

NatureServe

Quality Management Plan

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Submitted to:
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Wetlands Program Development Grant:
**Biodiversity Values of Geographically Isolated Wetlands:
An Analysis of 20 States**



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NatureServe Quality Management Plan

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NatureServe Quality Management Plan

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{TC" Approval Page "}

In accordance with EPA Order 5360.1, following is a Quality Management Plan for all work involving the collection, inventory, monitoring, assessment, and management of information on species and ecosystems, and the development of information products, data management tools, and conservation services by or under the control of NatureServe, whenever such work is funded wholly or in part by the U.S. Environmental Protection Agency.

NatureServe Concurrence:

_____ Date: _____
Mark Schaefer
President and CEO

NatureServe Approval:

_____ Date: _____
Mary Klein
VP of Natural Heritage Network Operations and
NatureServe Quality Assurance Manager

EPA Approval:

_____ Date: _____
Margarete Heber, QA Manager
QA Officer, Office of Wetlands, Oceans and Watersheds

NatureServe Quality Management Plan

Section 1. MANAGEMENT AND ORGANIZATION

The purpose of this section is to document the overall policy, scope, applicability, and management responsibilities of the NatureServe quality management system.

1.1 NatureServe

NatureServe is a non-profit conservation organization dedicated to providing the scientific information and technology needed for effective conservation. NatureServe represents a network of member programs that collect, aggregate, and analyze data about the plants, animals, and ecological communities of the Western Hemisphere. Known as natural heritage programs or conservation data centers, these programs operate in all 50 U.S. states, in 11 provinces and territories of Canada, and in many countries and territories of Latin America and the Caribbean. NatureServe and its natural heritage member programs not only collect and manage detailed information on species and ecosystems, but develop information products, data management tools, and provide conservation services to help meet local, national, and global conservation needs.

1.2 Mission Statement

NatureServe's mission is to develop, manage and distribute authoritative information critical to the conservation of the world's biological diversity. As described in our 2001 Strategic Plan, *Knowledge to Protect the Diversity of Life*, NatureServe's vision is to help protect the world's plants, animals, and ecosystems by improving society's understanding of biodiversity and making this knowledge easily accessible to the public and those making decisions about land and water use. To accomplish this, NatureServe will develop needed data, tools, information products and expertise, and will provide objective, relevant and authoritative information that is easy to access, understand and use.

1.3 Quality Policy

NatureServe regards quality assurance and quality control activities as essential to the integrity of our data – its collection, management, evaluation, and analysis – and vital to our reputation as providers of high quality, unbiased information on species and ecological communities. Scientific data developed by NatureServe, or by NatureServe's network of natural heritage program members, are expected to meet established internal methodologies, criteria, and standards in order for the data to be deemed acceptable for use by others and included in projects and data products.

The goal of this Quality Management Plan (QMP) is to assure that decisions resulting from analyses of the data are based on sound science. Quality control procedures, both at the NatureServe corporate level and within individual member programs, are described in

the QMP to ensure that this goal is achieved, specifically through addressing the following:

- Objectives must be clearly defined for each NatureServe project;
- Existing NatureServe/natural heritage data models and methodologies defined for data collection, management, research, and analyses must be utilized, or in cases where NatureServe-specific methods are lacking for specific tasks in a project, methods and data analysis models to be used must conform to generally accepted standards and approaches within the relevant scientific discipline.
- Peer review is an important element of NatureServe's QA process, and must be carried out prior to publication or public release of the results from covered projects.
- Methodologies, criteria, and requirements defined for a project must ensure that the types of data collected and the procedures for collecting, managing, evaluating, and analyzing these data, will provide scientifically accurate results for interpretation.

To achieve the objectives enumerated above, NatureServe is committed to providing sufficient resources, including budget, staff, expertise, and time, for quality control procedures, thus ensuring a consistent approach to all EPA-funded research involving the collection and assessment of species and ecological community data.

1.4 Authority of Quality Assurance Managers

The implementation of quality control procedures within NatureServe requires that a number of individuals implement QA procedures to ensure that data at all levels – from data collection through the development of data products and analyses – meet the QMP. Appendix A provides specific details on NatureServe departments and staff responsible for these processes.

This Quality Management Plan designates Mary Klein, NatureServe Vice President of Natural Heritage Network Operations, as the Quality Assurance Manager (QA Manager) to ensure that these procedures are utilized for all covered NatureServe projects. The QA Manager is assisted by a Quality Assurance Team (QA Team) consisting of the QA Manager and the Director of Heritage Data Services Department (Shara Howie) together with the Director of the Science Information Resources Department (Margaret Ormes).

Implementation of quality assurance processes for data products and assessments developed for a specific NatureServe project is the responsibility of the manager of that project. Quality control processes utilized during the exchange of data between NatureServe and natural heritage member programs are implemented by information managers for the different science disciplines and natural heritage data services specialists. Within member natural heritage programs, the data manager typically has the role of ensuring that quality control procedures are implemented in the collection and management of data. QA responsibilities at these different levels are described below.

NatureServe QA Manager and QA Team

- Provides guidance on preparing the QMP;
- Annually updates the QMP;

- Provides guidance to project managers on complying with the QMP and, where necessary, preparing Quality Assurance Project Plans (QAPPs).

NatureServe Project Manager

- Prepares the QAPP for covered projects, which includes a description of the methodologies to be used and indicates project milestones that will require a QA review;
- Oversees data aggregation, assessments, analyses, and interpretation of the project results;
- Submits products to peer review as appropriate, and coordinates responses to reviewers comments.

NatureServe Heritage Data Services Specialist and Science Information Manager

- Utilizes quality assurance procedures incorporated in rules for matching and committing tabular and spatial data received from member programs;
- Utilizes quality assurance procedures through the application of import rules in order to copy data into the central databases;
- Applies quality control processes to verify tabular and spatial record integrity.

NatureServe Science Information Manager

- Implements quality assurance procedures in confirming scientific names, taxonomy, legal status, and assigned conservation status for species and ecological community data received from member heritage programs;
- Utilizes quality control processes to reconcile any differences between NatureServe central database information and data received from programs;
- Oversees the quality assurance processes utilized in data collection, entry, and management by NatureServe scientists.

Member Program Data Managers

- Oversees the quality assurance processes utilized in data collection, entry, and management by scientists and other program staff;
- Implements quality control procedures in the exchange of data with NatureServe.

The NatureServe QA Manager is encouraged to submit recommendations for modifications to the review process to be considered in the annual update of the NatureServe QMP. In addition, concurrence on the QMP and individual QAPPs will be obtained from the appropriate NatureServe supervisory staff.

1.5 Technical Activities and Programs Supported

The QMP described in this document is utilized for EPA-funded research and projects involving the collection, aggregation, and/or analysis of data on species and ecological communities and systems. The QA Manager shall periodically contact Project Managers (PMs) to review any project schedule changes that may affect Quality Assurance (QA) review. When a project milestone is reached that requires a QA review, the PM for that project has the responsibility of discussing the review with the QA Manager. Any

substantive findings of the QA review shall be resolved by consultation between the PM and the QA Manager before work on the project proceeds.

1.6 Management Commitment

The Quality Assurance program for NatureServe funded projects shall be managed by the NatureServe QA Manager. Sufficient resources shall be budgeted within the project to ensure that both the QA Manager and individual PMs are able to fulfill their responsibilities under this plan. PMs will assure that the quality system is understood and implemented by developing QAPPs, providing them to staff working on the projects, and overseeing implementation of the plans.

NatureServe Quality Management Plan

Section 2. QUALITY SYSTEMS COMPONENT

The purpose of this section is to document how NatureServe manages its quality system. This section defines the primary responsibilities for managing and implementing each component of the system.

2.1 NatureServe Quality System Description

The NatureServe QA System varies depending on whether QA procedures are applied by NatureServe staff (either through work on specific project or as part of data exchange with a member heritage program), or implemented within a natural heritage member program. Quality Systems at different levels are described below.

NatureServe – Project QA

1. Guidance by the QA Manager to staff preparing an application for EPA funding;
2. Designation of the PM by the relevant NatureServe Vice President prior to submission of a grant proposal to the EPA;
3. Preparation of a QAPP for a funded project by the designated PM, and independent review of the plan by the QA Manager and/or QA Team;
4. Evaluation of the data needed, sources for that data (e.g., NatureServe central databases), and software, expertise, staff, and any training needs for the project by the PM;
5. Periodic review by the PM of project tasks including data management, aggregation, evaluation, and analyses, as well as the release of information generated by the funded project;
6. Periodic review of the overall quality management system by the QA Manager and QA Team;
7. Preparation of the annual update for the NatureServe QMP by the QA Manager, and submission of the update to the EPA QA Manager.

NatureServe – Data Exchange QA

1. Utilization of rules for reconciling species and ecological community data received from member programs by database project specialists;
2. Further reconciliation of these data by botanical, zoological, and ecological science information managers, along with confirmation of specific attributes of these data and reconciliation of any discrepancies;
3. Application of import rules to these data and resolution of any data issues that result by the conservation data specialist;

4. Utilization of quality control processes to verify record integrity for the tabular and spatial records representing the imported data by the conservation data specialist.

NatureServe – Data QA

1. Periodic review, typically by the science information manager and heritage data services specialist, to ensure that standard methodologies and QA processes are utilized in data collection, entry, and management by NatureServe scientists and staff;
2. Identification of training needs for staff to ensure familiarity with natural heritage methodology and quality control procedures utilized with NatureServe, and provide or arrange for appropriate training;
3. Evaluation of data received from sources other than NatureServe scientists to ensure its reliability and quality before it is deemed acceptable for inclusion in the NatureServe database.

Natural Heritage Member Program QA

1. Periodic review, typically by the data manager, to ensure that standard methodologies and QA processes are utilized in data collection, entry, and management by scientists and other program staff;
2. Identification of training needs for staff to ensure familiarity with natural heritage methodology and quality control procedures utilized in the program, and provide or arrange for appropriate training;
3. Evaluation of data received from sources other than natural heritage program scientists to ensure its reliability and quality before it is deemed acceptable for inclusion in the program database;
4. Utilization of quality control procedures in both preparing data to be exchanged with NatureServe, and in reconciling data received from NatureServe upon completion of the exchange process.

2.2 Quality System Components

Components of the NatureServe quality system include:

Quality System documentation, which incorporates the QMP and project QAPPs. A QAPP is to be prepared for each applicable project by the designated PM, and reviewed by the QA Manager and/or QA Team. QAPPs shall include a detailed description of the methodologies to be used in the project, as well as schedules that provide specific project milestones requiring QA review.

NatureServe methodology documentation, which sets forth standards for all aspects of NatureServe data management processes, including procedures for how data is collected, mapped, and managed in member programs, as well as how ranking criteria are developed and conservation status assigned by NatureServe staff scientists. Most methods documentation is embedded in the Biotics 4 data management software that is in use by NatureServe and most of its natural heritage program members. Additional documentation is available in an online Biotics Knowledge Base.

NatureServe data exchange documentation, which provides stringent rules and detailed guidelines for evaluating data received from member programs, and reconciling differences and any other data issues before the data are accepted and added to the NatureServe Central Databases.

Natural Heritage Program documentation, which sets forth standard policies for work performed within the programs, including specific quality assurance and quality control procedures for species and ecological community data management.

Training programs are held regularly and are available to NatureServe and member program staff in order to familiarize them with fundamental NatureServe concepts and processes, including methodology, data models, and software applications used in collecting, managing, mapping, and assigning ranks to species and ecological community data, and the QA policies and procedures associated with these tasks. The cornerstone of this methodology and quality assurance training is a week-long core heritage training session, offered quarterly. The most recent session, held in October 2004, represented the 106th such session. More specialized training is provided for staff on topics such as distribution modeling and database administration, as well as advanced training on custom software applications. Presentations and other documentation created for training are published and available to all staff on an ongoing basis.

Quality Assurance Project Plans (QAPPs) are prepared by PMs for their designated projects, and each provides a description of the methods and QA procedures that will be used in project work.

Data Verification and Validation are specific for each project, and provide the means of ensuring that data assessment, evaluation, and analyses will enable scientifically valid interpretations of data.

2.3 Quality System Tools

NatureServe quality system tools consist of:

Quality Management Plan, which provides an overall system for implementing quality assurance policies.

Documentation of quality assurance procedures embodied in NatureServe and heritage methodologies and embedded in NatureServe's Biotics 4 software, the rules and guidelines for data exchange, and local member program processes for collecting and managing data.

Software routines for conducting standard data consistency procedures prior to the incorporation of member program data into NatureServe Central Databases

Training Programs, which familiarize staff with NatureServe and heritage methodologies, including quality assurance and control processes.

QAPPs, which provide project-specific descriptions of the methods and QA procedures to be used.

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Section 3. PERSONNEL QUALIFICATIONS AND TRAINING

The purpose of this section is to document the procedures for assuring that all personnel performing work for NatureServe have the necessary skills to effectively accomplish their work.

3.1 Statement of Policy

NatureServe and its natural heritage member programs endeavor to ensure that their staff and affiliated contractors have the knowledge and skills required to fulfill their job responsibilities, including such tasks as collecting, managing, mapping, and assigning ranks to species and ecological community data. In addition, some staff are required to have specialized knowledge on the use of custom software applications, distribution modeling, and various other analyses. Further, familiarity with NatureServe policies, methodologies, and any special requirements associated with EPA-funded projects are also required of staff and associated contractors.

3.2 Assuring Minimum Training and Skill-level

The PM shall prepare and submit to the appropriate NatureServe corporate supervisory staff a QAPP for the project that, among other things, identifies all critical staff needs. Critical staff are those individuals directly involved in data management, mapping, ranking, analysis, and, in some cases, data modeling. When new staff are to be hired, the position description shall identify the desired academic preparation and background experience, along with any specific job skills that are required.

The PM has lead responsibility to assemble necessary staff to undertake the project. When additional staff are hired, different levels of administrative oversight are applied depending on the number of hours per week and the duration of employment. All new staff positions are administered through individual departments, which are under the specific guidance of the PM and the general administrative guidance of NatureServe corporate staff.

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Section 4. PROCUREMENT OF EQUIPMENT, SUPPLIES, AND SERVICES

The purpose of this section is to document the procedures for purchasing equipment, supplies, and services that directly affect the quality of EPA-funded project results.

4.1 Procurement Procedure

The NatureServe Director of Grants and Contracts director, working with the Director of Finance and Operations, oversees all purchases incurred through EPA-funded grants. These departments are responsible for monitoring all financial activity to ensure compliance with applicable federal, state and awarding agency guidelines. Because project regulations are varied and complex, the NatureServe Grants and Contracts staff are available to provide PMs with assistance in understanding policies, procedures and related guidelines. The NatureServe Grants and Contracts department requires that the PM (or his/her designee) obtain a purchase order prior to purchasing any item through the NatureServe account.

4.2 Review of Responses to Solicitation

Specifications for all relevant purchases shall be prepared by the PM as part of the QAPP. As such, all purchase of items and all procurement of services are subject to the review of the QA Manager to ensure that said items and services satisfy all technical and quality requirements for the project. Should purchases, other than those explicitly identified in the QAPP be proposed, review of purchase specifications should be made by the QA Manager prior to initiating the purchase.

4.3 Quality Assurance for Procured Items and Services

Once an item or service is procured, it shall be the responsibility of the PM to examine the deliverables to verify that the item or service is of acceptable quality.

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Section 5. QUALITY DOCUMENTATION AND RECORDS

The purpose of this section is to document appropriate controls for quality-related documents and records that are determined to be important to the mission of NatureServe.

5.1 Identification of Documents Requiring Control

The PM, as part of the preparation of the QAPP, shall identify quality-related documents and records that require control. The QA Manager, as part of their QAPP review, may further expand the list of documents requiring control. All documents requiring control shall be listed in the QAPP and be subject to EPA review.

5.2 Conformance Review and Approval

Documents and records prepared as part of quality system requirements and listed in an approved QAPP as requiring control shall be subject to a systematic procedure to ensure their conformance with all technical requirements. The QAPP shall indicate the names of individuals authorized to issue, authenticate, revise and approve such documents. Any changes in the list of individuals so authorized shall be communicated to EPA.

5.3 Document Maintenance

Duplicate copies shall be made of all quality-related documents that are required as part of a project. The PM shall each maintain such documents in a project file for a period of not less than three-years following the completion of the project. The Finance and Operations department will maintain the official grant records for the project. Completion of the project shall mean the end of the grant contract. If required by EPA, copies of the quality-related documents shall be submitted to EPA as part of the final project report and other project closeout documentation.

5.4 Ensuring Legal Compliance

The PM, in consultation with the QA Manager, shall be responsible for ensuring that the non-financial, substantive aspects of EPA-funded work are, and remain in, compliance with applicable statutory, regulatory and EPA requirements for documents and records.

5.5 Data Sharing and Confidentiality Procedures

The QAPP shall reference the relevant data sharing agreement(s) between NatureServe and any natural heritage member programs that provide species and ecological community data for use in the project. In addition, the QAPP shall describe any confidentiality procedures to be used when the project involves the assessment, aggregation, management, and analysis of sensitive data, and should specify the types of documentation to be maintained in association with data sensitivity, if appropriate.

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Section 6. USE OF AUTOMATED DATA PROCESSING SYSTEMS

The purpose of this section is to document how NatureServe ensures that computer hardware and software satisfy the intended use.

6.1 Computer Hardware, Software, and Data Acquisition

The NatureServe Information Technology (IT) department provides oversight for the acquisition of computer hardware and software applications. PMs proposing the acquisition of computer hardware or software as specified and budgeted for the project will process their request through the IT manager. The PM will be responsible for

- Assessing and documenting any impacts of hardware and software changes;
- Evaluating and approving updated, expanded, or revised computer hardware and software to support data review and reporting activities;
- Ensuring that data and information managed and/or produced with computers will meet applicable project requirements.

6.2 Technical and Quality Requirements

The technical and quality requirements for computer hardware and software to be purchased for the project are prepared by the PM and reviewed by the IT manager. The use of computer hardware and software for the project is not subject to further involvement by the IT manager unless requested by the PM.

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Section 7. QUALITY PLANNING

The purpose of this section is to document how individual data operations are planned within NatureServe and its natural heritage member programs to ensure that data collected are of the quality necessary for the desired use.

7.1 Project Manager Involvement

The role of the QA Manager is limited to informing individuals preparing applications for EPA funding of the quality assurance requirements and advising PMs during the preparation of QAPPs of the need to incorporate systematic quality planning processes. Whenever the results of a research project have the potential of directly impacting other decision-making processes, the QA Manager shall advise the PM to seek the input of the affected parties during the preparation of the QAPP to ensure that the results are presented in a meaningful manner and meet the needs of the subsequent decision-makers. The QA Manager shall review the plan of work and periodic progress toward the completion of the funded project.

7.2 Determining Project Goals and Objectives

The proposal prepared for a project must identify the goals and objectives of that project. Due to the diversity of potential topics that may be proposed, no specific guidance is given to staff preparing proposals. However, all proposals are expected to include a clear statement of their purpose and, where applicable, the expected use of the information that is to be developed. Only when a proposal is of an applied research nature, and only when a specific policy or operational decision is to be made based on the research findings, will the systematic Data Quality Objectives process [as specified in *EPA Guidance for the Data Quality Objectives Process (QA/G-4)(EPA 1994)*] be applied.

7.3 Project Scheduling

General project schedules are to be provided as part of the proposal for project funding. More specific project schedules are to be developed as part of the QAPP for funded projects. Specific project schedules are to identify all applicable regulatory thresholds, contractual deliverables, the timing of resource needs (including staff, materials, equipment, and supplies), and any quality assurance intervals for QA Manager review.

7.4 Data Quality Needs

The type and quantity of data needed, sources of data, means of obtaining data, methods for analyzing data, determination of how the data will be used to support project objectives, and the performance criteria to be used for measuring quality are to be identified by the PM in the QAPP, and are subject to the review by the QA Manager.

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Section 8. IMPLEMENTATION OF WORK PROCESSES

The purpose of this section is to document how work processes are implemented within NatureServe to ensure that data or information utilized are of the necessary and expected quality for their intended use.

8.1 Ensuring Work Performance

The PM will ensure that project work is performed according to the approved QAPP, and any other related planning and technical documents. The role of the QA Manager is that of oversight. As such, the QA Manager provides a substantive review of the QAPP and periodic technical review of the assessment, aggregations, and analytical procedures utilized for the project.

8.2 Standard Operating Procedures

The QAPP should clearly identify the standard operating procedures to be used in the funded project.

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Section 9. QUALITY ASSESSMENT AND RESPONSE

The purpose of this section is to document how NatureServe determines the suitability and effectiveness of the implemented quality system and the quality performance of the programs to which the quality system applies.

9.1 Annual Assessment

No less than annually, an informal review of this QMP shall be performed, and the QMP revised if necessary and resubmitted to the EPA for review and reauthorization. The responsibility for ensuring the timely annual review of the QMP shall be that of the QA Manager. Comments shall be solicited from the PMs. The QA Manager will compile comments and make recommendations for changes to the QMP to the NatureServe Senior Management team. The QA Manager is authorized to formally submit the reviewed and revised (if necessary) QMP to the EPA.

9.2 Corrective Action

Should problems arise regarding the implementation of the QMP, or should there be changes to NatureServe staffing relative to the administration of the QMP, a review of the QMP will be undertaken, even if such review will occur at times other than that designated for the annual review. In such cases, comments will be solicited from persons that have direct experience with the QMP process and can provide the President of NatureServe with knowledgeable input regarding necessary changes. In the event of differences of opinion regarding aspects of the QMP, the President shall ultimately determine what, if any, changes are necessary and appropriate to the QMP. Until such time as EPA has approved a modified QMP, the prior, approved QMP shall remain in effect.

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Section 10. QUALITY IMPROVEMENT

The purpose of this section is to document how NatureServe modifies and improves its quality system.

10.1 Adverse Condition Identification, Prevention, and Correction

Quality system improvement is intended to be an on-going process. PMs as well as NatureServe corporate staff working on projects may periodically note changes that can either prevent situations that would result in poor quality data, or improve the standard operating procedures, administrative processes, and quality assurance system.

Recommendations for changes in quality systems that impact the QMP or related quality assurance/quality control systems shall be made to the QA Manager. The QA Manager shall take such recommendations under advisement in the annual assessment of the QMP and in other quality system activities.

10.2 Process Improvement Communication

All users of data that are assessed, aggregated, and analyzed for EPA-funded projects shall be identified as part of a QAPP. PMs shall have the obligation of treating such users as “customers,” and ascertaining the types of data, form of presentation and the likely use of information by such customers. Customer feedback shall be encouraged and, where appropriate, mechanisms for soliciting such input shall be identified in the QAPP.

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Appendix A. NATURESERVE QUALITY ASSURANCE RESPONSIBILITIES

