

May 6, 2005

Mr. Tim G. Bonzer, Compliance Lead
Radiation Management Unit
Hazardous Materials and Waste Management Division
Colorado Department of Public Health and Environment
4300 Cherry Creek Drive South
Denver, Colorado 80245-1530

Subject: Notice of Violation - Certain requirements of Title 25, Article 11, CRS, Colorado Radioactive Materials License Number 369-01, and the State of Colorado Rules and Regulations Pertaining to Radiation Control (the Regulations).

Dear Mr. Bonzer,

The following information is provided regarding the violations that were identified during an inspection of Cotter's laboratory on September 13-17, 2004; through an audit of dose calculations for 2003; and during an inspection conducted at the Canon City facility on March 9, 2005. The inspections and audits consisted of selective examinations of procedures and records, and the observations and interviews made by the inspectors.

The six items characterized as noncompliance and two items of concern from the inspection report are reiterated below followed by our analysis and response.

Item of Noncompliance:

1. *RH 4.6.5 of the Regulations states that the licensee shall limit the soluble uranium intake by an individual to not more than 10 mg in a week in consideration of the chemical toxicity.*

Contrary to this requirement, in correspondence dated December 3, 2004 the licensee provided data indicating that an employee (#3111) of the licensee working in the yellowcake production area had an intake of 22 mg of soluble uranium for the week of October 18, 2004.

The licensee must implement a radiation protection program sufficient to ensure compliance with the soluble uranium intake limits established in Part 4 of the Regulations. This shall include the use of appropriate procedures, properly maintained equipment, and adequate engineering controls to assure that intakes of soluble uranium by employees are As Low As is Reasonably Achievable (ALARA).

This violation is a repeat Item of Noncompliance, previously cited in the Department's October 13, 2000 Notice of Violation.

Cotter Response.

It is Cotter's opinion that to link this apparent intake of soluble uranium to potential occurrences from five (5) years ago is disingenuous. The supposed premise is the stated opinion as to the inadequacy of the radiation protection program.

We reviewed the reports from February 2000, the October 13, 2000 NOV and Cotter's follow-up response to that NOV dated November 15, 2000, which were concerning elevated urinalysis results that occurred in 1999. There is no apparent relationship between these events and the incident cited above partly because those intakes were related to inhalation exposure and not ingestion. In fact, in our follow-up to the October 13, 2000 NOV we concluded that no exceedance of the weekly soluble limit had occurred based on the best information regarding the date of the projected intake.

As to the adequacy of the radiation protection program, it should be noted that for 2004, the reported urinalysis of 15 ug/l was later finally reported by the contract laboratory as 12 ug/l and was the only uranium urinalysis out of 2,607 for 2004 that ever exceeded the RH-050 URANIUM BIOASSAY procedure criteria for an evaluation when a result is greater than 10 ug/l. Please note that Standard Industry Practice is to follow NRC Regulatory Guide 8.22 **Bioassay at Uranium Mills** which requires no evaluation unless the uranium urinalysis result exceeds 15 ug/l and also states that the uranium confinement and air sampling program are then deemed to be adequate. Therefore, Cotter's radiation protection program regarding uranium urinalysis exceeds that which is required by regulatory guidance and should not be deemed inadequate when in fact monitoring and follow-up are clearly beyond the standard of practice.

Relative to other aspects of the radiation protection program mentioned, specifically the transfer of materials at the milling facility via pipelines, it should be noted and understood that there are thousands of feet of pipelines consisting of various materials of construction, some permanent and some temporary throughout the facility. The operations and maintenance departments as well as the radiation and safety departments perform periodic walkthroughs of all operating areas looking for leaks, splits, areas that need refurbished, etc. and do in fact order repairs and replacements on the basis of those observations. The fact that an individual transfer line might somehow fail on occasion should not be a surprise to the RMU given the nature of the facility; this is a chemical plant and line breaks can occur.

For this particular activity, a walkthrough of the area was done by the Mill Superintendent, Environmental Coordinator/Radiation Safety Officer, Maintenance Foremen (2) and the Utility Foreman and then the mill superintendent prepared a work plan for this activity. Based on the walkthrough and subsequent evaluation with the Assistant RSO, it was determined that no special precautions were identified or were necessary for workers involved in this task since it is common practice to use portable pumps and lines to transfer materials from various tanks in the product area or other

milling facility buildings. Since the process objective was to transfer slurry, thus eliminating a concern of airborne particles, no additional protective requirements were established for radiological purposes. Standard Personal Protection Equipment (PPE) (work clothing, tyvek coveralls, rubber boots and safety eyewear) was routinely used for this activity.

The process of moving this material back and forth at least five hundred (500) times over a period of several months caused no other exposures. In fact, the line was put back in operation after the first incident, worked adequately for several more days and parted again. At that point it was taken out of service and a more permanent line was installed to prevent re-occurrence.

The primary cause of the ingestion and subsequent intake aside from the fact that the employee working with him stepped on the hose which parted was that the fact acknowledged by employee 3111 that his mouth was open and he did not adequately rinse his mouth thereafter.

Item of Noncompliance:

2. *RH 4.6.5 of the Regulations states that the licensee shall limit the soluble uranium intake by an individual to not more than 10 mg in a week in consideration of the chemical toxicity.*

Contrary to this requirement, in correspondence dated February 18, 2005 the licensee provided data indicating that an employee (#3111) of the licensee working in the Countercurrent decantation (CCD) area are had an intake of approximately 22 mg of soluble uranium for the week of January 17, 2005.

The licensee must implement a radiation protection program sufficient to ensure compliance with the soluble uranium intake limits established in Part 4 of the Regulations. This shall include the use of appropriate personal protective equipment (PPE), procedures, and training to assure that intakes of soluble uranium by employees are As Low As is Reasonably Achievable (ALARA).

This violation is a repeat Item of Noncompliance, previously cited in the Department's October 13, 2000 Notice of Violation.

Cotter Response

It is Cotter's opinion that to link this apparent intake of soluble uranium to potential occurrences from five (5) years ago is disingenuous. The supposed premise is the stated opinion as to the inadequacy of the radiation protection program.

Reviewing the reports from February 2000, the October 13, 2000 NOV and Cotter's follow-up response to that NOV dated November 15, 2000 which were concerning

elevated urinalysis results which occurred in 1999, there is no apparent relationship between these events and the incident cited above partly because those intakes were related to inhalation exposure and not ingestion. In fact, in our follow-up to the October 13, 2000 NOV we concluded that no exceedance of the weekly soluble limit had occurred based on the best information regarding the date of the projected intake.

In the incident cited above the employees were performing routine operations and failed to use their required PPE as required by operating procedures. As noted in our report, one employee had an elevated uranium urinalysis and an accompanying projected intake while the other employee working directly next to him and indicated he ingested fluid did not have an elevated urinalysis nor was an accompanying projected intake made for that individual.. As also reported, the projected amount of material that would have been ingested to produce that urinalysis and projected accompanying intake was for comparison on the order of an average glass of water (5-6 ounces) and in retrospect unlikely to have happened. Employee # 3111 has had a subsequent urinalysis above 15 ug/l not associated with an ingestion potential. Employee #3111 has been temporarily reassigned to a lower exposure area because of his history of uranium urinalysis results and to investigate the cause of that history.

Item of Noncompliance:

3. *License Condition 19.4 in License Amendment 41 (in effect at the time of the event) required the licensee to prepare a Radiation Work Permit (RWP) prior to start of any work, including maintenance, at any location of the licensed facility or site, which has radiation safety implications and for which no written procedure exists. The RWP shall specify appropriate radiological controls. The licensee must retained copies of the RWPs for no less than five (5) years for inspection by the Division.*

Contrary to this requirement, no RWP had been prepared for the activities during the week of October 18, 2004 that resulted in an employee having an excessive intake of soluble uranium. The licensee was also unable to provide the inspector with written operating procedures governing these activities.

The licensee must ensure that the RSO is familiar with ongoing activities at the site and that the RSO makes the determination if a RWP is required for a given task. The RSO shall specify appropriate radiological and safety controls for any work which has radiation safety implications and for which no written procedure exists. Should the activities governed under a RWP become routine or frequently performed activities, the licensee shall develop these work permits into written procedures and provide copies to the Department for review and incorporation into the license.

This violation is a repeat Item of Noncompliance, previously cited in the Department's December 7, 2004 Notice of Violation.

Cotter Response

As noted above in the response to Item of Noncompliance 1, this activity was covered by a written description of the activity (Attachment 1), was evaluated by the RSO and Assistant RSO, required no additional radiological protection procedures and was conducted (with the exception of the incident cited above) in a satisfactory manner.

Item of Noncompliance:

4. *RH 4.5.1 of the Regulations requires that each licensee develop, document, and implement a radiation protection program sufficient to ensure compliance with the requirements of Part 4. RH 4.5.2 further states that the licensee shall use procedures and engineering controls based on sound radiation protection principles to achieve occupational doses and doses to members of the public that are As Low As Reasonably Achievable (ALARA).*

Contrary to these requirements, the licensee has failed to establish and implement an adequate radiation protection program. The licensee's radiation safety officer and radiation safety staff have failed to ensure that activities at the site were adequately evaluated for radiation safety implications (lack of radiation work permits). Engineering controls for transfer of radioactive materials were inadequate (temporary hose and pumps vs. appropriate plumbing) to protect workers and limit intakes. Corrective actions to a known safety problem were not adequate or timely (the use of the temporary hoses and pumps was not discontinued until a second disconnect occurred). Personnel failed to use appropriate PPE (face shield) in the CCD area, leading to intake of radioactive materials. Management ALARA meeting minutes failed to indicate the seriousness of issues and did not address the failure of the radiation safety program to establish appropriate RWPs, engineering controls, training, and supervision. Reports of the incidents and corrective actions were not completed in a timely manner.

The licensee must establish and implement an adequate radiation safety program to ensure compliance with the requirements of Part 4 of the Regulations. Specifically:

- A. *The licensee must ensure that routine activities at the mill are covered by an approved procedure. These procedures must specify appropriate protective equipment and safety precautions.*
- B. *Employees must be instructed in the approved procedures and safety precautions, including the use of appropriate PPE.*
- C. *Persons identified as authorized users on the license shall provide sufficient and appropriate supervision of all other individuals working at the mill to ensure their adherence to established procedures and to ensure their use of appropriate PPE.*

- D. *The Radiation Safety Officer (RSO) shall evaluate activities that are not covered under approved procedures. The RSO shall ensure that appropriate procedural and engineering controls are established for the work to be completed. The RSO shall also ensure that an RWP is issued and that workers are instructed in the specific safety precautions, PPE and limitations of the RWP. RWPs shall not be applicable for more than ninety (90) days. Activities beyond 90 days will require the establishment of approved procedures.*
- E. *Corrective actions following an incident shall include a root cause investigation and an analysis of the training, procedural, and/or engineering failures that contributed to the incident. The specific activities that lead to the incident shall be discontinued until the investigation is concluded and deficiencies are corrected. The investigation findings shall be documented at the conclusion of the investigation. Corrective actions and the date when those actions were completed shall be documented upon completion.*
- F. *Documents pertaining to incident investigations, incident reports, and corrective actions shall be available for review by the Department.*

This violation is a repeat Item of Noncompliance, previously cited in the Department's December 7, 2004 Notice of Violation.

Cotter Response

Cotter disagrees that the radiation protection program is inadequate. Based on the ultimate criteria of dose to the employee, the program is functioning in a satisfactory manner. As with all programs improvements can be made to further limit dose according to the ALARA concept. In that regard, we have provided training to inform supervisors and employees of the necessity for proper use of PPE in all processing areas.

Regarding ALARA meeting minutes, it is unclear to Cotter as to how the RMU can determine how seriously we considered the incidents. The fact is that the incident was discussed at ALARA meetings, including root cause considerations. It is pure speculation to assume that it was not taken seriously and absolutely not the case.

Regarding the reporting of these ingestion intakes, Cotter believes that the information and evaluations of the intakes were presented in a clear and appropriate manner. Nevertheless, Cotter acknowledges that the supporting documentation of investigation of the incidents can be improved. In that regard, during our recent annual independent audit of the radiation protection program by Mr. Bob Morris, CHP working for RETN Inc., Cotter requested that these specific issues be evaluated. We are awaiting the results of this evaluation and will then evaluate and implement the appropriate recommendations regarding the issues you have raised in this item and Items 1-3 above.

Item of Noncompliance:

5. *License Condition 27.1 in Amendment #41 and Condition 26.2 in Amendment #42 requires that the licensee's personnel and facility monitoring program shall be sufficient to enable the Division to estimate maximum potential occupational dose commitment and to demonstrate compliance with Part 4.*

Contrary to this requirement, dose calculation spread sheets for 2003 contained numerous errors, inconsistencies, and incomplete explanation keys for data fields.

The licensee must ensure that the contents of the spreadsheets used to determine worker doses are accurate, correct, and clearly explained with appropriate descriptions of data fields, abbreviations, etc.

Cotter Response

Cotter has previously addressed the answers to these concerns in a number of Department related discussions, meetings, and documents. Please review the documents listed below for a complete history of the correspondence provided by Cotter fulfilling the answers to these questions. Of particular significance was the submittal from Cotter to the RMU dated March 1, 2005. Based upon the finding above, it does not appear that the RMU considered this information or simply chose to ignore it. You will find that the items presented in the finding above have already been addressed by Cotter by means of that correspondence over two months ago. Cotter's March 1 correspondence was prepared in the context of discussions which occurred at the meeting convened at the Department's offices on September 10, 2004. The concerns related to Cotter's monitoring program and mill dose calculations spread sheets have been adequately addressed and closed out by Cotter for several weeks now.

Please refer to Cotter's response to the July 20, 2004 correspondence from CDPHE regarding Occupational Doses from 2003. This response was submitted on March 1, 2005.

Item of Noncompliance:

6. *RH 4.5 of the Regulations requires that each licensee develop, document, and implement a radiation protection program sufficient to ensure compliance with the requirements of Part 4. RH 4.9 requires that the licensee take suitable and timely measurements of concentrations of radioactive materials in air in work areas; or quantities of radionuclides excreted from the body; or combinations of these measurements for the assessment of occupational doses. RH 4.15.1 of the Regulations requires that the licensee make surveys of radiation levels in unrestricted areas and radioactive materials in effluents released to unrestricted areas to demonstrate compliance with the dose limits for individual members of the public. License Condition 26.2.1 in Amendment #41 and*

Condition 25.2.2 in Amendment #42 requires that the licensee meet specific detection capabilities for the measurement of radioactive materials.

Contrary to these requirements, in a report dated November 2, 2004 provided by Mr. Ed Wallace, numerous deficiencies have been identified with the procedures, data management, analysis, quality control, and worker training for Cotter's on-site radiochemistry laboratory. The laboratory operations are key to the analysis of bioassay samples, assessing airborne contamination levels in the workplace, determining radioactive material content in effluents, environmental monitoring, and dose assessment for workers and members of the public. The cumulative effect of the laboratory deficiencies renders the laboratory results unacceptable for the purposes of demonstrating compliance with Part 4.

The licensee must take immediate action to employ the services of an outside radiochemistry laboratory (subject to Department approval) to perform the laboratory analysis of all samples that are required for determining compliance with Part 4 (i.e. bioassay samples, breathing zone samples, general air samples, effluent sampling, environmental sampling, and other samples used for the assessment of public doses). In addition, the licensee shall take prompt action to correct the identified deficiencies within the laboratory. The licensee must submit a plan to the Department describing the corrective actions and deadlines to address the following laboratory deficiencies:

A. Radioactive Material Calibration Standards Preparation & Control

Develop & Implement an 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.*

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.*

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.*

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.*

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.

Cotter Response

Cotter has previously addressed and undertaken appropriate corrective action relative to the primary concern expressed by Mr. Wallace regarding the analytical determinations for gross alpha, gross beta and uranium. As such, we will not repeat our response to those issues here. More specifically, Cotter addressed the concern about those laboratory operations in a document that was submitted to the Department on April 27, 2005 and addressed to Mr. Bonzer. Please refer to the response provided here for information responding to the remainder of the CDPHE concerns related to lab procedures, data management, analysis, quality control, and worker training.

Prior to the receipt of the Department's communication about the Laboratory, Cotter had engaged the services of RETN, Inc. of Westminster. RETN now maintains oversight of the laboratory operations through the placement of a full-time interim Laboratory Manager.

To elaborate on RETN's scope of work, the RETN team will be working closely with our laboratory management (and staff) to ensure that the procedures, spreadsheets and other products developed within the scope of work assigned to RETN are implementable and fully integrated into current Laboratory operations.

The tasks listed below are those listed in the *Report of the Radiochemistry Technical Audit*, dated *September 13 through 17, 2004* and in reference to Mr. Wallace's report dated November 2, 2004. These tasks have currently been determined by Cotter to be necessary laboratory improvements. Certain items listed in the Report will require discussions with the auditor prior to determining the appropriate effort/activity necessary to satisfy a resolution. In addition, a summary of items requiring resolution which RETN feels are most appropriately completed solely by Cotter are listed in a separate table (Cotter Task Table). The audit line items associated with each task are listed for your reference.

The integration of quality assurance or quality control principles into the procedures or programs will be based on current standards such as State of Colorado Regulatory Requirements, ANSI N13.30, ANSI 42.23, NELAC and other applicable documents, continuing the on-going goal of maintaining a Quality Assurance program consistent with good industry practices.

Audit Task Table (RETN)

Task 1: Develop a Training and Training Documentation Program.

The auditor acknowledged that the SOP reading review and signoff was “the first evidence of this upgrade”....”The lab still has a long way to go, but appears to be beginning to move in the right direction.” A framework for documenting training that is performed and establishing a protocol for formal refresher training and training of new hires will be developed. This will include preparation of required areas of training. This general protocol will be applicable to other radiation safety personnel positions. (1.0)

Task 1a: Develop qualifications for laboratory technicians with the concurrence of Cotter Mill and corporate management. (1.1.2)

Task 1b: Prepare an Initial Performance Review System for analysts as required by ASTM draft Standard WK4328 and ANSI 42.23. (1.2.1)

Task 1c: Revise QAP or applicable document to reflect the revised training program. (1.2.2)

Task 2: Sample Control

Task 2a: 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. (2.1.1)

Task 3: Radioactive Materials and Calibration Source Control

Task 3a: Develop an SOP to control preparation of calibration standards, including verification of new laboratory standards against old and a system of peer review for preparations, standard verification program. (3.2.1, 3.2.3, 3.2.4, 3.2.5, 3.2.6, 3.2.8, 3.2.9)

Task 3b: Develop standardized format for recording calibration standard preparation and possibly a spreadsheet for performing the calculations. (3.2.2)

Task 3c: Prepare a short summary documenting that the uncertainties due to current lab preparation methods have not adversely affected the results of the ability of the laboratory to provide valid data for dose assessment. (3.2.9)

Task 4: Reserved (Mr. Edgar Ethington’s List of concerns)

Task 5: Sample Preparation

Task 5a : Develop an M&TE procedure for instruments and equipment in the lab and a protocol for documenting checks, service and calibrations. (5.2.1.1, 5.2.2.1, 5.2.2.2, 5.2.2.3)

Task 5b: Develop a procedure for preparation of reagents used in the laboratory. Reference this procedure in other procedures as appropriate.

Task 5c: Revise QAP or other applicable procedures to address the review and implementation process for procedures and procedure revisions. Alternatively develop a procedure for preparing procedures.

Task 5d: Incorporate suggested changes into Appendix A through K, Digestion protocols, verify revisions with lab personnel and through walk down of the procedure.

Task 6: Radiochemical Analysis SOPs

Task 6a: Revise procedure SOP 5-1 Gross Alpha on filters and dust to include calculations, and other minor wording changes. (6.1.1.3 – 6.1.1.6)

Task 6b: revise SOP 5-3 Po-210 in water and soil (6.2)

Task 6c: revise/rewrite SOP 5-5 U- KPA according to standard operating procedures in use at other uranium sites. Include documentation of calibration information. Revise bench sheets and

sample identification. (6.3, 7.4.1.2, 7.4.1.3)

Task 6d: Incorporate the extensive revisions suggested by the auditor into SOP 5-9, Radiochemical procedure for Ra, Th, and Pb. This includes revising equations listed in the procedure. (6.4)

Task 7: Radionuclide Counting Operations/ Data Production Operations

Task 7a: Prepare a report to file that documents the amount of spray used does not cause the sample to be over the 20 mg limit or revise procedure to indicate that the samples have to be reweighed and calculations adjusted if necessary. (7.2.1.4)

Task 7b: Develop specific protocol for QC samples for alpha air samples

Task 7c: Assist Lab Staff in the revision of bench sheets to include more complete information. (7.3.1.5)

Task 7d: Develop a procedure for monitoring and trending LCS, and other QC and control samples and blanks. Establish control charts as appropriate. (7.3.1.6-7.3.1.7)

Task 7e: Review calculations and revise excel spread sheets as appropriate. Verify finished sheets. (7.3.1.8, 7.3.1.11, 7.3.2.1, 7.3.2.2, 7.3.4.1.)

Task 7f: Insure that all factors and calculations, including SD are documented in the appropriate procedures. Correct spreadsheets as required. (7.3.3.2, 7.3.3.3)

Task 7g: Establish a data review protocol for input data. (7.3.4.1)

Task 7h: Review QAP practices with lab staff and document as training. (7.3.4.2)

Task 7i: Revise bench sheets and spread sheets as suggested, including documentation of calculations and verification of calculations (7.5.1.2-7.5.1.6)

Task 7j: Revise alpha spec procedure formulas as necessary. (7.5.1.8)

Cotter Task Table

Task
1.1.1 Prepare organizational chart with names
2.2.1-2.2.2 Information on SSTR form
3.1.1 Second Source Standard
3.1.1 Obtain new standards from a traceable source
3.2.1 Assess degree of uncertainty to be added to the TPU due to current method of calibration standard preparation.
3.2.4 Error in the Ra-226 standard
3.2.5 Standard verification program
3.2.7 Second source standards
5.1.1.1 MSDS update – done
5.1.2.1 Labeling of in-house prepared chemicals
5.1.2.2, 5.1.2.3, 5.1.2.4 Storage of chemicals
5.1.2.5 , 5.1.2.6 Hydrofluoric acid safety and first aid
5.1.2.7 Document measurements made of face velocity of hoods in the laboratory or through Safety
5.1.2.8 Fire blanket placement
6.1.1.1 Including intended use statement in SOP
6.1.1.2 Air filters tared before use.
7.2 1E-16 uCi/ml air limits
7.2.1 Tared air filters
7.2.1.2 Background count times
7.2.1.3 Protocols for sample id on reports
7.2.1.5 QC for alpha air filter runs

Task
7.2.1.6 BZA samplers
7.3 Questions on validity of data
7.3.1.1 SSTR questions
7.3.1.3 Extended background count times
7.3.1.4 Preferential treatment of samples, etc.
7.3.1.9 Blank correction of samples
7.3.1.10 Blank counting procedures and use
7.3.3.1 Elimination of data from cycles
7.3.3.4 Clarify calculation of Berthold
7.3.4.3, 7.3.4.4 Pb-210 calculations
7.4.1.1, 7.5.1 Printer for KPA and alpha spec
7.4.1.8 Worksheet 04-01590 concentrations of LCS
7.5.1.7 Explanation to auditor on units

Cotter is taking prompt action to correct the deficiencies identified by CDPHE within the Laboratory. Subparts A thru E of CDPHE's request will additionally be fulfilled with the help and services of RETN. Cotter is working to have this completed in a timely manner.

No schedule for completion has been developed, however Cotter will update the RMU within 45 days on the status on Tasks listed above.

Item of Concern:

- A. *Based on the verbal description of the hose in use during the time of the incident on October 18, 2004, it is questionable whether or not the hose was in proper working condition. The hose was described as being very old, hard, and brittle. The poor condition of the hose may have been a contributing factor in the incident.*

Cotter Response

As noted in our response to Item of Noncompliance 1, please note that the Operation, Maintenance and Radiation Safety and Safety Departments routinely make rounds and inspect pipelines and make repairs when necessary.

Item of Concern:

- B. *The licensee was not able to comply with the Lower Limit of Detection (LLD) established in Annex B of the License. Based on a review of this criteria by the Department during the lab audit it was determined that for breathing zone samples all specified LLD are not achievable. However, the Department is concerned that the licensee failed to identify its own inability to comply with this license requirement in the analysis process. The licensee is responsible for understanding the requirements and limitations of the license and to comply with those requirements. If the licensee is unable to comply with a specific license requirement for technical*

reasons, the licensee must notify the Department so that the issue can be examined and so that appropriate adjustment to license requirements can be made.

Cotter Response

This issue was responded to in our April 27, 2005 correspondence regarding the laboratory operations and referred to in response to Item of Noncompliance 6.

If you have questions regarding this response please contact me at (719) 275-7413

Sincerely,

Jim Cain
Environmental Coordinator/
Radiation Safety Officer

cc: Mr. Richard Cherry
Mr. Pat Mutz
Mr. Steve Landau
Mr. Steve Tarlton

Attachment (1)