Quality Assurance Audit Report

Nye County NWRPO Audit Number NWRPO-2008-01

To: Darrell Lacy, Director

Cc: Levi Kryder, Geoscience Manager

From: Kathy Gilmore, Quality Assurance Officer/ Auditor

Subject: Audit Report on QA Program Elements

Purpose: To verify compliance with QA program elements.

Scope: The audit included an evaluation of the Quality Administrative Procedures (QAPs) that were developed to implement requirements established in the QA Program Plan (QAPP).

QAPs evaluated during the audit include:

QAP-3.1	Independent Technical Review
QAP-3.2	Documentation of Technical Investigations
QAP-5.1	Preparation of Quality Administrative Procedures
QAP-5.2	Preparation of Work Plans, Test Plans, and Technical Procedures
QAP-6.1	Issue and Control of Quality Assurance Documents
QAP-7.1	Procurement of Items and Services
QAP-8.1	Sample Management
QAP-12.1	Control of Measurement and Test Equipment
QAP-15.1	Control of Nonconforming Items or Activities
QAP-16.1	Corrective Actions
QAP-17.1	Records Management
QAP-18.1	Audits and Surveillances

Summary: As a results of the audit, it was determined that all QA program elements are in conformance with internal requirements with the exception of a few discrepancies that are described in the Audit Findings and Observations sections.

Auditor: Kathy Gilmore, QA Officer

Dates of Audit: 3/17/08 – 3/19/08

Persons Contacted: Darrell Lacey, Levi Kryder, Sherry Dudley, and John Klenke

Effectiveness of QA Program Elements Audited: The QA Program is being conducted in an effective manor in accordance with the QAPP and QAPs, however certain elements are not being followed that will possibly affect quality of future work if not addressed. Those elements are presented in the following.

Audit Findings:

Finding 1:

QAPP Rev 4. states in Section 5.3:

> "..QAO review will establish controls to assure that plans and procedures for data collection and analysis are completed before such activities take place."

It was found that Test Plan (TPN) 12.2 was not issued until after the work associated with the test plan had begun.

Root Cause:

It appears that circumstances made it difficult to delay field work governed by this test plan. Draft test plans and manufacturer's manuals were used in the field to perform the described work.

Suggested Corrective Action:

The QAO and Geoscience Manager will make certain that future work governed by Work Plans (WPs), Test Plans (TPs) and TPNs will not commence until final versions are transmitted to staff involved in the work and appropriate training has been completed. Due to the fact that draft procedures and manufacturer's instructions were followed during the work governed by TPN-12.2, the QAO does not feel that the quality of the data collected should be questioned.

Finding 2:

QAP 3.2 Rev 2, Documentation of Technical Investigations states in Section 5.1:

> "Scientific forms shall be assigned a unique identification number that includes the date, a reference to the NWRPO QA Plan or procedure in which the form is defined and a revision number."

After reviewing forms in TPs and TPNs, it was found that a unique identification number was not assigned to all scientific forms.

Suggested Corrective Action:

A unique identification number will be assigned to each scientific form in QA plans and procedures.

Finding 3:

QAP 6.1 Rev 1, *Issue and Control of Quality Assurance Documents* states in Section 5.3:

> "Approximately once yearly, the QAO shall verify that QA documentation is up to date by issuing a Documentation Verification Form and copies of the QAPM and TPM Indexes listing the most current versions of all QA documents. Document holders shall verify that the manuals assigned to them contain the documents listed on the Index and sign and return the form to the QAO. "

It was found that Documentation Verification Forms are not on file in the QARC.

Root Cause:

It is apparent that the previous QAO did not send out yearly Documentation Verification Forms to document holders, so therefore no forms are filed in the QARC.

Suggestions Correction Action:

A random check was performed on various document holders' QA manuals to assure that the manuals were up to date. It was found that the manuals checked were up to date. It was also verified that document holders have returned Document Receipt Forms. The QAO is fairly confident that QA manuals are kept current due to these checks. The QAO will transmit Documentation Verification Forms on an annual basis and will file in the QARC upon receipt.

Finding 4:

QAP 15.1 Rev. 1, *Control of Nonconforming Items or Activities* states in Section 5.1:

> "Upon discovery of a potential nonconformance, the following steps shall be taken:
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> - An NCR is filled out by the discoverer and submitted within two days of the discovery to the PI..."

QAP 15.1 also states the definition of a nonconformance in Section 3.3 as "...a deficiency in characteristic, documentation, or procedure that renders the quality of an item or activity unacceptable or indeterminate."

The QAPP states in Section 15.2:

"Examples of nonconformances include 1) not preserving a water sample according to the prescribed procedure for certain chemical analyses, 2)receiving sand-sized mixed –rock from a vendor instead of Colorado silica sand specified in the procurement document, 3) receiving an instrument-detection limit instead of the method-detection limit as requested..."

It was found that Nonconformance Reports have not been submitted to the QARC since 1999 (NCR-99-1).

Suggested Corrective Action:

After further investigation, it was determined that problematic issues that may arise are documented in scientific notebooks and memos and corrected by technical staff before affecting quality. Data limitations and data censoring information are incorporated in metadata reports submitted with all QARC data packages. There is not a concern that quality has been affected due to the absence of Nonconformance Reports, however it would be an improvement to the program to implement the formal process of submitting Nonconformance Reports due to the occurrence of a nonconforming item or activity.

The QAO will review other applicable procedures and requirements and will suggest whether the current QAP should be implemented as it is currently written or revised. Discussions will occur with staff to determine the path forward. Revisions and additional training may be required to help implement the QAP.

Audit Observations:

Observation 1:

QAP-3.1 Rev 1, *Independent Technical Review* states:

> "Technical reviewers shall meet the following criteria:
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> - Have no direct participation in developing the document, unless such participation is approved by the QAO"

No documentation of QAO approvals of reviewers directly involved with document development was found in the QARC. This does not mean that reviewers were not approved by the QAO or not properly trained, but there was no apparent documentation in the QARC.

Recommendation: It is recommended that documentation of the QAO approval of reviewers be included in the review package submitted to the QARC. The Technical Review Form could also be edited to include a line for QAO approval of reviewers.

Observation 2:

QAP-7.1 Rev 1, *Procurement of Items and Services* includes several elements that are unclear and hard to follow. Some steps in the process are not followed because of the conflict with Nye County purchasing procedures.

Recommendation: It is recommended that the QAP is revised to include clear and concise instructions that also comply with Nye County purchasing procedures and applicable NQA-1

requirements. The QAO will review NQA-1 and will discuss proposed revisions with the Geoscience Manager.

General Audit Recommendations: It is recommended that QAPP, QAPs, WPs, TPs, and TPNs be revised to reflect new organization changes, and other improvements deemed necessary by the QAO and technical staff in order to improve program implementation.

Required Actions: The Director or designee needs respond to the findings and observations within 30 days of receipt per QAP-18.1, *Audits and Surveillances*.