QUALITY MANAGEMENT PLAN

FOR THE

ENVIRONMENTAL HEALTH SECTION

Revision 7

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Environmental Health Section
North Dakota Department of Health
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Bismarck, North Dakota

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QUALITY MANAGEMENT PLAN. NORTH DAKOTA DEPARTMENT OF HEALTH, ENVIRONMENTAL HEALTH SECTION.

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ABBREVIATIONS/ACRONYMS

AQ	Division of Air Quality
CBI	Confidential Business Information
CLP	Contract Laboratory Program
CO	Chief's Office
CQAP	Construction Quality Assurance Plan
DPM	Designated Project Manager
DQO	Data Quality Objective
EHS	Environmental Health Section
EPA	U.S. Environmental Protection Agency
GIS	Geographic Information System
ITD	Information Technology Department
LAN	Local Area Network
LS	Division of Laboratory Services
MF	Division of Municipal Facilities
NDCC	North Dakota Century Code
NDDoH	North Dakota Department of Health
QA	Quality Assurance
QAM	Quality Assurance Manager
QAPP	Quality Assurance Project Plan
QC	Quality Control
QMP	Quality Management Plan
QO	Quality Objective
QS	Quality System
QSR	Quality System Review
SAP	Sampling and Analysis Plan
SOP	Standard Operating Procedure
WM	Division of Waste Management
WQ	Division of Water Quality

EXECUTIVE SUMMARY

One goal of the North Dakota Department of Health (NDDoH), Environmental Health Section (EHS), is to ensure that all environmental projects produce data results that are of known quality and that the data results are of the quality needed and expected for their intended uses. Because EHS data are frequently used in environmental decisions, that data must be of sufficient quality and adequate quantity, appropriately documented, and scientifically and legally defensible.

EHS personnel use specific quality management processes during all data collection and interpretation activities performed when conducting EHS business. The specific quality management practices used in the EHS make up the Quality System (QS) as described in this Quality Management Plan (QMP). This QMP reflects provisions of the U.S. Environmental Protection Agency's (EPA) Requirements for Quality Management Plans, EPA QA/R-2 and EPA Region 8 Quality Management Plan. It applies to all EHS activities that generate or obtain data that characterize or assess environmental media, effluents and wastes. A categorical list of those activities includes:

1. Data generated by the sampling of air, water, land and wastes and the laboratory analyses of the samples
2. Data generated and used for design, construction and operation of remediation or treatment systems
3. Data generated through computer modeling efforts
4. Data acquired from sources outside the EHS; for example, from the EPA and through databases, publications and contracts for services

The EHS organization and management principles, as identified in this document, rely on staff empowerment and encouragement of good performance to attain the goals and objectives of this QMP.

QUALITY MANAGEMENT PLAN
ENVIRONMENTAL HEALTH SECTION

1.0 MANAGEMENT AND ORGANIZATION

1.1 Document Purpose

This Quality Management Plan (QMP) describes the quality management processes that the North Dakota Department of Health (NDDoH) Environmental Health Section (EHS) uses to maintain a Quality System (QS). Its purpose is to provide a management strategy that ensures that environmental data developed by the EHS are of sufficient quality and adequate quantity, appropriately documented, and scientifically and legally defensible.

1.2 Supersession

This document replaces Revision 6 of the EHS QMP dated August 2008.

1.3 Statement of EHS Quality Assurance Policy

1.3.1 Definition of QA and QC

Quality Assurance (QA) is an integrated system of management activities involving planning, implementation, assessment, reporting and quality improvement to ensure that a process, item, data or service is of the type and quality needed and expected by the decision makers and the public.

The EHS implements QA through:

1. Delineated responsibilities for QA
2. QA Project Plans (QAPPs)
3. QA training

Quality Control (QC) is the overall system of technical activities that measures the attributes and performance of a process, item or service against defined standards to verify that the process, etc., meets the stated QA objectives and/or requirements. The EHS typically implements QC on a project-by-project basis through reviewing the implementation of QAPPs and related data assessments.

1.3.2 Importance of QA and QC

The EHS goals regarding environmental contaminants are:

1. To identify the presence of environmental contaminants in areas of potential exposure to humans and the environment
2. To determine impacts of environmental contaminants on human health and ecosystems
3. To determine if, how and by whom such threats to human health and the environment should be remediated
4. To monitor compliance with environmental regulations

QA and QC are integral to the functions of the EHS because quality data ensure the scientific credibility of the information upon which decisions are based. Proper QA enhances proper planning, reducing the likelihood of duplicate or repetitive sampling, thereby reducing costs to the public.

1.3.3 Objectives of QA and QC

Environmental data collected by the EHS are generally intended for input to a decision process. It is imperative that EHS decisions are supported by environmental data of sufficient quality and adequate quantity, appropriately documented, and scientifically and legally defensible.

The EHS QS intends to encourage, monitor and ensure that environmental activities are well planned and designed to address the needs and objectives of the EHS projects conducted in North Dakota. The primary objective of the EHS QS is to ensure that all environmental projects produce data of known quality and of the type, quantity and quality needed for their intended use.

The objectives of the EHS QMP are to:

1. Encourage the use of QA and QC principles in the management of environmental projects
2. Facilitate the timely identification, improvement and/or correction of problems and QA systemic weaknesses
3. Identify EHS staff training needs
4. Provide for continuous improvement in project operations

The primary management principles that the EHS uses in its QS are:

1. Empowerment of staff
2. Promoting good performance as opposed to the use of punitive management practices

1.4 Organization and Responsibilities

1.4.1 EHS Organization and Data Generation

The EHS is one of seven sections of the NDDoH. Each section is sub-organized into divisions. The EHS is organized as follows:

- Chief's Office (CO)
- Division of Air Quality (AQ)
- Division of Laboratory Services (LS)
- Division of Municipal Facilities (MF)
- Division of Waste Management (WM)
- Division of Water Quality (WQ)

A director who reports to the EHS Chief, as illustrated in the EHS organizational chart (Figure 1) heads each division in the EHS. Within the AQ, MF, WM and WQ divisions, staff are organized in programs (Figure 1). Those programs having projects[1] that generate environmental data are responsible for developing QAPPs[2] in accordance with QMP requirements.

Occasionally, the EHS may contract for environmental services in fulfillment of duties delegated by state law. In such circumstances, QMP requirements also apply to those acquired contractual services (see Sections 1.4.3, 1.5, 1.6 and 3.5).

The CO is responsible for oversight of the EHS QS for QA and QC as described in this QMP, while each program is responsible for the preparation, implementation and assessment of its QAPP(s).

1.4.2 Position and Authority of QA Officer

The EHS Quality Assurance Manager (QAM) is located in the CO. The QAM normally operates independently of direct environmental data generation, model development and technology development. The QAM reports directly to the Chief of the EHS.

This reporting relationship provides the QAM with sufficient authority to ensure independent oversight of QS implementation throughout the EHS.

The minimum qualifications of the QAM position are a Bachelor's degree in physical, environmental, chemical or biological sciences or engineering and five years experience in the environmental health field. Two years of experience must involve environmental field testing or

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[1] The EHS makes a distinction between the terms "program" and "project" throughout this QMP, since "program" refers to an organization unit (see Figure 1). A program can be responsible for more than one project. When a program conducts only one project, the terms "program" and "project" are interchangeable.

[2] Any reference to a QAPP in this QMP is synonymous with Sampling and Analysis Plan (SAP).

laboratory analyses and/or equivalent combinations of education and experience, indicating a thorough knowledge of EHS requirements, testing procedures, QA/QC and supervision.

1.4.3 Management and Staff Responsibility for QA

It is the policy of the EHS that the primary responsibility for QA resides with each program manager and/or designated project manager (DPM) and each program staff member in each division. QC, the oversight and improvement of QA implementation and performance, is an integral part of program management and contractor oversight and is vested with DPMs, program managers and division directors.

In the case of grants, cooperative agreements and similar instruments by which the EHS awards money to a second party for the environmental work, the DPM who has oversight shares responsibility for QS implementation with the award official for said instrument. Section 1.6 of this QMP elaborates on those specific responsibilities.

Program managers report to the director of the division in which they are located, and generally provide leadership and supervision to staff, some of whom serve as project managers. Program managers are responsible for identifying environmental projects that need QA and QC.

The DPM is the staff member who works within a specific project and has immediate managerial or technical control of that project (see program managers in Figure 1). The DPM is responsible for specifying project data quality requirements and approving the QAPP. The DPM may also be a program manager.

For the purposes of this document, the DPM is the person with responsibility and authority to approve a QAPP. In cases where the DPM identity is unclear or responsibility rests with more than one individual, the program manager will designate a single individual to perform that function.

1.4.4 Resources

Program managers, together with DPMs, must determine the resources needed to ensure that an adequate level of QA and QC is achieved for all projects within their respective programs. Division directors must account for adequate resources in their management and budgeting strategies.

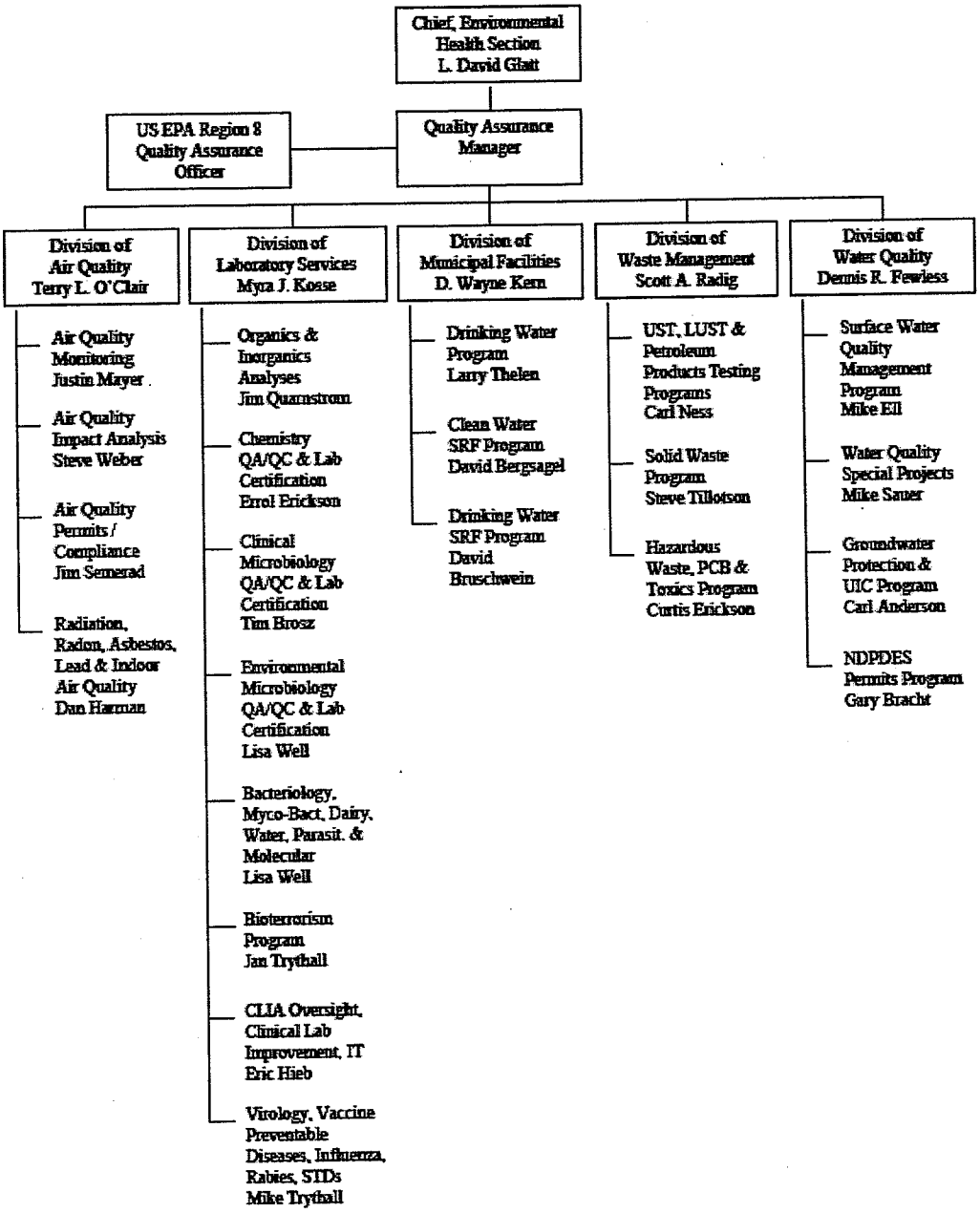

Figure 1. Environmental Health Section Organizational Chart

1.5 Types of Activities Specifically Covered by the QMP

This QMP applies to all EHS activities that generate or obtain data that characterize or assess environmental media, effluents and wastes. A categorical list of those activities includes:

1. Data generated by the field sampling of air, water, land and wastes and the laboratory analyses of the samples
2. Data generated and used for design, construction and operation of remediation or treatment systems
3. Data generated through computer modeling efforts
4. Data acquired from sources outside the EHS (e.g., from EPA and through databases, publications and contracts for services)

This QMP does not cover certain data collection activities; those activities are listed in Section 1.5.5. Whenever EHS personnel/contractors perform those activities, the DPM has full responsibility for ensuring all EHS QA and QC requirements are met. When such activities are performed with EHS funds, the DPM having oversight is responsible for ensuring the receiving organization complies with all relevant EHS QA and QC requirements.

This QMP does not cover activities performed by members of the regulated community who do not use EHS funds. In the absence of regulatory requirements that would take precedence, DPMs are encouraged to include EHS QA and QC requirements as part of any negotiated agreement with the regulated party.

Chapter 2.0 identifies the specific EHS QS applicable to each of the identified components. The environmental activities included in each category are discussed in the following sections.

1.5.1 Data Generated by Field Sampling and Laboratory Analysis

Some examples of covered activities are the generation of environmental data, including fieldwork for the purposes of collecting samples for later chemical, physical or biological analyses; the collection of in situ measurements; field work for site reconnaissance; and compliance inspections.

Environmental media samples are commonly collected and analyzed to accomplish the following goals:

1. Confirm the presence or absence of pollutants or contaminants.
2. Determine concentration levels of various sample components.
3. Delineate the horizontal and vertical distribution.
4. Evaluate rate and direction of transport.
5. Determine eventual fate of the identified pollutants.
6. Determine the baseline and background concentrations.
7. Determine the effectiveness of treatment.
8. Determine their sources of contamination.
9. Establish time trends.

10. Monitor change
11. Evaluate progress.
12. Evaluate compliance with environmental laws and regulations.

Sampling may be conducted for site characterization, for ongoing monitoring projects, or during remediation and removal activities.

Data also may be collected to use as an input for risk screening and/or assessment calculations incorporating exposure to humans, wildlife and the environment. Any EHS program may use such risk calculations as appropriate or required by regulation or EHS policy. A QAPP must adequately address data collection activities conducted for the EHS, including Data Quality Objectives (DQOs). Required QAPP elements are discussed in Section 3.1, and suggested additional elements are listed in Chapter 8.0.

Activities covered under this category include collecting media samples in the field, observing and recording field observations, performing analyses in the field and in field laboratories, and analyzing samples in laboratory settings. Examples of media include solid or liquid waste, fluid discharges or emissions, groundwater, surface water, soil, sediment, air and biota.

Measurements include physical measurements and observations made in the field such as flow rates, water levels, particle sizes, geological matrices, temperature, and wind speed and direction. This category also covers biological monitoring and sampling activities such as habitat evaluation, species identification and diversity assessments. Portable equipment is used to make field chemical determinations of parameters such as pH, specific conductance and dissolved oxygen. Analyses of chemical constituents can take place in field laboratories or at commercial or government laboratories. A QAPP must describe methods of collection, analysis, transportation and documentation for each of the aforementioned activities.

1.5.2 Design, Construction and Operation of Remediation or Treatment Systems

The design, construction and operation of environmental technology must be supported by an effective level of QA and QC to ensure that performance of the technology meets expectations. Environmental technologies include bench scale and pilot treatment projects to determine effectiveness and the design, construction and monitoring of remediation systems. Environmental technologies may include emission/effluent control, waste remediation and pollution abatement, and they may utilize mechanical, chemical or biological processes.

The QS for construction activities control is discussed in Section 3.5 of this document.

1.5.3 Data Generated through Computer Modeling

EHS decision makers sometimes use data generated from environmental computer models developed by both the EHS and outside sources. The QS used by the EHS for control of model-generated data is discussed in Section 3.4.1.

1.5.4 Data Collected from Outside Sources and Databases

EHS decision makers sometimes use information and data from outside sources or databases. Examples of such data include, but are not limited to, toxicological data, historic stream characteristic and flow data, climatological data, field data collected by a regulated party and exposure data.

When outside data are used, EHS staff are encouraged, whenever possible, to obtain and review the QA and QC practices followed during original data generation. Professional judgment must be used to weigh the value of all information used in EHS decision making. It is not feasible for EHS staff to thoroughly review and validate all information and data obtained from outside sources. The quality system used in the EHS for outside data is discussed in Section 3.4.3.

In addition, any data used for purposes other than that originally intended must be reviewed to ensure the data are suitable for the new application.

1.5.5 Activities not Covered

This QMP does not cover the following environmental sampling or data collection activities:

1. Data collected only for safety or workplace regulations
2. Collection of employee medical monitoring data

1.6 Policy on Cooperative Projects and Sites

Occasionally, the EHS uses external entities for the collection and analyses of environmental samples and data later used for decision-making. The activities of these entities are managed through grants, cooperative agreements, interagency agreements or contracts.

Examples of entities external to the NDDoH and the EHS include, but are not limited to, potentially responsible parties, state and local agencies, and EHS contractors. Oversight of the entities' activities may be conducted through periodic EHS reviews .

The following are specific requirements for environmental sampling or data collection by outside entities that receive EHS funding:

1. Agreements and contracts with state agencies, universities and academic institutions, tribes and communities must require a QAPP and/or SOP for any environmental sampling. The DPM is responsible for review and approval of a QAPP and/or SOP.
2. If work by a private party is required under an enforcement agreement, the agreement will detail the QA and QC roles of the EHS and the private party.
3. If work by a private party is voluntary (i.e., there is no formal or enforcement agreement) and will be provided to the EHS, EHS review and approval of the work's QA is suggested to avoid misunderstandings of goals and data usage. In this case, a private party has the right to proceed without such approval, but the EHS can decide not to use the data if judged inadequate to support the proposed use.

1.7 Document Distribution

The QAM will distribute this QMP via e-mail to everyone listed in the EHS organizational chart (Figure 1). In addition, the QAM will facilitate posting this QMP on the NDDoH website, which can be accessed by EHS staff and the public.

2.0 QUALITY SYSTEM COMPONENTS

2.1 General Quality System

The CO coordinates the EHS QS as described in this QMP.

> This QMP reflects relevant provisions of EPA Requirements for Quality Management Plans, EPA QA/R-2, EPA/240/B-01/002, March 2001 (Reissued May 2006); and related provisions of the Quality Management Plan for the U.S. Environmental Protection Agency Region 8, November 2002.

The QAM is responsible for maintaining and updating this QMP. The EHS and QAM will review this QMP annually and adjust it in content and applicability as appropriate.

Division directors are responsible for ensuring that staff understand the QS as described in this QMP. All QAPPs must be consistent with the EHS standard for such plans as described in Chapter 3.0.

2.2 Team Approach

Each DPM has access to technical experts for assistance in quality objectives development, evaluation of project work plans and associated QA documents. Within the EHS, there are groundwater sampling specialists, hydrologists, geologists, chemists, scientists, engineers, waste management specialists, biologists, microbiologists, air quality modelers, water quality modelers and air quality specialists. Each project team leader or DPM should involve the appropriate specialists relevant to site or project issues. The DPM has the primary responsibility of ensuring that the environmental data collected are of the type and quality required to meet project objectives.

2.3 Scope of Application

The EHS QS applies to all EHS projects for which environmental samples are taken to perform chemical, physical or biological tests and generate environmental data. It applies to activities conducted directly by EHS personnel, and activities performed under EHS agreements when resulting environmental data are intended for use in EHS-funded projects. QA requirements for outside data sources are included in Section 3.4.3 of this QMP.

The QS also should be used as a model in all negotiated agreements, consent decrees, etc., when the EHS directs or requests that another party (e.g., state agency, regulated entity) perform data collection for EHS programs.

2.4 Components of the Quality System

The QS for the EHS consists of the following components:

Quality Assurance Project Plans	Chapter 3.0
Personnel Qualifications and Training	Chapter 4.0
Procurement of Items and Services	Chapter 5.0
Records	Chapter 6.0
Computer Hardware and Software	Chapter 7.0
Planning	Chapter 8.0
Work Processes	Chapter 9.0
Quality Assessment and Improvement	Chapter 10.0

Figure 2 shows a paradigm of core QMP QS provisions.

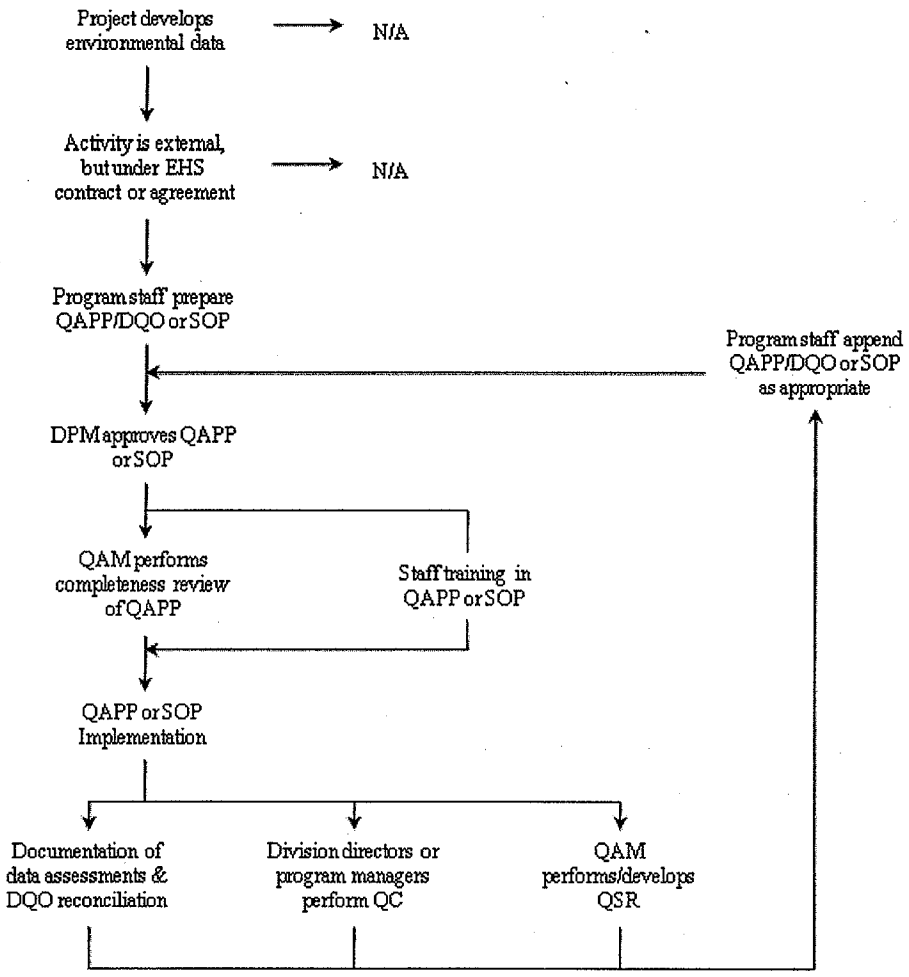

Figure 2. Abridged Paradigm for the EHS Quality System

3.0 QUALITY ASSURANCE PROJECT PLANS

3.1 QAPPS

Each division or program is responsible for developing project QAPPs, and all QAPPs must be consistent with the QMP.

DPMs are responsible for QAPP approval and periodic review of the implementation of QAPPs, including SOPs (see Chapters 9.0 and 10.0). The QAM is responsible for ensuring QAPP completeness.

> QAPPs must be developed as specified in EPA Requirements for Quality Assurance Project Plans, EPA QA/R-5, EPA/240/B-01/003, March 2001 (Reissued May 2006).

A QAPP must address all environmental data collection activities conducted by or on behalf of the EHS. A QAPP must adequately address the following 24 elements:

Project Management

1. A1 Title and Approval Sheet
2. A2 Table of Contents
3. A3 Distribution List
4. A4 Project/Task Organization
5. A5 Problem Definition/Background
6. A6 Project/Task Description
7. A7 Data Quality Objectives (DQOs) and Criteria
8. A8 Special Training/Certification
9. A9 Documents and Records

Measurement/Data Acquisition

10. B1 Sampling Process Design (Experimental Design)
11. B2 Sampling Methods
12. B3 Sample Handling and Custody
13. B4 Analytical Methods
14. B5 Quality Control
15. B6 Instrument/Equipment Testing, Inspection and Maintenance
16. B7 Instrument/Equipment Calibration and Frequency
17. B8 Inspection/Acceptance of Supplies and Equipment
18. B9 Non-Direct Measurements (Secondary Data)
19. B10 Data Management

Assessment/Oversight

20. C1 Assessments and Response Actions
21. C2 Reports to Management

Data Validation and Usability

22. D1 Data Review, Verification and Validation
23. D2 Verification and Validation Methods
24. D3 Reconciliation with Data Quality Objectives and User Requirements

Because the degree of QA/QC activities for each project differs, a graded approach should be employed in planning the work. As such, one or more of the 24 elements may not apply to a particular project ("N/A"), or it may be appropriate to combine one or more elements into a single item. In that case, the combined item should be referenced when discussing a particular QAPP element.

Prior to scheduling sampling or laboratory services, a QAPP must be reviewed for technical adequacy and compliance with the QMP and approved by an appropriate EHS representative. The QAM and DPM jointly perform the approval. Although the DPM is free to use any technical resources in the review, approval will never be delegated outside of the EHS. A QAPP for a long-term project must be reviewed at least annually for continued relevance and revised, as needed. However, a QAPP may be revised whenever the DPM deems it necessary. Revisions to a previously approved QAPP must undergo the same review and approval process as the original version.

Every field investigation must be conducted in accordance with an approved QAPP to ensure DQOs will be met. When splits are collected from the regulated community for oversight purposes, the approved project QAPP is used to define the EHS sample handling and analytical requirements. In this case, the EHS does not prepare additional QA documents to define the sample collection and handling activities.

3.2 Control of Data Collection Activities

Certain practices are required to control environmental data collection activities. The following practices are described in sections 3.21 through 3.24:

1. Development and approval of a QAPP
2. Development of DQOs
3. Production of a report documenting reconciliation with DQOs
4. Satisfaction of minimum analytical QA and deliverable requirements

3.2.1 Approved QAPP

QAPP preparation, review and approval, as described in Section 3.1, are required for all EHS environmental data collection activities. Certain emergency actions are permitted under a pre-existing generic QAPP. These actions are limited to time-critical events and true emergencies that pose an imminent health or environmental threat requiring immediate actions by EHS staff or its contractors.

3.2.2 Data Quality Objectives

DQO development is required for each project. For many projects, DQOs may be a simple statement of why data are being collected and what data outputs will be considered significant. QAPP reviewers must ensure that the QAPP specifically addresses the technical adequacy of DQOs.

> For some projects, it may be appropriate to use the complete statistical hypothesis testing approach as described in Guidance on Systematic Planning using the Data Quality Objectives Process, EPA QA/G-4, EPA/240/B-06/001, February 2006.

DQOs are intended to accomplish the following:

1. Clarify the study objectives.
2. Define the most appropriate types of environmental samples or data to collect.
3. Determine the most appropriate conditions for collecting the environmental samples or data.
4. Specify the uncertainty level acceptable as the basis for establishing data quantity and quality needed (i.e., sufficient quantity and adequate quality).

3.2.3 Documentation of DQOs Reconciliation

Elements D1, D2 and D3 of Section 3.1 require a QAPP to identify data assessment procedures. Those elements specifically include items on how data will be reviewed, validated and qualified. Element D3 requires reconciliation with stated DQOs and user requirements. With respect to the original DQOs, a field and analytical data usability and limitations assessment must be documented after completion of all data collection activities.

3.2.4 Minimum Analytical QA and Deliverable Requirements

All analytical work performed must be specified in a project QAPP and meet minimum standards as defined in the laboratory's SOPs and the specific method employed. Any additional QA/QC and deliverable requirements contained in the technical specifications of a project QAPP must also be performed, documented and provided by the laboratory. The DPM is responsible for directly communicating any additional requirements to appropriate laboratory personnel. Failure to comply with these requirements may result in rejection of data and, when applicable, nonpayment for the defective products.

3.3 Standard Operating Procedures

EHS staff are encouraged to incorporate the use of an SOP whenever a task is to be repeated frequently. An SOP promotes reproducible work products and consistency in and among EHS project operations. Any staff member may prepare an SOP when desired. The program manager reviews and approves each SOP (see Section 1.4.3). QAPPs may include SOPs.

3.4 Quality System for Data Collected from Modeling, Electronic and Database Sources

3.4.1 Computer Modeling Data

EHS staff frequently use mathematical and computer-based models for the prediction of certain environmental events and effects, and for contingency planning. The reliability of the outputs of such modeling efforts is dependent upon the accuracy of the input data, suitability of the model and accuracy of the modeling process. It is not feasible for EHS staff to verify, calibrate and/or validate all models that may be used; however, EHS staff are encouraged to use well-known or established models when available.

When using a computer-based model to predict events or effects, certain documentation is required. Within the documentation, the DPM must indicate the name, source and identification information for the model used, including the model's version number if applicable. In addition, the DPM must identify the source for any input information used within the model. The DPM must indicate whether the data were collected by the EHS under the other applicable provisions of this document, or whether the data were obtained from a "secondary" source such as an agency, industry, database or publication. If secondary source data were used and more than one source of appropriate secondary data was available, the DPM must explain why that particular source was selected.

Chapter 7.0 includes a description of the computer hardware and software the EHS currently uses.

3.4.2 Environmental Database Systems

EHS environmental database system administrators must identify any major data quality weaknesses of their data system and establish a plan and timeline for improvement. Therefore, written QA/QC plans are required for all EHS database systems. Protocols dealing with data ownership, accuracy, timeliness and completeness should be promoted in a model guide. The model guide defines system data quality standards and how those standards are measured. The model guide also describes what practices and tools are used to ensure that the data quality standards are met consistently. The programs use their respective database systems for environmental decision-making. Through inspections, split sample analyses and performance audits, the programs are responsible for verifying data accuracy and validity and follow-up on questionable data. Section 7.3 contains additional discussion on this topic.

3.4.3 Data Obtained from Outside Sources

Occasionally, EHS staff use data and information collected or generated by sources outside of the EHS. These are frequently referred to as "secondary" data sources. There are numerous possible secondary data sources. Examples of these include, but are not limited to, toxicological data used in risk assessments, climatological data, historic stream flow and monitoring data collected by other federal and state agencies, new technological and scientific issues covered in the scientific literature, and data collected by other parties without the use of EHS funds.

When using secondary data sources, it is usually not possible for the EHS to validate or review all of the data. In these situations, the EHS requires that the DPM ensure that project files and records indicate the source of the data and efforts undertaken to review or validate the data. If multiple sources of the same or similar information are available, the project records should indicate why that particular source was selected.

3.5 Quality System for Remediation Systems

3.5.1 Construction Quality Assurance Plan

The EHS requires preparation of a Construction Quality Assurance Plan (CQAP) when using EHS funds to design, construct or operate a remediation system. A remediation system is any system intended for storage, handling or treatment of wastes or contaminated media prior to discharge to the environment. These systems often include facilities constructed as surface impoundments, waste piles, landfills, waste isolation systems, artificial wetlands, treatment facilities or similar systems. This requirement does not apply to actions conducted in response to a true emergency, such as a time-critical response.

The EHS DPM with authority over the site or grant must review and approve the CQAP. A CQAP must address the following elements:

1. Responsibilities and Authorities of Organizations and Key Personnel Involved
2. Personnel Qualifications
3. Inspection Activities
4. Sampling Strategies and Corrective Actions
5. Documentation

Although CQAP preparation is not required of regulated entities that do not receive EHS funds, it is strongly advised that this item be included as part of negotiated agreements as appropriate. The following sections include an explanation of each CQAP component.

3.5.2 Responsibilities and Authorities of Organizations and Key Personnel Involved

The CQAP must identify all organizations involved in the design, construction and operation of the system. The CQAP must include a discussion of authorities and responsibilities of the organizations as they relate to the plan. The CQAP should identify and describe responsibilities of key personnel such as the construction QA manager and the DPM.

3.5.3 Personnel Qualifications

The CQAP must include qualifications of key project personnel such as the construction QA manager and the construction inspector.

3.5.4 Inspection Activities

The CQAP must present the planned observations, tests and inspections to ensure that installation meets or exceeds all design criteria, plans and specifications. Activity schedules or periodic frequencies must also be established. Any system designed to treat or remediate waste material or a waste stream must also include a schedule of tests to measure the efficiency of the waste treatment/reduction process or show that effluents comply with applicable state and federal regulations.

Inspection activities typically include visual observations, field testing and measurements, laboratory testing and evaluation of test data. Most often, those activities will be associated with one of the following four items:

1. Inspection of materials used to certify that they meet design criteria
2. Construction QC to measure conformance with project plans, specifications and design criteria
3. Construction QA to determine final product quality and conformance with project specifications (For larger projects, it is recommended that periodic inspections be conducted at the completion of various phases rather than waiting until project completion.)
4. Regulatory inspections performed to ensure compliance with all applicable codes, regulations and permits

3.5.5 Sampling Strategies and Corrective Actions

The CQAP must address sampling methods, sample size, methods for determining sampling locations, frequencies of sampling, test methods and acceptance, and rejection criteria for compliance with design specifications. The CQAP must address corrective actions for failed tests.

3.5.6 Documentation

This portion of the CQAP must describe the QA reports to be prepared during design, construction and operation. The CQAP must include report description and frequency. Also identified will be the party responsible for report development and the party to whom the reports are submitted.

4.0 PERSONNEL QUALIFICATIONS AND TRAINING

4.1 Qualifications

The NDDoH participates in the Class Evaluation System administered by the state's Office of Management and Budget, Division of Human Resource Management Services. All EHS job positions are classified, and each job class has a written description of general duties, required education or training and related applicable experience.

The EHS employs engineers, scientists, geologists, biologists, chemists, microbiologists and other specialists for job functions that include or relate to environmental testing, information analyses, media sampling and data interpretation. Education, coupled with training and work experience, provides the EHS staff with technical knowledge in environmental health disciplines that are the foundation for QAPP and/or SOP implementation.

Division directors, program managers and DPMs also possess knowledge of state laws, rules and guidelines of assigned programs (see Figure 1).

4.2 Training

EHS technical training should occur when an employee lacks prior relevant or direct experience in the specific QAPP or SOP. Senior EHS program staff or technical staff who have a minimum of two years of relevant on-the-job experience and are proficient in the QAPP or SOP should give the training. The training may occur using classroom or on-site demonstrations, in the laboratory or via the internet (e.g., webcast), as appropriate.

4.3 EPA Supplemental Training

EHS staff will participate in EPA-sponsored QA training, when such training is scheduled in North Dakota. All EPA-sponsored QA training should be arranged with the QAM, who will coordinate with the appropriate EHS division directors, program managers or DPMs. In particular, the following training themes are recommended:

1. Regional QS Strategies
2. DQOs
3. QAPPs and SOPs

5.0 PROCUREMENT OF ITEMS AND SERVICES

5.1 Procurement of Supplies

The EHS orders common office supplies by requisition from the state's Office of Management and Budget, Division of Central Services. Some sampling supplies are purchased from retail hardware outlets and equipment suppliers.

5.2 Selection of Contractors

The EHS solicits contractors through a competitive procurement process. The EHS evaluates all bids and/or proposals based on requirements or evaluation criteria specified in the solicitation. QA and QC services are typically included in these contracts. Prime contractors choose their subcontractors and are responsible for performance oversight, which often includes QA and QC functions.

5.3 Evaluation of Deliverables

The DPM reviews deliverables received from contractors to ensure that work objectives are met and recommendations are justified and documented. A contract often requires written approval by the DPM for deliverables and invoices received. If the deliverables condition is unsatisfactory and cannot be rectified through revisions or re-sampling, the DPM must notify the contracting and/or project officer. Contractual requirements addressing the QA and QC requirements are generally based on the project QAPP.

6.0 DOCUMENTS AND RECORDS

6.1 Documentation and Handling

It is EHS policy to adequately document its organization, functions, policies, decisions, procedures and transactions. The EHS will adhere to the records archival policies of the state's Information Technology Department, Records Management Division, and any applicable record retention requirements of environmental laws as delegated by the EPA.

All documents in North Dakota are subject to the state's open records law unless declared "enforcement protected" by legal counsel. Directors, program managers or DPMs are responsible for records relevant to their division, programs or projects.

All project records must be kept in an official project file by the DPM. At a minimum, project records must be retained in the office for the life of the project or until updated/obsolete, plus at least three years. After that period, they must be transferred to the State Archives.

> "80 (SPS) PROGRAMS, PROJECTS, AND SERVICES
> 801201 PROJECT DOCUMENTATION
> Description: This series contains all the records stored in the project repository. These could include historical documents such as business cases as well as any charters, plans, schedules, and reports. It may also include other products of project management such as meeting minutes, scope changes, deliverables/project acceptance, risk logs, issue logs, quality-related documents, budgets, variance reports, recovery plans, schedules, project status reports, copies of RFI/RFP and contracts (including all attachments/addendums), and relevant e-mail communications.
> Retention: Three years after project is completed.
> Disposition: Transfer to the State Archives."
> (Source: www.nd.gov/itd/files/retention/998/998001_descriptions.pdf)

6.2 Confidential Document

Because of their nature and content, some documents collected, received or generated may require special handling procedures. Documents of this category may include, but are not limited to, "enforcement sensitive" or "enforcement confidential," "attorney/client," or "confidential business information" (CBI). These documents have specific, overriding handling procedures. Documents classified as CBI are handled as required by project-specific CBI requirements. Only EHS staff members are allowed to see documents classified as "enforcement confidential." All confidential documents must fit one of the exceptions identified in the state's open records law, North Dakota Century Code (NDCC) Chapter 44-04.

Note: "If a record contains both open and closed or confidential information, the portions that are not open must be removed prior to disclosing information for an Open Records Request, i.e., Social Security Number."
(Source: www.nd.gov/itd/files/retention/998/998001_descriptions.pdf)

6.3 Document Preparation

EHS staff members at multiple levels prepare planning documents and project reports. The EHS also allows contractor personnel to prepare drafts of documents, whenever that task is within the purview of the contract.

Revisions of any document must follow the same approval process as the original document. It is the responsibility of the DPM to maintain version control following revisions and to ensure all parties using the document have the current version. Removal of obsolete and superseded documents should be accomplished in the same manner as described in Section 6.1.

The EHS encourages its staff to incorporate the use of an SOP whenever a task is to be repeated frequently. The use of an SOP promotes reproducible work products and long-term consistency in EHS operations. Any staff member may prepare an SOP when believed necessary. The program manager must approve the SOP. Transmittal and distribution of an SOP and related documents are the responsibility of the program manager and/or DPM.

6.4 Requirements for Field Documentation

Documentation of field activities establishes procedures, identifies written records, enhances and facilitates sample tracking, standardizes data entries, and identifies and establishes authenticity of sample data collected. Proper documentation ensures that all required and essential information is consistently acquired and preserved. Timely, correct and complete documentation establishes the chain of custody, a requirement for data intended for evidence in court proceedings.

Field records must be generated and stored as denoted in project-specific QAPPs and SOPs.

Guidance for field records is provided in Standard Operating Procedures for Field Sampling Activities, EPA Region 8, June 1994, and its subsequent revisions.

7.0 COMPUTER HARDWARE AND SOFTWARE

7.1 Computer Hardware

The EHS has a Local Area Network (LAN), which can only be accessed using a security password. The state's Information Technology Department (ITD) maintains the LAN. LAN server data are backed up and checked daily for computer viruses by the EHS computer system administrator. Real-time virus checking is also employed. The EHS computer system administrator, who is located in the CO, reports directly to the EHS Chief.

The ITD also establishes policies and standards for purchasing network hardware and software. Computer equipment used by EHS staff is procured and maintained by the EHS division directors or their delegated staff.

Biennially, the NDDoH prepares an information technology plan, as required by the ITD. An NDDoH Information Technology Committee determines the adequacy and appropriateness of each division's hardware and software technology.

7.2 General Computer Software

Computer software for completing basic office tasks, available through the LAN, is maintained by the EHS system administrators. This software provides word processing, database and internal communication functions.

In addition, the WQ division currently holds six floating licenses for Geographic Information System (GIS) software. GIS software is specialized to handle both databases and the spatial information associated with the data. Each floating license can be used any time at any desktop that has the GIS software installed on it. A maximum of six licenses may be used at any given time. Once an EHS staff member creates a map using one of the floating licenses, any other EHS staff member may open the saved map in a read-only fashion by installing free GIS software (e.g., ArcReader or ArcExplorer). North Dakota has a statewide GIS Technical Committee, which includes representatives from seven state agencies who guide and develop standards and policies relating to statewide GIS data standards and data acquisition. The broader-based associate members of the GIS Technical Committee, including all individuals in federal, state, county or municipal government, education and business, provide a forum for sharing ideas and solutions related to GIS applications in the state.

7.3 Environmental Database Systems

EHS environmental database systems are maintained either by EPA or the EHS. Each system has its own update and backup schedule. The responsible database systems administrator controls access.

A list of software used by the EHS to supply EPA with information or to locally archive data is contained in the following table.

Laboratory Services - Chemistry:	Northwest Analytical LIMS
Laboratory Services - Microbiology:	StarLIMS version 9.0
Drinking Water:	SDWIS version 2.3
Surface Water 319 Watershed Projects:	GRTS Database (direct entry)
Surface Water:	STORET version 2.0 (through 12/2008) WQX (start 01/2009)
	Sample Identification Database (SID) (Access 2003)
	Ecological Data Application System (EDAS) (Access 2003)
	Assessment Database (ADB) (Access 2003)
Water Quality:	NDPDES State Database and PCS/ICIS Database
Air Quality:	Permitting and Compliance Database
UST and LUST Programs:	UST Access 2007
Hazardous Waste:	RCRAInfo
Asbestos Control:	ACTS version 7

The respective database systems administrator in each division/program provides documentation, development and training.

7.4 Specialized Computer Models

Section 3.4 contains the specific QS for control of electronic data.

Computer-based modeling is used to predict outcomes based on the current conditions and on extrapolations or measurements of previous conditions. Modeling programs have been developed to predict migration routes and rates, and to estimate contaminant distribution and concentrations for use with several fluid media including ground water and air. Such models are prepared with site-specific parameters and are calibrated using known data before predictions are attempted.

Briefly, a model's suitability can be determined based on:

1. The suitability of a model's conceptual approach
2. The logic of a model's simplifying assumptions
3. The presence of well-defined, understandable limitations
4. Data needs and data quality needs consistent with the project objectives
5. EPA peer review and/or stakeholder acceptance of model output
6. Compliance with relevant guidance

7.4.1 Requirements for Modeling Efforts

The EHS uses mathematical models to make systematic regulatory assessments and environmental decisions; determine environmental fate and transport; estimate pollutant loadings; develop protection zones; assess exposure, hazard, damage and health risk; and to make projections and predictions. For these reasons, the EHS must assure the quality of all modeling systems. All information regarding the suitability of a model and its outputs must be documented in writing and contained in the project records. The EHS recommends using an SOP for:

1. Model selection
2. Assessment of results for all environmental model data generated

7.4.2 Responsibilities, Authorities and Personnel Qualifications

Individual DPMs with direct or oversight authority for any project are responsible for assuring the suitability of all models and data received by the EHS.

To the extent possible, the DPM should be familiar with the qualifications of all contractors or grantee personnel conducting modeling efforts. All personnel conducting modeling exercises must have the education and experience appropriate for the job.

8.0 PLANNING

The QAPP is the planning document for the generation and acquisition of environmental data. A complete QAPP contains several topical elements including DQOs (see Section 3.1).

When appropriate, additional topical elements that should be included in the QAPP are:

1. Project customers
2. Schedules and critical milestones
3. Applicable laws and rules
4. Applicable SOPs
5. Existing information or data
6. Documentation of QAPP implementation
7. Assessment of QAPP functionality
8. Distribution of the QAPP
9. Project budget

9.0 IMPLEMENTATION OF WORK PROCESSES

9.1 Pre-sampling Requirements

QAPP or SOP development and implementation is required for all projects producing environmental information or data (see Section 3.2.4). Before collecting and/or analyzing any samples, a QAPP or SOP must be approved. An exception to this may be a "classic emergency" and a time-critical situation.

Once a QAPP or SOP is completed and approved for implementation, the DPM informs EHS program staff or other persons, as needed, of the QAPP or SOP requirements (see Sections 1.4.3, 3.1 and 3.3). EHS staff or others who implement those requirements should be briefed and/or trained (see Section 4.2).

All laboratory analyses are performed using methodologies approved and published by the EPA or others such as the American Society for Testing and Materials (ASTM). Detailed analytical method SOPs for many analytes are found in the LS methods manuals. Upon completion of analyses, LS transmits data electronically and/or by hard copy to appropriate EHS staff.

9.2 Laboratory Coordination

Requests for environmental sampling assistance and analytical services are scheduled by LS on a first-come first-served basis, unless otherwise prioritized by EHS senior management. LS personnel may be asked to provide technical assistance in the development of QAPPs or SOPs. This up-front involvement is helpful when arranging analytical services.

9.3 Documentation

When obtaining, holding or analyzing environmental media samples, any deviation in a QAPP or SOP must be documented and explained (see Section 6.4).

10.0 ASSESSMENT AND RESPONSE

10.1 Quality System Reviews

The EHS QAM must perform Quality System Reviews (QSRs) of EHS project QA and QC activities. A QSR can be limited to a single project. A QSR will evaluate the provisions of this QMP for thoroughness and effectiveness.

> Guidance for performing QSRs is contained in Guidance on Assessing Quality Systems, EPA QA/G-3, EPA/240/R-03/002, March 2003.

The QAM will conduct an annual overall assessment of the EHS quality system and provide a report to the EHS Chief and EPA Region 8 Quality Assurance Office.

10.2 EHS Project QC

Division directors, program managers, DPMs or individual staff members are responsible for assessing the quality of the work performed under their authority. This can be done several ways as appropriate to the specific project and the budget. Examples include:

1. Third party observation (independent assessment) of the work in progress
2. A field audit by qualified EHS staff
3. A laboratory audit by qualified EHS staff
4. EHS or contractor validation of selected data sets
5. Internal audits performed by the contractors

10.2.1 Field Audits

Field audits consist of on-site visits to the sampling locations, observation of sampling practices, review of project records and sampling SOPs, and documentation of findings. The primary intent of such audits is to ascertain if QAPP-specified practices are being followed.

The lead auditor must be an EHS employee when sampling is being conducted by EHS personnel/contractors. Audits may be requested through the QAM and performed by non-project personnel to avoid the appearance of bias. All field audits will result in the production of a written report.

10.2.2 Laboratory Audits

An audit may be conducted of an external laboratory used for sample analyses to determine if the laboratory's practices and procedures are consistent with the QAPP and/or SOP requirements. The audit may be performed while samples are under analysis or after analysis is completed. The audit will consist of an on-site visit to the laboratory, observation of its analytical practices when possible, review of its QAPP and SOPs, and documentation of findings.

10.3 Laboratory QC

10.3.1 Data Inspection

When analyses results are received, an inspection of analytical deliverables may be conducted to determine if the work performed is consistent with laboratory tasking instructions.

The inspection is required for work performed under the Contract Laboratory Program (CLP), but it may not be required for other projects. Payment for lab work should not be authorized until the inspection confirms satisfactory performance by the laboratory.

10.3.2 EHS Laboratory QC Responsibilities

The LS Quality Assurance Plan details the specific quality control responsibilities for various positions within the division. LS personnel must ensure that methodologies adhere to QC requirements and project-specific QC requests are followed.

10.3.3 EHS Laboratory Certifications

The LS is audited by a team from EPA Region 8 once every three years for certification under the Safe Drinking Water Act. This team may also review analyses performed under the Clean Water Act. To maintain full certification for regulated drinking water parameters, the laboratory is required to satisfactorily analyze each parameter in water supply performance evaluation studies acquired from approved private providers. This annual requirement is identical to the requirement private laboratories must meet to maintain full certification status for regulated drinking water parameters.

At least once every three years, the LS laboratory certification officer performs audits of in-state laboratories certified for drinking water, wastewater and solid/hazardous waste testing under the North Dakota Environmental Laboratory Certification Program.

11.0 QUALITY IMPROVEMENT

11.1 Quality System Reviews

Management can use a QSR to assess conformance with the QMP and to target areas needing improvement. A QSR can culminate in a written report when warranted.

11.2 EHS Project QC

Any QC improvement needs will be addressed at the staff level with the DPM or program manager. Issues that cannot be resolved will be elevated to the division director's attention and, if necessary, the QAM and Chief of the EHS. Appropriate changes must be made to improve plan quality.

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