSTO Quality Systems Science Center (QSSC), offers guidance to NARSTO participants concerning the preparation of project quality system planning documentation and the preparation of NARSTO research, modeling , and assessment reports.

This handbook provides quality planning guidance for NARSTO programs/projects to use, first, as they develop project planning documentation, and second, as they report project results and assessment activities. Using the guidance in this handbook will help ensure preparation of consistent project planning/proposal documentation that will facilitate a more straightforward review by NARSTO funding agencies.

The NARSTO ***Quality Systems Management Plan (QSMP)*** defines a set of quality system documentation, starting with the upper level QSMP, that identifies NARSTO program quality assurance and data management requirements and guidelines (See QSMP Sect. 3.1). Within the flexible QSMP framework, Program/Project Managers will establish a ***Program Quality Management Plans (PQMP)*** as the second level of quality planning. Individual PQMPs should describe only the directly applicable quality activities and expectations for that specific program. The third level of quality planning will occur at the project level, where each Principal Investigator is responsible for developing a ***Quality Integrated Work Plan (QIWP)*** (Figure 1). The scope, content, and level of detail of a QIWP should be based on the nature of the project and applicable PQMP guidance. With each successive level, the specificity of requirements and quality management activities increases. This ***NARSTO Quality Planning Handbook*** is a supplement to the QSMP and provides specific tools to assist principal investigators in developing QIWPs, standard operating procedures, and NARSTO reports and publications. Program/Project Managers and Principal Investigators should evaluate the applicability of the guidance to their project and incorporate appropriate elements into the project documentation.

It is not the intent of the NARSTO Program to require a program/project to develop additional or separate quality management plans if approved equivalent plans are currently in place. Established programs/projects should review their existing documentation including, for example, quality management plans, quality assurance project plans, and sampling and analysis plans, against the NARSTO QSMP and supporting handbooks, to ensure that all applicable quality assurance and data management elements have been adequately addressed. A statement of equivalency with the NARSTO QSMP or updates and additions to the existing documentation, if any are needed, may be incorporated through an approved cover letter or addendum to the existing documentation as appropriate.

Project Planning and Data Archival Process

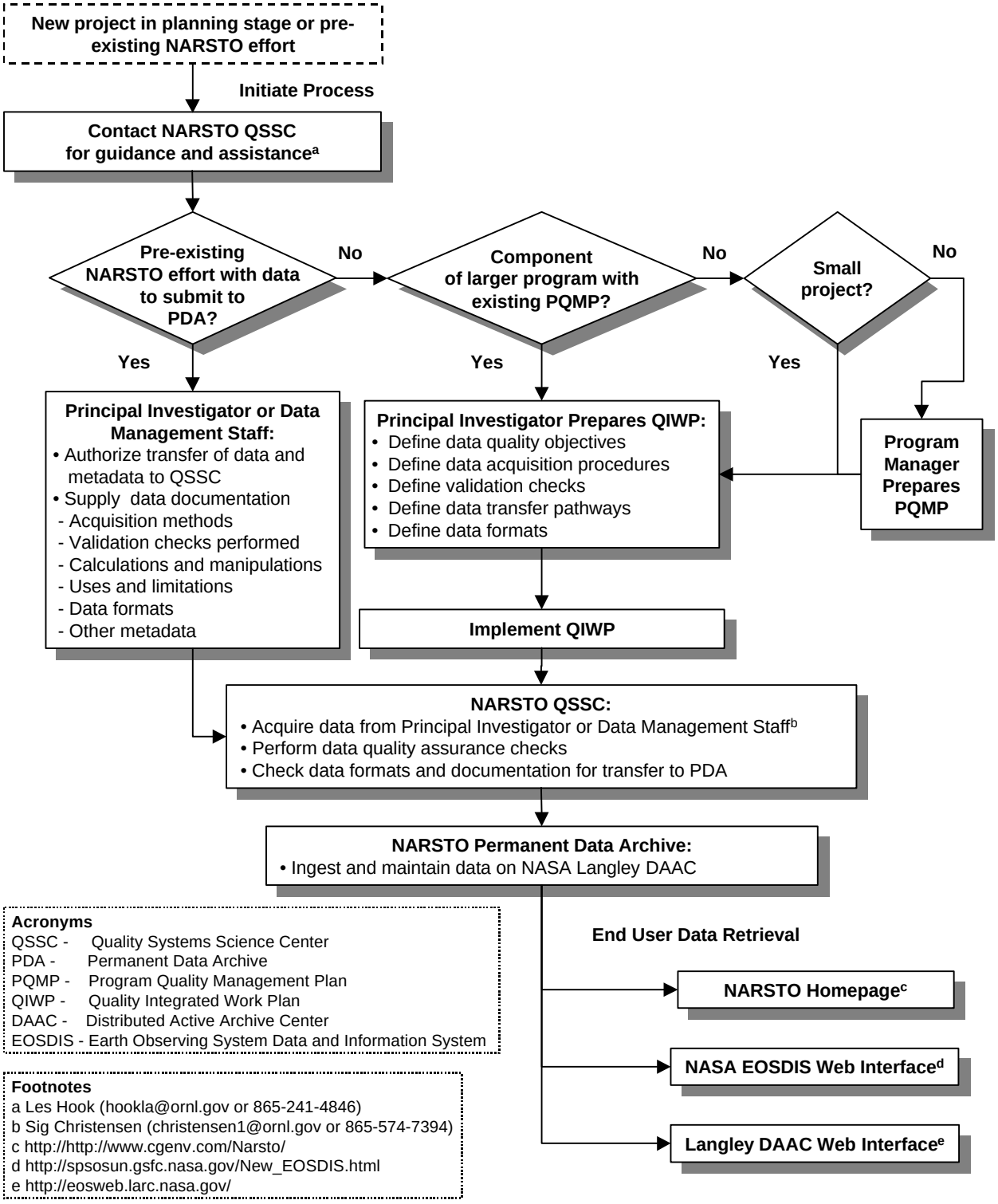

Figure 1. Project Planning and Data Archival Process

NARSTO programs/projects may need to develop new quality management documentation (e.g., PQMP or QIWP) that will meet the quality assurance and data management requirements of two or more high level programmatic and/or funding agencies (e.g., EPRI and US EPA). In these cases, authors should state in the introductory sections that the following documentation will be equivalent to and consistent with the NARSTO QSMP and the other program's quality systems requirements. The particular formats utilized to present program/project plans is not as critical as the content and eventual project implementation of the plans. Note, however, that the NARSTO QIWP format does efficiently combine project quality planning and project implementation planning under a single document cover.

The QIWP may be initiated as a project proposal, with the Principal Investigator completing applicable sections to a level of detail needed to meet the proposal review needs of the likely funding group(s). For an individual Principal Investigator, not affiliated with a larger monitoring program or regional air quality study, the level of quality planning called for in the QIWP should be sufficient to ensure the quality, credibility, and reliability of the project's results.

This handbook is intended to be a dynamic document that can be modified and expanded as often as needed to meet the needs of the NARSTO program. In order to present this information in as cost-effective and as efficient a manner as possible, the hard copy distribution of this handbook will be kept to a minimum. A configuration-controlled web accessible copy will be linked to the NARSTO Home Page.

1.1 Purpose/Scope

This handbook contains detailed QIWP templates that have been developed to assist Principal Investigators. The templates contain the typical requirements for any QIWP developed for the three general project types: monitoring and measurement research and development projects; model development projects; and model application projects.

The QIWP is the project work plan with the critical quality assurance, quality control, and data management activities integrated into a single working document. A QIWP must be prepared by each Principal Investigator before conducting project activities. The QIWP is where project Principal Investigators (1) discuss their understanding of the science and data quality issues, (2) develop project-level quality objectives in accordance with the PQMP and any other pertinent technical, management, and client input, and (3) describe how the agreed-upon objectives will be achieved by the project. The QIWP will also address any personnel training requirements, systems maintenance, and operating procedures. The scope of the QIWP will depend on the level of effort involved, the end usage of the data to be generated, and type of project proposed. Note that all products provided to policy makers, policy analysts, and air quality managers must have been developed using an approved QIWP and meet the data/product quality objectives stated therein.

Project Managers or Principal Investigators who have an existing model or historical measurement data to submit to the NARSTO Permanent Data Archive (PDA) should develop a limited QIWP. The QIWP should follow the monitoring, research and development template, but the scope should be limited to just the data submission task. The contents of the QIWP should include only the sections necessary to efficiently transfer the quality assured data products to the QSSC (e.g., Section 5).

This handbook also contains guidelines for preparing project standard operating procedures, the NARSTO research project publication policy, format and peer review guidelines. Specifications are given for issuing reports with the NARSTO logo and NARSTO policies concerning Principal Investigator intellectual property rights and handling of promotional material and press releases.

The NARSTO programmatic goal in providing this guidance is to move towards more consistent and comprehensive project documentation. While established programs/projects may have plans and procedures in place, new projects to be funded in the future, will benefit from having available a supported set of planning and implementing resources.

1.2 Audience

The principal readers and users of this guidance document are program/project managers and Principal Investigators. The Principal Investigators have the primary responsibility for preparing a project's QIWPs and standard operating procedures (SOPs). Other members of the project team may also find this document useful in understanding the process for review and publishing of project reports.

1.3 How to Use this Handbook

The QSMP identifies the NARSTO program quality assurance, assessment, work process and project documentation requirements and guidelines for ensuring NARSTO product credibility, reliability, accessability and quality. This handbook supplements the QSMP by providing more specific guidance and tools for planning and implementing project tasks.

Established research and modeling programs may already have work plans that address the components discussed in the following sections and document templates. For them, the templates may serve as a review or check of presently implemented activities. When a new task or revisions of current work plans (QIWPs) is undertaken, this guidance should be evaluated for applicability.

New programs/projects should use the templates to develop their new QIWP, follow up with applicable references, and consult with the QSSC to take advantage of previously implemented processes and documentation that may meet their needs. WordPerfect and MS Word files of this document and templates are available. Consult the "User Information for the NARSTO Quality Management Documents" available on the QSSC web page for file access information.

1.4 Roles and Responsibilities

Quality Systems Science Center

The QSSC will work closely with Program/Project Managers, Principal Investigators, and the Committee on Quality Systems and Data Management to develop and update program/project document templates. This guidance will be distributed and maintained in the ***NARSTO Quality Planning Handbook*** (this document). The QSSC will support programs and projects through the development and review of PQMPs, QIWPs, and SOPs, per QSMP Sect. 4.1.

Management Coordination Office

The Management Coordination Office will coordinate the peer review of reports and publications and maintain the NARSTO policy defining the review and approval process.

Program/Project Managers

Program/project managers develop quality documentation (PQMPs) and review and approve QIWPs for specific program activities.

Principal Investigators

The Principal Investigator will use the templates and guidance to ensure that an approved QIWP and SOPs are in place to guide their NARSTO research and modeling activities and that reports and publications for NARSTO distribution have been reviewed as described in this handbook.

1.5 Organization

This document is divided into seven sections, followed by three appendixes.

Section 1 defines the purpose, scope, organization, and audience for the document and gives general suggestions on how to use this handbook.

Section 2 discusses PQMP development.

Section 3 discusses QIWP development.

Section 4 discusses SOP and research protocol (RP) development.

Section 5 discusses Annual Quality Assessment Report (AQAR) development.

Section 6 describes dissemination of NARSTO research results including the format and review of publications and offers guidelines for the effective communication of NARSTO results.

Appendixes

Appendix A Quality Integrated Work Plan Template for Monitoring and Measurement Research and Development Projects

Appendix B Quality Integrated Work Plan Template for Model Development Projects

Appendix C Quality Integrated Work Plan Template for Model Application Projects

2.0 PROGRAM QUALITY MANAGEMENT PLAN (PQMP) DEVELOPMENT

A PQMP will be prepared by each NARSTO Program/Project Manager. The PQMP establishes quality and data management objectives, requirements and specifications. The detail provided for each PQMP element will be left to the discretion of the Program/Project Manager in consultation with the Science Team Co-chairs. Additional information for preparing a PQMP may be obtained from the American National Standard ANSI/ASQC E4-1994: *Specifications and Guidelines for Quality Systems for Environmental Data Collection and Environmental Technology Programs*[1]. The PQMP should, at a minimum, address the following items:

- **!** Program Planning, Organization, and Communications
- **!** Program Management Assessment
- **!** Program Implementation
- **!** Program Data Acquisition
- **!** Program Data Evaluation and Assessment
- **!** Program Data and Records Management

The QSSC will work with Program/Project Managers to assist with the preparation of the PQMP. Refer to similarly titled sections in the QIWP templates in Appendixes A, B, and C for guidance on PQMP section content.

NOTE: No specific template is currently provided for the PQMP. It appears that existing agency/line management requirements/guidance for quality program plans is sufficient. Several useful references are available, such as, ANSI/ASQC E4-1994, EPA QA/G-2 Guidance for Preparing Quality Management Plans, EPA QA/R-5 EPA Requirements for Quality Assurance Project Plans, and EPA QA/G-5 Guidance on Quality Assurance Project Plans.

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[1] American Society for Quality, 611 East Wisconsin Avenue, Milwaukee, WI 53201-3005, (414) 272-8575, (Publication Orders: 800-952-6587, Item T55)

3.0 QUALITY INTEGRATED WORK PLAN (QIWP) DEVELOPMENT

The QIWP is the project work plan with the critical quality assurance, quality control, and data management activities integrated into a single working document. The format provides for discussion of science and data quality issues, identification of project-level quality objectives in accordance with the PQMP and any other pertinent technical, management, and client input, and to describe how the agreed-upon objectives will be achieved by the project. The QIWP will also address any personnel training requirements, systems maintenance, and operating procedures.

The scope of the QIWP will depend on the level of effort involved, the end usage of the data to be generated, and whether one is developing a QIWP for a monitoring or research and development project, a model development project, or a model application project. Detailed templates have been developed that identify and describe the typical requirements for all three project types. Please refer to the appropriate template in the appendixes.

The QIWP should, at a minimum, address the following items for the particular type of project:

For Monitoring and Measurement Research and Development Projects

- Project Planning and Organization
- Project Management Assessment
- Project Implementation
- Project Data Acquisition
- Project Data Management
- Project Records Management
- Project Routine Controls and Procedures
- Project Technical Assessment and Response

See template in Appendix A.

For Model Development Projects

- Project Description
- Project Management
- Project Software Verification and Validation
- Project Configuration Management
- Project Model Evaluation, Validation, and Testing
- Project Contingency Management
- Project Summary and Evaluation

See template in Appendix B.

For Model Application Projects

- Project Description
- Project Management
- Project Model Application Design
- Project Scientific Basis and Technical Requirements
- Project Quality Control Procedures for Model Applications
- Project Data Requirements and Quality Control Procedures
- Project Model Software Maintenance
- Project Contingency Management
- Project Summary and Evaluation

See template in Appendix C.

4.0 STANDARD OPERATING PROCEDURES (SOPS) AND RESEARCH PROTOCOLS (RPS)

A portion of the monitoring and research and development activities conducted under NARSTO will use standard routine procedures. These standardized activities require that each specific step in the procedure is conducted in a pre-determined manner and order. Any deviation from the established routine may introduce uncertainty into the results of the procedure. Non-routine procedures and activities should be covered by less formal research protocols (RPs). Research protocols will usually apply to a smaller group of individuals and may not need to be as detailed. Review and approval of RPs may be limited to that group.

Standard operating procedures (SOPs) are written documents that detail the method for an operation, analysis, or action with thoroughly prescribed techniques and steps. It is officially approved as the method for performing certain routine or repetitive tasks. SOPs are protocols for all routine activities, especially those that are involved in the environmental data operations, which generally involve repetitious operations performed in a consistent manner. SOPs should ensure consistent conformance with organizational practices, serve as training aids, provide ready reference and documentation of proper procedures, reduce work effort, reduce error occurrences in data, and improve data comparability, credibility, and defensibility. They should be sufficiently clear and written in a step-by-step format to be readily understood by a person knowledgeable in the general concept of the procedure. SOPs should be written by individuals performing the procedures that are being standardized. SOPs for data collection methods must be included in a QIWP either by reference or by inclusion of the actual method. If a method is referenced, it must be stated that the method is followed exactly or an addendum that explains changes to the method must be included with the SOP. If a modified method will be used for an extended period of time, the method must be revised to include the changes to appropriate sections. In general, approval of SOPs occur during the approval of the QIWP. [Source: Quality Management Plan for The Office of Air Quality Planning And Standards, U.S. EPA]

The SOPs and RPs should contain clear and explicit descriptions of the activities to be conducted. To facilitate the use of SOPs and RPs a consistent format should be used within a program/project and for similar types of activities. Refer to the U.S. DOE Standard, Writer's Guide for Technical Procedures, DOE-STD-1029-92, December 1992, or EPA QA/G-6 Guidance for the Preparation of Operating Procedures for Quality-Related Operations, EPA/600/R-96/027, November 1995 for examples.

4.1 Suggested Format for a Technical SOP or RP (from EPA QA/G-6)

- **Procedural Section:**

  After the title page, the following are topics that may be appropriate for inclusion in a technical SOP or RP:

  a. Scope & Applicability,
  b. Summary of Method,
  c. Definitions (acronyms, abbreviations and specialized forms used in the SOP),
  d. Health & Safety Warnings (indicating operations that could result in personal injury or loss of life and explaining what will happen if the procedure is not followed or is followed incorrectly; listed here and at the critical steps in the procedure),
  e. Cautions (indicating activities that could result in equipment damage, degradation of sample or possible invalidation of results; listed here and at the critical steps in the procedure),
  f. Interferences,
  g. Personnel Qualifications,
  h. Apparatus & Materials (list or specify; note also designated locations where found),
  I. Instrument or Method Calibration,
  j. Sample Collection,
  k. Handling & Preservation,
  l. Sample Preparation and Analysis,
  m. Troubleshooting,
  n. Data Acquisition, Calculations & Data Reduction,
  o. Computer Hardware & Software (used to manipulate analytical results and report data), and
  p. Data Management & Records Management

- **Quality Control and Quality Assurance Section**

  QC activities should be designed to allow self-verification of the quality and consistency of the work.

- **Reference Section**

Each Principal Investigator is responsible for the development and maintenance of SOPs and RPs for their research activities. SOPs and RPs must be attached to or referenced in the QIWP submitted for review and comment.

5.0 ANNUAL QUALITY ASSESSMENT REPORT (AQAR)

The QSSC and each Principal Investigator will prepare an AQAR to summarize the quality management and assessment activities conducted during the previous calendar year. The scope of a project AQAR will be dependent upon the level of effort involved in the particular project and the end usage of the data generated. A project AQAR should address the following items, as applicable, in sufficient detail to provide the QSSC with a clear understanding of the quality of the data generated:

- Summary of quality assurance/quality control (QA/QC) activities
- Summary of QA/QC problems
- Certification of the implementation of QIWP quality management activities
- Documentation of the implementation of QIWP quality management activities
- Corrective actions
- Technical/statistical evaluation of quality control (QC) data
- Results of audits
- Summary of success/failure to meet data quality objectives (DQOs)

6.0 DISSEMINATION OF RESEARCH RESULTS

6.1 Format and Review of NARSTO Publications

6.1.1 Publication of Papers

The principal author of said papers will have the responsibility for seeking comments of affected project participants with respect to proposed publication. Other participants will be informed of the availability of proposed papers by the NARSTO Management Coordination Office and may comment directly to the author, if desired. Comments will be solicited concurrently with submission for publication.

6.1.2 Publication Under the NARSTO Logo

6.1.2.1 Format

Documents published under the NARSTO Logo must be formatted in accordance with (1) the publication guidelines established by the American Meteorological Society[2], (2) the guidance published in the first issue of each volume of Atmospheric Environment (*Preparation of Papers for Atmospheric Environment, Revised September 1996*), or (3) the specific format requirements of the author's sponsoring organization.

6.1.2.2 Peer Review

All draft reports must be submitted to the NARSTO Management Coordinator for approval to use the NARSTO Logo on the cover of the report. The NARSTO editorial staff and the leaders of the NARSTO Technical Program Teams will assist with the peer review process. Reviewers of the document will be asked to consider the following questions:

- Is the study an original contribution in the field and relevant to the NARSTO program?
- Does the report advance the NARSTO objectives?
- Does the author make errors in inference, interpretation, or mathematical analysis?
- Does the material lend itself to application in the field?
- Is the author's presentation clear and well-organized?
- Is the abstract informative, giving the essence of the research in clear terms?
- Is the report prepared following the guidelines for the manuscript preparation or the specific format requirements of the author's sponsoring organization?

The Chair of the Publications Committee will normally obtain the opinion of two independent referees. The independent reviewers may be compensated to assure

[2] Bulletin of the American Meteorological Society, Vol. 76, No. 8, pp S1-S32, August 1995

timeliness. The comments received from the independent reviewers will be sent to the author for consideration and appropriate modifications to the manuscript. When the author complies with the reviewer's comments, the NARSTO Management Coordinator will inform the author of the decision to accept or reject the manuscript for publication as a NARSTO report.

6.1.3 NARSTO Reports

Internal reports will be distributed only among participants. A copy will be kept on file at the NARSTO Management Coordination Office and made available upon request to program participants. External reports are those that summarize, integrate, and/or interpret NARSTO results and are meant for public distribution. Such reports will first be reviewed and approved for release. If the NARSTO Logo is to be affixed to either an internal or external report, this action shall be taken in accordance with Section 6.1.2.

6.1.4 Promotional Material and Press Releases

Each participant is free to promote individual research efforts. However, when the work of another organization is entrained with that research, or when attribution is ascribed, or the name of another entity evoked, comment and approval must be solicited from these latter entities before the release or publication of the research.

6.1.5 Intellectual Property

The rights to intellectual property shall be governed by existing patents, copyrights, contracts, federal assistance agreements, cooperative research and development agreements, memoranda of agreements or understanding; and in accordance with federal and international laws.

6.2 Guidelines for the Effective Communication of NARSTO Results

One of NARSTO's main goals is to serve as a clearinghouse of credible scientific information upon which policy decisions and cost-effective control options can be based. The ability to effectively communicate modeling and monitoring project results to policy makers, air quality managers, and funding agencies may, in large part, determine whether the NARSTO program will be viewed as a success. The guidelines in this section are offered to stimulate your thinking about the most effective manner in which to present your results and to serve as a review checklist while you prepare and review reports and presentations.

These "Guidelines for the Formulation of Scientific Findings to be used for Policy Purposes" were developed by the Oversight Review Board of the National Acid Precipitation Assessment Program. These guidelines are presented in the following nine items.

1) Is the statement sound?

Have the central issues been clearly identified? Does each statement contain the distilled essence of present scientific and technical understanding of the phenomenon or process to which it applies? Is the statement consistent with all relevant evidence --- evidence developed through NARSTO research or through analysis of research conducted outside of NARSTO. Have apparent contradictions or interpretations of available evidence been considered in formulating the statement of principal findings?

2) Is the statement directional and, where appropriate, quantitative?

Does the statement correctly quantify both the direction and magnitude of trends and relationships in the phenomenon or process to which the statement is relevant? When possible, is a range of uncertainty given for each quantitative result? Have various sources of uncertainty been identified and quantified, for example, does the statement include or acknowledge errors in actual measurements, standard errors of estimates, possible biases in the availability of data, extrapolation of results beyond the mathematical, geographical, or temporal relevancy of available information, etc. In short, are there numbers in the statement? Are the numbers correct? Are the numbers relevant to the general meaning of the statement?

3) Is the degree of certainty or uncertainty of the statement indicated clearly?

Have appropriate statistical tests been applied to the data used in drawing the conclusion set forth in the statement? If the statement is based on a mathematical or novel conception model, has the model or concept been

validated? Does the statement describe the model or concept on which it is based and the degree of validity of that model or concept?

4) Is the statement correct without qualification?

Are there limitations of time, space, or other special circumstances in which the statement is true? If the statement is true only in some circumstances, are these limitations described adequately and briefly?

5) Is the statement clear and unambiguous?

Are the words and phrases used in the statement understandable by the decision makers of our society? Is the statement free of specialized jargon? Will too many people misunderstand its meaning?

6) Is the statement as concise as it can be made without risk of misunderstanding?

Are there any excess words, phrases, or ideas in the statement which are not necessary to communicate the meaning of the statement? Are there so many caveats in the statement that the statement itself is trivial, confusing, or ambiguous?

7) Is the statement free of scientific or other biases or implications of societal value judgments?

Is the statement free of unreasonable bias due to a specific schools of scientific thought? Is the statement also free of words, phrases, or concepts which have political, economic, ideological, religious, moral, or other personal, agency- or organizational-specific values, overtones, or implications? Does the choice of how the statement is expressed rather than its specific wording suggest underlying biases or value judgments? Is the tone impartial and free of special pleading? If societal value judgments have been discussed, have these judgments been identified as such and described both clearly and objectively?

8) Have societal implications been described objectively?

Consideration of alternative courses of action and their consequences inherently involves judgment of their feasibility and the importance of effects. For this reason, it is important to ask if a reasonable range of alternative policies or courses of action have been evaluated? Have societal implications of alternative courses of action been stated in the following general form?:

> "If this(particular option) were adopted then that (particular outcome) would be expected."

9) Have the professional biases of authors and reviewers been described openly?

Acknowledgment of potential sources of bias is important so that readers can judge for themselves the credibility of reports and assessments.

APPENDIXES

APPENDIX A

QUALITY INTEGRATED WORK PLAN TEMPLATE FOR MONITORING AND MEASUREMENT RESEARCH AND DEVELOPMENT PROJECTS

NOTES TO USERS:

This Template is designed to help program managers and scientists develop quality assurance documentation for research and development (R&D) and monitoring projects. By responding to the elements presented under the following Sections, an individual researcher or a team of researchers can generate a comprehensive Quality Integrated Work Plan (QIWP) for the project under consideration. All projects funded, managed or performed by **THE INSTITUTION** must be supported by an approved QIWP. Minimum required QIWP approval for a project consists of sign-off by the Program/Project Manager for **THE INSTITUTION**.

- The use of the word "project" in this template is synonymous to the following words: program, task, study, work assignment, technical directive or in-house technical effort.
- Please replace all parentheses with the information requested therein.
- If a section or certain section elements do not apply to your specific project, please enter your rationale for excluding that section/element as your response under that section/element.
- When you have finished your response for a given section, delete the template discussion.
- The Document Control Format is in the Header of this template document.

Project _____

Revision No. _____

Revision Date: ___ / ___ / _____

QUALITY INTEGRATED WORK PLAN

(PROJECT TITLE)

(PROJECT NUMBER)

(INSTITUTION)

Prepared by:

_____ _____

Principal Investigator Date

Approval:

_____ _____

Program/Project Manager Date

Approval:

_____ _____

NARSTO Science Team Co-Chair Date

Project _____

Revision No. _____

Revision Date: ___ / ___ / _____

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Project _____

Revision No. _____

Revision Date: ___ / ___ / _____

DOCUMENT DISTRIBUTION LIST

List individuals who will receive copies of the approved Quality Integrated Work Plan.

Individual	Organization	Document Version	Receipt Confirmation Date

Project _____

Revision No. _____

Revision Date: ___ / ___ / _____

QUALITY INTEGRATED WORK PLAN FOR (PROJECT TITLE)

1.0 PROJECT PLANNING AND ORGANIZATION

Planning and organization are critical to the success of monitoring, modeling and R&D projects. The primary purpose of planning and organizing is to identify and clarify work requirements, objectives, and responsibilities. The need for planning is often de-emphasized or overlooked, especially when costs and scheduling issues are presumed to be more critical. The planning and organizational assumptions made for a project should be continually evaluated to ensure that the project is on track. Sections 1, 2, and parts of 3 relate to management functions and address the Quality Assurance aspects of the overall project. The remaining Sections relate to the technical functions specific to the accomplishment of the overall project. These sections address the Quality Control aspects of the critical work activities being performed under the project. For example, Section 2 refers to the assessments (e.g., audits, peer reviews, data quality assessments, data management reviews) planned by the management team to evaluate, guide and manage the overall project. In Contrast, Section 7 refers to those doing the work and their assessment of the performance characteristics of the systems designed to accomplish their phase of the project. If the project involves multiple phases and several institutions are conducting the work, then Section 7 should be prepared by each institution responsible for a critical phase of the project effort. Please respond to each subsection listed below.

1.1 Introduction

Provide the what, why, how, when, and where for your project. What are you proposing? Why are you proposing it, and why are you recommending this specific approach? What do you expect to learn? How will you use the results? Where will the project be conducted? When will the project begin and end?

1.2 Background

List any pertinent background that will help place this project in perspective. Is it part of a larger program; expansion of a smaller project; independent effort; collaborative effort; single pollutant; multiple pollutant; pilot scale; large scale; in-house; extramural; etc.?

1.3 Project Scope and Work Objectives

The scope of the project and the establishment of work objectives may appear deceptively straightforward and simple; however, this aspect of project planning often receives little attention. The establishment of clear objectives is perhaps the most

important part of planning. The objectives should be developed through the participation of all organizations and disciplines affected by or interfacing with the planned work. The use of a workshop or peer review is often an effective way to ensure participation by the appropriate disciplines and organizations. Appropriate review and approval should be obtained from the participating organizations. When data are an essential work product, this section must state the project Data Quality Objectives (DQOs). Once established, the work objectives should be clearly communicated to all affected parties. Please discuss the questions, issues, and DQOs important to the work effort, describe the various organizations and disciplines required to accomplish the work and clearly state the project objectives.

1.4 Project Description

The description and definition of specific work activities normally follow the establishment of work objectives. The work activities should be developed with input from the involved and affected organizations and disciplines. **Document the relationship between the planned measurement and analysis activities and stated NARSTO scientific, policy, and assessment goals.** Work activities should receive sufficient review by peers and supervisory approval to assure technical adequacy, identify constraints, and communicate any unusual or special requirements. Please define your work activities and describe how those activities will lead to the accomplishment of the work objectives.

1.5 Experimental Design

The statistical design of experiments can enhance significantly the success of a project. Statistical design can make the project more cost effective, can optimize the acquisition of data, and can maximize the information obtained from the statistical evaluation of that data. To accomplish this, the questions to be answered by the project must be correctly formulated; a method(s) must be selected that will meet the accuracy required and guard against the various pitfalls that might be encountered; and the general patterns of number, spacing, and interrelation of the individual observations must be correctly chosen. The statistical design provides an important determinant to the success of the research project, whether the major objective is the testing of one or more null hypotheses or the estimation of attributes (characteristics or parameters), such as means or percentiles. Projects designated as "range finding" will follow the same tenets. However, range finding projects may require deviations that must be documented in writing and caveated appropriately during the planning phase.

The primary factors considered in statistical design are the hypothesis(es) to be tested; the dependent, independent and co-variables to be estimated; the desired precision characteristics of the estimated measurement variables; and the required discriminatory power of the test [i.e., the ability of the design to differentiate the null hypothesis (H_o) from the alternative hypothesis (H_a)]. **All ongoing research will provide quantitative**

assessments of uncertainties and caveats associated with using the scientific results. The assistance of a statistician is recommended.

Please address the following elements that apply to your project:

- Hypothesis(es) to be tested
- Dependent and independent variables; and, any key co-variables
- Acceptable ranges for the precision and accuracy of estimated variables
- Discriminating power (or ability) of test(s)
- Acceptable limits on the number of false positive and false negative results

1.6 Personnel Qualifications

An important factor affecting all work activities is the qualifications of those doing the work. An effort must be made to review and verify the applicable education and experience of project personnel. Using adequately qualified people is a requirement for all monitoring, modeling and R&D projects. Certification or additional training may be required for some project personnel. The concept of qualifying scientists, engineers, and technicians to perform specific tasks implies that qualification requirements are established for each work activity. Management is responsible for the qualifying process, which can range from a simple verification (e.g., a brief CV) showing a person is qualified because of education, experience, and job knowledge. Different circumstances may call for demonstrated job skill proficiency. Please document the required qualifications for your project.

1.7 Training Required

Providing training is a basic management responsibility. The need for training and the type of training required is a management decision. Management should establish a training system to assure that technicians are adequately trained and that they are retrained as changes in work practices occur. Such a system should be developed based on job requirements relating to skills, knowledge, and levels of competency required for adequate job performance. Training records should be maintained that give visibility to the training system and that show the past and current training status of each person, which may include scientific and engineering personnel. Training provided to technical personnel should be documented. Please describe any training that must be completed before you can accept personnel assigned to your project.

1.8 Communication Plan

The how, when, where, and by whom the study results are distributed and communicated is a very important management issue. Therefore, communication policy issues must be identified by management during the planning phase. Providing a plan designed to establish lines of communication and dissemination for information and data between study participants and nonparticipants is important. This will assure that authorized recipients receive information/data in a timely manner. The plan should be approved by the study management team to ensure against the inappropriate or unauthorized discussion of policy issues or premature release of study results. Please identify any anticipated formal and informal communications requirements such as a report to Congress, press release, data release to a region, state, city, or to the public in general. A spokesperson must be identified who can authorize the release of information. Identify the anticipated recipients of authorized information, giving name, title, address, and telephone number. Specifically list any caveats/disclaimers/policy implications anticipated. Please discuss below what communication will be required for this project and who will be responsible.

2.0 MANAGEMENT ASSESSMENT

The review of research and development work by scientists and engineers not involved with the work and who have at least the same level of expertise as those doing the work is often called peer review. Peer review is perhaps the practice most used for verifying the technical adequacy of work. One of the most frequent forms of peer review occurs when results are prepared and submitted for publication in a technical journal or for presentation at a technical meeting. Research and development organizations often establish a peer review system for their own work. Generally, in-house reviewers are used. For the more important work, however, an organization may go outside for reviewers, particularly for reviewers with levels of expertise higher than that available in-house or with established reputations in a particular field. In addition, the use of outside reviewers supports the concept of reviewer independence alluded to above. Other effective management assessment tools are the Management Systems Review (MSR), the Technical Systems Audit (TSA) and the Performance Evaluation (PE).

Please discuss below what forms of assessment will be required for this project and who will be responsible.

2.1 Assessment Responsibility

Peer reviews and/or audits should be planned and conducted by the organization responsible for the work, normally the funding organization(s). Depending on the project, the plan may recommend an audit by an independent second or third party. The funding organization is also responsible for following up on recommendations and comments coming from a peer review, including the documentation of actions taken to ensure that all issues raised have been addressed. If peer review is anticipated, who is responsible for conducting the review(s) of your project.

2.2 Assessment Type(s)

Peer review can be informal or formal. Audits and MSRs are more formal in nature. An informal review can consist of a review of work by uninvolved co-workers, a review by persons outside the work group, or the publication and presentation of papers that are subject to peer review within the scientific community. Formal reviews, on the other hand, are characterized by the following: the establishment of a formal review plan; the use of experts outside and independent of the organization; the issuance of a peer review meeting notification letter identifying participants, time and place where presentations about the work are made to the participants and a detailed report of the review is issued; and a written response from the organization is required regarding recommendations and comments made by the reviewers. Please show your plans for audits and/or peer reviews and propose a tentative schedule.

2.3 Assessment Usage

Peer reviews and audits should be used to evaluate project plans and to verify the technical adequacy of procedures and techniques. Peer reviews should always be used when the work goes beyond the state-of-the-art and when new or unusual experimental techniques are used. Formal peer reviews should be used when any of the following actions occur: major changes are being made in an investigation, significant reports are being issued that will have major impact on a project, a major milestone has been reached, or corrective actions are being recommended for deficiencies (including accidents) having major impact on the project. Please discuss your project review plans.

2.4 Assessment Criteria

Peer reviews and audits should be planned and conducted using the following criteria: reviewers/auditors are not directly involved with the work; reviewers/auditors have technical expertise in the field; reviewers/auditors are provided with sufficient information about the work, including purposes and objectives, to adequately evaluate the work; and results of the peer review or audit are documented. Please verify that your planned reviews/audits meet these criteria.

2.5 Assessment Documentation

The degree of documentation will depend on the type of review/audit. Documentation of an informal review could be simply the signing and dating of a page in a data record by a qualified reviewer. It could be a dated and signed letter from the reviewer to the manager of the organization stating what was reviewed and giving comments on the work. The publication of a paper in a scientific journal is a form of documentation since papers submitted to most journals are reviewed before being accepted and published. Formal peer reviews, MSRs and audits should be documented with a report that includes, in detail, the following kinds of information: date of review, place, participants, activities reviewed, evaluation process used, results of evaluation, and recommendations.

Each Principal Investigator should prepare an Annual Quality Assessment Report (AQAR) to summarize the quality management and assessment activities conducted during the previous calendar year. The scope of a project's AQAR will be dependent upon the level of effort involved in the particular project and the end usage of the data generated. At a minimum, a project AQAR should contain sufficient detail to provide the reader with a clear understanding of the quality of the data generated.

These reports, including any notification letters and responses from the organization, should become a part of the records associated with the project. Please describe the assessment documentation requirements for your project.

3.0 PROJECT IMPLEMENTATION

The project implementation section should communicate the basic steps that must be taken to accomplish the objectives of the project. This section must describe how the work will be conducted and how the project objectives will be achieved.

3.1 Project Responsibilities

The planning phase should emphasize clear and specific assignments of responsibility. Responsibilities should be defined in writing and an organizational chart naming responsible individuals should be prepared. Organizational interfaces should be defined. Please define the responsibilities and interfaces for all management and technical personnel (including QA/QC professionals) associated with this project.

3.2 Project Design Criteria

The establishment of design criteria is critical when designing experiments or models or monitoring projects in response to the objectives and work tasks prescribed above. Please address your project requirements under each of the following elements.

- Site Selection
- Sample Collection Media
- Sample Type(s) (including QC samples)
- Sampling Time and Frequency
- Sample Collection
- Sample Handling
- Sample Custody
- Sample Preparation
- Sample Analysis

3.3 Data Quality Indicators

The identification of data quality indicators is an important exercise, particularly when planning a monitoring project. These indicators normally represent either the minimum acceptable levels of data quality or they are statistically determined data quality goals needed to achieve the objectives of the project. Please discuss these indicators and how they will be determined for this project.

- Accuracy requirements
- Precision requirements
- Detection limit requirements
- Comparability requirements
- Completeness requirements
- Representativeness requirements

4.0 DATA ACQUISITION

The practices used to acquire, screen, preserve, and analyze data are crucial to all projects. Such practices should be documented as written instructions, procedures, data sheets or other acceptable format. In this way, requirements relating to the acquisition, protection, and evaluation of data are established and readily available. Describe the technical practices you intend to use to accomplish the objectives of your project.

4.1 Data Recording

Data must be recorded in some manner when they are produced, otherwise, they will be lost. Recording may be done manually in a laboratory notebook, in a log book, or on data sheets; or it may be done by an automatic recording device or computerized system. Regardless of the recording method used, provisions should exist to permit the recording of observations, ideas, or other kinds of information that the researcher or developer encounters during a project, including changes made in steps taken and conditions used. Please describe the preferred data acquisition and recording methods for your project.

4.2 Identification of Data

Practices should be established to assure that all data are clearly identifiable and traceable to the project from which the data were produced. It is very important that this identification and traceability be maintained (protected) throughout the needed lifetime of the data. Please describe the practices to be used on your project.

4.3 Control of Erroneous Data

Practices are needed for controlling data that are erroneous, rejected, superseded, or otherwise unsuited for their intended use. These practices should provide for the identification, flagging, and/or segregation of inadequate data to avoid their inadvertent use. The use of electronic notebooks and computerized data acquisition systems presents special control problems. If electronic data collection systems are used on your project, you should describe the controls imposed to protect the integrity of the data and information recorded. Refer to the ***Data Management Handbook*** for a list of data qualifier flags. Describe the practices for controlling data considered unsuitable under your project.

4.4 Data Evaluation

The statistical and/or mathematical methods used to evaluate data are dependent on how much planning preceded the data collection process and on whether a formal statistical design was followed when the data were collected. When the data are collected according to a preplanned, statistically designed experiment, as described under Section 1.5, the use of analysis of variance methods is appropriate.

Occasionally, maintaining all of the variables at the prescribed series of constant levels may be difficult or impossible (or serious economic penalties may be associated with such an approach). Under these circumstances, analysis of covariance, regression, or general linear model methods can be used to infer the relationships or factor effects. To ensure that the best use can be made of experimental results, it is important to preplan and design the entire experimental program so the data, when collected, will be suitable for analysis by one of the standard statistical methods. Please describe the statistical and/or mathematical methods you plan to use to evaluate the data generated under your project.

4.5 Data Validation

All NARSTO data and research products will be validated. Principal Investigators should specify in the QIWP specific validation checks that will be performed for any given research product. A validation level and status discussion should be included in the metadata record or information associated with the data or research product. Please refer to QSMP Sect. 4.2.1 for general validation guidelines. Describe the validation checks to be performed on the data you are planning to collect.

5.0 DATA MANAGEMENT

The data management activities that should be discussed in the QIWP are the minimum set needed to support your project implementation plan (Sect. 3) and data acquisition, evaluation, and validation activities (Sect. 4). Address the following data management elements as they apply to your project in sufficient detail to ensure adequate planning and control of the data activities. When appropriate, reference the ***Data Management Handbook*** as the source of project guidance.

- Types of data to be collected, processed, and utilized
- Data sources
- Data management resources needed
- Data collection activities
- Data processing activities
- Data verification and validation activities
- Data management and geographic information systems (GIS) systems to be used
- Data, data base, and systems controls and administration
- Data reporting needs
- Data archival -- project and NARSTO Permanent Data Archive

6.0 RECORDS MANAGEMENT

Records provide the supporting evidence for the technical interpretations, judgements, and decisions made during a project. Records preparation and control should be an integral part of work activities. Project records (particularly those in logbooks, data sheets, chromatograms, electronic printouts, laboratory notebooks and manual calculations) may be subject to reviews and evaluations, which may occur several years after a record was produced. They should provide the historical information needed for reviews, reevaluation, planning future research and development activities, and for use in other activities that may be based on the results of the project.

Many acceptable and varied methods can be found that discuss the use and management of project records. The selected method or system should include certain generally accepted features and practices. An effective system of records management will provide records that are legible, identifiable and retrievable.

6.1 Records Management System

At the earliest practical time, a system for managing project records should be developed. Data records must be protected to avoid loss and controlled to permit retrievability. Written instructions and other descriptions of the records system should be prepared and distributed to appropriate personnel. The practices established for records management should consist of a documented system that includes or references procedures for records generation, identification, authentication, indexing, distribution, disposition, retention times, storage, preservation, safekeeping, and retrieval. Please describe the records management systems for this project by responding to the following sections..

6.2 Records Identification, Authentication, and Indexing

Project records identification, including an appropriate indexing system, should include sufficient information to permit identification of the record with the item or activity to which it applies. The authentication practices (which may include stamping, initialing, signing, dating, and transmittal statements) should result in records that are clearly traceable and identifiable as the valid product of the responsible organization, individual, or project. The indexing system must provide information that permits information retrieval. Describe the records identification, authentication, and indexing practices to be used on this project.

6.3 Records Distribution and Storage

The records management system should clearly define records distribution and handling practices. Individuals or the organization responsible for distribution, receiving, and storage of records should be identified. It is important that the practices followed provide for interim or work-site handling and storage before the records are transferred to central storage facilities. Interim and final storage instructions should be

established to provide necessary retrieval capability, physical preservation, and safekeeping. Facility requirements for records storage should be identified. Please describe the distribution and storage practices to be used for your project.

6.4 Records Retrieval

The indexing system must provide information that permits information retrieval. Lack of retrievability may create suspicion about the quality of data. Please describe the records retrieval process to be used for your project.

6.5 Records Retention

A very important part of this indexing/identification system is the records retention policy. The retention policy should have clearly established rules and instructions that permit disposal of records when they are no longer needed. Raw data that may have significance in the future explanation and verification of the results should be retained on some long-term basis. Project managers must determine what should be discarded and when. Some researchers and developers discard raw data soon after they have been evaluated, compiled, and reported. However, the availability of raw data can be important if a problem surfaces after the project is completed. That can be particularly true if the person who produced the data is no longer available. Raw data may be sent to the Permanent Data Archive to ensure their long-term retrievability. Describe the records retention policy for your project.

7.0 ROUTINE CONTROLS AND PROCEDURES

The suitability of equipment and materials can play a significant part in the acceptability of data. Control over the handling and use of equipment and materials should be established and maintained throughout a project. The elements of this section suggest the types of control that should be incorporated into the project process. Standard Operating Procedures (SOP) or research protocols should be in place for many of these types of activities.

7.1 Control and Calibration of Measurement and Test Equipment

The adequacy of data is highly dependent on how measurement equipment used to produce data is selected, calibrated, and used. Technically sound practices should be established and used to provide for appropriate selection, calibration, adjustment, maintenance, identification, handling, and storage of measurement equipment. Calibration procedures should include criteria that show when equipment is out-of-calibration and actions required to reestablish calibrations, and frequency of calibrations. The selection, preparation, use, and maintenance of calibration standards should be included as part of calibration procedures. A records management system should be maintained so that the calibration status of individual measurement devices is readily verifiable. Please briefly describe, attach, or reference the measurement device procedures to be used on this project.

7.2 Procedures

Much laboratory and field work, even in an R&D environment, involves routine (repetitive) activities. The operation of instruments, the preparation of apparatus, the testing of equipment, and the analysis of materials are examples of routine laboratory activities. Typically, projects are a blend of the routine (the repetitive, the known) and the new (the untried, the unknown). The degree of each depends on the particular project.

Most routine activities are carried out in a planned, systematic, and controlled manner so that the results will be based on proven and sound technology. The process used to produce such an outcome often involves discrete actions taken in a specific order. Any change in an action or in the order without a valid reason will most likely result in an unsatisfactory outcome. To control the processes and avoid errors, standard operating procedures (SOPs) are written that provide guidance for those doing the work. To be effective and to help provide credibility to the activity being performed, procedures should be well written, complete, and correct. Any changes or modifications made to or deviations from an SOP during the project life-cycle must be documented, signed and dated. Reviews of procedures should be done on a planned schedule.

Non-repetitive activities (the non-routine, the untried) are initially planned, but may be subject to changes as an experiment or study proceeds. Less formal research protocols (RPs) are more appropriate for such activities. However, the initially planned RP must

be clearly written in an easy to follow step-by-step format. Any changes made to an RP during the project life-cycle must be documented, signed and dated.

Please describe the procedures and research protocols that will be applied under your project(s) and attach the documentation to your completed QIWP.

7.3 Establishing the Adequacy of Technical Practices

Many practices and techniques used regularly by scientists and engineers are established and recognized by the technical community as technically adequate when applied properly. Such practices are often called Standard Operating Procedures (SOPs). A common practice used to establish the adequacy of technical activities is to reference published work that has a relationship to the work being done. The references should support the technical adequacy of practices used and verify their applicability. References should be documented in the laboratory records system and in technical reports as appropriate. Peer review can also be used to verify technical adequacy. Of course, once the technical adequacy of a practice has been established, the user should follow it. If changes are made to established practices, those changes must be carefully documented and signed by the individual making the changes. Please describe how your project will verify technical adequacy.

7.4 Maintenance of Equipment

Equipment must be maintained in proper working order. Provisions should be made for identifying equipment items not working properly and for controlling their use until they have been repaired. In some laboratories, a maintenance and repair log is maintained for each item of equipment. Such a log documents the status of each item. Please discuss your equipment readiness requirements and attach the applicable SOPs/Protocols.

7.5 Quality of Consumables

Quality requirements for consumables should be established and specified. When possible, provisions should be made for identifying and verifying the quality of consumables before they are used, particularly if the use of deficient materials would have a significant or adverse effect on a project. Please discuss your quality requirements for consumables used on your project and attach the applicable SOPs/Protocols.

7.6 Labeling

Labels should include appropriate information relating to identification, composition, safety hazards, stability, storage and handling requirements. Industrial labels should be used to identify laboratory substances, particularly bulk chemicals and biological agents. Requirements should be established for corrective actions when a label is

missing or incorrect. Please discuss your labeling requirements and attach the applicable SOPs/Protocols.

7.7 Acceptance of Equipment and Materials

When the purchase of equipment and materials is required, specifications and other requirements that define the desired characteristics should be clearly established and included in procurement documents. Control over those documents should be established so that changes in specifications and other requirements are not made without proper review and approval. Acceptance of equipment and materials should be based on verification that specifications and other requirements have been met through inspection upon receipt or through suppliers' certification. Please discuss your equipment and materials acceptance criteria and attach the applicable SOPs/Protocols.

7.8 Storage of Equipment and Materials

Storage containers should protect materials from contamination and other adverse effects. Storage conditions should meet special requirements such as limits of exposure to light, humidity, and temperature. Those requirements should be stated in the appropriate procedures. Please discuss your storage requirements and attach the applicable SOPs/Protocols.

8.0 TECHNICAL ASSESSMENT AND RESPONSE

The unpredictability associated with research and development means that mistakes and failures can occur. Problems in a system can cause a project to go off track. If not found and corrected, these problems can lead to loss of data, erroneous data, or even incorrect interpretation of the data. Problems can result from something as simple as an improperly trained technician operating a piece of equipment. A system to identify and evaluate problems, and to correct them in a way that minimizes recurrence, should be established and used.

8.1 Assessment Procedures

Most problems are found during the normal performance of work. Defective equipment and materials are often found through inspections and tests when received from suppliers. Defective equipment and inadequate data can be found through calibration activities. Inadequate data may also be found by peer reviews and through statistical evaluations. Tags, markings, or other means of positive identification should be used on defective materials and equipment to prevent their improper use. Problems can occur in operational and administrative activities associated with the technical work. Those problems are often found by applying auditing and surveillance techniques. Prompt reporting of problems will assure that corrective actions can be taken before more serious consequences occur. Please describe your procedures for problem identification.

8.2 Assessment Evaluation

Problems should be evaluated to learn the true causes. The important part of an evaluation is identifying the required actions for correction, including the actions required to preclude recurrence. A peer review process should be used, when justified, to assure technical adequacy of the evaluations. Please describe your procedures for evaluating problems.

8.3 Assessment Response and Follow-up

Responsibilities for taking a response action should be identified and a schedule for response established. The assigned actions and schedules should be recorded and reported to responsible project management. The final actions taken should be documented and reported. It is important that actions taken be reported and communicated to the responsible and involved technical and managerial participants. Follow-up is a necessary action to assure that prescribed assessment response(s) has been taken. Please describe your assessment response and follow-up requirements.

NOTE: All pertinent Standard Operating Procedures (SOPs) or Protocols (or other documentation) associated with the responses made under each of the previous sections must be attached to the printed version of this document when submitted for review and approval. Referenced procedures and protocols that are accessible in the open scientific literature do not need to be attached. However, the funding institution's designated Project Manager and Quality Assurance Manager reserve the right to request copies of these documents before approving this QIWP.

APPENDIX B

QUALITY INTEGRATED WORK PLAN
TEMPLATE FOR MODEL DEVELOPMENT PROJECTS

NOTES TO USERS:

This Template is designed to help program managers and scientists develop quality assurance documentation for model development projects. By responding to the elements presented under the following Sections, an individual researcher or a team of researchers can generate a comprehensive Quality Integrated Work Plan (QIWP) for the project under consideration. All projects funded, managed or performed by **THE INSTITUTION** must be supported by an approved QIWP. Minimum required QIWP approval for a project consists of sign-off by the Program/Project Manager for **THE INSTITUTION**.

- The use of the word "project" in this template is synonymous to the following words: program, task, study, work assignment, technical directive or in-house technical effort.

- Please replace all parentheses with the information requested therein.

- If a section or certain section elements do not apply to your specific project, please enter your rationale for excluding that section/element as your response under that section/element.

- When you have finished your response for a given section, delete the template discussion.

- The Document Control Format is in the Header of this template document.

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Revision No. _____

Revision Date: ___ / ___ / _____

QUALITY INTEGRATED WORK PLAN

(PROJECT TITLE)

(PROJECT NUMBER)

(INSTITUTION)

Prepared by:

_____ _____

Principal Investigator Date

Approval:

_____ _____

Program/Project Manager Date

Approval:

_____ _____

NARSTO Science Team Co-Chair Date

Project _____

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QUALITY INTEGRATED WORK PLAN
FOR
(PROJECT TITLE)

1.0 Project Description

This section describes the concepts underlying the project, based on an evaluation of needs by those who will use the models. This section identifies the **client and the client's needs and expectations**. This section defines the **problem**, outlines a **solution strategy**, states the **goals** for the project and the model(s). This section also defines the **scope** and **constraints** of the projects and the model(s), and describes user characteristics. This section must also include a description of the anticipated model parameters. The model description should discuss the following model characteristics:

- model origin and its original purpose
- essential parameters and variables
- spatial extent (individual, group, population, geographic area)
- spatial resolution (location independent/dependent, dimensionality)
- Temporal extent (length of modeling period)
- Temporal resolution (time step)
- Model structure (e.g., theoretical vs. Data driven, stochastic vs. deterministic, structural framework)

Please describe this project and the model parameters to be applied under this project.

2.0 Project Management Plan

This section defines the technical and managerial processes necessary to satisfy the project requirements. This section describes the **project organization and responsibilities (including quality assurance and quality control)**, the **product structure**, the **scope of work**, the **resources,** the **methods**, the **procedures**, and the **product delivery schedules**. This section also describes **planned documentation** (reports, journal articles, manuals, etc.) required to present the details of the model and the procedures to ensure completeness of the documentation and quality of the product.

Good model development documentation characteristics include a complete description of the equations on which the model is based, the underlying assumptions, the

methods used to solve the equations, the boundary conditions that can be incorporated in the model, and the limiting conditions.

Crucial end-product documentation characteristics include users' instructions for operating the code, instructions for preparing data files, example problems complete with input and output, programmers' instructions for code maintenance, computer operators' instructions, hardware/software requirements, and a report of the initial code verification.

3.0 Software Verification and Validation

This section describes software verification and validation activities (including unit and integration testing) that will be used during the development phases of the model, the preprocessing software, and the data acquisition. These tests ensure that the software developed will satisfy stated user needs and performance criteria. In addition, the resulting documentation must refer to or contain all standards used in the project, including those on coding and design. Please describe the anticipated software verification and validation activities for this project.

4.0 Project Configuration Management

The section describes how model documentation, software, and other deliverables will be configured and managed. This includes documenting all the activities necessary to save, control, trace, and audit software and model evolution. The resulting documentation describes the processes required to: identify and control changes, ensure that changes have been properly implemented (according to verification and validation procedures), report on changes to other interested parties, and define and track products and their baselines. This section must describe procedures for version control and notation, and configuration audit and status reporting. This section must define configuration log formats and other configuration management standards. Please discuss the configuration management activities and procedures planned for this project.

5.0 Model Evaluation and Testing

This section should describe a protocol for model evaluation that defines the appropriate questions to be addressed by the project, describes the tests to be performed and discusses how those tests relate to the questions posed. The protocol should also address how the testing will be done, describe the data to be used, and what procedures will be used for the interpretation of the test results. In addition, this section should define a review process that involves the model developers and yet provides for independent review to ensure objectivity and an unbiased evaluation.

6.0 Project Risk Management

This section addresses the risks associated with the satisfactory completion of the project. It describes the **methods and procedures used to assess and control the project risk factors**. This includes both short- and long-term risks to the project **schedule**, **cost**, and the adequacy and quality of the **deliverables**. This section attempts to identify, confront, and eliminate model system (or software) risk factors before they become obstacles or threats to successful software operation or major sources of software reworks, and science related risks. Please discuss the planned project risk assessment and risk control activities.

7.0 Project Summary and Evaluation

This section summarizes the project and **provides a record of the project successes and failures**. It documents the reviews the project has received from internal and external sources, and makes recommendations based on the project experiences. Its purpose is to preserve the lessons learned during the project for use by other projects. Please provide a plan and schedule for project peer reviews and a listing of individuals who will receive copies of peer review and final reports.

NOTE: All pertinent Standard Operating Procedures (SOPs) or Protocols (or other documentation) associated with the responses made under each of the previous sections must be attached to the printed version of this document when submitted for review and approval. Referenced procedures and protocols that are accessible in the open scientific literature do not need to be attached. However, the NARSTO Science Team Co-Chair and the designated NARSTO QA Manager reserve the right to request copies of the references before approving this QIWP.

APPENDIX C

QUALITY INTEGRATED WORK PLAN
TEMPLATE FOR MODEL APPLICATION PROJECTS

NOTES TO USERS:

This Template is designed to help program managers and scientists develop quality assurance documentation for model application projects. By responding to the elements presented under the following Sections, an individual researcher or a team of researchers can generate a comprehensive Quality Integrated Work Plan (QIWP) for the project under consideration. All projects funded, managed or performed by **THE INSTITUTION** must be supported by an approved QIWP. Minimum required QIWP approval for a project consists of sign-off by the Program/Project Manager for **THE INSTITUTION**.

- The use of the word "project" in this template is synonymous to the following words: program, task, study, work assignment, technical directive or in-house technical effort.

- Please replace all parentheses with the information requested therein.

- If a section or certain section elements do not apply to your specific project, please enter your rationale for excluding that section/element as your response under that section/element.

- When you have finished your response for a given section, delete the template discussion.

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QUALITY INTEGRATED WORK PLAN

(PROJECT TITLE)

(PROJECT NUMBER)

(INSTITUTION)

Prepared by:

_____ _____

Principal Investigator Date

Approval:

_____ _____

Program/Project Manager Date

Approval:

_____ _____

NARSTO Science Team Co-Chair Date

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QUALITY INTEGRATED WORK PLAN
FOR
(PROJECT TITLE)

1.0 Project Description

This section describes the purpose of the project, based on an evaluation of needs by those who will use the results. This section identifies the client; defines the **problem**; justifies the **approach**; states the **goals** for the project; define the **scope** and **constraints** on the project, the models, and the data; describes **model characteristics**; and outlines a **solution strategy**. This section must also include a description of the model parameters. The model description should discuss the following model parameters:

- model origin and its original purpose
- parameters and variables
- spatial extent (individual, group, population, geographic area)
- spatial resolution (location independent/dependent, dimensionality) and domain(s)
- Temporal extent (length of modeling period)
- Temporal resolution (time step)
- Model structure (e.g., theoretical vs. Data driven, stochastic vs. deterministic, structural framework)
- Model assumptions and limitations

Please describe this project and the model(s) to be applied under this project.

2.0 Project Management Plan

This section defines the technical and managerial processes necessary to satisfy the project requirements or reference an existing document providing the same information. This section describes the **project organization and responsibilities including quality control (QC)**, the **product**, the **scope of work**, the **resources,** the **methods**, the **procedures**, and the **product delivery schedules**.

3.0 Model Application Design

This section summarizes the planned model executions and analysis procedures including a rationale for the type and number of model runs and provides initial estimates of computer resource needs. The minimum discussion under this section

must cover **hardware/software, and memory requirements** for data processing, model executions, and analysis/visualization applications. This section should also discuss available **computing resources**, **model/data portability**, **data storage requirements**, and approximate **execution time** for typical model runs.

4.0 Scientific Basis and Technical Requirements

This section describes the scientific basis and technical requirements for the project approach and models and how the approach, models, and data meet the project objectives. This section must discuss the scope, technical requirements, and the theory underlying the science incorporated in the models. For example, does the science support the air quality, meteorological, emissions, and chemistry-transport modeling requirements of the project? This section must discuss mathematical formulations, algorithms, numerical techniques, required parameterizations, assumptions, and limitations; and/or, reference published documents containing this information. This section must also identify the methods and procedures used to evaluate the models (e.g., sensitivity test, model evaluation), and the information obtained from these efforts; or discuss plans for such activities. Please describe the scientific concepts and discuss technical requirements of this project.

5.0 Quality Control Procedures for Model Applications

This section describes procedures to ensure the integrity of the model, data processing and analysis executions. Describe procedures and safeguards to ensure the correct model version and correct input/output files were used for model execution and analysis of results. This section also includes procedures for archiving model results and for the periodic review of archives for obsolescence.

6.0 Data Requirements and Quality Control Procedures

This section discusses the project input and output data characteristics and requirements. The discussion must also describe the procedures used to ensure compliance with project input and output data specifications. Some specific parameters to be discussed include: sources of original data, criteria for data acceptance or rejection, modifications to the original data, QC procedures for input/output data, data format conventions, data conversion issues, and data maintenance and archiving procedures. Please discuss the data requirements and planned data quality control procedures for this project.

7.0 Project / Model Software Maintenance

This section will describe the processes for modifying the software components of the project after project initiation to correct faults, improve performance or other attributes, or adapt to a changed environment. Project software may include model data processing, analysis, visualization code, modeling framework code, etc. This section should define or reference procedures for the preservation, documentation, verification, validation and configuration management applied during the evolution of the application code once its initial operational version has been released. The maintenance documentation describes enhancements to the system, problem fixes, porting problems, and retesting procedures. Please describe the software maintenance procedures for this model application.

8.0 Project Risk Management

This section addresses the risks associated with the satisfactory completion of the project. It describes the **methods and procedures used to assess and control the project risk factors**. This includes both short- and long-term risks to the project **schedule**, **cost**, and the adequacy and quality of the **deliverables**. This section attempts to identify, confront, and eliminate risk factors before they become obstacles or threats to successful project completion. Please discuss the planned project risk assessment and risk control activities.

9.0 Project Summary and Evaluation

This section summarizes the project and **provides a record of the project successes and failures**. It documents the reviews the project has received from internal and external sources, and makes recommendations based on the project experiences. Its purpose is to preserve the lessons learned during the project for use by other projects. At a minimum, provide a plan and schedule for project peer reviews and a listing of individuals who will receive copies of peer review and final reports.

NOTE: All pertinent Standard Operating Procedures (SOPs) or Protocols (or other documentation) associated with the responses made under each of the previous sections must be attached to the printed version of this document when submitted for review and approval. Referenced procedures and protocols that are accessible in the open scientific literature do not need to be attached. However, the NARSTO Science Team Co-Chair and the designated NARSTO QA Manager reserve the right to request copies of the references before approving this QIWP.