Making Internal Audits Effective

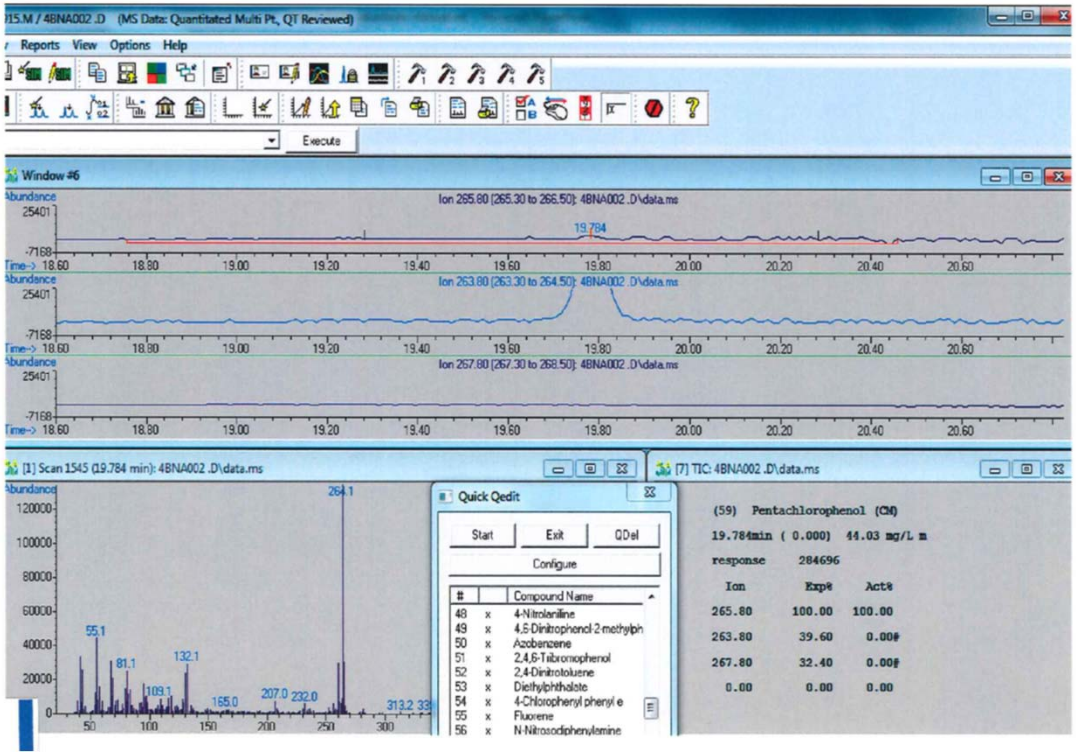
TNI Assessment Forum

January 2016

PIMA COUNTY

In My Previous Life…As an Assessor…

- If a lab didn't have any internal oversight – you can guarantee there would be issues in the lab.
- Better to disclose serious findings discovered by the lab, rather than be discovered by an assessor through an external audit.
- Internal audits need to include raw data review.



Over 7 MI to make up a baseline to get the CCV from 0 mg/L to 44.

In My Current Life…As a Lab Manager

- Internal audits are only meaningful if proper corrective action is put in place.
- Proper training of internal auditors is essential for proper lab overview.
- Supervisors need to do proper data review as well in facilitating internal audits.
- Keep in Mind...Internal Audits are for Self-evaluation & Improvement.

Lab Size Doesn't Matter...

- Whether you are a large or small laboratory, If you choose to be an accredited laboratory, you need to perform internal audits prior to seeking certification, and on a regular basis thereafter.
- Identify your weak spots and give yourself time to correct and implement.
- You need to be familiar with the standard and state requirements to ensure you are meeting them: website, checklists provided by state/TNI.
- Internal audits can be done by QA Staff, Supervisor, Lab Manager, peer or a 3rd party assessor.

Quality Systems Toolbox
http://www.qualitysystems.com/support/pages/9-auditing

- The audit process is a mandatory requirement of ISO9001 (TNI V1:M2 – Section 4.14). Audits are required to monitor and report on the effectiveness of the implementation of the quality management system.
- A documented procedure is required by the standard.
- We suggest you enroll in a professional development course before jumping into the role of Auditor.
- An alternative is to use an external consultant to perform your internal audits for you.

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- Internal Audits need to be scheduled at planned intervals to check that the quality system conforms to the IS0 9001 Standard and that the system is effectively implemented and maintained.
- We recommend the organization perform at least one complete Internal Audit prior to the actual Certification Audit. Findings raised at this audit should be documented. The organization should make every effort to “close-out” these findings before the External Audit takes place.
- The standard recommends that you plan audits to take into consideration the status and importance of the processes and work activities undertaken by your organization.

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A few tips to consider when scheduling your audits:

- prior to the initial Certification Audit you need to have audited all the processes identified in your management system at least once.
- as new processes are introduced they may need auditing several times over quite a short period of time to verify workflows and finalize record keeping requirements.
- you cannot audit processes that you manage / control yourself – what this means is that even in smaller organizations, it is advisable to have at least two internal auditors trained and available. If this is not possible you may need to consider using an external resource.

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Audit Checklists need to be prepared prior to the actual audit.

- There are several options for the format of the audit checklist:
  - a formal checklist can be prepared using a pre-formatted list of questions, or
  - you can use a photocopy of the procedure being audited and mark this up with questions and points to verify.
- The completed Audit Checklist needs to include the names of any personnel interviewed as well as details of documents and records reviewed. Cross reference any non-conforming findings to your Nonconformance Register.

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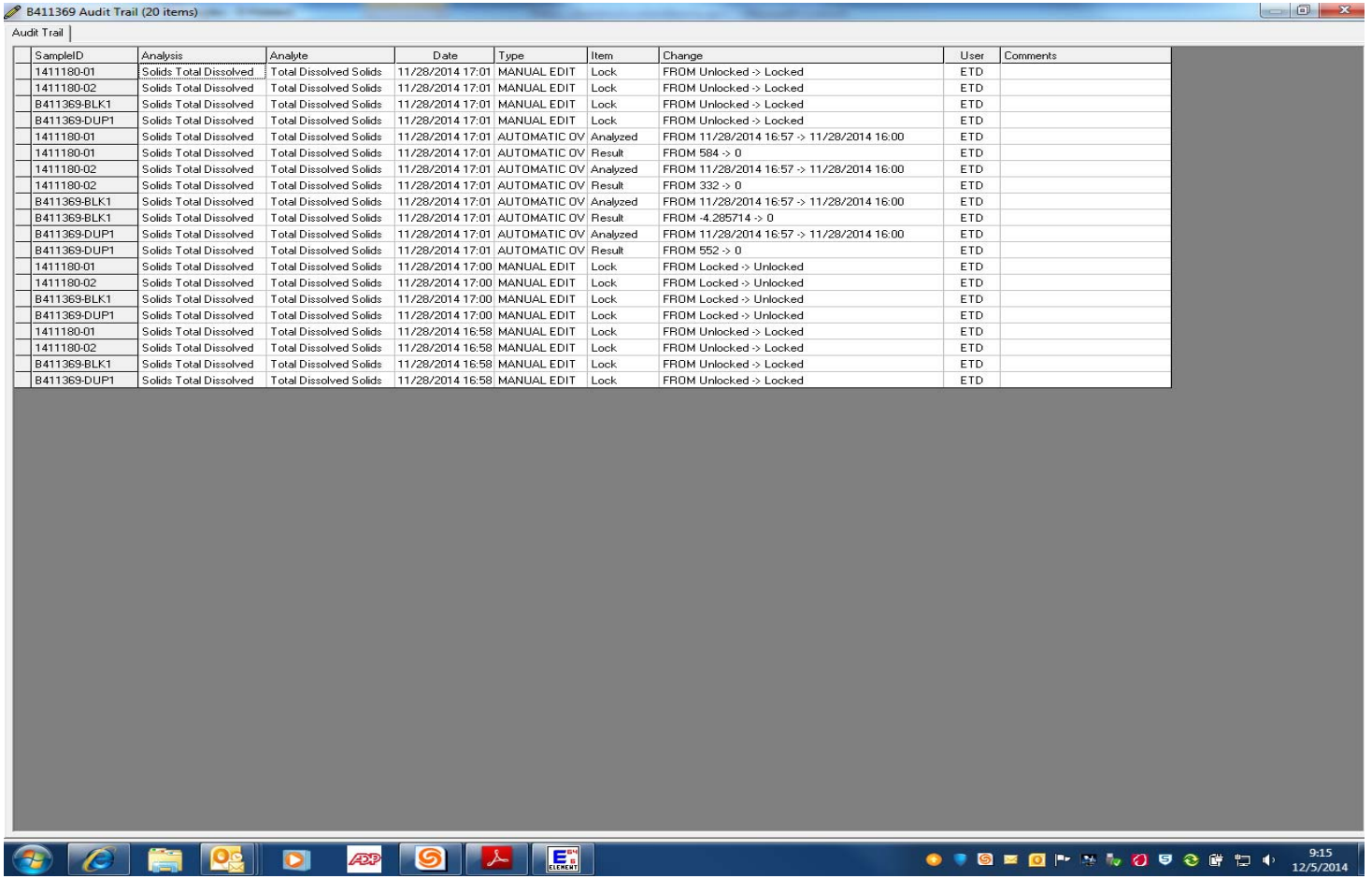
- Findings raised at both Internal and External Audits need to be followed up and the corrective actions taken must be verified as effective.
- Typical records to be maintained are:
  - Audit Report
  - Audit Findings
  - Audit Checklists
  - Audit Schedule
- You can refer to standard ISO 19011 for guidance on auditing. It sets out requirements on training and experience for auditors, and requirements for how audits should be planned.

Pima County Lab Background

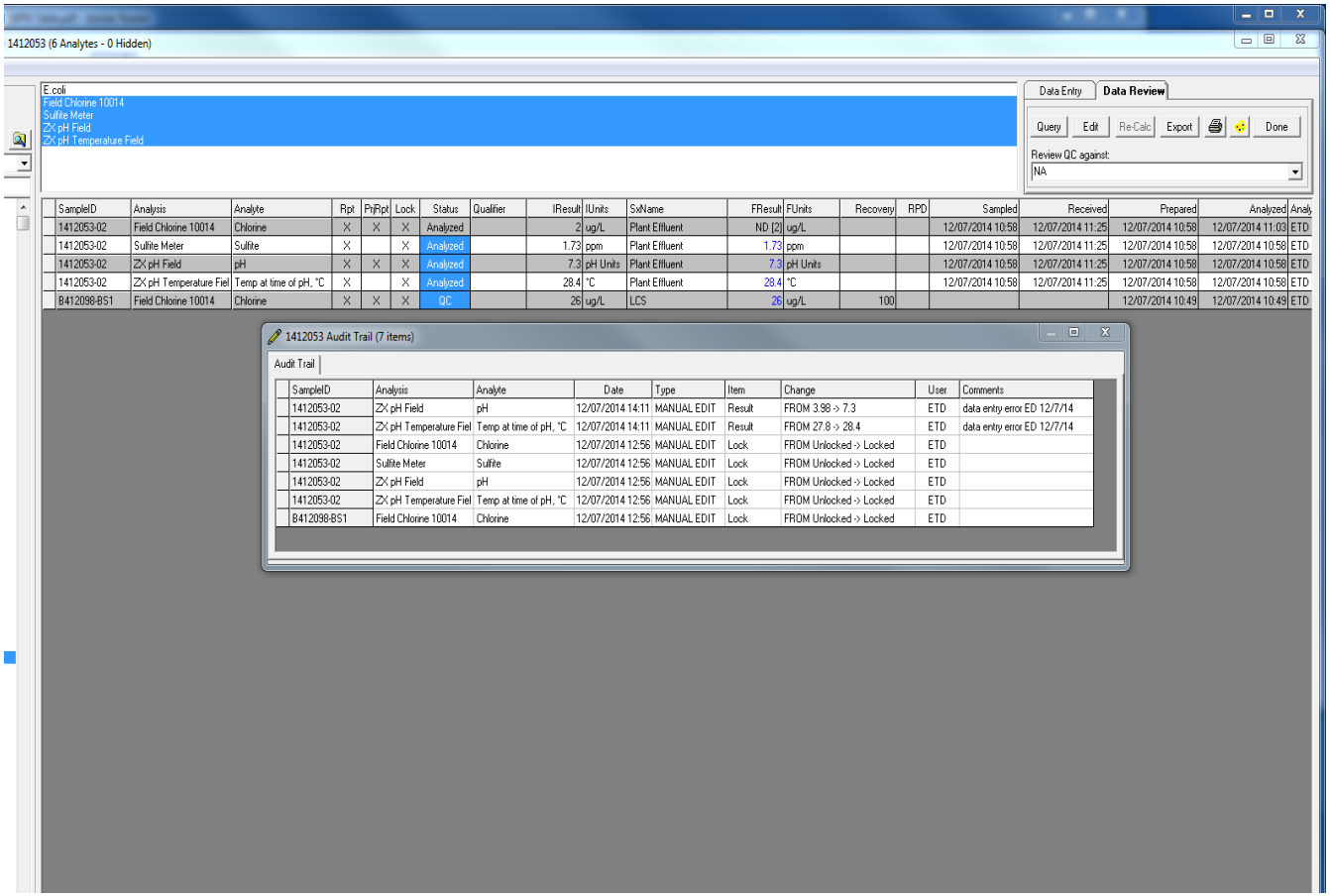
- 30 current employees: Inorganic & Metals/Organic/Micro & Wet Chemistry/ QA & Safety.
- Average 55,000 work orders (COC's) annually.
- QA unit with a Supervisor and 2 chemists that do Internal Audits & maintain Training Records.

Pima County Audit Schedule

- Averaging 8 Internal in-depth Audits annually. The Goal is to Schedule 12 Annually.
- in addition to Scheduled Audits, it may be necessary to conduct special audits as a follow up to corrective actions, PT results, complaints, regulatory audits or alleged data integrity issues. These audits address specific issues.
- Aim is to audit 2 Methods per Unit (Micro/Inorganic/Organic), in detail.
- Audit Processes and Safety, as well.
- Our LIMS, ELEMENT, contains an Audit Trail that Supervisors, QA and Lab Manager use Daily when Reviewing Data.
  - NOTE: If you find something Serious...then what???



Analyst changed analysis time to show that tests were completed earlier since he normally clocked out at 1630 as was listed in his timesheet.



Analyst changed a pH and temperature result when he noticed later in the day that the result he wrote down would have been a violation (faulty meter) but he never changed LIMS to show the true reanalysis time, which in fact, was a different sample all together.

PIMA COUNTY REGIONAL WASTEWATER RECLAMATION DEPARTMENT
COMPLIANCE & REGULATORY AFFAIRS OFFICE
LABORATORY SERVICES, QUALITY ASSURANCE UNIT
PH 520.724.6200, FAX 520.724.6071

2015 INTERNAL AUDIT LOG

AUDIT NO.	LAB UNIT	FOCUS PARAMETER	LIMS ID	AUDITOR	DISTRIB DATE
15001	Inorganic	EPA 350.1 Ammonia	1501095-01, -03	JD/SN	2/18/15
15002	Inorganic/QA	Annual HF Safety Audit	NA	SN	In P.
15003	Microbiology	Total Solids, Volatile Solids	N/A	JD	5-12-15
15004	Inorganic	Inhalation Hazards	NA	NP	5-18-15
15005	Inorganic	TKN EPA 351.2	Batch B507056	JD	8/07/15
15006	Organic	Semi-Volatiles, EPA 625	Batch B507308	JD	In P.
15007	Microbiology	Chlorine and pH-data download	NA	SN	In P.
15008	Tres Rios and Agua Nueva Satellite Lab Safety	Building 52 Safety Observation	NA	NP Jacob Butler	10-30-15

All deficiencies corrected as they were found.

N/A	Not Applicable
ND	Not Distributed
In P.	Audit in Progress

Indigo	Inorganic Unit
Pink	Microbiology Unit
Green	Organic Unit
80% Gray	Quality Assurance Unit
Dk Red	All Lab Units
Red	Immediate Attention

CRAO Internal Audits Checklist

1. Make sure you have access to EPA/SM document, SOP, Quality Manual, TNI rules, State rule (if applicable), Lab licensed parameters.
2. Compare the SOP to the EPA or Standard Methods document. If there are differences, note the exact references of both documents for later.
3. Check the SOP is signed and current.
4. Check SOP references are correct. The references listed should be available in the lab.
5. SOPs must have listed frequency, the amount, acceptance criteria, and calculations of all QC for that method.
6. Review available past audits.

   Review past performance evaluations. Are they handled the same as regular samples? Are they performed 2X per year?
7. Review Training documents and Initial Demonstration of Capability for the analyst. EL V1M4-2009, 1.6.)
8. If the analyst has performed the test for more than a year, review the Ongoing Demonstration of Capability. (EL V1M4-2009, 1.6.3
9. If the method requires an MDL, review (LOD) MDLs and make sure they are current. FIA are quarterly and (ICP 2X a year?). Check the calculations. Standard Methods MDLS.
   a. This QC sample shall contain the analyte at no more than 3X the LOD for single analyte tests and 4X the LOD for multiple analyte tests. (EL V1M4-2009, 1.5.2.1, b.)
10. Check the validity of the LOQ (EL V1M4-2009, 1.5.2.2).
11. Check written records for QC, Standards for expired chemicals/reagent. Check to see if written records match what is in the lab. Records should include dilutions, Mfg., Lot number. Traceability. CoAs. Reagent quality.
12. Instrument Calibration (EL V1M4-2009, 1.7.1.1)
    - Frequency of Calibration, if stated, is met
    - Method of Calibration (linear, quadratic, etc.) is followed.
    - Minimum number of points obtained. 3 unless stated by method.
    - Point isn't dropped from the middle of the curve.
    - Sufficient data to reconstruct the initial calibration. (EL V1M4-2009, 1.7.1.1.b.)
    - Check Calculation.
    - Lowest calibration point should be at or below the LOQ. (EL V1M4-2009, 1.7.1.1.f.)
13. Continuing Calibration
    - Frequency, acceptance criteria follows the SOP/method.
    - Check Calculation.
14. QC- Check they were run in the correct order. QC checks were performed in the correct order.
15. Blanks, LFB, Spikes Spike Dups
    - Performed with acceptance criteria, frequency stated in method/SOP.
    - Check Calculation.
    - Record of Corrective Action, why it was necessary, if it worked.
    - Further action taken if necessary.
    - Make sure a QC was not just reran till they get the correct answer.
16. Check final reports for accuracy, Qualifiers, correct MDLs or PQLs. Agrees with COC and LIMS.
17. Check Chain of Custody for errors.
18. Check Maintenance Logs.
19. Thermometer calibration.
20. Laboratory water quality and testing.
21. Check Extraction/Digestion records.
22. Prep times accurate?
23. Ethic program in place? Documented?
24. Review data audit trail in LIMS, if possible.
25. Are mistakes crossed out, initialed and dated?
26. Is the accredited method reflected in the procedure, raw data, and final report?

PIMA COUNTY
REGIONAL WASTEWATER RECLAMATION DEPARTMENT
COMPLIANCE AND REGULATORY AFFAIRS OFFICE LABORATORY SERVICES
2955 W Calle Agua Nueva, Tucson, AZ 85745 Telephone: (520) 724-6200 FAX: (520)724-6071

INTERNAL AUDIT

AUDIT NUMBER: 15005
AUDIT FOCUS: EPA 351.2 – Total Kjeldahl Nitrogen
DISTRIBUTION DATE: 8-12-15

The Objective:

This audit will provide Laboratory Management with a useful tool to assess the methodology and quality control criteria of the system status and update current practices to reflect required regulations.

The report includes findings and recommendations.

NOTE: The focus will be on the SOP and data acquisition and management in Element for the analysis batch B507056, analyzed on 7-06-15.

Jenelle Chraft please respond to any findings by 9-4-15.

Joseph Doranski
Quality Assurance Chemist
Ext. 46032

Summary of Findings:

- The MDL determination worksheet (Y:\Lab Svcs_Shared Data\Lab\MDLS\Inorganic\EPA 351.3 TKN\Current MDL) for the TKN dated 6-19-14 shows two different values for the analyte concentrations. The "Analyte Level" is 0.6 µ/L (cell D-12), but the Standard Concentration is listed at 0.7000 µg/L (cell I-13). Additionally, the current MDL spreadsheet has no lot number or Element reagent number for the standard that was used; sheet states "Lot Number: See prep sheets".
- Method EPA 351.2, 9.2.4 requires MDLs every six months. The current MDL was performed in June of 2014.
- SOP 5.23, Section 13.5 has the incorrect symbols (<) for the calibration curve acceptance criteria.
- Data audit trail in Element has no comment recorded of the manual edit for the changed result for sample 1507004-01. Manual edit of results in Element must be explained in the comments section of the audit trail in Element.
- The calculation for the Method of Standard Additions worksheet (see attached) has the slopes reversed; first slope should be 0.422 and the MSA slope should be 0.38635906.
- Sample 1507003-04 was run after a blank failure but before rerunning the blank, which then passed. Sample 1507003-04 was not reanalyzed after the blank passed.
- Reagents R403194 and R309166 could not be located. Element has no discard dates for these reagents.
- Element is missing data for the following reagents:

Reagent Number	Received Date on container	Received Date In LIMS	Open Date on container	Open Date in LIMS	Expiration Date on container	Expiration Date in LIMS
R309168	9-20-13	9-20-13	4-11-15	missing	9-21-28	9-21-28
R408276	8-26-14	8-26-14	12-6-14	missing	8-26-29	8-26-29
R403194	Not Found	3-21-14	Not Found	missing	Not Found	3-21-30
R501195	1-15-15	1-15-15	5-8-15	2-24-15	7-15-24	7-15-24
R307298	7-30-13	7-30-13	None	missing	7-30-29	7-30-29
R309166	Not Found	9-20-13	Not Found	missing	Not Found	9-21-28
R410270	10-28-14	10-28-14	None	missing	8-31-19	8-31-19

1.

- Reagent R506258 preparation note in Element is unclear; it states to preserve with 1000 mL of concentrated H_2SO_4.
- Section 14.2 of the SOP states that the start and completion times of the digestion be recorded in the comments section of the Element batch sheet. There are no completion times of the digestion recorded for batch B507056.

RECOMMENDATIONS:

1. Reference the SOP (5.23) section to which1.11 refers.
2. Add prepared reagents shelf life to SOP 5.23, section 12.
3. Initial and date all Lachat maintenance log entries, example 7-29-15.

AUDIT FOCUS: TKN system status

AUDIT BASIS: QC internal audit
QA INSPECTOR: JD

Method Requirements

1.	EPA 351.2, Sect. 2.1	Samples are heated in the presence of H_2SO_4 for two and one half hours.	■Yes	□No
2.	EPA 351.2, Sect. 2.1	Residue is cooled and diluted to 25mL.	■Yes	□No
3.	EPA 351.2, Sect. 4.1	Samples that are suspect to high nitrate concentrations are diluted and reanalyzed.	■Yes	□No
4.	EPA 351.2, Sect. 7.1	Reagent water is ASTM Type II or equivalent.	■Yes	□No
5.	EPA 351.2,	Digestion solution prepared using 133g K_2SO_4 and 7.3g $CuSO_4$ in 800 mL reagent water and then adding 134mL concentrated H_2SO_4 and	■Yes	□No

	Sect. 7.3, Note 1	diluting to 1L.		
6.	EPA 351.2, Sect. 7.3, Note 1	Samples contain 10mL of digestion solution per 25mL of sample.	■Yes	□No
7.	EPA 351.2, Sect. 9.2.4	MDL established for the analyte every six months.	□Yes	■No
8.	EPA 351.2, Sect. 9.3.1	At least one laboratory reagent blank run in the batch.	■Yes	□No
9.	EPA 351.2, Sect. 10.1	At least three standards are analyzed, not including the blank.	■Yes	□No
10.	EPA 351.2, Sect. 10.5	Standards are sampled in decreasing in decreasing concentrations.	■Yes	□No

SOP/QC

1.	SOP 5.23, Sect. 12.2	Hypochlorite solution made day of analysis.	■Yes	□No
2.	SOP 5.23, Sect. 12	Reagents and standards used for analysis are not expired. Shelf life of reagents used for B507056 are undefined in the SOP, except the hypochlorite solution. Element shows expiration dates that appear to be arbitrary.	■Yes	□No
3.	SOP 5.23, Sect. 13.1	At least five standards are prepared, including 0.0(blank).	■Yes	□No
4.	SOP 5.23, Sect. 13.2	The pH of standards adjusted to same pH as the samples. No record of pH adjustment found.	□Yes	■No
5.	SOP 5.23, Sect. 13.5	The r^2 calibration coefficient value is ≥ 0.9950, or the r value is ≥ .09975. SOP has "<" rather than "≥" the r^2 and r values.	□Yes	■No
6.	SOP 5.23 Sect. 14.1	10 mL of Digestion Reagent #1 added to all samples and standards. No reference found in the data that this was done.	□Yes	■No

7.	SOP 5.23, Sect. 14.2	Start and completion times of the digestion recorded in the digestion log and the comments section of the Element batch sheet. No record of digestion times were recorded in the Element bench sheet.	☐Yes	■No
8.	SOP 5.23, Sect. 14.3	Five minutes elapsed after removal of digestion tubes before addition of 20 mL of RODI water. No record of this	☐Yes	■No
9.	SOP 5.23, Sect. 15.4.1	The concentration of SCV control standard used was 20 ppm with recovery acceptance set at ± 10%.	■Yes	☐No
10.	SOP 5.23, Sect. 15.4.2	Calibration Check Standard analyzed immediately after calibration, after every 10 samples, and at the end of the run (20 ppm, ± 10%).	■Yes	☐No
11.	SOP 5.23, Sect. 15.5.1	At least one Laboratory Reagent Blank (LRB) was analyzed with the batch (LRB ≤ MDL).	■Yes	☐No
12.	SOP 5.23, Sect. 15.5.2	Laboratory Fortified Blank (LFB) spiked with 250µL of spiking solution (90-110% recovery)	■Yes	☐No
13.	SOP 5.23, Sect. 15.5.3	Spike and Spike duplicates run every 10 samples with 250µL of spiking solution with 90-110% recoveries and duplicate relative deviation.	■Yes	☐No
14.	SOP 5.23, Sect. 13.5	Calibration curve r^2 value 0.9950 (or r<0.9975).	■Yes	☐No

Reagents

1.	Element	All reagents unexpired?	■Yes	☐No
2.	Element	Prepared standards and reagents documented in Element? R506258 preparation note states "Preserve with 1000 ml conc. H_2SO_4". .	■Yes	☐No
3.	Element	Dilutions of standards and reagents documented in Element?	■Yes	☐No
4.	Element	Purchased standards are documented in Element? Only one reagent in Element has an open date. (R307298)	☐Yes	■No
5.	SOP 5.23, Sect. 15.4.1	Both primary and secondary source controls are used?	■Yes	☐No

Element

1.	Element	All controls and spikes have associated Reagent #s assigned in the batch/sequence?	■Yes	☐No
2.	Element	Control charts maintained?	■Yes	☐No
3.	Element	MDL current?	■Yes	☐No
4.	Element	Duplicates, matrix spike recoveries, blanks, and standard recoveries are all correct for the method?	■Yes	☐No
5.	Element	Reporting units, significant figures, hold times are correct?	■Yes	☐No
6.	Element	Current version of SOP available?	■Yes	☐No

Maintenance

1.	A.A.C R9-14-615 B, 12.	Maintenance log current?	■Yes	☐No
2.	A.A.C R9-14-615 B, 12.	Maintenance performed per manufacturer's specifications?	■Yes	☐No

Training

1.	EL-V1M4-2009-Rev1.1, Sect. 1.6.2.1	The analyst has current training records.	■Yes	☐No
2.	SOP 5.23, Sect. 15.5.4	Yearly on-going demonstration of capability completed.	■Yes	☐No

REFERENCES:

1. TNI, the NELAC Institute Standards, 2009 Edition, E1-V1 2009.
2. QuikChem® 8500 Series Automated Ion Analyzers Training Manual, May 2008, Edition 4.
3. *Methods for Chemical Analysis of Water and Wastes,* EPA-600/R-94/100, August, 1993, "Determination of Kjeldahl Nitrogen" Method 351.2, (Colorimetric, Automated Phenate).
4. *Lachat Instruments QuikChem Method,* 10-107-06-2-D, May, 2001.
5. CRAO Lab SOP 5.10, Method of Standard Additions, Revision 5, effective 8/8/13.

6. CRAO Lab SOP 5.23, Determination of Total Kjeldahl Nitrogen (TKN), EPA 351.2, Semi-Automated Colorimetry, Revision 7, effective 08/25/14.
7. Arizona Administrative Code Title 9 Chapter 14, *Department of Health Services Laboratories.*

Small Lab Internal Audit Reviews

- Peer review of data and entry. Need a second set of eyes.
- Comparisons of SOP, referenced method and actual procedure.
- Properly completed bench sheets & reagent/standard traceability.
  - Five years from now will you know what lot you used?
- Checklists are a big help. Identify what should be checked, Daily, weekly, Monthly, etc.
- From sample receipt to sample report.
  - Can you put all the vital records back together?

Thanks to North Gila county Sanitary district for insight – 8 accredited methods/2 lab employees

Questions???

Barbara A. Escobar

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