

# STATE OF COLORADO

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*Dedicated to protecting and improving the health and environment of the people of Colorado*

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Colorado Department  
of Public Health  
and Environment

April 12, 2005

Richard Cherry, President  
Cotter Corporation  
7800 East Dorado Place, Suite 210  
Englewood, CO 80111

Subject: **Notice of Violation**

This letter is a Notice of Violation of 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).

These violations 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 your 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.

If proper actions are not taken by the licensee, on the basis of the violations (Items of Noncompliance) cited in this letter, the Division will consider the institution of proceedings to revoke, suspend or modify the license as necessary.

Your written response must be submitted within thirty (30) days of receipt of this letter and must include: (1) a detailed description of the corrective actions which have been taken to achieve compliance; (2) plans to achieve compliance with the requirements which cannot be remedied within thirty (30) days; and (3) other relevant information. Any proposed compliance schedules or plans to achieve full compliance after thirty days must specifically include implementation deadlines for each of the key components of the plan. If these deadlines are not met, this will provide the Division a basis, without further notice, to institute proceedings for suspension, revocation or modification of your license, as provided in RH 3.23 of the Regulations.

The following Items of Noncompliance with the State of Colorado *Rules and Regulations Pertaining to Radiation Control* (The Regulations) and the conditions of your Radioactive Materials License were noted:

Prepared by: \_\_\_\_\_ Reviewed by: \_\_\_\_\_ Reviewed by: \_\_\_\_\_ Mailed by: \_\_\_\_\_  
Date: \_\_\_\_\_ Date: \_\_\_\_\_ Date: \_\_\_\_\_ Date Mailed: \_\_\_\_\_

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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.*

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.*

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.*

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.*

- 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.

- 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.

Items 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.

- 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.

As required by RH 10.2 of the Regulations, this notice must be posted so as to permit individuals engaged in licensed activities to observe it on the way to or from any particular licensed activity location to which the document applies. Any acknowledgment to this report by the licensee shall be posted within five (5) working days after dispatched by the licensee. Such documents shall remain posted for a minimum of five (5) working days or until actions correcting the violations have been completed, whichever is later.

The number and type of violations identified in this **Notice of Violation** indicate a serious and substantial inability of the licensee to demonstrate compliance with the requirements of the license and the Regulations. These items must be address with considerable urgency to the satisfaction of the Department.

Representatives of this Division will conduct an inspection to verify compliance within six (6) months from the date of this Notice. If you have any questions concerning this letter, please contact Mr. Thomas Pentecost of this Division at (303) 692-3458.

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TGB:TP

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