NYE COUNTY WATER DISTRICT

QUALITY ADMINISTRATIVE PROCEDURE

TITLE: **Audits and Surveillances**	REVISION: **0** DATE: **01-20-15** PAGE: **1 of 12**
PROCEDURE NUMBER: **NCWD QAP-18.1**	SUPERSEDES: **None**
APPROVAL General Manager 1/21/15 Date	CONCURRENCE Technical Manager 2-10-15 Date Quality Assurance Officer 1/21/15 Date

1.0 PURPOSE

This quality administrative procedure (QAP) describes Nye County Water District (NCWD) requirements and responsibilities for internal surveillances and audits of quality-affecting activities conducted by NCWD personnel and external surveillances and audits of contractors and commercial vendors, such as analytical laboratories, not operating under the NCWD Quality Assurance Program Plan (QAPP).

2.0 APPLICABILITY

This QAP applies to the performance of surveillances and audits for activities subject to the requirements of the NCWD QA program.

3.0 DEFINITIONS

3.1 ***Audit***—planned and documented investigation, examination, or evaluation of objective evidence to determine compliance of the NCWD technical program with established procedures, instructions, drawings, and other applicable documents.

3.2 ***Condition adverse to quality (CAQ)***—a nonconforming condition that, if left uncorrected, will have a significant negative effect on the quality of the NWRPO technical program or the safety of personnel.

3.3 ***Corrective action***—action taken to correct and prevent the recurrence of a nonconformance.

3.4 ***Nonconformance***—a deficiency in characteristic, documentation, or procedure that renders the quality of an item or activity unacceptable or indeterminate.

3.5 ***Quality administrative procedure***—a procedure developed to implement the quality assurance (QA) requirements for the NCWD QA program.

3.6 ***Surveillance***—monitoring a quality-affecting item or activity to verify that it conforms to specific requirements of NCWD QA plans and procedures.

4.0 RESPONSIBILITIES

4.1 General Manager

The General Manager or designee is responsible for ensuring that the QA Officer (QAO) establishes an audit and surveillance program for NCWD technical programs and that QA and technical personnel have the appropriate support and authority to meet audit and surveillance objectives in a timely manner.

4.2 Quality Assurance Officer

The QAO is responsible for developing, scheduling, and implementing the NCWD audit and surveillance program. The QAO is also responsible for providing the scope and schedule for planned audits or surveillances to the General Manager or designee, Technical Manager (TM), and Principal Investigator (PI). The QAO is also responsible for developing an audit plan, performing the audit as planned, performing pre- and post audit briefings, and preparing the audit report.

4.3 Technical Manager

The TM is responsible for participating in audit conferences and ensuring that the PI responds to audit and surveillance reports in an appropriate and timely manner.

4.4 Technical Personnel

NCWD technical personnel are responsible for fully supporting audits or surveillances as needed and requested by NCWD QA personnel.

5.0 PROCESS

The QAO may perform several surveillances each fiscal year. A full audit of the NCWD QA program shall be performed at least once annually or as requested by the TM.

5.1 Audit or Surveillance Initiation

The QAO shall schedule audits and surveillances at a frequency commensurate with the status and importance of the activity.). Additional audits or surveillances shall be conducted when deemed necessary by the QAO.

5.2 Audits

The QAO shall identify areas or activities to be audited and a tentative schedule for the audit.

5.2.1 Preparation of the Audit Plan

The QAO shall develop an audit plan for each audit containing the following information:

- Preparation date of audit plan
- Unique audit number
- Audit schedule
- Audit scope, including specific areas or activities to be audited
- Checklist of items to be audited.
- Applicable documents (e.g., procedures, regulations, or standards) that govern the audited activities
- Responsible person(s) to be notified for audit

Attachments 1 and 2 present a sample audit plan and checklist.

5.2.2 Audit Notification

The QAO shall notify the responsible PI of the area to be audited. Notification shall include the following:

- Audit scope
- Scheduled audit date

Notification shall generally be provided at least 5 working days prior to the initiation of an internal audit; however, unscheduled audits may occur when deemed necessary by the QAO. Formal written notification shall always be provided for external audits of contractors or commercial vendors.

5.2.3 Pre-Audit Conference

A pre-audit conference shall be held to discuss questions regarding the audit and its scope. The conference shall be attended by the TM and one or more representatives (including the PI or designee where possible) responsible for an area of work or activity to be audited. At the conference, the following shall be done:

- Introduce the conference attendees
- Establish communication
- Present the basic elements of the audit plan (i.e., scope, items to be examined, and proposed schedule)
- Schedule and discuss the format of the post-audit conference
- Discuss possible assistance needed by conference attendees to achieve audit goals

5.2.4 Audit Activities

Audit interviews and the examination of activities shall be documented in detail by the QAO. The auditor shall request specific items of evidence for examination. If an item cannot be produced immediately, the QAO shall allow a reasonable amount of time for it to be produced; if it cannot be produced in a reasonable amount of time, it shall be noted on the audit checklist as "not available for audit," and evaluated for a possible negative finding. Upon completion of the audit, the audit team shall ensure that the audit checklist is complete and prepare a draft audit report, detailing both favorable and unfavorable findings and/or observations.

5.2.5 Post-Audit Conference

A post-audit conference shall be held immediately following the audit and attended by the individuals who attended the pre-audit conference. The audit team shall discuss its findings and observations with the TM and responsible PI. Suggestions shall be made regarding corrective action on any findings. If deemed necessary, a tentative follow-up audit date shall be established.

5.2.6 Audit Report

A final audit report shall be prepared by the QAO and issued to the responsible PI, TM, and General Manager or designee for review within 15 days of the audit. A sample audit report is presented as Attachment 3. Nonconforming conditions described in Section 5.4, requiring prompt corrective action shall be reported to the responsible PI, TM, and General Manager or designee immediately. The audit report shall contain, at a minimum, the following:

- Audit date, subject, purpose, and scope
- Responsible individual(s) contacted
- Audit activities
- Determination of the effectiveness of the QA program elements for providing the required control on the activity audited
- Findings and observations, with a detailed description of the root cause, where possible
- Proposed corrective action, with measures suggested to prevent recurrences
- Recommendations for improvements to the QA program and or implementation
- Planned follow-up audit or surveillance, if required

Copies of audit reports shall be submitted to the QARC.

5.2.7 Response to Audit Report

The responsible PI or designee shall respond in writing to the final audit report within 30 days of receipt. The PI shall investigate all findings, observations, and proposed corrective action. The PI shall notify the QAO in writing of planned corrective action activities before the response date. Nonconformances and respective corrective actions identified during the audit shall be resolved according to Sections 5.4 and 5.5.

Follow-up action described in the audit report, including another audit or surveillance of the deficient areas, shall be taken no later than 60 days after the audit.

If it is discovered during a follow-up audit or surveillance that the nonconformance has not been satisfactorily corrected, this fact shall be documented in a follow-up audit report, and additional audits shall be conducted until the nonconformance is corrected.

5.3 Surveillances

5.3.1 Surveillance Plan

A surveillance plan shall be prepared by the QAO addressing, as appropriate, the same elements as the audit plan described in Section 5.2.1.

5.3.2 Surveillance Notification

The QAO shall notify the responsible PI or designee of the surveillance scope and schedule at least 5 working days prior to the surveillance; however, an unscheduled surveillance may be made when deemed necessary by the QAO. Formal written notification shall always be provided for external surveillances of contractors or commercial vendors.

5.3.4 Surveillance Activities

Surveillance personnel shall verify specific items in the surveillance checklist by examining the appropriate data, equipment, and records and, when necessary, interviewing the responsible PI and staff members. Interviews and examinations shall be documented in detail by surveillance personnel. At the completion of the surveillance, the QAO shall write a draft surveillance report detailing both favorable and unfavorable findings and observations.

5.3.5 Post-Surveillance Conference

The QAO shall conduct a conference immediately following the surveillance and discuss any findings and observations with the responsible PI and/or staff member, as appropriate. The QAO shall clarify findings with the attendees and resolve them during the conference, if possible. The QAO shall also establish a closure plan and schedule for any remaining findings.

5.3.6 Surveillance Report

The QAO shall prepare the final surveillance report and submit it within 15 days to the responsible PI, TM, and General Manager or designee for review. Findings identified as nonconformances, as defined in QAP-15.1, that require prompt corrective action shall be reported to the responsible PI, TM, and General Manager or designee immediately. The surveillance report, similar in format to the audit report, shall contain the following:

- Surveillance date, subject, purpose, and scope
- Name of the QAO and participating team members
- Responsible individual(s) contacted
- Surveillance activities
- Findings and observations, with a detailed description of the root cause, where possible
- Proposed corrective action, with measures described to prevent recurrence
- Planned follow-up surveillance, if required

A copy of the surveillance report shall be submitted to the QARC.

5.3.7 Response to Surveillance Report

The responsible PI or designee shall respond in writing to any remaining findings and observations in the final surveillance report as soon as practicable but no later than 30 days of receipt of the report. The response shall include the corrective action plan, and its implementation schedule for all outstanding findings and observations. The findings identified as nonconformances and the respective corrective actions shall be resolved as described in Sections 5.4 and 5.5.

Follow-up action described in the surveillance report, including another surveillance of the deficient areas, shall be taken no later than 30 days after the PI response.

If it is discovered during a follow-up surveillance that the nonconformance has not been satisfactorily corrected, this fact shall be documented in a follow-up surveillance report, and additional surveillance(s) shall be conducted until the nonconformance is corrected.

5.4 Control of Nonconforming Items of Activities

5.4.1 Identification of Nonconformance and Proposed Corrective Action

Upon discovery of a potential nonconformance, the following steps shall be taken:

- The discoverer notifies the PI, TM and QAO of the potential nonconformance in an email or memo. If the nonconformance is discovered in the field, the TM shall be notified by phone and documentation made in the scientific notebook.
- The names of the discoverer and responsible PI and a brief description of the nonconformance are provided in communications with the PI, TM, and QAO.
- A proposed corrective action and schedule are provided by the PI and/or the TM and submitted to the QAO.
- The nonconformance, proposed corrective action, and schedule are documented in the NC/CA logbook by the QAO. The nonconformance and associated corrective action shall be assigned a unique number consisting of the letters “NC” for nonconformance, 2 numbers indicating the nonconformance in sequential order, and the year of the occurrence (i.e. NC-01-2014).

5.4.2 Condition Adverse to Quality

If a nonconformance is deemed to be condition adverse to quality (CAQ), the following steps shall be taken:

- The QAO verbally notifies the TM and General Manager or designee immediately, and follows up with a written notification.
- The TM, PI or designee immediately stops all work associated with the CAQ, and a written notification of the action is sent to the QAO.
- The QAO, in consultation with the General Manager and attendees of the nonconformance discussions, determines whether the stopped work is to remain halted, immediately communicates this decision verbally to the responsible PI, and follows up with a written notification.

- The PI ensures that the decision of the QAO is implemented.

5.4.3 Tagging of Nonconforming Items

Upon confirmation of a nonconforming item, the PI or designee shall ensure that the nonconformance is clearly identified by attaching a tag to the item, marking it "DO NOT USE", or using another appropriate method and isolating it immediately. If a nonconformance tag is used, the name of the PI and the nonconformance number shall be specified on the tag.

If the nonconformance is an activity, the PI shall inform impacted personnel via a memo copied to the QAO and TM.

5.4.4 Nonconformance Discussions

The QAO shall coordinate discussions with the discoverer, PI, and TM to decide whether the specified item or activity is a nonconformance. The discussions shall be held soon after discovery, unless the discoverer believes that the potential nonconformance is a CAQ, in which case the discussions shall be convened as soon as possible to decide whether work shall remain stopped until corrective action can be implemented.

If it is determined during discussions that the item or activity in question is not a nonconformance, no further action is required.

If it is determined that the item or activity is a nonconformance, the QAO will document it as such in the NC/CA logbook, an actions described in Section 5.5.

5.4.5 Logging a Nonconformance

The following shall be logged by the QAO in the NC/CA logbook:

- Date of discovery
- Names of the discoverer and responsible PI
- Brief description of the nonconformance
- Proposed corrective action and schedule
- Proposed date of the required follow-up surveillance
- Proposed date of completion of the follow-up action

The QAO shall review the NC/CA logbook semi-annually and sign it to verify that it has been reviewed. In addition, the QAO shall track all nonconformances and prepare an annual report for the General Manager or designee indicating possible trends.

5.5 Corrective Action

The identification, documentation, and resolution of nonconformances shall be completed according to Section 5.4.

5.5.1 Corrective Action Documentation

The QAO shall log all nonconformances within two weeks of the nonconformance discussions.

The information logged by the QAO in the NC/CA logbook shall contain an analysis of the underlying cause of the nonconformance; the corrective action to be taken in order to correct the nonconformance and prevent its recurrence; the corrective action completion schedule; and an analysis of the impact of the nonconformance on activities, data, analyses, and/or experiments.

In addition to the entries in the NC/CA logbook and those mentioned above, the following entries shall be made by the QAO:

- Corrective action and schedule
- Completion dates of the corrective action follow-up surveillance

5.5.2 Corrective Action Follow-Up Surveillance

The QAO shall perform a follow-up surveillance within two weeks of the proposed date for corrective action completion. The surveillance shall determine whether the corrective action has corrected the nonconformance and prevented its recurrence.

5.5.3 Corrective Action Implementation

If the follow-up surveillance determines that the corrective action has been successfully implemented and that recurrence of the nonconformance has been prevented, the QAO shall document the implementation and correction in the NC/CA log book and remove the nonconformance tag and include in NC/CA log book (if applicable). These actions shall complete all required activities and close out the nonconformance.

If the follow-up surveillance indicates either that the corrective action has not been implemented or that it does not effectively correct the nonconformance, a discussion shall be arranged by the QAO and the procedure for an initial nonconformance shall be followed.

5.5.4 Review of Corrective Actions

The QAO shall review the logbook semiannually and sign it to verify that it has been reviewed. In addition, the QAO shall track all nonconformance's and corrective actions and prepare an annual report for the General Manager or designee indicating possible trends and providing suggestions for reversing negative trends and implementing subsequent required actions.

6.0 RECORDS

Documents generated by this QAP are QA records and shall be submitted to the QARC by the QAO. Prior to submittal, the QAO shall ensure that each document is complete, legible, and adequately identifiable, as specified in NCWD QAP-17.1, *Records Management*.

The QA records generated by this QAP shall include the following:

- Auditor and surveillance personnel qualifications
- Audit and surveillance schedules, plans, checklists, and reports

7.0 REFERENCES

NCWD QAP-17.1, *Records Management*. Quality Administrative Procedure. Nye County Water District (NCWD). Pahrump, Nevada.

8.0 ATTACHMENTS

Attachment 1 Sample Audit Plan

Attachment 2 Sample Audit Checklist

Attachment 3 Sample Audit Report

Attachment 1
Sample Audit Plan

Audit Plan Prepared: January 20, 2012
J. Jones, Lead Auditor

Quality Assurance Audit Plan
Nye County Water District
Audit Number NCWD-29

1.0 SCOPE

This audit includes all quality-affecting activities associated with the field activities within the Waterlevel Measurement Program.

2.0 SPECIFIC AREAS (ACTIVITIES TO BE AUDITED)

Water level monitoring team

Equipment calibration and standardization, verification of procedures for sounding wells and recording data.

3.0 RESPONSIBLE PERSON(S) TO BE NOTIFIED

J. Gonzales
B. Richardson
C. Windsor

4.0 APPLICABLE REFERENCE DOCUMENTS

NCWD QAP-12.1, *Control of Measuring and Test Equipment*

NCWD TP-9.9, *Measurement of Groundwater Levels Using Electric Well Sounders*

NCWD WP-10, *Groundwater Level Monitoring and Evaluation*

5.0 PLANNED DATES OF AUDIT

June 21 – 22, 2012.

6.0 CHECKLIST

See attached.

Attachment 2
Sample Audit Checklist

Form NCWD QAP-18.1-2 Rev.0
01-20-15

Nye County Water District
QUALITY ASSURANCE AUDIT CHECKLIST

Page ____ of ___

Date of Evaluation:	
Type of Activity:	☐ Audit
	☐ Surveillance
Auditors/Surveillance Personnel:	
Controlling Document:	
QA Program Plan:	
Activity Evaluated:	

Criterion/Requirement	**Comments/Recommendations**

Attachment 3
Sample Audit Report

QUALITY ASSURANCE AUDIT REPORT

Nye County Water District
Audit Number NCWD-29

Date: July 3, 2012

To: J. Gonzales, Responsible Supervisor/PI

From: NCWD Quality Assurance Officer

Subject: Audit of Water Level Monitoring Program

PURPOSE: To verify that the controls established by the NCWD Quality Assurance Program are effective in assuring that all measuring and test equipment is adequately controlled, calibrated and standardized at specified intervals, and adjusted when necessary. The aim of this audit as well as the entire QA program is to provide adequate confidence that the NCWD activities will result in valid data.

SCOPE: The audit covered the procedures delineated for the Water level Monitoring team and related QA procedures dealing with the control of measuring and test equipment.

SUMMARY: The measuring and test equipment utilized during NCWD water level monitoring activities appears to be in control and to be gathering valid data.

QAO: D. Jones

Dates of Audit: June 21 - 23, 2012

Person Contacted: J. Gonzalez

AUDIT CONDUCT: All NCWD water level monitoring instruments were evaluated. Equipment calibration and standardization procedures were audited against the NCWD QAP 12.1, Revision 4, 6/15/03, entitled Control of Measuring and Test Equipment; as well as Procedures for Water Level Monitoring (NCWD Technical Procedure TP-9.9).

The audit conducted was focused on the items on the audit checklist (Attachment 2).

Recommendations: Implementation of the governing procedure NCWD QAP-12.1 could be improved by requiring in NCWD QAP-12.1 that calibration records be submitted to the QARC semi-annually.