Response to Findings:

RTI International Audit Report

40 Code of Federal Regulations (CFR) Part 58 Technical Systems Audit (TSA) of Clean Air Status and Trends Network (CASTNET) Program Ozone Monitoring Process

Prepared by:

Air Resource Specialists, Inc.

Prepared for:

The National Park Service Air Resource Division (NPS ARD)

July 2014

Section 2: General Program

Findings

FINDING 1:
(Section 7) Prior to the TSA, RTI reviewed the QAPP and ARS SOPs posted on the CASTNET Web site. During the TSA, ARS also presented the RTI auditors with the ARS GPMP QAPP. After a complete review of all QA documents (CASTNET QAPP, ARS GPMP QAPP, ARS SOPs, and checklists used by ARS staff and NPS site operators), RTI has the following findings:

1. The ARS GPMP QAPP is not listed on the CASTNET Web site. This is the primary quality management document that the ARS management and staff and NPS site operators use for their quality system.
2. Both of the QAPPs need to update the organizational charts for the NPS and ARS management and staff involved with the CASTNET program.
3. The CASTNET QAPP has information regarding ARS activities and involvement at the NPS sites, but there is no ARS management signature on the approval page.
4. The ARS GPMP QAPP is dated July 2009 and needs to be reviewed, updated, and approved by NPS and ARS (see separate list of issues and concerns in Section 7 of this report).
5. The ARS SOPs posted on the CASTNET Web site are not current. The supporting checklists for the ARS staff and NPS site operators need to be reviewed to determine if these checklists are still being used properly.
6. There is a lack of communication between ARS and AMEC on the process and responsibilities for posting the most recent versions of the ARS SOPS to the CASTNET Web site.

Discussion:
Prior to the TSA, RTI was informed that the current CASTNET QAPP and ARS SOPs were posted on CASTNET Web site. During the TSA, the ARS GPMP QAPP was presented to RTI that closely matches the ARS SOPs and activities. The RTI auditor did not ask either Mr. Stewart or Mr. Kirk if they have considered adding the ARS GPMP QAPP to the CASTNET site as a point of reference for personnel involved with the NPS sites.

The organizational charts for ARS and NPS management and staff needs updated in both QAPPs. Mr. Kirk provided the RTI auditor a copy of the most recent ARS-NPS organizational chart involving the CASTNET program during the TSA. A copy of the organizational chart can be found in Section 3.

The CASTNET QAPP is relatively up-to-date (Revision 8.1 dated October 2013) and discussed the ARS activities and their involvement at the NPS sites. In reviewing the approval page, there are no ARS management approval signatures, some management personnel are no longer with the program, and the signatures are dated for February 2011.

The RTI auditor discussed with Mr. Kirk that the ARS GPMP QAPP needs to be reviewed, updated, placed on a reviewing schedule, and submitted to upper management and NPS for approval. The RTI auditor reviewed the QAPP and has provided some of the issues and concerns in Section 7 of this report.

Based on a conversation with Mr. Marcus Stewart (AMEC) and Mr. Kirk, a process will be re-established for the posting of current ARS SOPs to the CASTNET Web site. ARS will establish an annual reviewing process for reviewing and updating SOPs to the CASTNET Web site. Mr. Kirk is aware of the outdated SOPs and as time allows will review SOPs and return the process to annual reviews. Mr. Kirk will also review the checklists listed in the Field Calibration SOPs to determine if these checklists are still be used and are valid. There have been some equipment upgrades that have made some of the checklists outdated. Ms. Jessica Ward provided RTI with updated revision of SOP 3340 (Revision 4.3 in March 2012 and Revision 4.4 in October 2013) that were

not posted on the CASTNET Web site.

RECOMMENDATION:
AMEC and ARS management need to discuss if there are enough differences in each of their quality management systems to determine if it is necessary to have the ARS GPMP QAPP also posted on the CASTNET Web site. It could be beneficial because the information provided in the ARS GPMP QAPP closely matches the activities conducted by ARS staff at the NPS sites. Both QAPPs (CASTNET and ARS-NPS) need to be updated to include the current ARS-NPS organizational chart. The CASTNET QAPP also needs changes and corrections to the CASTNET QAPP approval page (changes in personnel and adding ARS management representative, reviewed with updated approval signatures) and change or explanation of company name change from MACTEC to AMEC. The ARS GPMP QAPP prepared in July 2009 needs to be reviewed, updated, and sent through ARS and NPS for approval. A reviewing schedule needs to be developed and followed. If it is decided the ARS GPMP QAPP will be posted to the CASTNET Web site, a process for doing so also needs to be developed. The ARS SOPs need to be reviewed, updated, and submitted for approval to ARS management. All checklists need to be verified with the field specialists that they are still being used. Updated examples of the checklists need to be added to the ARS GPMP QAPP and ARS SOPs. Along with the process to post the ARS GPMP QAPP to the CASTNET Web site, the current ARS SOPs also need to be posted. This process should be documented in both QAPPs.

ARS Response:
ARS plans to work with the NPS to update the QAPP by 2015. During the next revision organizational charts will be updated as needed. The NPS will consult with the EPA to decide if it is necessary to post the NPS QAPP in addition to the CASTNET QAPP on the CASTNET web site. If the consensus is that there would be value in making this QAPP available on this site, then ARS will work with the EPA to post the document. Although the most recent QAPP is not currently available on the CASTNET web site, it is available at each of the stations for site operator access. ARS will discuss with the CASTNET group whether or not management signature on the CASTNET QAPP approval page is appropriate and will sign off on the QAPP if necessary. ARS and AMEC will work with the EPA to determine a schedule for updating documentation on the CASTNET web site on an annual basis.

FINDING 2:
(Sections 4 and 7) It was not apparent that all field specialists completed the required checklists in the Field Calibration SOPs.

Discussion:
In conversations with Mr. Kirk and Mr. Mike Slate, it was inconclusive if all field specialists were completing the required checklists or forms in the Field Operation SOPs. Several of these checklists revolve around the 6-month calibration. There are checklists:

- SOP 3000 "*Procedures for Semiannual Maintenance Visits to a National Park Service Ambient Air Monitoring Station*"
    - Semiannual Site Visit Pre-trip Preparation Checklist
    - Semiannual Site Visitation Checklist
    - Equipment Maintenance/Repair Record
    - NPSAIR Capital Equipment Inventory Checklist

- SOP 3050 "*Siting of Ambient Air Quality Monitoring Stations*"
    - Information Management Center (IMC) New Site/Site Relocation Form

- SOP 3100 "*Calibration and Routine Maintenance of Thermo Environmental Instruments Model 49c or 49i Ozone Analyzers* "
    - Pre-maintenance Ozone Calibration Form

- SOP 3160-2100 "*Calibration of ESC 8816 or 8832 Analog Input Card*"
    - ESC Voltage Analog Input Card Calibration Check Form

Some of these checklists are electronic and others are hard copies. There are also checklists in the SOPs for equipment used at the NPS site that have been updated and replaced. Thus, the checklists are outdated.

RECOMMENDATION:
These SOPs and checklists should be reviewed and updated based on a designed and approved schedule. ARS should have a training session conducted by the QA Manager to explain the forms and their proper completion, review, and storage. Old checklists should be removed from the SOPs and completed examples of the current checklists should be added to the ARS SOPs and ARS GPMP QAPP.

ARS Response:
SOPs and checklists will be reviewed on a regular basis to verify the information contained within is current. Training sessions will be held as needed to review the content and steps outlined in these documents. Old checklists will be removed from SOPs and the QAPP as they become obsolete. In the meantime, ARS field specialists have re-implemented the use of the existing checklists.

FINDING 3:

(Section 4) There are no formal training records for the NPS field operator, but training is provided by the field specialists during the 6-month calibration based on the Semiannual Site Visitation Checklist form.

In Section A.8 of the ARS GPMP QAPP "*Gaseous Pollutant Monitoring Program Quality Assurance Project Plan (QAPP)"* it states that NPS site operators are trained on-site by ARS field staff, but does not describe in detail the method for training, the frequency of the training, or where the training records will be maintained.

In Section 4.2.8 of the ARS SOP "*Procedures for Semiannual Maintenance Visits to a National Park Service Ambient Air Monitoring Station*" it states:

> Following the completion of all scheduled calibrations and maintenance, spend as much time as required with station operators to ensure that the operators have a complete and working knowledge of their required duties. The overall quality of network operators directly translates to the quality of network data. The field specialist will:
>
> - ✓ **Observe operator -** Observe the operator perform a complete station check and review procedures for zero checks, precision span checks, and multipoint calibrations.
> - ✓ **Review log notes** - Review operator log notes, station checklists, calibration forms, other data documentation, and overall station organization.
> - ✓ **Train** - Further train the station operator on any aspect of multipoint calibrations, precision checks, data reporting, data transmittal, or other operational requirement where deficiencies are observed.
> - ✓ **Review changes -** Thoroughly review any changes in SOPs or operations with the station operator.
> - ✓ **Verify on-site SOPs** - Verify that the current versions of all SOPs are available on-site, and update if necessary to reflect any changes in instrumentation, procedures, or protocols.
> - ✓ **Verify inventory** - Verify that the operator has an adequate inventory of all required forms and consumable supplies, including desiccant, particulate filters, gloves, printer ink, and similar items.
> - ✓ **Encourage/answer questions** - Encourage station operator comments and fully answer any questions the operator may have. Note any operator comments or suggestions.
> - ✓ **Inform -** Update the operator on the monitoring program goals and objectives. Instill in each operator a sense of purpose to stimulate self-interest and responsibility.

The field specialist checks the blocks and documents the corrective action. The training record process is not complete until the site operator signed and dates the form acknowledging the training was received.

Discussion:
At the ROM406, site, Mr. Kirk and Mr. Slate stated the site operators are trained three different ways: 1) From previous site operator, 2) during new site or relocation setup, and 3) every 6-month calibration. Since the site operator was not present during the onsite visit, the RTI auditor could not confirm with her (Ms. Dyan Harden)

the method she was trained. ARS also does not maintain or track NPS training records. The only trackable method for determining the site operator's training would be through the Semiannual Site Visitation Checklist. The items for the field specialist to choose from are listed in the finding.

RECOMMENDATION:
The training regimen is there, but not describing the type of training performed or having the site operator sign and date the Semiannual Site Visitation Checklist form as acknowledgment of receiving the training does not complete the record. The type of training needs to be documented as well as the field operator signing off and dating the checklist. ARS could add a signature box at the end of the Semiannual Site Visitation Checklist form as well as a comments box that would explain the type of training provided during the visit. These forms are already maintained on the primary server at ARS and the information regarding the training provided by the field specialist can be documented to provide field operator training support. During the next 6-month visit, the field specialist can re-assess the progress of the field operator based on the previous training.

ARS Response:
The semi-annual checklist will be modified to include a detailed training section and signature page. This documentation will be signed off on during each 6-month visit and training session. The details of the training that was provided will be listed in this documentation. Hard copy and electronic copies will be kept at ARS. Hard copies will also be stored in each station.

FINDING 4:
(Section 6) ARS does not have an SOP that outlines a test plan for evaluating software updates and testing changes. There is no formal documentation tracking the changes or updates, thus no results of any recent updates. Software development is performed in-house (no commercial company) and is verified, but not documented.

Discussion:
Ms. Ward stated that any changes to the data process are thoroughly tested by a minimum of the database programmer plus the IMC manager before the changes are released for use. Requirements related to the update were provided to the software developers by the IMC manager and discussed to ensure understanding. The software developers made the required updates in the appropriate software application modules, and tested both the modified modules and the entire application within the development environment using test monitoring sites and configurations based on real monitoring sites. Data values were compared between the test sites using the updated software and the real monitoring sites using the production software. The updated software was then published in a test environment, used on the test sites and a subset of real monitoring sites, and closely monitored by the software developers and IMC staff until all were confident the update was working correctly. The updated software was then put in place as the production software.

SOP 3340 "Information Management Center (IMC) Concept and Configuration for the National Park Service Gaseous Pollutant Monitoring Program" states under the responsibilities of the Database Manager to:

- Design, develop, implement, test, and maintain database, data acquisition, data communications, site documentation (DataView), trip report forms, and applications software to meet evolving program needs
- Ensure that all software licenses and updates are current
- Maintain and upgrade project and request Web site hardware configurations and software.

SOP 3340 does not state where the design plan, test plan, and results are maintained. RTI Auditors are satisfied that prior to implementation of internally developed new software packages and/or changes in programming scripts, each are fully tested by multiple qualified personnel prior to field implementation.

RECOMMENDATION:
In Section 14.0 Data Management of the *Quality Assurance Handbook for Air Pollution Measurement Systems, Volume II, December 2008* (*QA Handbook)* discussed the importance of validating and testing your software

programs. The Database Manager (Database programmer) and IMC Manager validate that changes to the software after updates or changes do not affect the quality of the data measurements and calculations, but the design plan, test plan, and results of the test should be documented and maintained to demonstrate the software is within compliance.

While a single form to document testing parameters is likely impossible (due to the variability and likely complexity of all potential software development packages), it is recommended that any tests performed as part of the testing procedure are documented in some manner and stored for future review.

ARS Response:
ARS is currently working on implementing a tracking system to document all changes made to the AQDB. This tracking system will log who requested a change and the date the change was requested. It will also record the reasons for the change as well as document the testing procedures. The appropriate SOPs will be updated to describe this tracking system.

FINDING 5:
(Section 6) An occurrence of data not being invalidated or flagged in reporting databases (Data for wind direction based on June 10, 2013 audit has not been invalidated or flagged in reporting databases). As of November 12, 2013, this data has not been flagged.

Discussion:
Ms. Ward stated the data will be invalidated back to the last good check. At the time of the TSA, the ARS trip report from August confirming the audit finding in June had not yet been finalized and released to IMC.

The result of the audit is first verified to determine that it was an accurate result. In this case, the audit result was confirmed by the ARS calibration check that was done a few months later. These types of results are reviewed monthly when validating data, but the results are usually available after data have been "finalized" for the month. In this case, the corrections are generally made as soon as the result has been confirmed and the appropriate course of action has been determined, and always prior to preparing the annual report and beginning the annual data certification process.

There exists adequate SOP's and Technical Instructions for submitting data to AQS (and other supporting agencies), however the timeliness of resubmitting invalidated data should be addressed. ARS personnel informed RTI Auditors that the Trip Report from August confirming the wind direction issue had not been finalized, so no action to the data could take place.

RECOMMENDATION:
In following SOP instructions, determine the root cause of the problem and provide the necessary documentation to validate or invalidate the data for this particular event. Updating SOP's to include information on specific invalidation steps after a found instrument failure, and time frame to complete steps should be added. If timeliness is still insufficient, additional unscheduled site audits may be needed to expedite data invalidation process.

ARS Response:
Since this TSA occurred, the ARS calibration visit report confirming the results of the failed wind direction response during the audit has been finalized and is now ready to be used in the data validation process. The data in question based on this failure will be invalidated and the results of both the audit and the ARS calibration visit will be used as the supporting documentation for invalidating the data. SOP's will be updated as necessary to outline in detail the steps that are taken to take invalidation action following an instrument failure.

Section 4: Field Operations

FINDING 1:
It was not apparent that all field specialists completed the required checklists in the Field Calibration SOPs.

Discussion:
In conversations with Mr. Kirk and Mr. Mike Slate, it was inconclusive if all field specialists were completing the required checklists or forms in the Field Operation SOPs. Several of these checklists revolve around the 6-month calibration. There are checklists:

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ARS Response:
SOPs and checklists will be reviewed on a regular basis to verify the information contained within is current. Training sessions will be held as needed to review the content and steps outlined in these documents. Old checklists will be removed from SOPs and the QAPP as they become obsolete. In the meantime, ARS field specialists have re-implemented the use of the existing checklists.

FINDING 2:
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ARS Response:

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Section 6: Data and Data Management

FINDING 1:
ARS does not have an SOP that outlines a test plan for evaluating software updates and testing changes. There is no formal documentation tracking the changes or updates, thus no results of any recent updates. Software development is performed in-house (no commercial company) and is verified, but not documented.

Discussion:
Ms. Ward stated that any changes to the data process are thoroughly tested by a minimum of the database programmer plus the IMC manager before the changes are released for use. Requirements related to the update were provided to the software developers by the IMC manager and discussed to ensure understanding. The software developers made the required updates in the appropriate software application modules, and tested both the modified modules and the entire application within the development environment using test monitoring sites and configurations based on real monitoring sites. Data values were compared between the test sites using the updated software and the real monitoring sites using the production software. The updated software was then published in a test environment, used on the test sites and a subset of real monitoring sites, and closely monitored by the software developers and IMC staff until all were confident the update was working correctly. The updated software was then put in place as the production software.

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Section 7: Quality Control and Quality Assurance

FINDING 1:

Prior to the TSA, RTI reviewed the QAPP and ARS SOPs posted on the CASTNET Web site. During the TSA, ARS also presented the RTI auditors with the ARS GPMP QAPP. After a complete review of all QA documents (CASTNET QAPP, ARS GPMP QAPP, ARS SOPs, and checklists used by ARS staff and NPS site operators), RTI has the following findings:

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2. Both of the QAPPs need to update the organizational charts for the NPS and ARS management and staff involved with the CASTNET program.
3. The CASTNET QAPP has information regarding ARS activities and involvement at the NPS sites, but there is no ARS management signature on the approval page.
4. The ARS GPMP QAPP is dated July 2009 and needs to be reviewed, updated, and approved by NPS and ARS.

- General issues: In reviewing the ARS QAPP, many tables, diagram, and exhibits are displayed several pages after the discussion of the table, diagram, or exhibit. To make it easier for the reader, it might be more straightforward to add the table, diagram, or exhibit right after the text in the QAPP. For instances, the organizational chart (Figure A4-1) is mentioned on page 10, but the reader needs to turn to page 27 to see the chart. Between pages 10 and 27 is the complete Section A text with all project management responsibilities.
- Cover page: The QAPP is outdated (July 2009) and a reviewing schedule needs developed for the future reviews)
- A1: Are management listed still involved?
- A2: QA/G-5 has been updated
- A3: Staff involved and last paragraph states QAPP will be reviewed annually
- A4: Network QA Manager Organizational chart shows independence from technical work, but there is no discussion in the text. Is the QAM only responsible for overseeing QA documentation? Who is responsible for reviewing internal and external audits and assessments and overseeing corrective/preventive actions are remedied? Are these responsibilities of the QA advisor or QA Coordinator? There are several types of audits discussed, who oversees these audits, tracks them, and determines if corrective action steps were performed successfully?
- A4: QA Coordinator has very little responsibility and should have some of the tasks listed for the QA Manager.
- A6.1: Confirm number in paragraph starting, “As of July 1, 2009… “ are still correct.
- A6.2: Independent Field Performance Audits-Discuss where the results of these audits are maintained and how used towards the QA program.
- A6.2: CASTNET Program Auditor-Discuss where the results of these audits are maintained and how used towards the QA program.
- A6.2: EPA NPAP audits-Discuss where the results of these audits are maintained and how used towards the QA program.
- A6.2: TSAs-Are these TSAs really being performed and at this frequency? Be careful of listing all of these audits. If they are listed in the QAPP with a time line, they need to be completed and results need to be maintained for reviews.
- A6.2: Data Management Assessments-Document how tracking is performed.
- A6.2: Statement-These documents are reviewed and revised (if necessary) annually.
- A8: More information on where training records for ARS and NPS staff are maintained

- A9: Do you have hard copies of any data or forms?
- Section B-watch mentioning SOPs by number, just in case they may change or be removed.
- References: check for more current documents

5. The ARS SOPs posted on the CASTNET Web site are not current. The supporting checklists for the ARS staff and NPS site operators need to be reviewed to determine if these checklists are still being used properly.
6. There is a lack of communication between ARS and AMEC on the process and responsibilities for posting the most recent versions of the ARS SOPS to the CASTNET Web site.

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The organizational charts for ARS and NPS management and staff needs updating in both QAPPs. Mr. Kirk provided the RTI auditor a copy of the most recent ARS-NPS organizational chart involving the CASTNET program during the TSA. A copy of the organizational chart can be found in Section 3.

The CASTNET QAPP is up-to-date (Revision 8.1 dated July 2013) and discussed the ARS activities and their involvement at the NPS sites. In reviewing the approval page, there are no ARS management approval signatures, some management personnel are no longer with the program, and the signatures are dated for February 2011.

The RTI auditor discussed with Mr. Kirk that the ARS GPMP QAPP needs to be reviewed, updated, placed on a reviewing schedule, and submitted to upper management and NPS for approval. The RTI auditor reviewed the QAPP and has provided some of the issues and concerns in Section 7 of this report.

Based on a conversation with Mr. Marcus Stewart (AMEC) and Mr. Kirk, a process will be re-established for the posting of current ARS SOPs to the CASTNET Web site. ARS will establish an annual reviewing process for reviewing and updating SOPs. Mr. Kirk is aware of the outdated SOPs and as time allows will review SOPs and return the process to annual reviews. Mr. Kirk will also review the checklists listed in the Field Calibration SOPs to determine if these checklists are still be used and are valid. There have been some equipment upgrades that have made some of the checklists outdated. Ms. Jessica Ward provided RTI with updated revision of SOP 3340 (Revision 4.3 in March 2012 and Revision 4.4 in October 2013) that were not posted on the CASTNET Web site. ARS SOPs to the CASTNET Web site was undetermined.

RECOMMENDATION:
AMEC and ARS management need to discuss if there are enough differences in each of their quality management systems to determine if it is necessary to have the ARS GPMP QAPP also posted on the CASTNET Web site. It could be beneficial because the information provided in the ARS GPMP QAPP closely matches the activities conducted by ARS staff at the NPS sites. Both QAPPs (CASTNET and ARS-NPS) need to be updated to include the current ARS-NPS organizational chart. The CASTNET QAPP also needs changes and corrections to the CASTNET QAPP approval page (changes in personnel and adding ARS management representative, reviewed with updated approval signatures) and change or explanation of company name change from MACTEC to AMEC. The ARS GPMP QAPP prepared in July 2009 needs reviewed, updated, and sent through ARS and NPS for approval.

A reviewing schedule needs to be developed and followed. If it is decided to post the ARS GPMP QAPP to the CASTNET Web site, a process will need to be developed. The ARS SOPs need reviewed, updated, and submitted for approval to ARS management. All checklists need to be verified with the field specialists that they

are still being used. Updated examples of the checklists need to be added to the ARS GPMP QAPP and ARS SOPs.

Along with the process to post the ARS-NPS QAPP to the CASTNET Web site, the current ARS SOPs also need to be posted. This process should be documented in both QAPPs

ARS Response:
ARS plans to work with the NPS to update the QAPP by 2015. During the next revision organizational charts will be updated as needed. The NPS will consult with the EPA to decide if it is necessary to post the NPS QAPP in addition to the CASTNET QAPP on the CASTNET web site. If the consensus is that there would be value in making this QAPP available on this site, then ARS will work with the EPA to post the document. Although the most recent QAPP is not currently available on the CASTNET web site, it is available at each of the stations for site operator access. ARS will discuss with the CASTNET group whether or not management signature on the CASTNET QAPP approval page is appropriate and will sign off on the QAPP if necessary. ARS and AMEC will work with the EPA to determine a schedule for updating documentation on the CASTNET web site on an annual basis.