

Quality Systems Management Plan



NARSTO Quality Systems Science Center

NARSTO Quality Systems Management Plan

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ABBREVIATIONS

AQAR	Annual Quality Assessment Report
DAAC	Distributed Active Archive Center
DQOs	Data Quality Objectives
EOSDIS	NASA Earth Observing System Data and Information System
GIS	Geographic Information System
LaRC	Langley Research Center
MSR	Management Systems Review
NAFTA	North American Free Trade Agreement
NASA	U.S. National Aeronautics and Space Administration
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
RPs	Research Protocols
SOPs	Standard Operating Procedures
U.S. EPA	United States Environmental Protection Agency
WWW	World-Wide Web

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 Systems Management Plan was released.

Revised Edition 1.0, March 1, 1999

Various updates and clarifications were added related to the newly expanded scope of NARSTO. Scope was generalized to encompass all tropospheric pollutants including ozone, ozone formation precursors, and particulate matter.

Revised Edition 1.0, September 30, 1999

Various updates and clarifications were made related to the dissolution of the NARSTO Committee on Quality Systems and Data Management. Sections outlining roles and responsibilities were modified as needed with responsibilities reassigned to the Management Coordination Office and Quality Systems Science Center. Other changes included adding a new cover, changing the document font and point size, and incorporating other editorial changes.

NARSTO QUALITY SYSTEMS MANAGEMENT PLAN

EXECUTIVE SUMMARY

NARSTO is a public/private partnership, whose membership spans government, the utilities, industry, and academe throughout Mexico, the United States, and Canada. Its primary mission is to coordinate and enhance policy-relevant scientific research and assessment of tropospheric pollution behavior, with the central programmatic goal of determining workable, efficient, and effective strategies for local and regional air-pollution management.

In accomplishing this goal, NARSTO is charged with establishing and maintaining effective communication channels between its scientific effort and its client community of planners, decision-makers, stakeholders, and strategic analysts. It is also charged with providing a cross-organization planning process, which determines the most effective strategies for scientific investigation. NARSTO coordinates the allocation of financial resources to implement these strategies, and monitors progress of its effort toward fulfillment of its programmatic goal.

The NARSTO organization will plan and coordinate independently sponsored programs that result in projects and tasks designed to identify and resolve policy-relevant science questions related to (a) anthropogenic and biogenic air-pollution sources and emissions, (b) the complex physical and chemical processes affecting the accumulation of pollutants in the troposphere, (c) the potential of certain pollutants to react and generate oxidants and fine particles in the troposphere, (d) the development, intercomparison, and application of atmospheric models, (e) the development of monitoring studies and methodologies needed to assess emission control effectiveness for selected air pollutants and their precursors, and (f) the attainment of the national air-quality goals and standards established by each member Nation.

Quality management is a shared responsibility of all NARSTO participants. The **Quality Systems Management Plan (QSMP)** is the first and highest level of NARSTO program quality assurance and is the umbrella under which all quality-related activities will be planned and conducted. 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. Quality management activities should be implemented as a consistent and cost-effective function that is integrated throughout all levels of management and operations. Governmental and private funding agencies should incorporate applicable elements of the QSMP into their program and project planning documents. To avoid duplication and maximize the use of existing project and quality systems documentation, programs and projects are encouraged to reference existing documentation and document the equivalency of quality plans.

Project Planning and Data Archival Process

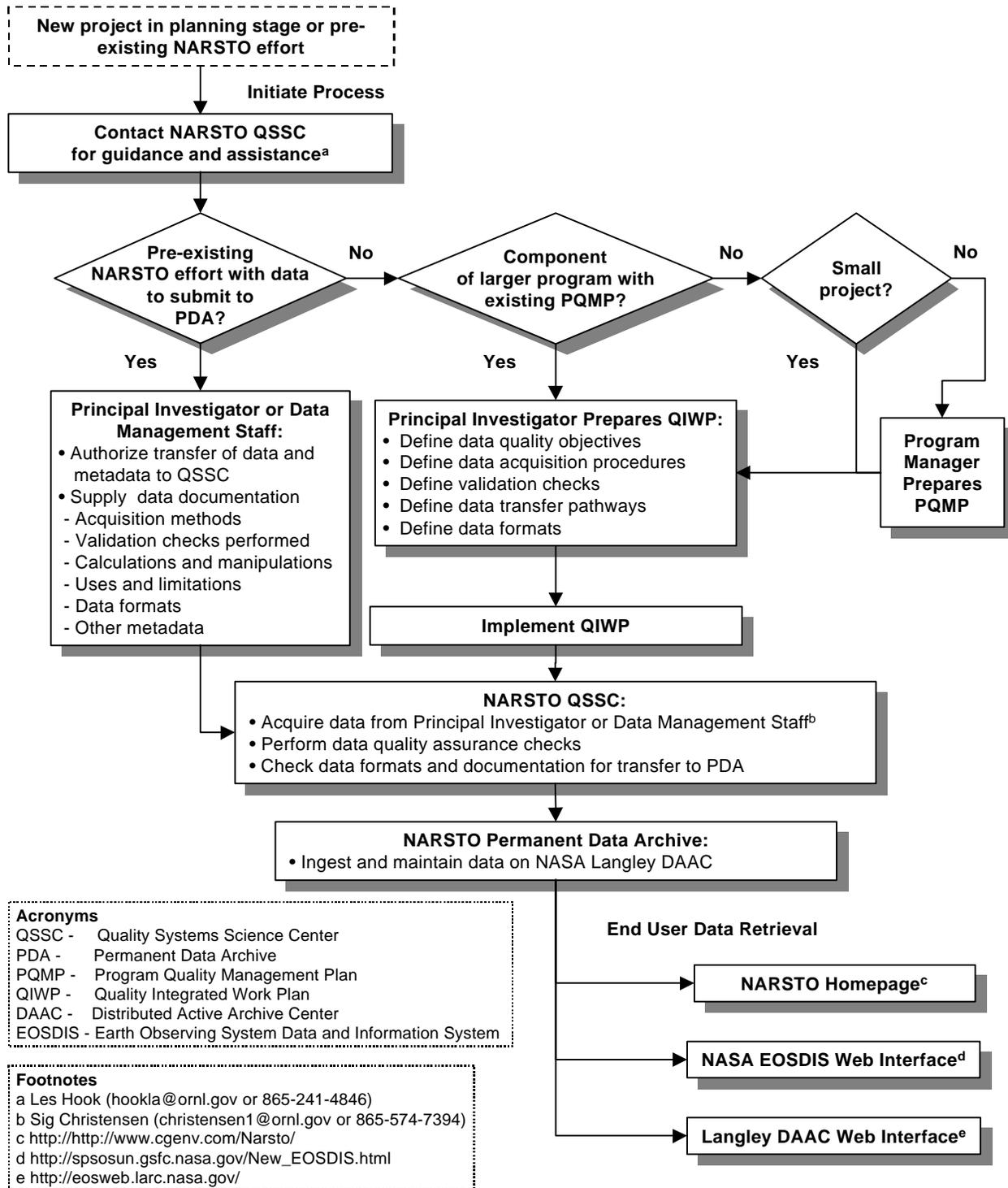


Figure 1. Project Planning and Data Archival Process

The QSMP identifies the NARSTO program quality assurance and data management requirements and guidelines for ensuring NARSTO product credibility, reliability, accessibility and quality; i.e., the keys to NARSTO success. This QSMP was developed to provide NARSTO managers and principal investigators with the appropriate tools to (1) plan research and modeling activities to meet identified NARSTO science objectives, (2) assess their research outputs against those objectives, and (3) deliver their quality assured research products to the client community in a timely manner. The QSMP guidelines are flexible to accommodate all measurement and modeling projects and should be interpreted in the context of the project's objectives, size, and sophistication.

The QSMP is supplemented by the **NARSTO Quality Planning Handbook** and the **NARSTO Data Management Handbook**. The handbooks contain templates, formats, and other guidance materials designed primarily to aid the project planning and implementation processes. The ideal concept is for Program/Project Managers and Principal Investigators to utilize the guidance as project plans and project documentation are being developed. Project documentation should be tailored for the specific project and agreed upon and used by the project team. Managers and investigators should use the assistance of the NARSTO Quality Systems Science Center (QSSC) to ensure that project documentation, data, and metadata, are suitable for ingestion to the NARSTO Permanent Data Archive (PDA).

The QSSC, located at the Department of Energy's Oak Ridge National Laboratory at Oak Ridge, Tennessee, will implement the QSMP. Under the direction of the Executive Steering Committee, the QSSC will perform a coordination and oversight role for quality systems management activities to ensure the functionality of the integrated quality assessment process. The QSSC will support project development of data quality objectives (DQOs); provide consultation on quality assurance, quality control, and data management procedures; and perform management and technical quality assessments as needed.

The QSSC will plan and coordinate NARSTO data management, data archival, and data dissemination activities. Timely sharing of and access to quality assured NARSTO data and research products (e.g., computer models, methods, procedures, and reports) by the scientific community is essential to the success of the NARSTO program. All NARSTO products must be validated through a documented quality assurance process before release to the client community and public. NARSTO scientists should strive to document their data at a level sufficient to satisfy the well known "20-year test". That is, someone 20 years from now, not familiar with the data or how they were obtained, should be able to find data of interest and then fully understand and use the data solely with the aid of the documentation archived with the data.¹ Publicly available data will be maintained at the NARSTO Permanent Data Archive (PDA) located at the Distributed Active Archive Center (DAAC) operated by the NASA/Langley Research Center (LaRC). NARSTO will make maximum use of the world-wide web (WWW) for distribution of data and other research products from its home page at <http://www.cgenv.com/Narsto/>.

¹ National Research Council, Committee on Geophysical Data, *Solving the Global Change Puzzle, A U.S. Strategy for Managing Data and Information*, National Academy Press, Washington, D.C., 1991.

1.0 INTRODUCTION

NARSTO is a public/private partnership, whose membership spans government, the utilities, industry, and academe throughout Mexico, the United States, and Canada. Its primary mission is to coordinate and enhance policy-relevant scientific research and assessment of tropospheric pollution behavior, with the central programmatic goal of determining workable, efficient, and effective strategies for local and regional air-pollution management.

In accomplishing this goal, NARSTO is charged with establishing and maintaining effective communication channels between its scientific effort and its client community of planners, decision-makers, stakeholders, and strategic analysts. It is also charged with providing a cross-organization planning process, which determines the most effective strategies for scientific investigation. NARSTO coordinates the allocation of financial resources to implement these strategies, and monitors progress of its effort toward fulfillment of its programmatic goal.

The NARSTO organization will plan and coordinate independently sponsored programs that result in projects and tasks designed to identify and resolve policy-relevant science questions related to (a) anthropogenic and biogenic air-pollution sources and emissions, (b) the complex physical and chemical processes affecting the accumulation of pollutants in the troposphere, (c) the potential of certain pollutants to react and generate oxidants and fine particles in the troposphere, (d) the development, intercomparison, and application of atmospheric models, (e) the development of monitoring studies and methodologies needed to assess emission control effectiveness for selected air pollutants and their precursors, and (f) the attainment of the national air-quality goals and standards established by each member Nation.

The purpose of this document is to identify NARSTO program quality assurance requirements and guidelines and data management practices for ensuring NARSTO product credibility, reliability, accessibility and quality; i.e., the keys to NARSTO success. Within this framework, this Quality Systems Management Plan (QSMP) is designed to provide NARSTO managers and principal investigators with the appropriate tools to (1) plan research and modeling activities to meet identified NARSTO science objectives, (2) assess their research outputs against those objectives, and (3) deliver their quality assured research products to the client community in a timely manner. The QSMP guidelines are flexible to accommodate all measurement and modeling projects and should be interpreted in the context of the project's objectives, size, and sophistication.

NARSTO is organized to establish and maintain communication between scientists conducting the research and its clients. The client community includes policy-makers, decision-makers, strategic analysts, and other stakeholders. Each stakeholder requires relevant, readily available, and credible data and information. NARSTO will provide relevant and high-quality assessment tools to policy makers, scientists, and air quality managers. NARSTO will make maximum use of the world-wide web (WWW) for distribution of data and other research products from its home page at <http://www.cgenv.com/Narsto/>.

The primary NARSTO goal is to generate knowledge and assessment tools for the credible, efficient and effective management of tropospheric pollution problems in various regions of North America in a timely and tractable manner. Air quality simulation models are one of the major quantitative tools used in the regulatory and air quality management processes. Models may also be used to provide guidance on policy concerns. Key science goals of NARSTO are to develop these assessment tools and to characterize/quantify the effects of model uncertainties on predictions of control strategy effectiveness.

2.0 QUALITY SYSTEMS MANAGEMENT

2.1 Purpose

The purpose of the NARSTO quality system is to ensure the credibility, reliability, accessibility, and policy relevancy of all NARSTO products. Successful implementation of the quality system is essential to meeting our goal of providing credible scientific data and high-quality assessment tools for use by policy makers, scientists, and air quality managers in making policy decisions and designing cost-effective control options. Quality management activities should be implemented as consistent and cost-effective functions that are integrated through all levels of management and operations. Quality management is a shared responsibility of all NARSTO participants.

The NARSTO Quality Systems Management Plan (QSMP) establishes the overarching continental NARSTO quality assurance and data management requirements, standards, specifications, and guidelines. However, it is incumbent on each NARSTO Program/Project Manager and Principal Investigator to establish, within the flexible QSMP framework, the quality and data management requirements and specifications that are commensurate with their specific NARSTO related activity. The Quality Systems Science Center (QSSC) will assist participants in identifying appropriate quality management activities.

2.2 Scope

The NARSTO quality system will be applied to the management, planning, implementation, and assessment of a well-defined set of data acquisition, analysis, modeling, and evaluation activities. NARSTO will conduct process-level research and development to gather and analyze the data necessary to reach NARSTO science and policy goals in the following four principal scientific and technical work areas:

Observations Research

- ! Atmospheric monitoring/measurements and data analysis -- focusing on the design, operation, and maintenance of monitoring/networks, the planning for intensive sampling campaigns, method development, and observational based analyses.

Modeling/Chemistry Research

- ! Chemistry and modeling -- focusing on air quality and meteorological model development, model applications research, model evaluation, laboratory and smog chamber studies, chemical mechanism development.

Emissions Research

- ! Emission -- focusing on model development, process and activity analysis, source and ambient emissions field studies, emission projections and control technology implications analysis.

Integrated Analysis and Assessment

- ! Analysis and assessment activities -- including assessments of primary and secondary air pollutants in the troposphere and their sources, transport, transformation, and concentrations, assessments of ecosystem exposure, recommendations for data management, archival, and dissemination, data analysis across Technical Program Teams, spatial and temporal mapping of primary and secondary pollutants in the troposphere, integration of NARSTO results and communication of findings to other Technical Program Teams to policy-makers and to the public.

2.3 Organization, Roles, and Responsibilities

NARSTO has developed a comprehensive science driven research strategy to provide a unified, cohesive, and scientifically sound basis for planning and implementing tropospheric pollution research. The emphasis on science team input and communication, quality assurance, and scientific review and oversight is reflected in the organization. Figure 2-1 shows the NARSTO quality management structure. The NARSTO organizational structure and programmatic roles and responsibilities are identified in the NARSTO Charter². Following are descriptions of the roles and responsibilities of NARSTO management and research staff with respect to implementing quality system and data management activities.

2.3.1 Executive Steering Committee

The Executive Steering Committee has the responsibility to establish the overall strategy, program vision, and mission statement; identify major policy relevant science questions and objectives; and define policy and science relationships. The Executive Steering Committee will select a responsible party to coordinate NARSTO quality system and data management activities. In addition, the Committee approves NARSTO strategy documents, assessments, and other major NARSTO products. The Executive Steering Committee has the ultimate responsibility for implementing the NARSTO quality system.

2.3.2 Management Coordinator

The Management Coordinator has the designated responsibility to oversee NARSTO program data management and quality assurance activities and coordinate program outreach, information dissemination, communications, and technology transfer activities.

The NARSTO Management Coordination Office will be responsible for QSSC oversight and will form committees as needed to formulate NARSTO quality assurance and data management policy or to conduct management audits/reviews.

The QSSC Director, in collaboration with the NARSTO Management Coordination Office, is authorized to acquire expertise and to establish contractual agreements, within the limitations of the QSSC budget, for the purpose of efficiently and effectively accomplishing the responsibilities, goals and mandates of the QSSC.

² NARSTO Research Strategy and Charter. U.S. Environmental Protection Agency. November 1994.

NARSTO Quality Management Structure

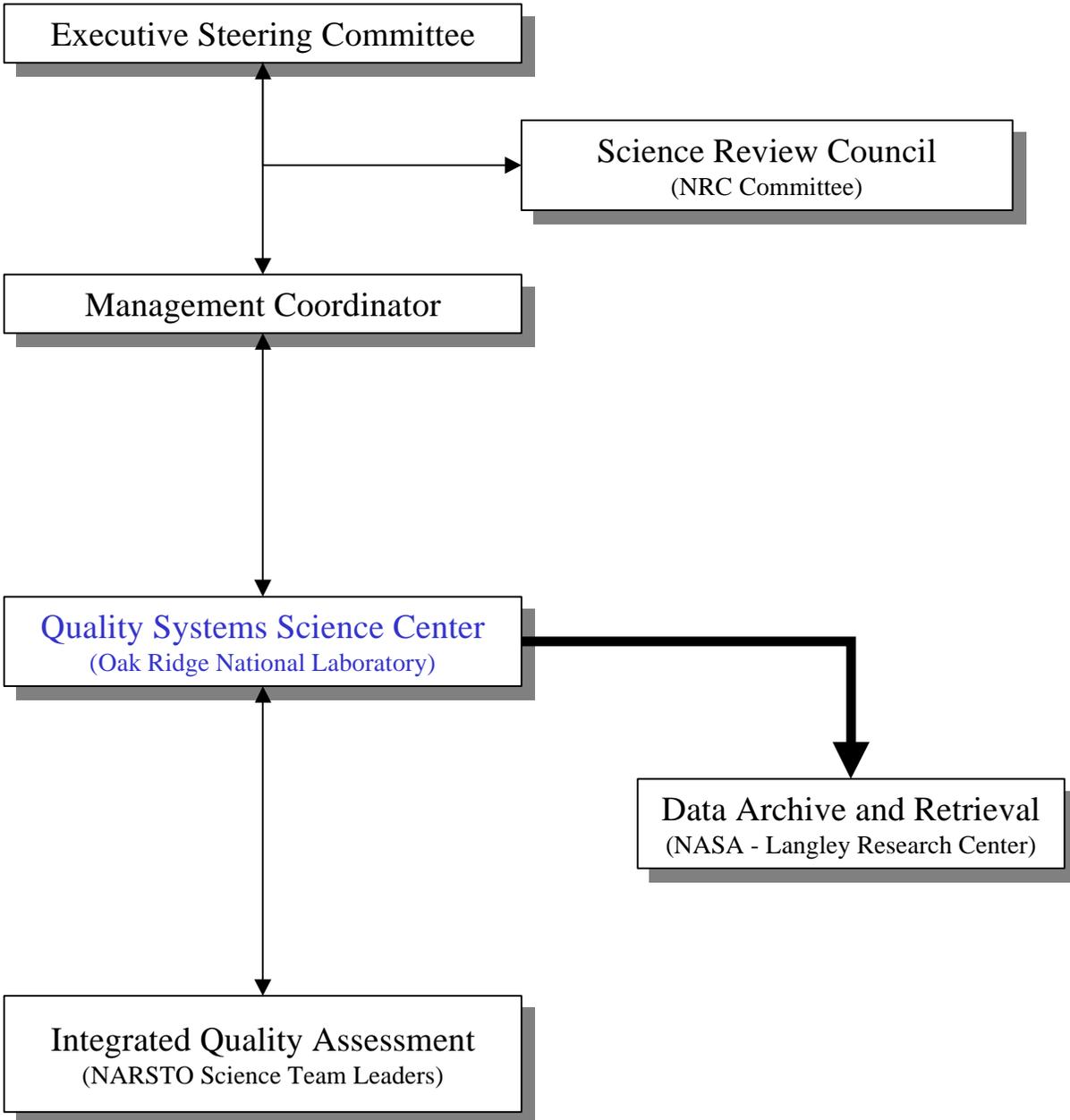


Figure 2-1. NARSTO Quality Management Structure

2.3.3 Quality Systems Science Center (QSSC)

Quality systems management and data management coordination activities will be implemented by the QSSC. The QSSC will implement the NARSTO QSMP under the direction of the Executive Steering Committee. The QSSC will ensure that relevant quality management systems are planned and implemented under the NARSTO program; plan and conduct quality assurance reviews of the critical NARSTO program elements; and plan and coordinate NARSTO data management, data archival, and data dissemination activities. The QSSC will manage and integrate quality assessment activities to ensure the credibility, reliability, accessibility, and policy relevancy of NARSTO products. The QSSC will report quality assessment results to the Executive Steering Committee.

The NARSTO strategy for implementing total quality management is built around the QSSC. The QSSC provides the communications, critical oversight, and constructive assistance necessary for maintaining consistency and quality of all NARSTO products so that the program can achieve its pre-defined policy goals. The QSSC is an essential and integral part of the NARSTO program and the operational mechanism for integration and coordination of all quality assurance and assessment activities in NARSTO. The QSSC must be independent of NARSTO data generation activities in order to fulfill oversight responsibilities.

QSSC staff expertise will include atmospheric chemistry, quality systems management, and data management coordination. The QSSC will support Program/Project Managers and Principal Investigators in the areas of project data quality objectives (DQO) definition, quality assurance and data management planning, data management coordination, and in a quality assessment oversight role for the NARSTO Program as discussed in the following sections.

2.3.3.1 Project DQO and Planning Support

QSSC quality assessment activities will follow an "integrated" or "end to end" approach. This approach follows the life-cycle of a project from the establishment of data quality objectives (DQOs) through to the quantification of uncertainty associated with products provided to decision makers. To ensure effectively implementation of this approach, the QSSC will establish a strong working relationship with the Principal Investigators and responsible Program/Project Managers during the identification and conceptualization of a NARSTO project. The QSSC should be involved with the definition of project DQOs.

The QSSC will:

- ! Provide guidance for and facilitate, as needed, the DQO development process³.
- ! Assist Principal Investigators to clearly define project assessment questions and DQOs and ensure that they guide the development of the research design.
- ! Assist Principal Investigators to document the relationship between the measurement, analysis, and assessment activities and NARSTO scientific, policy, and assessment goals.

³ EPA QA/G-4. *Guidance for the Data Quality Objectives Process*. EPA/600/R-96/055. September 1994.

- ! Assist Principal Investigators to develop assessment processes to identify and quantify the uncertainty associated with using the NARSTO scientific results in decision making processes.
- ! Coordinate with the scientific teams to provide estimates of causes and effects under alternative conditions.

2.3.3.2 Quality Assurance and Data Management Planning Support

The QSSC will support Program/Project Managers and Principal Investigators with the planning of quality assurance and data management activities. The QSSC will provide guidance and, as needed, facilitate the planning for the implementation and assessment of quality assurance, quality control and data and records management practices and procedures. The focus of these planning activities should be on enabling the program and/or project to readily determine whether or not they have met their established DQOs, quantifying the resultant uncertainty in the data set, and documenting their project activities. Support activities include:

- ! Assist Program/Project Managers with development and review of Program Quality Management Plans (PQMP), as needed.
- ! Coordinate with the Program/Project Managers to implement quality systems and data management activities to ensure the functionality of the integrated quality assessment process.
- ! Assist Principal Investigators with development of Quality Integrated Work Plans (QIWP), Standard Operating Procedures (SOPs), and Research Protocols (RPs), as needed.
- ! Provide guidance on and facilitate the planning and execution of quality system and performance audits.
- ! Work with Principal Investigators to ensure that project data and research products conform to the prescribed formats and documentation standards.
- ! Review quality-related documents (i.e., PQMP, QIWP, SOPs, etc.) prepared for NARSTO research activities.
- ! Develop and maintain the ***NARSTO Data Management Handbook***.
- ! Maintain the ***NARSTO Quality Planning Handbook***

2.3.3.3 Quality Assessment

The QSSC will adopt comprehensive quality assessment methodologies (scientific systems audit tools) that will enable the QSSC to ensure the credibility, reliability, accessibility, and policy relevancy of all NARSTO products. These methodologies, discussed further in Section 7, will provide the QSSC with the critical tools to perform the integrated quality assessment functions that are essential to achieving the main objective of the NARSTO quality assurance (QA) program.

The QSSC will focus on specific quality assurance and data management issues and perform systems and performance audits based on project objectives, requirements, specifications, and expectations for the observations, modeling/chemistry, and emissions research activities.

The QSSC will perform quality assessment activities as appropriate for the NARSTO research activities listed below, report quality deficiencies or nonconformances to standards, if any are observed, require corrective measures as appropriate, and verify implementation of corrective actions.

Observations Research

- ! Review monitoring network and project experimental designs, instrument and analytical method calibrations, and evidence of completed personnel training on standard operating procedures.
- ! Perform systems and performance audits for chemical and meteorological measurements, recognizing different approaches for criteria versus non-criteria pollutants.
- ! Perform scientific systems audits for data analysis.

Modeling/Atmospheric Chemistry Research

- ! Review model comparison results against field data, policy study design analysis, policy related uncertainty analysis and/or model intercomparison.
- ! Undertake system and, where appropriate, performance audits for laboratory and modeling activities identified by QSSC.
- ! Review experimental design, research protocols, and methods.

Emissions Research

- ! Review emission monitoring and modeling activities.

Integrated Analysis and Assessment

- ! Ensure that cross-cutting data analyses among observations, modeling/chemistry, and emissions research activities and model evaluations and validations are performed according to the integrated plan for the NARSTO science and policy objectives.

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. The QSSC will work closely with the Analysis and Assessment Team Co-chairs and will conduct integrated quality assessments as required by the Co-chairs or higher NARSTO authority.

The QSSC will prepare quality assessment reports on a regular (or assigned) schedule and will prepare an Annual Quality Assessment Report (AQAR) (Section 7.3) for submission to the Executive Steering Committee through the NARSTO Management Coordinator.

2.3.3.4 Data Management Coordination

The QSSC will work closely with Program/Project Managers and Principal Investigators to (1) develop data management specifications and guidance, (2) provide data processing and quality assurance support, and (3) facilitate the archival of NARSTO data and research products. Specific duties in these areas of responsibility include, but are not limited to:

Specifications and Guidance

- ! Establish data format and documentation specifications for data and research products and distribute and maintain specifications in the ***NARSTO Data Management Handbook***.

Data Processing and Quality Assurance

- ! Obtain data generated during past NARSTO field campaigns from Principal Investigators and program/project archives.
- ! Coordinate the quality assurance of data and metadata from past and future NARSTO field campaigns as needed.
- ! Assist in the development of NARSTO-specific data quality assessment tools.
- ! Survey analysis and data management software utilized in the scientific community with the goal of sharing approaches and software in areas like visualization, statistics, quality control, and data management.

Data Archival

- ! Coordinate the transfer of quality assured NARSTO data from Principal Investigators and program/project archives to the NARSTO Permanent Data Archive located at the NASA/Langley Research Center (LaRC) Earth Observing System (EOS) Distributed Active Archive Center (DAAC).
- ! Notify the LaRC DAAC of forthcoming NARSTO products.
- ! Facilitate the actions needed to assure data compatibility and machine interoperability with the LaRC DAAC.

- ! Manage, maintain, and upgrade as needed (in cooperation with LaRC personnel and Principal Investigators) all NARSTO products submitted to the Permanent Data Archive.
- ! Coordinate the upgrading of NARSTO products in the Permanent Data Archive.
- ! Ensure that records are maintained of all public and private requests for NARSTO products.

2.3.4 NARSTO Permanent Data Archive

The central repository for all NARSTO data and products will be the NASA Langley Research Center (LaRC) Distributed Active Archive Center (DAAC). All NARSTO data processed by the QSSC and data-related products (e.g., computer model source codes) generated by NARSTO Principal Investigators will be archived and made available from the NASA LaRC DAAC. Once data and data-related products are submitted to the LaRC DAAC they are ready for public access. The LaRC DAAC will store the data on existing LaRC DAAC mass storage hardware (i.e., 3490 tape cartridges). Data and supporting metadata will be made available to anyone without charge on a variety of media and via the Internet through the NASA Earth Observing System Data and Information System (EOSDIS) interface. It is the responsibility of the QSSC to ensure successful transmission of NARSTO data and metadata processed by the QSSC to the LaRC DAAC. NARSTO data-related products should be routed to the QSSC for archival at the LaRC DAAC.

2.3.5 Science Team Co-Chairs

NARSTO programmatic research strategies and activities will be coordinated by Science Team Co-Chairs in each of the four main research areas as described in Section 2.2. The Science Team Co-Chairs will:

- ! Identify the state-of-the-science.
- ! Identify NARSTO relevant science questions.
- ! Review research results and suggest revisions to work plans.

2.3.6 Program/Project Managers

NARSTO research activities will be planned and coordinated by Program/Project Managers who will:

- ! Identify the state-of-the-science.
- ! Identify NARSTO relevant science questions.
- ! Review research results and periodically revise work plans.
- ! Define the DQOs.
- ! Prepare a PQMP defining specific quality and data management requirements and activities following guidance provided in the ***NARSTO Quality Planning Handbook***.

- ! Coordinate with the QSSC to implement the quality systems and data management activities at the project level to ensure the functionality of the integrated quality assessment process.

2.3.7 Principal Investigators

NARSTO research projects will be planned and implemented by Principal Investigators who will develop, for each project, a QIWP as described in Section 3.1.3 and following the template provided in the ***NARSTO Quality Planning Handbook***.

The Principal Investigator will document in the QIWP during project planning that:

- ! DQOs are clearly defined and that they guide the development of the research design from which all else follows.
- ! The links between the measurement, analysis, and assessment activities, and the key policy decision junctures are established and functional.

The Principal Investigator must ensure that:

- ! Ongoing research will provide quantitative assessments of uncertainties and caveats associated with using the NARSTO scientific results.
- ! Assessment tools to be provided to policy makers, policy analysts, and air quality managers will be developed using an approved QIWP and will meet the data/product quality objectives stated therein.

For each project, Principal Investigators will develop, as needed, standard operating procedures (SOPs) as described in Section 3.1.4.

3.0 QUALITY SYSTEM DESCRIPTION

There are three levels of quality management guiding NARSTO program implementation: the Executive Steering Committee, the Program/Project Managers, and the Principal Investigators. The quality and data management specifications established by each level of NARSTO management are documented in the NARSTO Quality Systems Management Plan (QSMP), the programs' Program Quality Management Plans (PQMP), and the projects' Quality Integrated Work Plans (QIWP), respectively. Figure 3.1 shows the NARSTO quality documentation flowdown strategy. Document preparation and data management guidance is addressed in the QSMP supporting documents. Documentation of all activities involved in the collection, transfer, processing, validation, and reporting of data is of critical importance, not only for determining the quality of the data, but also for defending the quality of the data.

The quality and usability of the data and research products generated under NARSTO research and development activities are directly dependent upon the effectiveness of the quality system enacted. Data generated under NARSTO must be of known, sufficient, adequate, and documented quality if, when applicable to the measured parameter, the data are to meet the requirements of both state and federal agencies for the determination of national air pollution control strategies. Moreover, the importance of consistent implementation of an effective quality system across NARSTO projects cannot be overstated as NARSTO data may be used to establish international cross-boundary air pollution control strategies. The establishment of tri-national research partnerships for the harmonization of monitoring designs and methods should be encouraged to ensure the quality and maximum usability of the data and research products.

3.1 Quality System Documentation

The successful accomplishment of any NARSTO project depends on the communication and understanding of the needs and expectations of each management level. Quality system requirements flowdown from NARSTO management to the project implementation level. With each successive level, the specificity of requirements and quality management activities increases.

The following descriptions are presented to provide NARSTO Program/Project Managers and Principal Investigators with an understanding of the flowdown of quality system specifications and to assist with the development of quality and data management documentation. A discussion concerning the equivalency of quality systems documentation for existing and new programs/projects is in Section 3.3.

NARSTO Quality Management Documentation

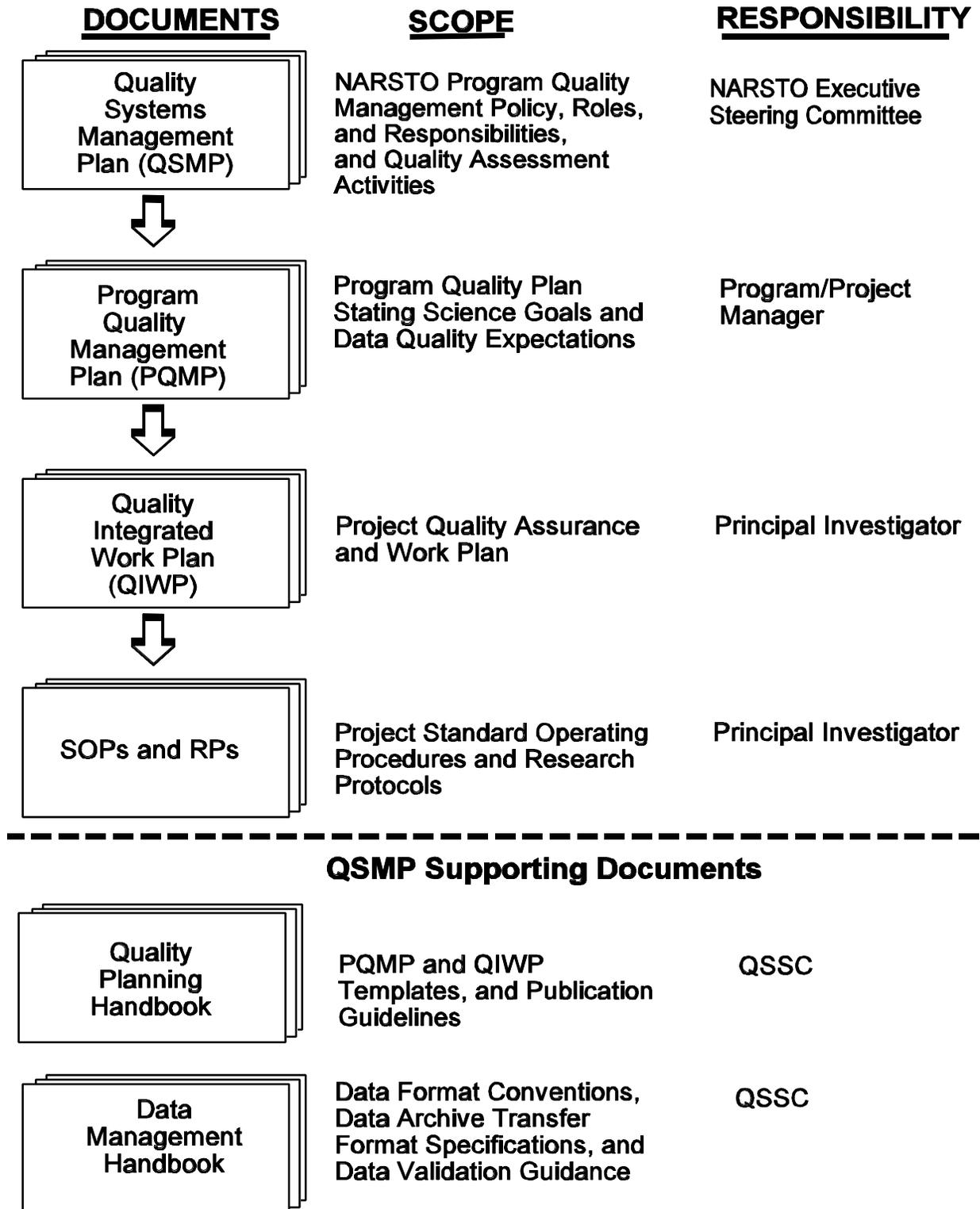


Figure 3-1. NARSTO Quality Management System Documentation

3.1.1 Quality Systems Management Plan (QSMP)

This document, the NARSTO QSMP, establishes the overarching continental NARSTO quality and data management requirements, standards, and specifications. The QSMP also defines the organizational structure and roles and responsibilities for implementing these specifications, including the role of the QSSC. The QSMP defines the responsibilities of NARSTO Program/Project Managers and Principal Investigators for identifying specific quality and data management requirements and specifications that are appropriate for their specific NARSTO program areas and tasks.

3.1.2 Program Quality Management Plan (PQMP)

A PQMP will be prepared by each NARSTO Program/Project Manager. The PQMP establishes quality and data management objectives, requirements and specifications. Individual PQMPs should describe only the directly applicable activities and expectations for that specific program. 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. The QSSC will work closely with the Program/Project Managers to assist with the preparation of the PQMP. 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*⁴. The PQMP should, at a minimum, address the following items:

- ! Program Planning and Organization
- ! Program Management Assessment and Communications
- ! Program Implementation
- ! Program Data Acquisition
- ! Program Data Evaluation and Assessment
- ! Program Data and Information Management

3.1.3 Quality Integrated Work Plan (QIWP)

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 will be prepared by each Principal Investigator before conducting monitoring, modeling, or research and development 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 whether one is developing a QIWP for a monitoring or research and development project, a model development project, or a model application project. The QSSC will work closely with the Principal Investigator and members of the program/project team to

⁴ American Society for Quality, 611 East Wisconsin Avenue, Milwaukee, WI 53201-3005, (414) 272-8575, (Publication Orders: 800-952-6587, Item T55)

provide assistance in the preparation of the QIWP. The QIWP should be submitted to the QSSC for review and concurrence and to the appropriate Program/Project Manager for approval.

To assist Principal Investigators with project planning, detailed QIWP templates have been developed that identify and describe the typical requirements for any QIWP developed for the three project types. Please see the **NARSTO Quality Planning Handbook** for a copy of the templates. Additional guidance on QIWP development may be found in the ANSI/ASQC E4-1994 Standard.

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

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

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

3.1.4 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 routine activities are often standardized, and, as such, 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. Recognizing this fact, NARSTO requires standard operating procedures (SOPs) for all routine activities. Each Principal Investigator is responsible for the development and maintenance of SOPs for their routine research activities. SOPs must be attached to or referenced in the QIWP submitted for review and comment.

Cooperation and exchange of information among Principal Investigators is encouraged during SOP development. In particular, the establishment of tri-national research partnerships for the harmonization of methods should be encouraged to ensure the quality and maximum usability of the data and research products.

Non-routine procedures and activities should be covered by research protocols (RPs). Principal Investigators are responsible for the development of RPs. A copy of the RPs must be attached to the QIWP submitted for review and comment.

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 for similar types of activities. The **Quality Planning Handbook** contains format and content guidance.

3.1.5 NARSTO Quality Planning Handbook

The Quality Planning 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. The Handbook contains the NARSTO research project publication policy and 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. Guidance and references for developing SOPs and RPs are also included.

3.1.6 NARSTO Data Management Handbook

The Data Management Handbook contains detailed data format, unit, and syntax conventions plus data archive transfer format and metadata specifications useful to project data management staff. Also included are descriptions of data quality indicator flags, data validation checks appropriate for the various levels, and guidance for managing and administering data and data systems.

3.2 Communication of Quality Assurance and Data Management Issues

The QSSC is the primary communication link between the four NARSTO research activities and the Executive Steering Committee regarding NARSTO quality assurance, quality control, and data management issues. QSSC reports to the Executive Steering Committee through the NARSTO Management Coordination Office. It works closely with the Science Review Council and the Science Team Co-chairs (i.e., observations, chemistry/modeling, emissions, and analysis/assessment).

To successfully conduct its mission of quality assessment the QSSC must have access to all data and documentation generated by NARSTO policy and research and development activities. In addition, the QSSC will require the submission of specific quality-related documentation from Program/Project Managers and the Principal Investigators (e.g., see Figure 3.1 and Section 4).

The QSSC and each Principal Investigator will prepare an Annual Quality Assessment Report (AQAR) to communicate to the Executive Steering Committee the quality management and assessment activities conducted during the previous calendar year. Principal Investigators will submit their AQAR to the QSSC for compilation into a summary report to be submitted to the Executive Steering Committee. 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.

3.3 Quality Systems Management Interactions

3.3.1 Equivalency of Quality Systems Documentation

3.3.1.1 Existing Quality Management Plans

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.

3.3.1.2 New Quality Management Documentation

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 PI completing applicable sections to a level of detail needed to meet the proposal review needs of the likely funding group(s). For an individual PI, 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.

3.3.2 NAFTA Joint Quality Assurance Program

Throughout the evolution and execution of the NARSTO quality program the QSSC will harmonize, where appropriate, procedures with the "Joint Quality Assurance Program" being developed by the North American Free Trade Agreement (NAFTA) countries and aimed at providing a reliable and harmonized characterization of the environment across the North American continent.

3.3.3 Quality Assurance Elements not Specifically Addressed in NARSTO QSMP

The NARSTO QSMP relies heavily on the ANSI/ASQC E4-1994 Standard as a source reference for structure, QA specifications, and guidelines. For QA elements not directly addressed in the NARSTO QSMP (e.g., procurement), users should refer to ANSI/ASQC E4-1994 and review specifications and guidelines for applicability. Relevant elements in other standards may also be applicable to NARSTO activities including ISO9001⁵.

3.3.4 NARSTO QSMP Implementation by Federal and State Governments, their Agencies, Private Industry, and Contractors

The QSMP becomes a requirement when invoked under the NARSTO umbrella as part of a programmatic agreement or a two-party agreement (e.g., grants, cooperative agreements, interagency agreements, and contracts). To that end, governments and their agencies, universities, and private industry participating in the NARSTO Program should implement the QSMP and incorporate applicable elements into their existing quality programs for NARSTO-related activities. QSMP requirements, in turn, flowdown to the PQMP and the QIWP for the program/project. The NARSTO QSMP should be specified as an applicable guidance/requirements source in contracts for tasks and services in support of NARSTO activities.

⁵ ANSI/ASQC Q9004-1-1994, Quality Management and Quality Systems Elements--Guidelines

4.0 DOCUMENT AND RECORDS CONTROL

Document and record control processes will be implemented to help ensure the credibility, reliability, reproducibility, and accessibility of all NARSTO documents, data, and research products. All levels of NARSTO management will establish and maintain processes for the timely preparation, review, approval, issuance, use, control, revision, and maintenance of identified quality-related documents and records. Documents, broadly defined, include all NARSTO plans, reports, data, and research products such as, models of environmental processes and conditions, and methodologies. Records are a selected subset of completed documents that provide objective evidence of the quality of an item or process and must be controlled.

The purpose of this section is to outline the process for control of quality system management documents, to identify the process for validation and access of data and research products, and specify the control of project records. The preparation and use of the appropriate documentation is essential to assure and defend the quality of NARSTO products.

4.1 Control of Quality System Management Documents

For the quality system management documents identified in Figure 3.1, the persons or organizations responsible for preparing, supporting preparation, reviewing, concurring with, and approving these documents are shown in Table 4-1. In addition, document web accessibility status and points of contact are indicated.

Documents, including revisions, should be reviewed for conformance with the quality system requirements and approved by the authorized personnel for general use. Revisions should be reviewed by the same groups as the originals.

4.2 Control of Project Documents, Data, and Research Products

By enacting a set of appropriate controls, NARSTO will assure that all project documents, data, and data products generated are of validated and documented quality, are accessible in a timely manner, and are distributed to NARSTO participants and clients after appropriate reviews. The responsibility for assuring the quality of NARSTO products does not rest solely with one group, rather it is shared by all participants with guidance from the QSSC and appropriate committees. Each Program/Project Manager will, within their PQMPs, delineate procedures for identifying, preparing, reviewing, approving, revising, maintaining, archiving, and distributing all pertinent project documents, data, and research products. The procedures developed should be pertinent to all types of documents and records, including printed and electronic media.

Documents (primarily printed media) requiring control may include, but are not limited to: health and safety plans, standard operating procedures, audit reports, field notebooks, personnel qualifications, procurement forms, equipment manuals, data reduction and analysis calculations, field data forms, and chain-of-custody forms.

Table 4-1. Quality System Management Document Control / Accessibility Summary

DOCUMENT >>>>	QSMP	PQMP	QIWP	SOPs	Quality Planning Handbook	Data Management Handbook	Annual Quality Assessment Report
RESPONSIBLE PARTY //							
Executive Steering Committee Co-Chairs	R,A						R
Management Coordinator	R,C				R,A	R,A	
QSSC	P	S,R,C	S,R,C	R	P	P	P
Science Team Co-Chairs	R,C	R,C			R,C	R,C	R
Program/Project Manager		P,A	R,A	R			R
Principal Investigator			P	P,A			P
ACCESSIBILITY							
Web Access	Yes	Referenc e	Referenc e	Referenc e	Yes	Yes	Yes
Web Configuration Control POC	QSSC				QSSC	QSSC	QSSC

A=Approve, R=Review, P=Prepare, C=Concur, S=Support Preparation, POC=Point of Contact

Data (primarily electronic media) requiring control may include, but are not limited to: sampling and analytical data, quality control data, emissions inventories, and model outputs.

Research products (both printed and electronic media) requiring control may include, but are not limited to: press releases, project summaries, project reports, draft open literature publications, air quality and meteorological models, emissions models and projections, and assessment tools, such as, methods, procedures, measurement technologies, and modeling methodologies.

4.2.1 Data and Research Product Validation

All NARSTO products must be validated. Recognizing the potential for NARSTO to generate research products other than “data” is important. Other possible products are simulation models, methods, procedures, and reports. Each of these products must be validated. A validation level and status discussion must be included in the metadata record or information associated with the research product. The following general levels of validation will be used in NARSTO, however, Program/Project Managers and Principal Investigators should specify in the PQMP and/or QIWP, more specific validation checks that will be performed for any given research product. Table 4-2 summarizes the characteristics and status of data and research products at each level of the validation process. Refer to the ***NARSTO Data Management Handbook*** for further details regarding applicable data validation checks.

Level 0 Validation consists of research products subjected to minimum processing in the field and/or in the laboratory by project staff. Level 0 designations will be given to raw data and other research products that have not been audited or peer reviewed. Level 0 status will remain in force until all audits or peer reviews associated with Level 1 validation of the product have been completed and the investigator’s response recorded.

Level 1 Validation consists of research products subjected to quality assurance and quality control checks and data management procedures. As part of the Level 1 process, site documentation is reviewed for completeness and performance compared with other locations. Compliance with documented data quality objectives, standard operating procedures, and research protocols is evaluated in the Level 1 process. Audit and peer review reports have been evaluated (and necessary corrective actions taken) for all research products designated Level 1. The comparison and cross-checking activities done under Level 1 may be conducted by the project staff, QSSC, and/or the scientific community.

Level 2 Validation consists of research products that have undergone interpretative and diagnostic analysis by the project staff or the scientific and/or client community. A validation level and status discussion must be included in the metadata record associated with the research product.

Level 3 Validation consists of research products and data that have received intense scrutiny through analysis or use in modeling.

Table 4-2. NARSTO Data and Research Product Validation, Documentation, and Access Summary

	Data and Research Product Status at Validation Levels 0, 1, 2, and 3.			
	Level 0	Level 1	Level 2	Level 3
Review Status	Raw Data and Un-reviewed Products	QA'd Data and Peer Reviewed Products	Data Analyses Completed and Products Assessed	Continuous Use in Analysis and Modeling
Processing and Reviews Performed by --	Project	Project, QSSC and Subject Matter Experts	Project and Scientific and/or Client Community	Project and Scientific and/or Client Community
Metadata Records	Incomplete	Project and QSSC Checks Documented and Review Comments Resolved	Assessment Issues Documented and Users Guides Available	Applicable Records Reviewed (e.g., site logs and performance audits)
Access	Project and NARSTO Program	Public Release	Public Release	Public Release
Distribution	Within 12 Months of Generation	When Level 1 Reviews are Complete	When Level 2 Reviews are Complete	When Level 3 Reviews are Complete
Source	Project	LaRC DAAC and QSSC	LaRC DAAC and QSSC	LaRC DAAC and QSSC
Format	Project Specific	LaRC DAAC Format and Product Specific	LaRC DAAC Format and Product Specific	LaRC DAAC Format and Product Specific
Change Control Point of Contact	Project	Project and Product Specific	Project and Product Specific	Project and Product Specific

4.2.2 Data and Research Product Access and Distribution

The research products generated by NARSTO are intended for use by participants, policy makers, and the general public. These products will be used to advance the state of scientific knowledge of oxidant and fine particulate matter precursor formation and fate in the troposphere over North America.⁶

The following policy is designed to recognize all existing agreements between sponsor and investigator, foster free exchange of information among participants, avoid debilitating controversy within NARSTO, and provide all participants the opportunity to review and comment on relevant materials. NARSTO research products include data and metadata, data models, methods, procedures, papers for publication, promotional materials, press releases, intellectual property, and all internal and external program reports and public outreach program communications. Guidelines for publication of research results are contained in the **NARSTO Quality Planning Handbook**.

4.2.2.1 Product Access

Level 0 research products generally consist of initial results that have not been officially checked and validated, but may be useful in providing preliminary consolidated results for interpretative and diagnostic analysis by participants. *Normally, these results are not approved for public release.* Level 1, Level 2, and Level 3 results are approved for public release and will be available via the Internet.

4.2.2.2 Product Distribution

Level 0 research may be distributed only within participant and co-investigator groups in response to request or as part of an automatic distribution approved by a project oversight committee. All data/products will be made available to participants within 12 months of their generation/production. Recipients of these data/products are expected to proactively participate in the quality control of the product. They may use these products in their work. However, before reporting any findings of fact, or opinion, based upon these products, the recipient must submit such reports to the provider of the research product for review and comment.

Level 1, Level 2, and Level 3 research products contained in the official NARSTO data archive have been approved for public release. Distribution of other research products will normally be affected through the responsible Program/Project Managers or the QSSC.

⁶ Major portions of the policy presented below were adopted from the Southern Oxidant Study Information Policy, January 1, 1992.

4.3 Records

NARSTO requires that sufficient records shall be specified, prepared, reviewed, and maintained to reflect the achievement of the required quality for the work completed. To reiterate, records are completed documents that provide objective evidence of the quality of an item or process. The PQMP and/or QIWP should state requirements and responsibilities for record transmittal, distribution, retention, protection, preservation, traceability, disposition, and retrievability. The PQMP and/or QIWP should also identify how the disposition of records, in accordance with regulatory requirements, schedules, or directives from senior management, will be accomplished.

5.0 PERSONNEL QUALIFICATIONS AND TRAINING

All monitoring, modeling, and research and development activities conducted under NARSTO should be conducted by qualified and trained personnel. Training and qualification requirements for personnel will be based on the project and/or specific activities to be conducted. Requirements for formalized training and/or certification of personnel will be determined by the appropriate NARSTO functional team and/or the Principal Investigator. If required, training may consist of either formalized classroom instruction or on-the-job training by the appropriate Principal Investigator or member of the functional team. The QSSC will evaluate the qualifications and training of personnel during the systems audit and management systems review.

Training will be provided by the QSSC to introduce and familiarize the appropriate personnel with the quality systems and data management documents. In addition, the QSSC may provide documentation, and if necessary training, to provide Principal Investigators and staff with a working knowledge of the quality assessment tools and quality control strategies required.

6.0 IMPLEMENTATION OF WORK PROCESSES

All research activities (projects, tasks, and studies) must be covered by an approved planning document that describes the work and how it will be implemented. The document should specify DQOs. The planning document should also discuss how the resulting data/information and research products (e.g., reports and models) will be assessed, validated, and reported. The PQMP and QIWP documents described in Section 3.1 fulfill this requirement. The project Principal Investigator should follow the approved QIWP throughout the project life cycle. However, deviations and/or changes to the approved QIWP are allowed; but such actions must be documented, and may require prior review and approval by the same authority that originally approved the QIWP. It is imperative to the credibility of NARSTO that all data and assessment tools provided to policy makers, policy analysts, and air quality managers were developed using an approved QIWP and meet the data/product quality objectives stated therein.

Work processes are defined and their execution realized through a series of flowdown steps, as shown in Section 3, Figure 3.1. This QSMP and the supporting **Quality Planning** and **Data Management Handbooks**, identify those policies, activities, and procedures that are common to all programs and projects. Program Quality Management Plans establish the DQOs and quality management requirements for programs and projects and finally, the specific QIWP, documents the who, what, when, where, why, and how of project implementation. Standard operating procedures and research protocols should be prepared for routine monitoring and research activities. Implementation of work processes should include the routine evaluation of performance against established technical and quality specifications.

7.0 COMPUTER HARDWARE AND SOFTWARE

NARSTO project monitoring, research and development, analysis, modeling, and data base management activities will rely heavily on the application of numerous computer systems utilizing various hardware and software configurations. The performance of the hardware and software will potentially affect the quality of the results. Computer hardware and software used in the NARSTO program should be installed, tested, used, maintained, controlled, and documented to meet the requirements of the user and commensurate with the risk to the project of disruptions to work schedules and the risk of potentially erroneous results affecting policy decisions. Specifically, projects must :

- ! describe the process for ensuring that all hardware and software configurations meet program requirements.
- ! describe how changes to hardware and software configurations will be controlled to assess the impact of the change on performance.
- ! describe or reference the processes for developing software, for validating, verifying, documenting, and maintaining configuration control of the software for its use, and for assuring that the software meets user requirements.
- ! describe how purchased software is evaluated to meet users requirements.

The Principal Investigator should document how the project will manage its computer hardware and software operations that directly impact the quality of the environmental data and research products.

Computer hardware and software configurations integral to a data acquisition system or measuring and testing equipment that are factory calibrated do not require further testing unless the scope of the software changes or modifications are made to the hardware/software configuration.

8.0 ASSESSMENT AND RESPONSE

To implement an effective quality assessment program will require an "end to end" approach; that is, from the establishment of data quality objectives (DQOs) to the quantification of uncertainty for "assessment tools" provided to decision makers and air quality managers. The primary focus of NARSTO quality assessment activities is the project. NARSTO quality assessment activities will include a combination of project technical self-assessments and QSSC independent management and technical assessments.

Assessment process guidelines are available to help NARSTO managers and Principal Investigators plan and carry-out their project oversight responsibilities.^{7,8} The overall process can be divided into distinct steps. The level of effort and detail necessary to complete each step depends upon the scope and complexity of the assessment. Assessments should be planned and implemented using a graded approach. Responses to assessment reports that identify conditions needing corrective action should be made in a timely manner. Once identified, appropriate actions should be implemented to correct the condition. Implementation should be documented and the effectiveness of the response verified. Projects and the QSSC will follow these typical steps for the planning and implementation of technical audits and management reviews:

- Planning
- Performance
- Report Preparation
- Corrective Action
- Follow-up and Closure

8.1 Project Technical Self-Assessment

Technical self-assessments are the most effective means to identify potential and existing problems. Reviews by those immediately responsible for overseeing and/or performing the work offer real-time process evaluation and immediate feedback to those performing the work. Projects know best their expectations for the performance of a system or process and can evaluate that relative to their documented project objectives and work plans. Therefore, each of the Principal Investigators should, in their QIWP, (1) define a series of assessment activities to identify potential and existing problems, (2) determine an implementation frequency sufficient to minimize data losses while not overburdening the project staff, and (3) establish a process to respond to any identified potential or existing problems.

8.2 Independent Assessment

The independent assessment of the activities conducted under NARSTO is of critical importance to the quality of research and monitoring activities. The QSSC will be responsible

⁷ Arter, Dennis R., *Quality Audits for Improved Performance*, Quality Press, 310 West Wisconsin Avenue, Milwaukee, WI 53203, (Publication Orders: 800-952-6587)

⁸ U.S. EPA, *EPA QA/G-3: Guidance for the Management Systems Review Process (1994 Draft Version)*, Contact Number: 919-541-7612

for conducting and coordinating the quality assessment of NARSTO activities, issuing reports documenting the results, and recommending, in conjunction with the appropriate committee, the appropriate corrective actions. The quality assessment tools to be utilized by the QSSC will consist of a series of specific audits, reviews, and, when appropriate, directed quality assessment experiments. These quality assessment tools will be tailored by the QSSC, in conjunction with Science Team Co-chairs and the Program/Project Manager, to provide a comprehensive quality assessment of the program/project under evaluation.

8.2.1 Management Systems Review

The management systems review (MSR) is an independent, qualitative assessment of an organization's quality system. The MSR will determine if the organization's quality system is being implemented in accordance with the approved QSMP and PQMP, and will evaluate the effectiveness of the quality system activities actually implemented. The MSR will examine all aspects of management systems, including planning, implementation, and other assessment processes. The results of the MSR will provide management with critical information on whether or not the applied quality system is meeting the needs of the NARSTO program. The MSR will identify any management system activities that need corrective action in order to insure that program objectives, can be met. Depending on the results of management system evaluations, the QSSC may perform additional technical quality assessments as described in the following sections.

8.2.2 Performance Evaluation

The performance evaluation (PE) is a quantitative examination of the measurement system utilizing independent, traceable standards. The PE is conducted by an independent auditor and may assess all or selected procedures conducted by a particular measurement system, from sample introduction through data reduction. To assure that the PE is unbiased, the independence of both the auditor and the audit materials are of critical importance. In those instances where the PE can not be conducted by the independent auditor, the audit standards will be provided to the analyst as "blind" samples so that the identity and concentration of the standards is unknown to the analyst. The results of the PE will be used to document the overall precision and bias of the measurement system being evaluated and determine if the measurement system is within the pre-established control limits. Based on the PE results, corrective actions may be required. Performance evaluation data must be flagged.

8.2.3 Systems Audit

The systems audit is a qualitative evaluation of all aspects of a measurement system conducted by an independent auditor. The systems audit will assess and document the facilities, equipment, standards, personnel qualifications, records, standard operating procedures, data storage, data reduction, data validation, operations, maintenance, and quality control protocols. The systems audit will use the approved QIWP and other project-specific quality documentation as the criteria for the audit and will look at procedures, documentation, and, in some cases, actual operations. At no time will the measurement system be challenged with standards. The information generated during the systems audit will be used to assess the compliance of the system with in-use project management and operations documentation. In addition, the systems audit may provide information on the comparability of the measurement system with other measurement systems. When used in conjunction with the performance

audit, the systems audit will document when the measurement system does not meet data quality objectives and provide useful information in formulating the appropriate corrective actions.

8.2.4 Data Quality Audit

The data quality audit is an independent evaluation of the protocols involved in the collection, transfer, processing, reporting, and validation of data. These activities are evaluated through a detailed review of the procedures, equipment, and programs used to process the raw data to the finished data product. In addition to the review of the previous activities, the data quality audit will assess the appropriate data quality indicators and the procedures for determining them. The success and or failure of the data to meet these data quality indicators will be documented and included in the database with appropriate flags.

8.2.5 Intercomparisons

The unique research nature of many NARSTO projects will generate data using non-standard methodologies. In many instances primary standards for these methodologies will be unavailable, thus rendering meaningless any attempts at assessing the data accuracy through performance audits. In these instances, the QSSC may recommend that the Principal Investigator(s) conduct a series of method comparison experiments to address the comparability of non-standard measurement techniques.

8.2.6 Surveillance

The QSSC may undertake on-site surveillances to observe field and laboratory monitoring and analysis activities and to confirm that procedures are being implemented as defined by the program/project. A surveillance plan and checklists will be developed based upon program/project procedures and applicable quality documentation. The plan, which identifies the scope and objectives of the surveillance, will be provided in advance to program/project managers. The field and laboratory activities will be evaluated for adherence to specified requirements. Any nonconformances will be documented in a surveillance report to program/project management as well as any positive observations that identify good practices. Program/project management will document and initiate actions as appropriate to correct conditions adverse to quality. The QSSC will verify the timely and effective completion of corrective actions.

8.2.7 Historical Data Evaluation

There will be instances when NARSTO research and development projects leave the project scientists no alternative but to use historical data sets that carry no quality indicators. In such cases, the appropriate NARSTO Program/Project Managers and the QSSC must be informed of the situation. The QSSC may suggest data set comparisons, special statistical treatment, or peer review in an attempt to establish some indication of "quality" for the data set under consideration. Historical data sets should be approved by the NARSTO Program/Project Manager and a QSSC representative before they are used on any project under the NARSTO umbrella.

Historical data from NARSTO affiliated regional programs, including the NARSTO-Northeast⁹, NARSTO-Canada East¹⁰, Southern Oxidant Study¹¹, and the 1997 Southern California Ozone Study¹² will be quality checked by the QSSC and archived at the PDA for use by the NARSTO research community and the public.

8.3 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 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 DQOs

⁹ Korc, Marcelo, Paul Roberts, and Don Blumenthal. *NARSTO-Northeast Data Management Plan*. Version 3.1, May 1996.

¹⁰ Racki, Manuela. *NARSTO-Canada East 1996 Meta Data Report*. July 1997.

¹¹ U.S. EPA, SDC-0055-080-SG-5003: *Southern Oxidant Study Data Archive (SOSDA) Users Guide*. November 1995.

¹² Fujita, Eric M., et al. *1997 Southern California Ozone Study (SCOS97) Field Study Plan*. June 1996.

9.0 QUALITY IMPROVEMENT

The quality of monitoring, modeling, and research and development products generated under NARSTO is the responsibility of NARSTO participants at all levels. When significant problems and/or deviations are identified, root causes must be determined. Actions must be taken to correct existing problems and to prevent future occurrences.

Quality improvement can be thought of as three distinct, yet interrelated activities: prevention, detection, and correction. Each Program/Project Manager will discuss, in their respective PQMP, the procedures and systems established to prevent, detect, and correct problems that could adversely effect the ultimate achievement of the quality objectives delineated by the Program/Project Manager.

Preventing problems that adversely effect quality is best conducted through a systematic program of advanced planning. The NARSTO problem prevention program is incorporated under the three-tier quality planning approach detailed in Section 3.0. The *first tier*, the Quality Systems Management Plan (QSMP), sets the overarching continental NARSTO quality and data management requirements, targets, standards, and specifications. The *second tier*, the Program Quality Management Plan (PQMP), is where the NARSTO Program/Project Managers establish their quality and data management objectives, requirements, and specifications. The *third tier*, the Quality Integrated Work Plan (QIWP), is where project Principal Investigators (1) discuss their understanding of the issues and the science, (2) develop project quality objectives in accordance with the PQMP and any other pertinent technical/management/client input, and (3) describe how the agreed upon objectives will be achieved to meet the client's product quality expectations. The QIWP will also address preventative measures, including personnel training, systems maintenance, and operating procedures.

The QSSC will, as described in Section 7.0, coordinate a series of audits aimed at detecting and correcting problems. However, these activities can not be conducted at a frequency sufficient to allow NARSTO to depend on them as the only activity for problem detection. Therefore, each of the Principal Investigators must, in their respective QIWP, delineate a series of assessment activities to identify potential and existing problems. These activities must be conducted at a frequency sufficient to minimize data losses while not overburdening the project staff.

Frequent monitoring of equipment and data products, an active program of quality control, and frequent correspondence between Principal Investigators and their staff are crucial to the prompt identification of problems. The detection of problems, both actual and potential, is accomplished by frequent and systematic monitoring of parameters indicating acceptable performance by both equipment and personnel. A discussion of such activities will be included in the QIWP. It will be the responsibility of Program/Project Managers to conduct adequate management oversight to ensure that these activities are being performed and that prompt corrections are made to minimize any adverse effects on NARSTO products.

The final step toward improving quality is the correction of problems. Once a problem has been identified steps must be taken to correct the problem and prevent its reoccurrence. A corrective action report should be initiated. Correction of problems can occur within the NARSTO structure from either management-level downward or from the staff-level upward. In

either situation, open correspondence is of critical importance to assure that all view points are considered and that management and staff concur on the corrective action. If required, corrective actions may be referred to the appropriate Science Team Co-Chair, ad hoc committee, or the QSSC for review and recommendation. In any case, the QSSC should be kept in the communications loop.

10.0 DATA MANAGEMENT

NARSTO is a composite organization consisting of federal/state/local governments, private industries, and academic institutions in Canada, Mexico and the United States. Collaboration, cooperation, and exchange of information among participants are critical to the success of NARSTO. NARSTO must balance the need for timely access to and distribution of electronic data across the program with the need for scientists to have sufficient time and flexibility to collect, quality assure, and analyze project data. The data management approach provides for the short-term maintenance of project data on distributed project data systems followed by the timely transfer of quality assured data to a long-term permanent data archive (PDA, Section 2.3.5). The PDA is accessible to the public. *In keeping with the philosophy of openness and sharing established in the NARSTO Charter, NARSTO Principal Investigators should make their data available to NARSTO partners and to the public within one year after data collection/generation*¹³.

Project scientists should adopt the data validation protocols discussed in Section 4 and the data format conventions described below to ensure data compatibility. NARSTO scientists are encouraged to comply with prevailing and future spatial data policy, public access policy and metadata content standards. NARSTO scientists should strive to document their data at a level sufficient to satisfy the well known “20-year test”. That is, someone 20 years from now, not familiar with the data or how they were obtained, should be able to find data of interest and then fully understand and use the data solely with the aid of the documentation archived with the data.¹⁴

10.1 Data Validation

All NARSTO products must be validated. Recognizing the potential for NARSTO to generate research products other than “data” is important. Other possible products are simulation models, methods, procedures, and reports. Each of these products must be validated. A validation level and status discussion must be included in the metadata record or information associated with the research product. The following general levels of validation will be used in NARSTO. Program/Project Managers and Principal Investigators should, however, specify in the PQMP and/or QIWP, more specific validation checks that will be performed for any given research product. Refer to the **NARSTO Data Management Handbook** for further details regarding applicable data validation checks. The following validation information is repeated here for completeness.

¹³ A program/project may specify an alternative data archival schedule in their approved PQMP/QIWP if project data delivery logistics, data validation activities, or data analysis activities will require more time.

¹⁴ National Research Council, Committee on Geophysical Data, *Solving the Global Change Puzzle, A U.S. Strategy for Managing Data and Information*, National Academy Press, Washington, D.C., 1991.

Level 0 Validation consists of research products subjected to minimum processing in the field and/or in the laboratory by project staff. Level 0 designations will be given to raw data and other research products that have not been audited or peer reviewed. Level 0 status will remain in force until all audits or peer reviews associated with Level 1 validation of the product have been completed and the investigator's response recorded.

Level 1 Validation consists of a complete data set of specified quality. The research products have been subjected to quality assurance and quality control checks and data management procedures. As part of the Level 1 process, site documentation is reviewed for completeness and performance compared with other locations. Compliance with documented data quality objectives, standard operating procedures, and research protocols is evaluated in the Level 1 process. Audit and peer review reports have been evaluated (and necessary corrective actions taken) for all research products designated Level 1. The comparison and cross-checking activities done under Level 1 may be conducted by the project staff, QSSC, and/or the scientific community.

Level 2 Validation consists of research products that meet Level 1 criteria and have also undergone interpretative and diagnostic analysis by the project staff or the scientific and/or client community. A validation level and status discussion must be included in the metadata record associated with the research product.

Level 3 Validation consists of research products and data that meet Level 2 criteria and have also received intense scrutiny through analysis or use in modeling.

10.2 Metadata Records

Metadata is information about the content, quality, condition, and additional characteristics of data or other research products. All NARSTO data and research products will have metadata records. The "Content Standards for Digital Geospatial Metadata,"¹⁵ approved by the Federal Geospatial Data Committee on June 8, 1994, has been mandated for use in the federal sector and encouraged in the private sector in an attempt to standardize geospatial data documentation. NARSTO embraces this standard and recommends its use, where applicable, by all NARSTO researchers. *A copy of the standard and a sample metadata can be obtained through the FGDC web site (<http://www.fgdc.gov/>) or via the "Anonymous FTP Address" given in the footnote at the bottom of this page.* A metadata record should be archived with the data/product it describes or it may be referenced and archived at a remote location.

10.3 Data Format Conventions

NARSTO will generate and use data and information in four major categories: *in situ* observations, remote sensing observations, gridded data, and geographic information system (GIS) coverages. These data may be formatted by individual projects in a number of ways to maximize local analysis and storage efficiency. It is important, however, that data transmitted to other NARSTO participants and the PDA conform to a common set of unit, syntax, and

¹⁵ Federal Geographic Data Committee Secretariat, c/o U.S. Geological Survey, 590 National Center, Reston, VA 22092, (703) 648-5514, Anonymous FTP: fgdc.er.usgs.gov

format conventions. Limiting the number of formats will facilitate data and research product sharing and minimize the conversions necessary to load the data into the permanent archive. These data format conventions are specified in the ***NARSTO Data Management Handbook***.

10.4 Data Archival

The types of electronic data envisioned in NARSTO PDA are: observational data (surface and aloft), image data, and modeling data. In addition, the PDA will accept Validation Level 0 (i.e., raw) data to ensure its long-term retention and availability.

NARSTO Principal Investigators will quality assure, validate, and store the data they produce. Each of these processes shall be carried-out in accordance with the recommendations and guidelines provided in this QSMP. NARSTO data may be stored by the Principal Investigator in one or more project data management systems or regional or program data archive. However, all NARSTO project data should be copied to the NARSTO PDA one year after collection/generation. If this is an unreasonable burden on a project, a program/project may specify an alternative data archival schedule in their approved PQMP/QIWP. Justification for an alternative schedule might include, for example, predefined project data delivery dates or extensive data validation and analysis activities requiring more time. The data archiving schedule should in no way limit or restrict the sharing of data within the program/project.

The NARSTO PDA is maintained by the Distributed Active Archive Center (DAAC) located at the NASA/Langley Research Center (LaRC). The LaRC DAAC will provide connectivity, search, browse, order and delivery systems to all parties interested in using the research products generated under the NARSTO umbrella. It will serve as the primary repository for all quality assured NARSTO data and final data products. The data transfer format and documentation requirements are contained in the ***NARSTO Data Management Handbook***. The QSSC Data Management Coordinator (see Section 2.3.4.4) will function as the link between the various programs/projects and the NARSTO PDA.

10.5 Data Retrieval

NARSTO data can be retrieved over the Internet using the NARSTO Home Page. Links are available from the NARSTO Home Page to the PDA at the LaRC DAAC. Additional links may be available to participating NARSTO organizations. Through these links, interested parties will have access to NARSTO databases and other related data sets. The NARSTO Home Page address is as follows: <http://narsto.owt.com/Narsto/>.

DEFINITIONS

Definition and usage of terms for the NARSTO QSMP are consistent with the American National Standard ANSI/ASQC E4-1994: "Specifications and Guidelines for Quality Systems for Environmental Data Collection and Environmental Technology Programs¹⁶" and the U.S. Environmental Protection Agency's definitions and usage of terms as identified in the glossaries of the following documents. The NARSTO scientific community is encouraged to adopt these definition and usage guidelines for their NARSTO programmatic documents and research reports. These documents are accessible at URL:

[http://www.epa.gov/r10earth/offices/oea/qaindex.htm#National QA Guidances.](http://www.epa.gov/r10earth/offices/oea/qaindex.htm#National%20QA%20Guidances)

EPA QA/R-5 EPA Requirements for Quality Assurance Project Plans

QA/R-5 is the intended replacement for QAMS-005/80. This external policy document will establish the requirements for QA Project Plans prepared for activities conducted by or funded by EPA. It is intended for use by organizations having extramural agreements with EPA. Current Draft Version: October 1997.

Availability: Final, April 1998. This document was placed into the Agency's directives clearance process in October 1997.

EPA QA/G-5 Guidance on Quality Assurance Project Plans

QA/G-5 provides non-mandatory guidance to help organizations develop a Quality Assurance Project Plans (QAPPs) that will meet EPA expectations and requirements. The document will provide a linkage between the DQO process and the QAPP. It will contain tips, advice, and case studies to help users develop improved QAPPs.

Final Version: EPA/600/R-98/018, February 1998.

¹⁶ American Society for Quality, 611 East Wisconsin Avenue, Milwaukee, WI 53201-3005, (414) 272-8575, (Publication Orders: 800-952-6587, Item T55)