



March 18, 2010

Mr. Steve Tarlton, Manager
Radiation Control Program
Hazardous Materials and Waste Management Division
Colorado Department of Public Health and Environment
4300 Cherry Creek Drive South
Denver, Colorado 80246-1530

Re: Semiannual Performance Report-Laboratory and Quality Assurance Programs

Dear Mr. Tarlton,

Please find enclosed the Semiannual Performance Report-Laboratory and Quality Assurance Programs for the July - December 2009.

If you have any questions, please contact me.

Sincerely,

A handwritten signature in black ink, appearing to read "J. Cain", with a horizontal line extending to the right.

Jim Cain
Environmental Coordinator/
Radiation Safety Officer

JC: kju

Attachments

PERFORMANCE REPORT

Quality Assurance Program - July - December 2009

This report addresses the validation of quality control samples and the quality assurance verification of sample data used in the Semiannual Effluent Report, the third (3rd) and fourth (4th) Quarter 2009 Routine Water Reports, and the third (3rd) and fourth (4th) quarter 2009 Employee Dose Reports. The data review and assessment process consists of the following activities:

- Review of field data and sampling practice by sampling and quality assurance personnel.
- Review of Sample Submittal Tracking Forms (SSTF), chain of custody, and LIMS log-in documents by quality assurance personnel.
- Review and approval of the analyzed sample results and QC data on a sample-batch basis by laboratory personnel.
- Review and approval of the analyzed sample results and QC data on a sample-batch or LIMS “WorkSheet” basis by quality assurance personnel.
- Investigation of questionable or non-compliant result data and subsequent follow-up.
- End-user (“Data User”) data review.
- Monitoring and reporting of QC related performance criteria by quality assurance personnel.

During any of these activities, corrective action follow-up may entail undocumented immediate request for needed investigation or corrections or the formally documented Data Request (DR), Data Verification Request (DVR), or Corrective Action – Improvement Request (CAIR) processes.

QUALITY CONTROL VALIDATION

The Colorado Department of Public Health and Environment (CDPHE) approval of the May 22, 2009 Revision of the Quality Assurance Program Plan for Environmental and Occupational Sampling and Monitoring Studies for the Cotter Corporation, Canon City Milling Facility And Lincoln Park, Colorado Superfund Site (acronym is “QAPP”) established Program Performance Criteria which put new and additional quality control and quality assurance requirements into affect. These new QA/QC requirements increased the expectations of quality control data processing and data qualification or flagging capabilities. Specific to this report the Program Performance Criteria require: 1) Calculation and monitoring of the “Total Uncertainty” (TU) of accuracy (Matrix Spike) and precision (Laboratory Duplicate) sample results; 2) Determination and monitoring of batch sample result “Usability” based on TU and/or related quality control factors; 3) Monitoring the percent of qualified or “flagged” data. 4) Calculation and monitoring of data completeness; and 5) Monitoring and control of specific analyte detection limits.

To accomplish these requirements quality control validation begins with review of the analytical records documented in the “WorkSheet” (sample batch) data packet. Packet contents are inventoried and any batch specific notations are reviewed. Sample results and detection limits are evaluated. Quality control calculations are verified.

Quality control results are evaluated for acceptability or requirement for qualification indicator. The TU is calculated and recorded. Sample batch usability is determined and recorded. The next phase of quality control validation should be conducted at the LIMS data base data processing level. The percent of qualified data and percent of data completeness is determined and monitored. Detection limits are compiled. QC trend charts may be generated.

The phased validation process described above relies heavily on a fully developed and implemented LIMS. At the individual "WorkSheet" processing level the LIMS would automatically qualify and flag results based on all batch quality control sample evaluations, determine data "Usability", calculate and track TU, and evaluate sample detection limits. The database level functions were previously identified. The development and implementation of all required LIMS QA/QC functions is in-progress at this time. In the interim (until LIMS finalization) the TU, usability, and data qualification are being determined and recorded by the Quality Assurance Department's data reviewer. The Quality Assurance Department has developed an excel spreadsheet to process and record TU and associated results. This spreadsheet calculates TU and determines data usability and qualifier flagging for the sample batches containing matrix spike and duplicate data. The usability of data in sample batches not containing matrix spike or duplicate quality control samples is determined manually on a batch by batch basis at this time. The percentage of qualified data, data completeness, and detection limit control are determined from queried LIMS records and TU-usability determination summaries.

A total of nine hundred ninety-three (993) LIMS Worksheets are included in the span of records assessed for this report. This total may include some records pertaining to samples collected during the first (1st) quarter of 2010. A significant portion of the total number of Worksheets are compilations of field measurements such as depth to water, pump rates, etc. or preliminary data such as preliminary alpha screening determinations which do not normally have quality control data associated with the recorded values. Reported data generated by non-Cotter laboratories is often recorded in the LIMS and given Worksheet identities. Such data has been subjected to Cotter review to the extent attainable by existing supplier-client agreements and seldom has associated quality control data carried into the Cotter LIMS.

Quality review and assessment has been completed on the report data generated by the Cotter on-site analytical laboratory for samples collected during the third and fourth quarter monitoring periods of 2009. Sample batch data folders ("Worksheet Data Packets") from four hundred fifty-two (452) analytical sample batches were reviewed. QAPP Section 10.2.4 "Data Completeness" for these reviewed Worksheet packets is ninety-nine point one percent (99.1%) with zero point nine percent (0.9%) "Qualified Data."

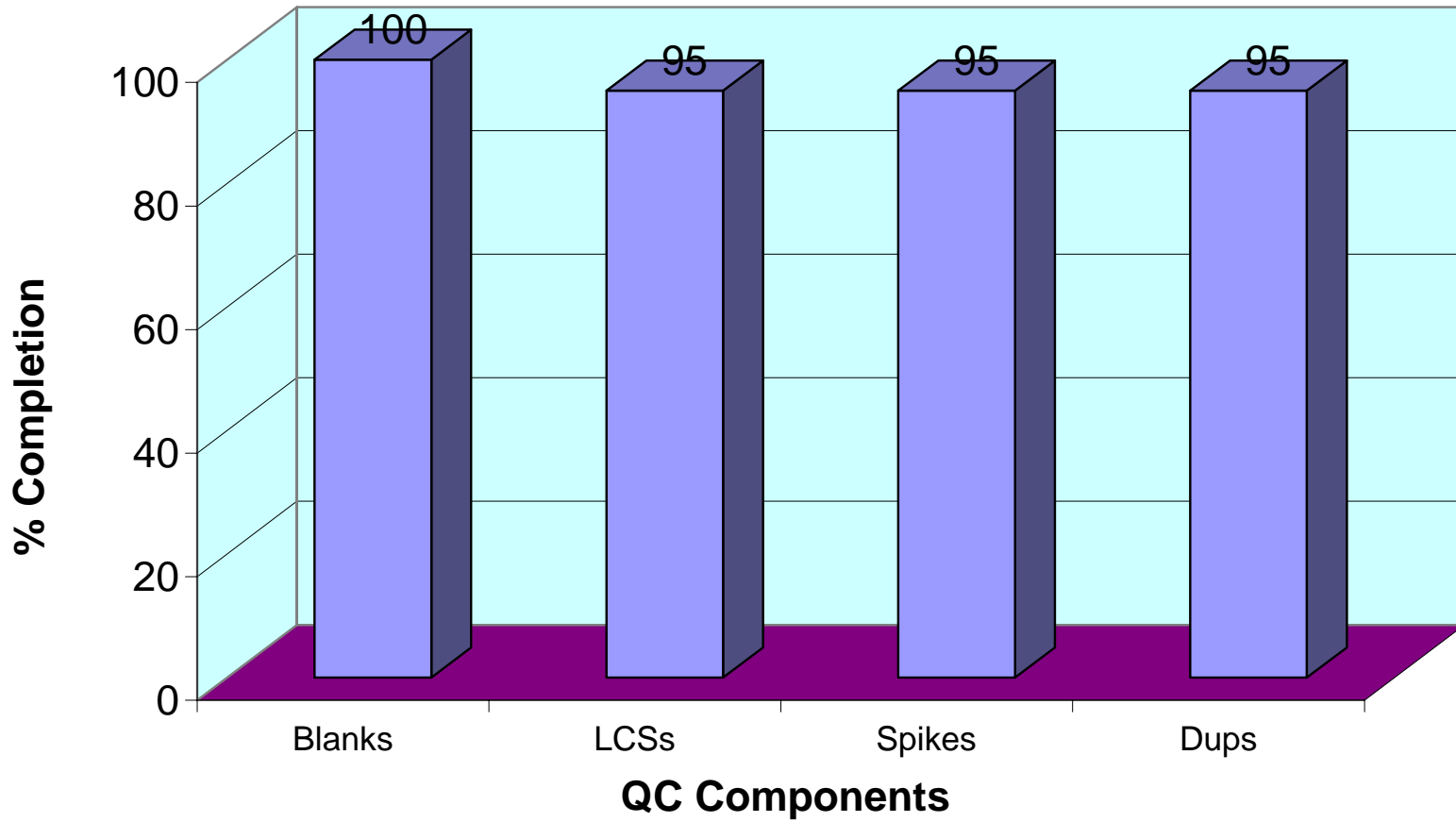
One (1) formal quality control related Corrective Action - Improvement Request, CAIR No. 281 was generated during this reporting period. This CAIR resulted in the decision to not include Lab Conductivity and Lab pH results in written reports. Also quality control documentation is not required for these measurements.

The overall percentages of completion of the quality control validation at the time this performance report is being written are depicted on the accompanying Figure PRQ1, *Quality Control Validation - July - December 2009*. The depicted quality control validation completion percentages are one hundred percent (100%) for QC blanks and ninety-five percent (95%) for each of the other three (3) QC data types. The ninety-five percent (95%) value may be attributed to two (2) factors: a detailed assessment of trend charts had not been performed and automated LIMS qualification of data is not yet implemented.

Figure PRQ1

Quality Control Validation

July - December 2009



QUALITY ASSURANCE VERIFICATION

General quality assurance verification may include evaluation of sampling and/or analytical procedures, program or project design and activities, and data processing. In addition to the review activities discussed previously, the data contained within the reports mentioned above undergoes other types of QA verification assessment. The basis for the additional data verification assessment may include historical knowledge of constituent levels, radiochemical equilibrium ratios, material-specific constituent proportions, known environmental conditions, or comparisons of final results to preliminary screening data. Data verification may also include evaluation of the reported detection limits versus required detection limits and the effect of any failed QC samples on data usability. Discovery of unacceptable, anomalous, or unexpected results is followed by a review of field or lab records, investigation of sample acquisition, handling, preparation or analysis, or a request for reanalysis. The Cotter Quality Assurance Department provides oversight and documentation of any required formal quality assurance follow-up.

A number of data verification investigations were documented by the Quality Assurance Department during the time period covered by this report. There were four (4) Data Requests (DR) recorded. Three (3) DRs were for additional new analyses of third (3rd) and fourth (4th) quarter occupational air samples or composites. The fourth (4th) was related to providing data dimensions (units). Four (4) Data Verification Request - Assay Correction Form investigations (DVR/ACFs) were generated by data reviewers and data users. All DVR/ACFs dealt with environmental sample results and all have been resolved. The DVR/ACFs addressed fourteen (14) sample results – nine (9) groundwater results generated by the Cotter Analytical Laboratory and five (5) environmental radon results reported by a non-Cotter entity. The DVR/ACFs resulted in five (5) changed or corrected results. There were eight (8) quality assurance related Corrective Action - Improvement Requests (CAIRs) this quarter. Five (5) involved requests for groundwater sampling procedure development or improvements. One (1) required improvement of sampling location (well head) identification. Another CAIR required management personnel discussion and agreement on lab conductivity and lab pH recording and reporting practices. The remaining CAIR requested investigation of environmental air monitoring data from a non-Mill related location in another part of the state. The QA Department also conducted and reported seven (7) quality assurance assessment “Evaluation” reports. Six (6) focused on environmental sampling and monitoring procedures and practices and one (1) summarized quality assurance sample results from the urinalysis occupational monitoring program. The findings made by the Quality Assurance Department during the quality assurance evaluation/assessment process often result in formal corrective action requests.

The semiannual report focused on evaluation of employee dose, environmental air, and stack discharge, and water quality data. The related quality assurance verification assessed data that can be categorized roughly into the following three (3) categories: Breathing Zone (BZ)/General Air (GA), Environmental Air and Stack, and Water Monitoring. The overall percentages of completion of quality assurance verification (BZ/GA ninety-eight percent (98%), Enviro Air/Stack ninety-eight percent (98%), and Water Monitoring ninety-eight percent (98%)) are depicted in the accompanying Figure PRQ2, *Quality Assurance Verification – July - December 2009*.

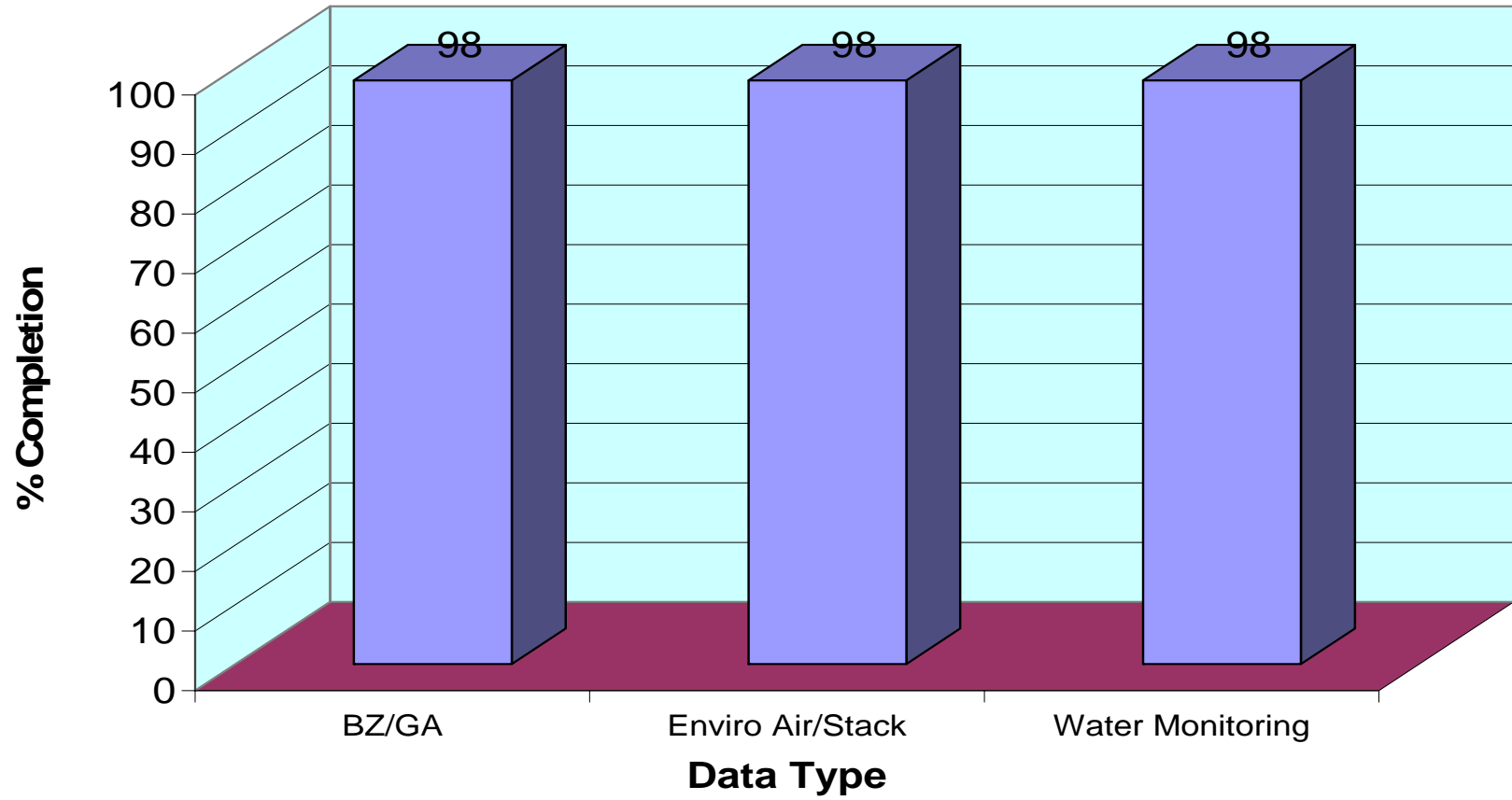
The completion is being estimated at ninety-eight percent (98%) rather than one hundred percent (100%) to allow for (1) possible overlooked data qualification and (2) an automated detection limit analysis that might have been applied by a more fully developed/modified and implemented LIMS system.

Data problems that were identified during the data quality assessments are summarized in the attached Error Analysis – July - December 2009 Tables. Table PRQ1 addresses quality control validation issues. Table PRQ2 addresses formally documented quality assurance verification errors.

Figure PRQ2

Quality Assurance Verification

July - December 2009



**Table PRQ1
Error Analysis
July – December 2009**

Description	Samples Affected	Frequency of Occurrence	Does Pattern Exist? Explain	Resolution
<p>1) The methodology used to assess quality control accuracy and precision data in the LIMS (Aspen) is not consistent with the methodology prescribed in the QAPP. 2) Data qualification and usability determination performed manually only.</p>	Blanks, Duplicates, Spikes, and LCSs.	Numerous	Yes. These discrepancies will continue to exist until the LIMS customization is complete and any required modifications to the QC processing sections of the LIMS have been completed.	Modification and customization of the Cotter LIMS is ongoing. The LIMS QC summary report is currently only used to verify proper data entry/data upload into LIMS. Until the upgraded LIMS is modified/customized and proven to meet all requirements for full QC assessment; QC review and approval will continue to be performed using calculations documented on the lab analysis result (LAR) printout in the data packet. Qualifier assignment, TU calculation, data usability determination, and data completeness calculation are performed by the QA Department at this time.
Manual data transfer and data input can result in erroneous information in analytical documentation and/or in the LIMS.	All data	< 5%	No. Due to the large volume of data that is manually transferred/input occasional random data entry errors are likely.	These types of errors are detected during internal laboratory and QA/QC data reviews. Corrections are made to the documentation and/or the LIMS database, as necessary. Electronic data transfer should greatly reduce these types of errors. The on-going modifications to the LIMS includes implementation of electronic data transfer wherever possible.
Laboratory confirmation measurements of groundwater sample field conductivity and pH determinations lack quality control documentation.	Groundwater LCond and LpH results	All groundwater sample batches delivered to Cotter Lab.	Yes. LCond and LpH WorkSheets have not included quality control data.	CAIR No. 281 addressed this discrepancy. For resolution the Laboratory and Environmental Departments agreed that laboratory conductivity and laboratory pH results will only be used for internal evaluation and will no longer be made available in data reports. Thus quality control documentation is not required.

**Table PRQ2
Verification Errors
July – December 2009**

Documented Quality Assurance Verification Errors					
Document or Record	Type	Number of Results	Apparent Error Type	Results of Investigation	Does Pattern Exist? Explain
DVR/ACF 2-8-2010-1	Groundwater	2	Anomalous results requiring reanalysis.	Reanalysis was required followed by correction in laboratory WorkSheet Data Packet and LIMS database.	This problem is usually encountered during data user QA review of results and is usually followed by a request for reanalysis. Only formal documented requests are listed here.
DVR/ACF 2-4-2010-1	Environmental Radon Determination by non-Cotter entity.	1	Data input error - incorrect date.	Vendor required to reissue environmental radon report.	This is an error associated with manual input of data. It is usually easy to detect and correct.
DVR/ACF 11-17-2009-1	Groundwater	2	Data input error - dilution factor.	Reported values off by combination of dilution factors.	This problem is occasionally encountered during review of lab data and comparison to historical data.
CAIR No. 279	Environmental Air Volume Calculation for samples at distant not-mill related site.	4	Data input error - suspected incorrect beginning time indicator value.	Response not yet received.	No. This is an unusual problem. It does not affect any Canon City Mill report data.

Note: Note: An additional 9 analyses' results were investigated and verified through the DVR/ACF documentation and required no change in reported values.

Performance Report –Laboratory Program
July-December 2009

This report describes the types and numbers of analytical determinations as well as the dates the results were posted to the Laboratory Information Management System (LIMS). All of the data was available in the LIMS no later than February 11, 2010. Some of the measurements, for example, environmental air perimeter weights and urinalysis for uranium, are typically posted within a week or two of collection.

- Gross alpha/beta breathing zone and general area air samples filters collected and submitted by Radiation Safety Department technicians for assessment of airborne concentrations relative to the ALARA program and to monitor occupational dose. The sample load resulting from this analysis was one thousand one hundred seventy-three (1,173) samples for the second (2nd) half of the year with preliminary results either available within twenty-four (24) hours of sample receipt or the next business day for samples collected on weekends. Final analysis of these samples in all cases was completed well within the report preparation requirements.
- Third (3rd) and fourth (4th) quarter anion data, one thousand two hundred fifty-eight (1,258) analyses
- Three hundred forty-two (342) environmental air perimeter filters, pre and post weighed for (684) perimeter weights.
- Occupational air, perimeter, stacks, soils, and water for total Uranium by KPA, two hundred eighty-two (282) samples.
- Perimeter, stacks, soils, and water data for ²²⁶Ra, ninety-two (92) samples.
- Soils for ²²⁴Ra, eighteen (18) samples.
- Perimeter, stacks, soils and water data for ²¹⁰Pb, eighty-three (83) samples.
- Water and stacks data for ²¹⁰Po, forty-one (41) samples.
- Occupational air, perimeter, stacks, soils, and water for ²³⁰Th, one hundred nine (109) samples.
- Occupational air, perimeter, stacks, soils, and water for ²³²Th, sixty-one (61) samples.
- Urines for Uranium seven hundred twenty-three (723) samples.
- Water samples: pH, conductivities eight hundred five (805) samples.
- Gross alpha & beta soils, waters fourteen (14) samples.
- Metals data for third (3rd) quarter Ca, Fe, K, Mg, Mn, Mo, Na and Se, seven hundred forty (740) analyses by Cotter, entered into LIMS by 11/12/09.
- Metals data for fourth (4th) quarter Ca, Fe, K, Mg, Mn, Mo, Na and Se, six hundred eighty (680) analyses by Cotter, entered into LIMS by 02/11/10.
- Twenty-nine (29) waters samples sent to ALS Laboratory Group for V, Sr, Cr, Co, Ni, Be and Se.

The Laboratory Program experienced unusual downtime and repairs for the Alpha Spectroscopy unit (ORTEC) which was out of service for six weeks from mid-August to early October. The metals analyzer (AA 800 Flame and Graphite) required four service calls and repairs which amounted to two (2) weeks downtime.