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Mr. Phil Egidi
Colorado Department of Public Health and Environment
Hazardous Materials and Waste Management Division
Radiation Management Program
4300 Cherry Creek Drive South
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RE: Review of Cotter Laboratory Status Document Dated 6-20-2005

Dear Mr. Egidi,

This document comprises a review of the Cotter Laboratory Status Document Dated 6-20-2005. The review is intended to provide data on the completeness of the response, correctness of the response, and the actions to be taken in future reviews.

The review is in two parts. The first part is entitled "Evaluation of the Cotter Laboratory Status Report Dated June 20, 2005". This section includes an evaluation of the Sections A through E of the Cotter Laboratory Status Document Dated 6-20-2005. Each section includes a restatement of the Cotter comments and the auditor's comments in bold, italic. The second section of the report is entitled "Attachment A-Cotter Radiochemistry Laboratory Audit Resolution - Status of Specific Items". This section comprises Cotter's spreadsheet listing the status of action items from the November 2, 2004 Report of the Radiochemistry Technical Audit of the Cotter Analytical Laboratory in Canon City, Colorado. The auditor's comments are listed in the comments section in Bold, Italic type under Cotter's comments.

If you have any other questions, please contact me at your convenience.

Sincerely,

Edward Wallace
Health Physicist

ESW
Attachments



Evaluation of the Cotter Laboratory Status Report Dated June 20, 2005

A. Radioactive Material Calibration Standards Preparation & Control

Develop & Implement a Standard Operating Procedure (SOP) for the Preparation and Control of Radioactive Material Standards. The SOP must address each of the following:

1. Preparation of both volumetric and gravimetric standards;
2. Use of a standard format for documenting calibration solution preparation;
3. Require documentation of all calculations so that a review and verification is possible;
4. Specify a standard preparation review system that involves at least 2 staff members;
5. Establish standard verification protocols and requirements for release to use as a standard;
6. Requirements and criteria for the expiration of standards;
7. Requirements for re-verification of expired standards prior to recertification for use;
8. Requirements and frequencies for recalibration of radioactive calibration sources; and
9. Requirements for storage of radioactive material calibration solutions and sources.

The completion of the SOP for the Preparation and Control of Radioactive Material Standards, addressing the items listed above, is anticipated to be the end of August, 2005. This procedure and the training of technicians on this procedure will be completed prior to the commencement standard verification process.

This action item is Cotter's response to Item A from the April 12, 2005 Notice of Violation Number 6. This item involves the update of the radioactive material calibrations standards program. The line items 1-9 are directly from the Notice of Violation. This is scheduled to be completed by the end of August 2005. My main comment is that this program revision is the cornerstone of the entire program. The revisions to the radioactive material calibrations standards program should be completed and reviewed prior to the authorization of any other work involving calibration solutions such as Uranium by KPA, Isotopic Thorium, Radium-226, Lead-210, and Polonium-210. The Gross Alpha-Beta analyses of air filters only involve the use vendor prepared calibration sources and should not be affected.

B. Standard Operating Procedure (SOP) Revisions

The SOPs need to be established in a standard format. The standard format shall address each of the following:

1. The SOPs must specify the materials and reagents to be used in sufficient detail to ensure that there is no confusion as to what the SOP is requiring.
2. Instructions shall be clear and sufficiently detailed to allow any analyst to complete the instruction regardless of his/her experience or seniority and shall not require the individual to have any special legacy knowledge.
3. The SOP shall completely specify all units used in the instructions or calculations.
4. All calculations listed must be complete.
5. All calculations must be checked and validated.

Procedures revisions are currently in progress. All procedures revisions are being made according to the requirements listed above and the specific comments in the Report of the September 13-17, 2004 audit. The KPA procedure is currently being revised. Other procedures are being reviewed. All procedure revisions will be completed by November 22, 2005.

This action item is Cotter's response to Item B from the April 12, 2005 Notice of Violation Number 6. Item B involves the rework of the Standard Operating Procedures program to correct deficiencies found in the review of the Cotter Analytical Lab SOPs. The line items 1-5 are directly from the Notice of Violation. The line items are the general tasks that need to be completed to bring the SOP program up to par. However, the laboratory still should address the specific items of concern for each SOP listed in the November 02, 2004 Report of the Technical Audit of the Cotter Analytical Laboratory. The laboratory lists a completion date of 11-22-05 for these changes. However, the individual procedures should be completed, reviewed, and approved prior to the commencement of the specific effected laboratory operations. This may necessitate phased implementation of new sops to allow resumption of analytical operations prior to 11-22-2005.

C. Data Analysis, Reduction, and Reporting Methods

Develop and implement a Standard Operating Procedure that governs all aspects of data analysis, reductions, and reporting. The SOP must address:

1. Specify the Quality Control sample types and frequency;
2. Specify Quality Control sample acceptance criteria;
3. Specify the formulas to be used for activity concentration, error, and MDA/MDC calculations;
4. Requirements for the development and validation of calculations used to generate data;
5. Requirements for validation of software (e.g., spreadsheets, databases , or instrument manufacturer's software) that is used to produce data before that data is used;

6. Specification of the raw data and supplementary information necessary to allow for future validation; and
7. Validate all software used to produce data before the data is used and maintain records of the validation.

As demonstrated to Mr. Wallace at the April 14, 2005 meeting, the requirement for the QC sample protocols (types and frequencies) is contained in the QAPP. The QAPP is an overriding document for all procedures. Revised procedures will contain the items listed in C. Verification and validation of current spreadsheets is currently in progress. The LIMS system database will also be verified. Bench sheets will be revised to include appropriate headers and to insure that all information required for calculation of sample concentrations is included. All revisions and verifications will be completed by November 22, 2005.

This action item is Cotter's response to Item C from the April 12, 2005 Notice of Violation Number 6. Item C involves the preparation of a Standard Operating Procedure to govern Data Analysis, Reduction, and Reporting Methods for preparation of analytical data . The line items 1-7 are directly from the Notice of Violation. The statement made that the QC sample protocols are all in the QAPP is correct. However, that were was not global evidence that those criteria had filtered down to the operational level. The other items such as the data reduction spreadsheets that need to be revised and controlled will benefit from uniform criteria for development, review and approval. This is another facet of the laboratory's operation that should be completed prior to the beginning of analytical operations. The revision of spreadsheets for analytical operation such as those for uranium KPA cannot be effectively completed prior to the development of this procedure. The time frame for completion of this procedure should be accelerated.

D. Quality Control and Quality Assurance

Establish and implement a QA/QC program to ensure that data is appropriately reviewed and approved before release. The QA/QC program shall address:

1. Specify Quality Control sample types and frequency;
2. Specify Quality Control sample acceptance criteria;
3. Specify steps to be taken in the event laboratory data does not meet quality control requirements;
4. Provisions and frequencies for independent reviews of data generated;
5. Practices for the laboratory's Control of Measuring and Test Equipment;
6. Specify acceptance criteria and inspection frequencies for the laboratory's measuring and test equipment;
7. Ensuring that acceptance criteria and inspection frequencies for the laboratory's measuring and test equipment are known and followed by all staff members; and
8. Specify protocols for dealing with measuring and test equipment that does not meet inspection acceptance criteria.

As demonstrated to Mr. Wallace at the April 14, 2005 meeting, the requirement for the QC sample protocols (types, frequencies and actions) is contained in the QAPP. The QAPP is an overriding document for all procedures. Procedure revisions will insure that all analytical procedures include references to the QC sample types and frequencies,

acceptance criteria and actions in the event that the sample acceptance criteria are not met. Revision to the procedures is in progress, beginning with the KPA procedure. The Control of Measurement and Testing Equipment (M&TE) is scheduled to be written. This procedure will proceduralize the tests that are currently being conducted, but not specifically documented, in addition to addressing any additional aspects which are not currently included in the program. The M&TE procedure will include acceptance criteria and inspection frequencies. This procedure is anticipated to be completed by the end of September.

This action item is Cotter's response to Item D from the April 12, 2005 Notice of Violation Number 6. Item D involves Quality Assurance and Quality Control. The line items 1-8 are directly from the Notice of Violation. The presence of QC Sample protocols and requirements in the QAPP did not seem to be adequate based upon analytical data reviewed. The QC sample protocols need to filter down to the bench level and into analytical work order review checklists. The requirements need to be formalized and incorporated into all analytical operations.

The generation of an SOP for the Control of Materials and Test Equipment is appropriate. This is an area of the laboratory operations that needs attention. The previous lack of documentation in the area of control of measuring and test equipment made it difficult to verify that equipment being used in analytical operations and other aspects of the lab was operating within operational limits. This procedure needs to be implemented as soon as possible to allow for commencement of analytical operations.

E. Laboratory Personnel Training

The training for each laboratory analyst needs to be reviewed, updated, and documented. The training shall include a thorough review and instruction in all revised SOPs and laboratory practices. The training program shall include a Demonstration of Competence (DOC) program for new staff members before they are allowed to perform independent work on samples.

Criteria for the Demonstration of Competence program is being developed. A protocol for continued training and competency demonstration for current laboratory analysts, which includes the current *read-only* training requirements for new procedures, will be established. The program will be in place prior to November 22, 2005.

This action item is Cotter's response to Item E from the April 12, 2005 Notice of Violation Number 6. Item D involves Laboratory Personnel Training. The creation of a new program for the training of laboratory staff and for verification of competence in the specific analyses will benefit the laboratory's operations. The requirements for the demonstration of competence for both current and new analyst will need to be reviewed. The current analysts should be evaluated regularly as a method of demonstrating continuing competence in the analyses.

Attachment A-Cotter Radiochemistry Laboratory Audit Resolution - Status of Specific Items

Review comments made by the auditor addressing the Cotter comments are listed in the comment section in Bold, Italic type.

Task	Current Status	Comment
1.1.1 Prepare organizational chart with names	in progress	
2.1.1 Add a step to sample receipt procedures to verify the pH with pH paper and revise sample form to record the results and correction the condition, if necessary.	in progress	In addition a check off will be added to the sample receipt form. Until that form is revised the pH check will be noted as a comment. <i>This is an acceptable solution.</i>
2.2.1-2.2.2 Information on SSTR form	to be resolved	The current sample receipt form contains the information that was requested in the audit report, in shorthand notation. When this notation is interpreted by the person receiving the samples the number and types of samples in the set is known. This form will be revised to include a section for number and types of samples. <i>Review of the changes made are required on this item.</i>
3.1.1, 3.2.7 Second Source Standard	to be resolved	Discussed during the 4/14/05 meeting but not resolved. <i>The second source standard should include the use of separate standards for LCS and calibration standards. This means a separate standard should be used for each of these tests. These standards should preferably be from at least standards with different preparation batches and serial numbers from the same vendor or two different standards from two different vendors.</i>
3.1.1 Obtain new standards from a traceable source	in progress	Pending approval of the request to possess the required standards. <i>I have reviewed the Cotter License Amendment 42 issued December 14, 2004. It does appear that the current license does not allow for possession of the liquid radioactive material calibration solutions required for laboratory operations.</i>
3.2.1 Assess degree of uncertainty to be added to the TPU due to current method of calibration standard preparation.	pending	Pending the receipt of standards. <i>The calculations used by the laboratory to develop the Total Propagated Uncertainty will need to be reviewed. These calculations should take into account t the normal counting or analytical uncertainty in the case of KPA plus the other preparatory uncertainties such as standards and sample preparatory uncertainties.</i>

Task	Current Status	Comment
3.2.4 Preparation of Standards	in progress	Addressed in the Standards Preparation Procedure and Technician Training (<i>See comments in the main body of the report</i>)
3.2.4 (bullet 4) Error in the Ra-226 standard	demonstrated	The correction of this error was listed in the log book. The correction was made and dated prior to the use of the standard in any analysis. Shown to Mr. Wallace during the 4/14/05 meeting. He agreed that this was satisfactory. <i>The laboratory staff did inform me that they corrected the error before any Ra-226 analyses were performed. The report stated that any work performed between 4-11-01 and 5-14-01 would need to be reevaluated. If no analyses were performed within the time frame listed then that is satisfactory.</i>
3.2.5 Standards verification program	pending	Contingent on approval of the receipt of the sources and delivery schedule by the source vendor. At least 2 months lead time from receipt of approval to possess the sources. <i>The verification of all new calibration standard solutions is required before the standards are used and new work performed. Additionally, any current standards should be verified prior to use. However, we have the chicken and the egg paradox. The laboratory does not have any standards suitable for reference and may have difficulty performing the initial verifications. The lab may want to consider ordering some standards prepared in larger volumes to the activity concentration per milliliter needed for final use. This will eliminate variability introduced in the standard dilution stage.</i>
5.1.1.1 MSDS update	completed	The notebook has been updated and is available to the laboratory staff. <i>This was verified during the 4-15-05 visit to the Cotter Analytical Laboratory.</i>
5.1.2.1 Labeling of in-house prepared chemicals	demonstrated	The labeling of the chemicals was completed at the time of the 4/14/05 meeting. Mr. Wallace observed the labeling and stated that it was satisfactory. <i>This is satisfactory.</i>
5.1.2.2, 5.1.2.3, 5.1.2.4 Storage of chemicals	completed	Flammable and corrosive chemicals had been relocated to appropriate storage cabinets and areas at the time of the 4/14/05 audit. Since that time and additional cabinet has arrived and is in use.

Task	Current Status	Comment
		<i>I did see the implementation of the flammable cabinets and corrosive cabinets. As of 4-14-05 additional corrosive storage was required. If this has been added and the corrosive reactive acids are stored separately this item will be complete.</i>
5.1.2.5 , 5.1.2.6 Hydrofluoric acid safety and first aid	demonstrated	Magnesium sulfate is an acceptable first aid for HF exposure to the skin according to the MSDS. Proper supplies are available in the lab and were shown to Mr. Wallace on 4/14/05. <i>The laboratory needs to address the delivery method or vehicle to incorporate magnesium sulfate for treatment of contaminated skin.</i>
5.1.2.7 Document measurements made of face velocity of hoods in the laboratory or through Safety	demonstrated	A venometer dedicated for use in the laboratory is in place. The protocol for recording readings will be addressed in the M&TE procedure. <i>As stated in Section D of the evaluation of the Laboratory status report these operations need to be addressed as soon as possible to allow for operation of the laboratory. One of the main problems with the Materials and Test Equipment Inspection protocols at Cotter was a lack of acceptance /rejection criteria to evaluate test results along with documentation. These need to be addressed.</i>
5.1.2.8 Fire blanket placement	in progress	The fire blanket was shown to Mr. Wallace and appropriate locations for mounting the blanket in the laboratory were discussed. <i>There were at least two locations in the lab that could be acceptable for mounting the fire blanket. This is a relatively simple operation to be complete and should be completed as soon as possible.</i>
6.1.1.1 Including intended use statement in SOP	in progress	Revision of procedures has begun. <i>Acceptable</i>
6.1.1.2, 7.2.1 Air filters tared before use.	verbally agreed	Discussed during the 4/14/05 meeting and Mr. Wallace agreed that this was not necessary since filters containing significant dust loading are digested. <i>The fact that the filters are undergoing complete dissolution does negate the need for concern over particle loading. However, the procedure was not specific on whether direct counting or digestion of 47mm filters would be</i>

Task	Current Status	Comment
		<i>employed. Direct counting of 47 mm filters from higher volume sampler could present difficulties from alpha attenuation from particulate loading.</i>
7.2 1E-16 uCi/ml air limits	verbally agreed	The application of the 1E-16 uCi alpha/ml to the LLD for occupational air samples was discussed with Mr. Wallace during the 4/14/05 meeting. It was agreed that the current regulations did not require this degree of sensitivity and that the degree of sensitivity required could be achieved under standard circumstances. This issue is also being addressed in the discussions for Amendment 42 to the Radioactive Materials License. At this time this a licensing issue between Cotter and CDPHE RMU.
7.2.1.2 Background count times	to be resolved	Discussed during the 4/14/05 meeting but not resolved. <i>This area needs to be resolved the laboratory needs to think about the frequencies for background determinations and the specified background count relative to routine samples. The lab needs to account for differentials between sample count times and background count times in the sample counting uncertainty and error calculations or maintain uniform sample and background counting times.</i>
7.2.1.3 Protocols for sample id on reports	in progress	<i>The lab needs to implement a uniform usage of the various client and lab sample identifications.</i>
7.2.1.5 QC for alpha air filter runs	in progress	Addressed in the revision of the laboratory QA procedures. <i>The proposed QA sample changes for alpha air filter samples will need to be reviewed.</i>
7.2.1.6 BZA samplers	verbally agreed	Discussed during the 4/14/05 meeting and Mr. Wallace agreed that this was an acceptable practice because the purpose of the air sample was known to the individual and it would be operated appropriately. <i>The conversation referenced indicate that the use of the BZA samplers in question was set up for a particular time period(e.g., 8 hour day) as opposed to a specific task (e.g, operations in a controlled area). In the case of the 8 hour day it is appropriate for the BZA sampler to be operated continuously.</i>

Task	Current Status	Comment
7.3 Questions on validity of data	to be resolved	This was discussed during the 4/14/05 meeting but not resolved. Various issues listed previous relate to this. <i>This item will require extensive additional communication and possible recalculation of data to ensure reliability</i>
7.3.1.1 SSTR questions	to be resolved	The sample transmittal sheet currently contains all of the information requested by Mr. Wallace. Some of this information is currently entered, free-format, on the form. This was discussed during the 4/14/05 meeting but not resolved. <i>The comment was not about the SSTR itself, but that the SSTR needs to be included with the Analytical Data Package to allow for proper data validation.</i>
7.3.1.3 Extended background count times	to be resolved	Discussed during the 4/14/05 meeting but not resolved. <i>As stated previously the lab needs to adjust it's methods so that background and sample count times are equivalent or that the appropriate adjustments are made to calculations like the counting uncertainty, LLDs and MDAs.</i>
7.3.1.4 Preferential treatment of samples, etc.	to be resolved	Discussed during the 4/14/05 meeting but not resolved. <i>Additional discussions are required on this item.</i>
7.3.1.9 Blank correction of samples	to be resolved	Discussed during the 4/14/05 meeting but not resolved. <i>Additional discussions are required on this item.</i>
7.3.1.10 Blank counting procedures and use	to be resolved	Discussed during the 4/14/05 meeting but not resolved. <i>Additional discussions are required on this item.</i>
7.3.3.1 Elimination of data from cycles	to be resolved	Discussed during the 4/14/05 meeting but not resolved. <i>Additional discussions are required on this item.</i>
7.3.3.3 Clarify the activity calculation of Berthold	completed	Demonstrated at the 4/14/05 meeting and a letter of concurrence was received. <i>Additional discussions are required on this item.</i>
7.3.3.3 Clarify the uncertainty calculation of the Berthold	in progress	The calculation performed by the Berthold instrument was verified. Non-vendor spreadsheet verification is in progress. <i>The uncertainty calculation used in the revised spreadsheets will need to be reviewed.</i>

Task	Current Status	Comment
7.3.4.3, 7.3.4.4 Pb-210 calculations	in progress	<p>The main reason for the discrepancy was the labeling of the cpm/dpm results from the Berthold. That being resolved, the calculations are being reviewed and if necessary revised during the verification of the spread sheets. The degree of uncertainty introduced by any changes will be addressed.</p> <p><i>The above explanation is not complete. One of the factors in this analysis was the cpm labeling error. The use of an LCS measurement to provide global recovery/ chemical yield factor to be applied to all samples is inappropriate. If a chemical yield factor is to be applied to the samples, an appropriate internal tracer must be added to each sample and recovery determined on a sample specific basis that accounts for the sample's individual matrix.</i></p>
7.4.1.1, 7.5.1 Printer for KPA and alpha spec	completed	<p>The printers have been installed.</p> <p><i>If instrument output is available from the printers serving both the KPA and Alpha Spec, then this item is completed.</i></p>
7.4.1.8 Worksheet 04-01590 concentrations of LCS	in progress	<p>verification of worksheets and spreadsheets is in progress.</p> <p><i>Additional discussions are required on this item.</i></p>
7.5.1.7 Units for the alpha spectroscopy spreadsheets	in progress	<p>verification of worksheets and spreadsheets is in progress.</p> <p><i>Additional discussions are required on this item.</i></p>