Quality Assurance and Quality Control Plan Development for CEM Systems

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Why Do We Need Quality Assurance and Quality Control for CEM systems?

- CEM systems are fallible.
  - Over time analyzer readings will drift and bias will occur.
  - Operating the system 24-7 means the CEM system will need maintenance.
  - The system needs to be monitored to ensure high availability

Why Do We Need a QA/QC Plan?

- QA/QC Plans ensure data integrity
- QA/QC Plans help produce and maintain data.
- Regulatory and corporate bodies need accurate emissions data.

Why Do We Need a QA/QC Manual?

- Personnel need to know….
  - What they are doing
  - How they will do it
  - Why they are doing it

- Note: It is important that everyone involved with the CEM system has access to the QA/QC manual.

What's Required to Develop the Plan Definitions

- Quality Assurance
  - Sets out the policies and provides information
  - necessary to collect high quality data.
- Quality Control
  - Sets out the procedures (working level SOP's) performed for the collection of high quality data.

What's Required to Develop the Plan

- Identify Facility Objectives for QA/QC and Regulatory Requirements
  - Certificate of Approval
  - Permit to Install
  - Ontario Regulations 419/05, 194/05, 127/01, etc
  - State regulations
  - EPA CFR 40 Part 60, 63, 75, etc.
    - Sub-parts
  - EPS Report 1/PG/7
  - Alberta CEMS Code
  - Corporate Requirements

What's Required to Develop the Plan
Identify Industry Allies

- Contact suppliers for information on the CEM system and components (operating manuals).
- Get plant specific operating procedures (right dept. doing the right job).
- Contact regulatory personnel and find out who can answer technical questions.
- Contact specialists in your sector who can provide you with valuable insight into compliance issues.

What's Required to Develop the Plan Identifying Your Personnel Resources

- Identify QA/QC tasks and Departments responsible.
- Survey department personnel who will be involved with the CEM system.
  - Determine current qualifications
  - Determine deficiencies
    - Staff numbers, and time, training
    - Budgetary constraints
  - Determine any future training needs
- Ensure training is completed before QA/QC tasks are to be preformed.

What's Required to Develop the Plan

- Organize an outline of major topics associated with Quality Assurance and Quality Control.
- Compile the data from all of your resources.
- Begin writing
- Good Luck

How to Write a QA/QC Manual: Quality Assurance section

- Quality Assurance Goals and Objectives
- CEM System Description and Design Considerations
- Exceptions/Clarifications/Alternate Methods
- Organization and Responsibilities
- Calibration and Quality Control Checks
- Data Acquisition and Analysis
- Preventative Maintenance Policy
- Corrective Action Program
- Performance Evaluations/Audits
- Document Control System
- Reports and Records
- Modifications and Upgrades
- Training and Qualification Policy
- References

How to Write a QA/QC Manual: Quality Assurance section

- Quality Assurance Goals and Objectives:
  - State the purpose of having the CEM system
    - Accuracy, and completeness
    - Regulator requirements and guidelines
    - State goals for emissions monitoring data

How to Write a QA/QC Manual: Quality Assurance section

- CEM System Description and Design Considerations
  - Principles of operation
  - Technical Specifications e.g. flow, temperature, sample location, shelter, system layout, and data handling.
  - Serial Numbers
  - Provide diagrams and photographs of the equipment

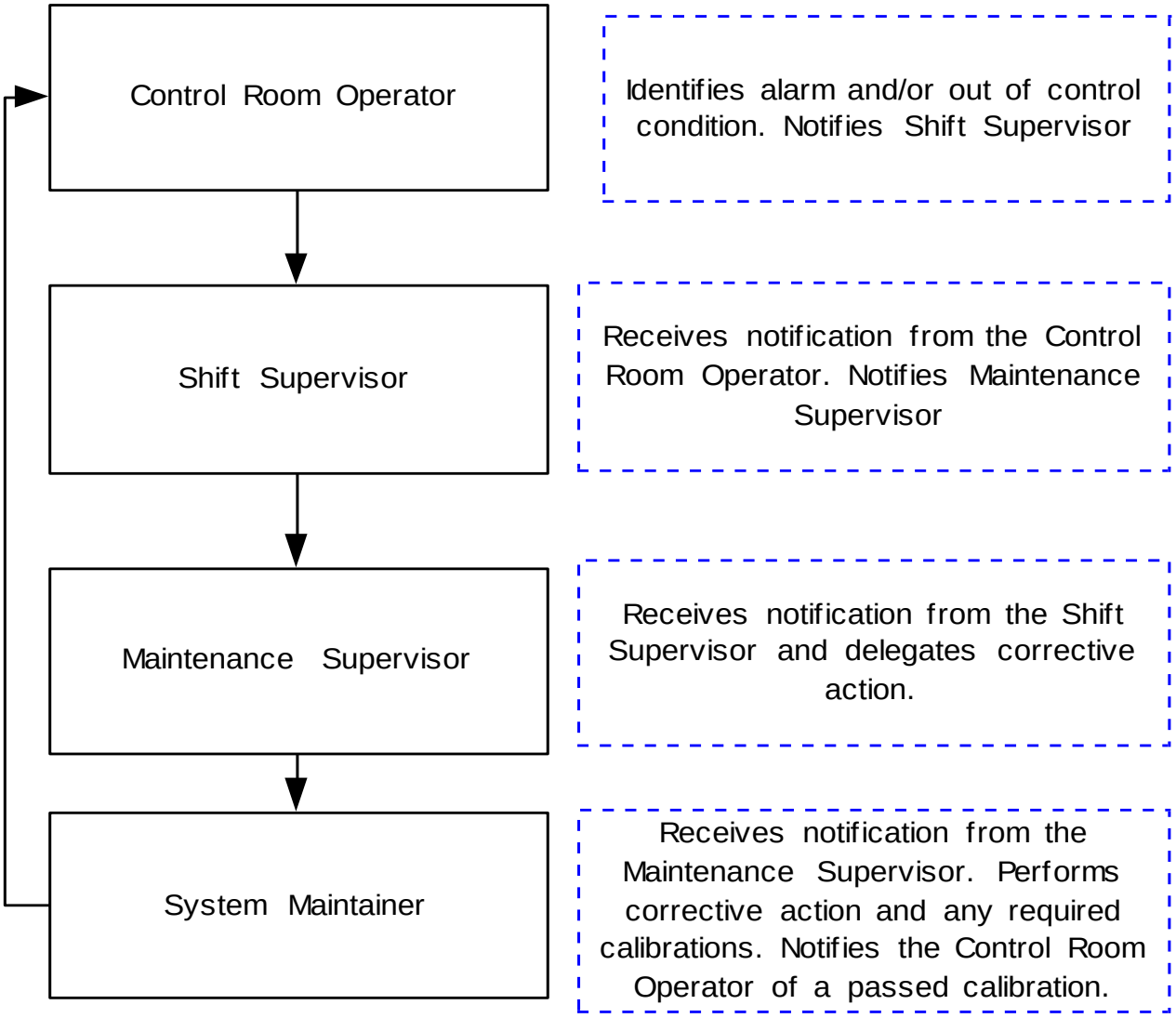
How to Write a QA/QC Manual: Quality Assurance section

- Exceptions/Clarification/Alternative Methods
  - Explain all necessary discrepancies between guidelines/regulations and the site CEM application
  - Describe the alternative activities/methodology that compensate for discrepancies

How to Write a QA/QC Manual: Quality Assurance section

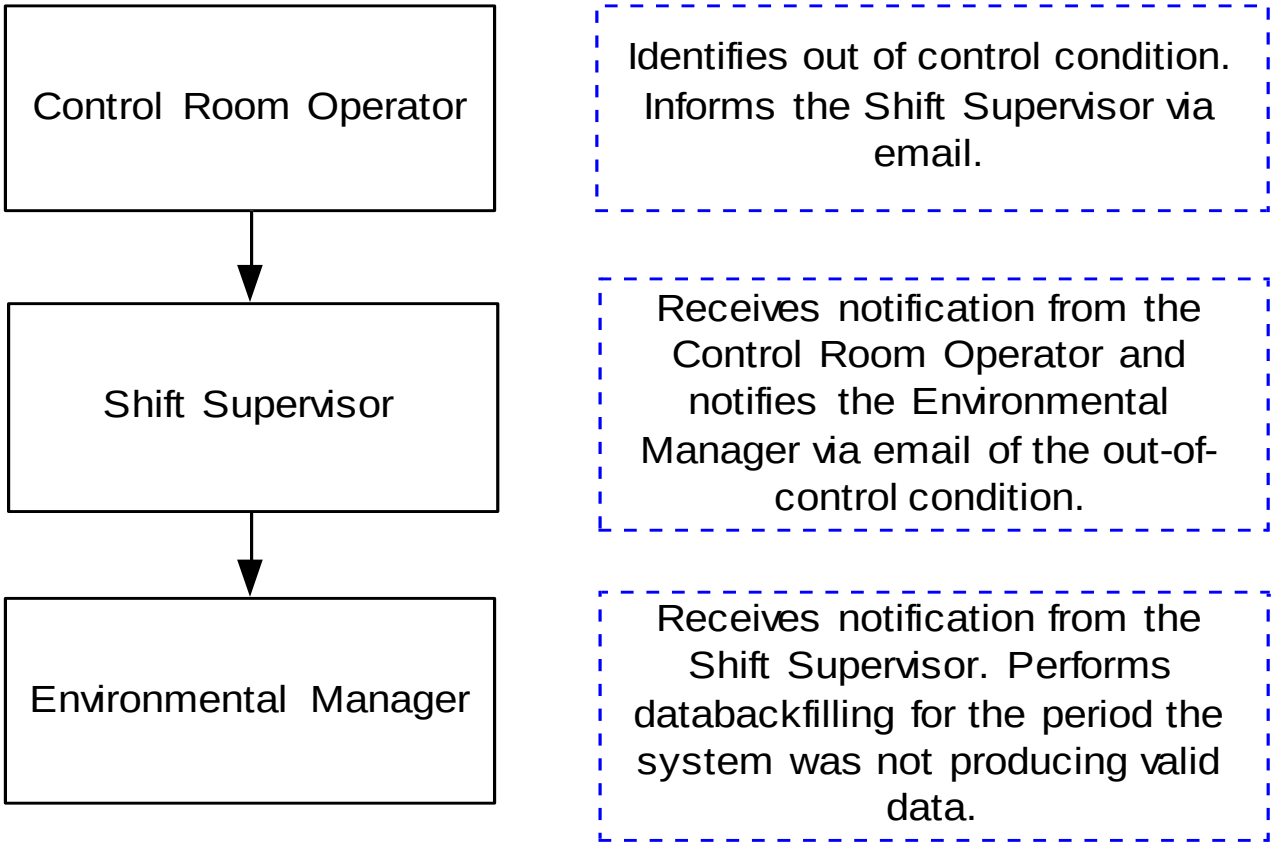
- Organization and Responsibilities
  - Clearly define tasks
  - Delegate which department will perform which tasks
  - Show all lines of communication

Example of What Happens When an Out of Control Condition Occurs and Must be Corrected…..
From a Maintenance Perspective



Example of Effective Flow of Communication When An Out of Control Condition Occurs…….

From a Data Management Perspective: Backfill



How to Write a QA/QC Manual: Quality Assurance section

- Calibration and Quality Control Checks
  - Describe the daily calibration and QC checks
  - Include any calculations
  - Corrective actions
  - Frequency and pass-fail criteria.

How to Write a QA/QC Manual: Quality Assurance section

- Data Acquisition and Analysis
  - Define what constitutes valid data
  - Describe the data acquisition system in detail
  - Show how data is communicated between devices
  - Roles and responsibilities for personnel involved

How to Write a QA/QC Manual: Quality Assurance section

- Preventative Maintenance Program (PM's)
  - Describe the preventative maintenance program and schedule.
  - Roles and responsibilities for personnel involved

How to Write a QA/QC Manual: Quality Assurance section

- Corrective Maintenance Program
  - Describe the policies for correcting any CEM System non-conformance
  - State what problems are corrected by plant personnel vs. Contactor
  - Roles and responsibilities for personnel involved

How to Write a QA/QC Manual: Quality Assurance section

- Performance Evaluations and Audits
  - Describe the scheduling of performance evaluations.
  - List what resources are needed to complete the tests.
  - Explain the out-of-control condition associated with evaluations and audits.

How to Write a QA/QC Manual: Quality Assurance section

- Document Control System
  - Describe the policies used to control all the documents
  - Indicate how they are approved
  - Describe the process for revision to the QA/QC Manual

How to Write a QA/QC Manual: Quality Assurance section

- **Reports and Records**
  - Describe in detail
    - What records must be maintained
    - Who maintains them
    - Where they are maintained
    - For how long
  - Reports required by the authorities, Describe
    - What reports are sent
    - When they are sent
    - Who are they sent to

How to Write a QA/QC Manual: Quality Assurance section

- **Replacement and Modification to CEM System**
  - Describe when modification to the system is necessary
  - Set control limits for replacement of the CEM system i.e.
    - Life expectance
    - Out-of-control duration
    - Frequency

How to Write a QA/QC Manual: Quality Assurance section

- Training and Qualification
  - Describe what training is necessary on the CEM system
  - Describe what qualification are needed to perform tasks on the CEM system or what qualifications are needed for job positions.
- References
  - Show all documentation that was referenced in the creation of the QA/QC Manual.
    - E.g. PG/7, CFR 40 Part 60, Part 75, etc.

How to Write a QA/QC Manual: Quality Control Section (SOP's)

- Startup and Operation
- Daily CEM System Operation and Inspection
- Daily and Manual Calibration Procedures
- Gas Bottle Check Procedures
- Preventative Maintenance Procedures
- Spare Parts List and Inventory Procedures
- Corrective Maintenance Procedures
- Data Backfilling Procedures
- Data Backup Procedures
- CEM System Security
- Data Approval and Reporting Procedures
- Quarterly Audit Procedures
- Semiannual Relative Accuracy Test Audit Procedures
- Bias Procedures
- Annual System Audit Procedures
- Management of Change

How to Write a QA/QC Manual: Quality Control Section (SOP's)

- System Start Up and Shut Down Procedures
  - Describe all the steps involved in the start-up and shut-down of each component of the CEM system
    - DAS software and hardware
    - Flow monitor
    - Gas Analyzer

How to Write a QA/QC Manual: Quality Control Section (SOP's)

- Daily Operation and System Checks
  - Describe the daily operations and routine inspections associated with the CEM system.
  - Examples of check sheets and log book entries should be included

How to Write a QA/QC Manual: Quality Control Section (SOP's)

- Calibration Procedures
  - List the steps necessary to perform calibrations on all of the equipment.
  - List the steps required for manual, semi-automatic, and automatic calibrations
  - Refer to the manufacturer's manuals for specific directions on performing calibrations when applicable

How to Write a QA/QC Manual: Quality Control Section (SOP's)

- Gas Cylinder Checks and Replacement
  - Describe in detail the procedure for the replacement and cross- referencing of cylinders.
  - Specifications for the rejection of gas cylinders and when they expire should be stated.
  - State what gas cylinders records must be kept and where they are stored.

How to Write a QA/QC Manual: Quality Control Section (SOP's)

- Preventative Maintenance Procedures
  - Detailed description of preventative maintenance activities, schedules, and record keeping requirements.
  - Detailed step-by-step procedures

How to Write a QA/QC Manual: Quality Control Section (SOP's)

- Spare Parts Inventory
  - Describe the steps taken to obtain spare parts
  - Describe the steps taken to maintain a sufficient inventory of spare parts to ensure system up-time

How to Write a QA/QC Manual: Quality Control Section (SOP's)

- Corrective Maintenance Procedures
  - Description of corrective maintenance activities and all documentation/communication that must occur when the CEM system has failed.

How to Write a QA/QC Manual: Quality Control Section (SOP's)

- Data Backfilling Procedure
  - Detail the backfill procedures to follow when the CEM system is not functioning or when the system is out of control.
    - Address DAS capabilities (auto/manual backfill)
    - Address who will do it
    - Have the approved calculations available

How to Write a QA/QC Manual: Quality Control Section (SOP's)

- Backup of CEM System Data
  - Describe the procedure for backing up the data acquisition system (DAS) on hard or soft copy.
    - Ensure backed up data can not be overwritten

How to Write a QA/QC Manual: Quality Control Section (SOP's)

- System Security
  - Detail all steps taken to ensure the security of the equipment and the integrity of data.
  - List which personnel are allowed access to the equipment and to the DAS.

How to Write a QA/QC Manual: Quality Control Section (SOP's)

- Quarterly Performance Evaluations
  - Detailed procedures on conducting all audits associated with the devices
  - Include roles and responsibilities
  - Gas cylinder tracking procedures
  - Scheduling
    - Contractors?
    - EPA protocol cylinders (availability)
    - Plant personnel (maintainers)
  - Test methods

How to Write a QA/QC Manual: Quality Control Section (SOP's)

- Semi-annual/Annual Performance Evaluations
  - Detailed pre-test plan for executing RATA's
    - Scheduling
    - Test methods
    - Calibration requirements
    - Reporting schedule
    - Any safety concerns.

How to Write a QA/QC Manual: Quality Control Section (SOP's)

- Bias Procedure
  - Describe the process of assessing and correcting for bias.
    - Who determines the correction value
    - Where does it get implemented
    - When does it get implemented
  - Include responsibilities for tracking of Bias Adjustment Factors.

How to Write a QA/QC Manual: Quality Control Section (SOP's)

- Annual Audit
  - Include a detailed audit strategy
    - Auditor selection
    - Scheduling
    - Audit plan
    - Necessary reporting

How to Write a QA/QC Manual: Quality Control Section (SOP's)

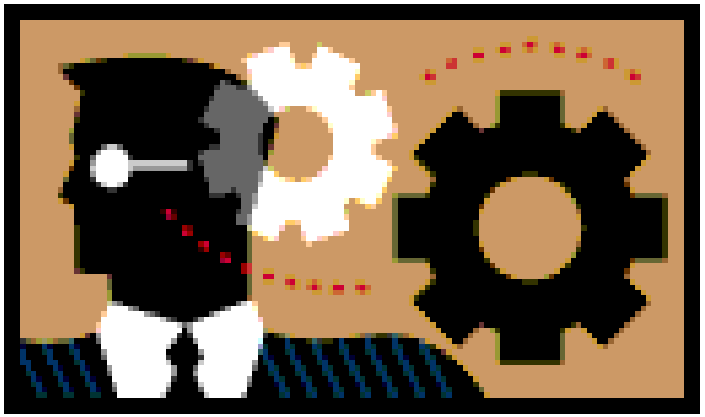
- Management of Change Procedure
  - As the parameters change outside of identified limits, so too will the CEM systems ability to provide valid data.
  - What affects availability?
    - Operating environment
    - Lifespan of equipment
    - Process changes

How to Write a QA/QC Manual: Quality Control Section (SOP's)

- Management of Change continued…
  - Scheduling of regular meetings to address issues of
    - Contingency based change
      - Reoccurring events (human, mechanical, other)
    - Parameter based change
      - Process or regulatory alterations
    - Long term (replacement) based change.
      - Lifespan of the equipment
  - Include roles and responsibilities of individuals at meetings

How to Write a QA/QC Manual: Quality Control Section (SOP's)

- Training Procedures
  - List what materials and resources are required for training.
  - List what types of training are required
    - E.g. On the Job Training or Factory Training



How to Write a QA/QC Manual: Appendix

- Facility Environmental Permit, Licence, or CofA
- Applicable Environmental Regulations
- CEM System Specifications
- Reference Method Procedures
- Blank Forms Check Sheets
- Cylinder Records
- Bias Adjustment Factor Record Keeping
- Training Records

Ways to Make the Plan and Manual Effective

- Have a team of individuals who understand their role gathering QA/QC data
- Enforce ownership of the QA/QC manual and the CEM system.
- Use easily understood language
- Use pictures, photographs, diagrams, and captions that simplify and explain.
- Have all information available in the manual and make it easy to find.
- Give step by step procedures to ensure that the necessary actions are taken.

Ways to Make the Plan and Manual Effective

- Schedule training for those involved in Quality Control Activities
- Revisit the effectiveness of planned activities when repeated problems occur
- Audit the plan with a qualified auditor
- Take the auditors suggestions and implement changes to the plan to ensure the Plans continued effectiveness

Areas of Concern in QA/QC Plan Manual Creation and Use

- Making the Manual an electronic document
  - Tracking of revisions can be difficult
  - Accessibility of information can become a problem
  - Signing of check sheets may not occur, which can lead to tasks not being completed.

Areas of Concern in QA/QC Plan Manual Creation and Use continued…

- Document Control becomes an issue when the QA/QC Plan crosses numerous facility chains of command.
  - QA/QC Plans often involve Environmental Departments and Electrical or Maintenance Departments
  - Ensure that a limited number of people are able to authorize and/or change the documentation.
  - Ensure that all copies are altered simultaneously and destroy all previous copies.

Tips from the Frontline

- Dismissing the importance of an effective plan will lead to downtime and a lack of data integrity
- Intimate knowledge of CEMS is necessary
- Knowing exactly what restrictions and guidelines apply to your facility is essential
- QA/QC manuals take a long time to develop

Thank You