

June 20, 2005

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

Re: Laboratory Modifications Status Report

Dear Mr. Tarlton:

In our letter of May 6, 2005, responding to the CDPHE Notice of Violation dated April 12, 2005, Cotter committed to providing a status report within 45 days relative to our progress in responding to laboratory program needs. Accordingly, Cotter's contractor RETN Inc. has provided such an update as outlined below:

The status of areas referenced in Item 6 of the 369-01 NOV 041205, as listed in sections A through E below, and in the Report of the September 13-17, 2004 Radiochemistry Laboratory Audit is addressed below. All timeframes are estimates, however, it is anticipated that all tasks will be completed within the 180-day timetable (November 22, 2005) as specified in the *Compliance Order, #05-05-23-01*. Any circumstances preventing the completion of a task by November 22, 2005 will be submitted to the CDPHE prior to November 22, 2005.

Items listed as "resolution required" in the accompanying audit resolution table (which follows the narrative here) still require discussion with Mr. Wallace to determine the acceptable resolution. Several areas of the audit report were not resolved during the April 14, 2005 meeting because of time constraints. Another meeting with the representatives of RMU and Mr. Wallace is requested to enable these items to be satisfactorily completed in a timely manner. Also, several items were verbally resolved or demonstrated to Mr. Wallace during the April 14, 2005 meeting. These items are noted as such. Please provide concurrence with this resolution status so that these items can be closed. Cotter will provide the CDPHE with 60-day updates on the completion and progress status of all items.

These items are being addressed by the staff of RETN, Inc. of Westminster with the assistance of Cotter Laboratory and Radiation Safety staff. Current RETN, Inc. staff supporting this effort includes one certified health physicist/ radiochemist, one certified health physicist/ industrial hygienist and two chemists, who are experienced in uranium and environmental chemistry. One chemist is assigned full-time to the position of interim laboratory manager.

In reference to Mr. Egidi's communication of June 15, 2005 regarding the KPA analysis, KPA analysis has been given careful investigation including review of digestion protocols and instrument operations. Revision of the current procedure is in progress. This revision includes incorporation of recently released manufacturer's documentation. The KPA has been configured to enable printed output and calibration protocol. However, the instrument is currently not operational due to a failed laser cartridge. The manufacturer's supplier of plasma laser cartridges is unable to supply a replacement due to manufacturing/production problems. The backordered cartridge is due by the end of June. When the system is again operational the draft of the new procedure will be walked-down and the revision finalized.

Status Summary

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.

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.

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.

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.

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.

In addition to the information provided above, Attachment A to this correspondence provides a current reporting of progress relative to the CDPHE Audit findings and annotates areas where additional discussion with the Auditor is needed in order to identify proper resolution of the issue. Please advise us as soon as possible as to when such a discussion meeting can be arranged.

Should you have any questions regarding this matter please contact me.

Sincerely,

Steven. D. Landau
Manager, Environmental Affairs

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

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.
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.
3.1.1, 3.2.7 Second Source Standard	to be resolved	Discussed during the 4/14/05 meeting but not resolved.
3.1.1 Obtain new standards from a traceable source	in progress	Pending approval of the request to possess the required standards
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.
3.2.4 Preparation of Standards	in progress	Addressed in the Standards Preparation Procedure and Technician Training
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.
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.
5.1.1.1 MSDS update	completed	The notebook has been updated and is available to the laboratory staff.
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.
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.
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.
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.
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.
6.1.1.1 Including intended use statement in SOP	in progress	Revision of procedures has begun.
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.

Task	Current Status	Comment
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.
7.2.1.2 Background count times	to be resolved	Discussed during the 4/14/05 meeting but not resolved.
7.2.1.3 Protocols for sample id on reports	in progress	
7.2.1.5 QC for alpha air filter runs	in progress	Addressed in the revision of the laboratory QA procedures.
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.
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.
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.
7.3.1.3 Extended background count times	to be resolved	Discussed during the 4/14/05 meeting but not resolved.
7.3.1.4 Preferential treatment of samples, etc.	to be resolved	Discussed during the 4/14/05 meeting but not resolved.
7.3.1.9 Blank correction of samples	to be resolved	Discussed during the 4/14/05 meeting but not resolved.
7.3.1.10 Blank counting procedures and use	to be resolved	Discussed during the 4/14/05 meeting but not resolved.
7.3.3.1 Elimination of data from cycles	to be resolved	Discussed during the 4/14/05 meeting but not resolved.
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.
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.
7.3.4.3, 7.3.4.4 Pb-210 calculations	in progress	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.
7.4.1.1, 7.5.1 Printer for KPA and alpha spec	completed	The printers have been installed.
7.4.1.8 Worksheet 04-01590 concentrations of LCS	in progress	verification of worksheets and spreadsheets is in progress.
7.5.1.7 Units for the alpha spectroscopy spreadsheets	in progress	verification of worksheets and spreadsheets is in progress.