

Efficient Sample Throughput:

How to Run Client Samples and Comply
with Accreditation Requirements,
Federal, State, Method, and Project
Specific Requirements

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The Process

- How to get started
- What to do
- The Outcome
 - ♦ EPA200.7, rev 4.4,
 - ♦ SW6010C, rev 3
 - ♦ DW Certification Manual, fifth edition
 - ♦ DOD – QSM, version 3
 - ♦ DOE, Quality Systems for Analytical Services, Rev 2.3
 - ♦ USACE, Louisville District, Laboratory Chemistry Guideline, (LCG) June 2002
- Summary

What To Do

- Read Method One Approach
 - ♦ Summarize data needs
- Summarize interferences or special handling
- Read other Requirements
 - ♦ Summarize data needs
- Create table
 - ♦ Define requirements for 80% of clients
 - ♦ Define additional requirements to be applied to specific clients

What To Do

- Perform method validation
 - ◆ Standard method
 - ◆ Non-standard method
 - ◆ Identify modification(s) to method
 - ◆ Document performance from validation
 - ◆ Define calibration
 - ◆ Define quality control - batch
 - ◆ Define quality control - monitoring

What To Do

- Write SOP
 - ◆ Client intended use defined
- Review SOP
- Approve SOP

The Cost

- Time to Prepare 6 – 8 days
 - ♦ Methods – 4 hours
 - ♦ Associated Requirements – 8 hours
 - ♦ Refinement – 8 hours – analyst meeting
 - ♦ Final Decision – 4 hours – analyst meeting
 - ♦ SOP writing – 16 hours
 - ♦ SOP review – 4 hours – minimal comments
 - ♦ SOP approval – 4 hours
- Method Validation 7 – 10 days
 - ♦ Assumes personnel are trained on equipment
 - ♦ May include DOC

The Outcome

- A spreadsheet of all the requirements
 - ♦ [Mentoricp.xls](#)
- Let's look at a few items
 - ♦ (no time for all today)
- What do you select?

Terminology

- Instrument Performance Check (200.7, 3.6)
 - ♦ Verify instrument performance during analysis (7.11)
 - ♦ After cal or start of test (9.3.4)
 - ♦ Every 10th sample and end (9.3.4)
 - ♦ %R, $\pm 5\%$ of calibration after initial cal (9.3.4)
 - ♦ %RSD < 3% replicate integrations ≥ 4 (9.3.4)
 - ♦ One rerun with blank allowed (9.3.4)

Terminology

- What is used in the other documents?
 - ♦ DW Certification Manual
 - Follow the method
 - ♦ DOE
 - No additional requirements
 - ♦ Initial Continuing Verification (ICV)
 - NELAC 2003 – 5.5.5.10
 - Beg and end of batch
 - Second source

Terminology

- ICV – 6010C –7.6
 - ♦ Second source (7.6 10.4.3)
 - ♦ Mid range of curve (10.4.3)
 - ♦ Within 10% R of true value (10.4.3)
- ICV – DOD QSM – Table B-6
 - ♦ After calibration
 - ♦ Second source
 - ♦ %R \pm 10% of all values
- ICV – Louisville LCG – Table 7
 - ♦ Mid Level
 - ♦ Second source
 - ♦ 90-110%

What is the QCS???

- Quality Control Samples (200.7 3.14)
 - ♦ Second source (7.12)
 - ♦ Quarterly prepared (7.12)
 - ♦ Initial, quarterly, new cal stds (9.2.3)
 - ♦ Need to meet data requirements (9.2.3)
 - ♦ Three analysis – mean concentration (9.2.3)
 - ♦ 5% of stated value (9.2.3)
 - ♦ Must pass to proceed (9.2.3)
 - ♦ (Includes Prep??)
 - YES – it is a spike of the LRB in definition of QCS
 - - that's subtle

The outcome - ICV

- Second source
- Beg of run after calibration
- No preparation
- Mid range cal standard
- %R, $\pm 5\%$ of true value after initial cal
- %RSD < 3% rep integrations ≥ 4 (LCG 3 int/reading)
- One rerun with blank allowed
- CCV (Continue with evaluation, e.g.DLs, other QC)
 - ♦ Cal Standard
 - ♦ Every 10 and end
 - ♦ %R, $\pm 10\%$ of true value

Daily Run

- Day of use 200.7 rev 4.4 and 6010C rev 3
 - ♦ Alignment and Optimization check
 - depends on instrument- mfg instructions
 - Method validation defines daily practice
 - 200.7 recommends use of CU/MN intensity ratio at 324.754 nm and 257.610 nm
 - ♦ Flow check, gases and rinse time
 - Plasma Standard
 - Rinse Blank

Daily Run

200.7 rev 4.4 and 6010C rev 3

- Day of use
 - ◆ Calibration – Zero and one Standard
 - ICV (See outcome on previous slide)
 - Calibration Blank
 - Low Level Cont Calibration Verification
 - ◆ Interference check solution (ICS)

Daily Run

- Sample Batch (client dependent not presented)
 - ◆ Method blank – preparation and no preparation
 - ◆ Lab control sample – preparation and no preparation
 - ◆ Run 10 samples
 - ◆ CCV and CCB
 - ◆ Run 10 samples
 - ◆ MS/MSD
 - ◆ Post digestion spike
 - ◆ Dilution Test (1:4)
 - ◆ Dilution Test (1:5)
 - ◆ Ending CCV and CCB

Which is more stringent?

200.7 rev 4.4 and 6010C rev 3

Other Frequencies

- MDL check (Quarterly)
- QCS (Quarterly)
- Linear dynamic range (Six Months)
- Update (Six Months)
 - ♦ Interelement spectral correction factors
 - ♦ Multivariate correction matrices

200.7 rev 4.4 and 6010C rev 3

Other Frequencies

- MDL (recommended annual)

200.7 rev 4.4 and 6010C rev 3

Now – Let's add

- NELAC 2003 Chapter 5
- EPA DW Certification Manual, Fifth Edition
- DoD QSM Final Version 3
- USACE, Louisville Chemistry Guideline (LCG) June 2002
- DOE Quality Systems for Analytical Services (QSAS) Revision 2.3

Now – Let's add

- Has anything changed?
 - ♦ Daily Run
 - ♦ Monthly
 - ♦ Quarterly
 - ♦ Six months
 - ♦ Annual
 - ♦ Second year

Daily Run

- Alignment and Optimization check
- Flow check, gases and rinse time
 - ♦ Plasma Standard
 - ♦ Rinse Blank
- Calibration – Three standards and blank
- ICS

Daily Run

- ♦ ICV (second source)
- ♦ Calibration Blank
- ♦ LLCCV (LOQ check NELAC)
- ♦ Method blank – preparation and no preparation
- ♦ Lab Control Sample – preparation and no preparation
 - LCS must be CRM (DOE)
- ♦ LFB at Reporting Limit (DW Manual)
- ♦ Run 10 samples
- ♦ CCV and CCB

Daily Run

- ◆ Run 10 samples
- ◆ MS/MSD
- ◆ Standard Addition
- ◆ Dilution Test (1:4)
- ◆ Dilution Test (1:5)
- ◆ Ending CCV and CCB

Other Frequencies

- Monthly
 - ◆ no specific requirements
- Quarterly
 - ◆ QCS (if LCS second source)
 - no need to remember this quarterly
 - Three analysis – mean concentration can be calculated from any three points
 - ◆ MDL Check (no digestion LCG)
 - ◆ MDL Check (digestion DoD)

Other Frequencies

- Six Months
 - ◆ LDR
 - ◆ Update CFs
 - ◆ Proficiency Testing (NELAC, DoD, etc.)
 - ◆ MAPEP (DOE)

Other Frequencies

- Annual
 - ◆ LOD check each instrument
 - ◆ Analyst Proficiency
- No time frame
 - ◆ Control charts (DW Manual)
 - ◆ Change in personnel, instrument type and method
 - DOC, MDL or low level check

Other Frequencies

- Second year
 - two months before 1 year SOP anniversary
 - ♦ Review efficiency of operation
 - ♦ Determine if requirements documents are updated
 - ♦ Review SOP
 - ♦ Determine if clients are sending samples
 - ♦ Evaluate QC and procedures for implementation
 - ♦ Update QC requirements if necessary
 - ♦ Update SOP
 - ♦ Perform QC at defined frequencies

Continue Evaluation

- Method Validation
- Initial Demonstration
- Instrument Change
- Analyst Change
- Method Change

The Outcome

- When do you look at this again?
 - ♦ Update to method
 - ♦ Change in work load or “product mix”
- How do you ensure efficient operations?
 - ♦ Design to address 80% of the client’s requests
 - Exceptions cost more to handle and may result in client’s needs not be met
 - ♦ Review design to evaluate effectiveness
 - ♦ Ensure sales staff (however named) understands when exceptions are needed to the process

Summary

- May seem an excessive time to complete
 - ♦ saves time later
- Allows easy updates
 - ♦ EPA 200.7 Rev 5 – update SOP
 - Saves time and \$\$ to update
- Write SOP for the procedure development
 - ♦ Communicate to everyone
 - ♦ Involve internal staff to ensure most efficient and effective operation

Any Other Ideas

- What type of process do you use in your laboratory?



- How do we get organizations to use a uniform QC standard?

Finale



Questions?

Each person using this material must review and ensure the materials are correct and complete. The preparer's assume no responsibility for the accuracy of this information

- Thank you

