

STATE OF COLORADO

Bill Owens, Governor
Jane E. Norton, Executive Director

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

4300 Cherry Creek Dr. S. Laboratory and Radiation Services Division
Denver, Colorado 80246-1530 8100 Lowry Blvd.
Phone (303) 692-2000 Denver, Colorado 80230-6928
TDD Line (303) 691-7700 (303) 692-3090
Located in Glendale, Colorado
<http://www.cdphe.state.co.us>



Colorado Department
of Public Health
and Environment

July 9, 2002

Cotter Corporation
7800 East Dorado Place, Suite 210
Englewood, Colorado 80111

Attention: Richard Cherry, President

This letter acknowledges Cotter's May 22, 2002, written response to the April 23, 2002, Notice of Violation (NOV). Your response is not complete and is inadequate to resolve all violations and concerns identified during the inspection conducted at your Canon City facility on March 18-22, 2002.

The corrective actions as described when implemented and maintained appear adequate to correct and resolve Items of Noncompliance 5, 9, 11, and 15; and to resolve the Items of Concern B, I, P, Q, and R. However, the adequacy of these corrective actions will be determined in a future inspection. The resolution of the Items of Concern F, J, and N will be evaluated during the renewal of the radioactive materials license.

The following provide a description of the specific issues which were not adequately addressed in Cotter's May 22, 2002, written response. These include Items of Noncompliance, Items of Concern, previously identified Unresolved Issues and facility management issues. Also provided is a brief description of actions needed to resolve these issues.

NOV Item 1 and Cotter's Response:

The deficiencies cited in Item 1 of the NOV indicate an inability for the licensee to determine occupational doses to workers from airborne materials and to demonstrate compliance with occupational doses limits.

The Department affirms that this violation is a repeat violation.

The Department also finds that Cotter's response has not provided the needed technical data and written procedures to resolve this repeat Item of Noncompliance.

The Department has met with Cotter Corporation personnel on June 6 and 11, 2002 to discuss many of the specific deficiencies in the dose determinations. The Department has also reviewed a revised protocol for apportioning radioactive materials from air filter analysis. We believe that progress is being made towards establishing an adequate dose assessment program.

In order to fully resolve this Item of Noncompliance, Cotter Corporation must provide detailed written procedures for determining worker doses from airborne radioactive materials; revised Excel spreadsheets which correspond to those written procedures; and technical data and analysis to support the established procedures.

NOV Item 2 and Cotter's Response:

A fundamental inadequacy in Cotter's ALARA program is a failure to promptly correct and document corrective actions for known deficiencies within the radioactive materials program. The described corrective actions for this Item of Noncompliance do not address this inadequacy.

In order to fully resolve this Item of Noncompliance, Cotter Corporation must provide a written procedure for maintaining a log of known program deficiencies and their corrective actions, including the date when the deficiency was identified and the date when corrective action was completed. This procedure should contain a strong commitment by Cotter Corporation to promptly correct deficiencies within the radioactive materials program which are identified during routine facility audits and the annual ALARA review. In addition, the log must track recommendations for program improvement and the dates when those improvements are addressed. The procedure should also require that a copy of the unresolved items in the log be provided quarterly to Cotter's corporate management. In addition, Cotter Corporation must provide a copy of the policies and training syllabus referenced in the May 23, 2002 response to this Item.

NOV Items 3 and 4, and Cotter's Responses:

Item 3 of the NOV indicates that bioassay sampling was not being conducted at the required frequency. Item 3 also referenced the inadequacies of the bioassay program identified in the independent ALARA audit conducted in 2001 by Dr. Noel Savignac. Dr. Savignac's audit clearly described how the general air sampling and breathing zone air sampling are not collected and analyzed in such a manner as to demonstrate compliance with weekly limits on intake. Cotter's May 22, 2002 written response to the NOV failed to address the deficiency in bioassay sampling frequency or the collection and analysis of air samples to help demonstrate compliance with weekly intake limits.

NOV Item 4 cited Cotter Corporation for failure to investigate or take corrective action when an individual's bioassay result exceeded 33 µg/L on April 30, 2001. Cotter's response to this Item included an analysis of that individual's intake. The result of that analysis indicate that the individual had an intake of 20 mg of soluble uranium for the week of April 4, 2001.

This level of intake exceeds the 10 mg/week limit established in RH 4.6.5 and constitutes an additional violation of the Regulations.

Exceeding the weekly intake limit for soluble uranium is a Repeat Item of Noncompliance, previously cited in the Department's Notice of Violation dated October 13, 2000.

In order to fully resolve these Items of Noncompliance, Cotter Corporation must provide a written procedure for implementing a bioassay program. The procedures must include the use of a log to track the timeliness of bioassay sampling, bioassay results, re-testing, and corrective actions.

NOV Item 6 and Cotter's Response:

The deficiencies cited in Item 6 of the NOV indicate that Cotter Corporation has not implemented procedures to achieve doses to members of the public that are as low as is reasonably achievable (ALARA). The delivery of packages to the gate is a reasonable means to limit unnecessary radiation exposure to a delivery driver.

In order to fully resolve this Item of Noncompliance, Cotter Corporation must provide a copy of the policy referenced in Cotter's May 23, 2002 response to this Item. That policy must establish reasonable controls to achieve doses to members of the public that are ALARA, including prohibiting the access of delivery drivers, or other members of the public who need not enter the site, to the restricted areas of the mill.

NOV Item 7 and Cotter's Response:

The deficiencies cited in Item 7 of the NOV indicate a inadequacy of the licensee's respiratory protection program. Cotter's response to this Item did not include written policies as required under RH 4.24.1.4 through 4.24.1.5.

In order to fully resolve this Item of Noncompliance, Cotter Corporation must provide a copy of the policies and procedures referenced in Cotter's May 23, 2002 response to this Item.

NOV Item 8 and Cotter's Response:

The deficiencies cited in Item 8 of the NOV indicate that Cotter Corporation does not have written procedures regarding the issuance, maintenance and testing of respirators, the supervision and training of personnel and written procedures for record keeping. Cotter's response to this Item did not include written procedures needed to establish an adequate respiratory protection program.

In order to fully resolve this Item of Noncompliance, Cotter Corporation must provide a copy of the procedures referenced in Cotter's May 23, 2002 response to this Item. Other procedures and policies need to address issues identified in "Manual of Respiratory Protection Against Airborne Radioactive Material, NUREG/CR 0041," as noted in Item 8 of our NOV, not just Regulatory Guide 8.15.

NOV Item 10 and Cotter's Response:

The deficiencies cited in Item 10 of the NOV indicate that Cotter Corporation does not have adequate procedures for performing surveys on equipment, packages and materials prior to their release from controlled areas. Cotter's response to this Item did not include written procedures needed to establish an adequate survey program.

In order to fully resolve this Item of Noncompliance, Cotter Corporation must provide a copy of the procedures referenced in Cotter's May 23, 2002 response to this Item. In addition, please forward with your reply to this letter, the temporary procedures that are currently used by your staff to perform beta-gamma release surveys.

NOV Item 12 and Cotter's Response:

The deficiencies cited in Item 12 of the NOV indicate that Cotter Corporation does not have adequate procedures for correcting beta dose rates during surveys. Cotter's response to this Item did not include written procedures needed to establish adequate survey methods.

In order to fully resolve this Item of Noncompliance, Cotter Corporation must provide a copy of the procedures referenced in Cotter's May 23, 2002 response to this Item. In addition, the information you provided with your response concerning a beta correction factor of "2" is incomplete. Please provide the calculations used to determine the beta correction factor. Note: see Reg. Guide 8.30, Appendix C, for an example of calculations used to determine a beta correction factor.

NOV Item 13 and Cotter's Response:

The deficiencies cited in Item 13 of the NOV indicate that records for survey of vehicles and equipment leaving the property have not been completed properly. Cotter Corporation has committed to an RSO review of the survey documents and re-training of personnel on RHS 2-15 that pertains to release of equipment to unrestricted areas. However, the response states that this procedure will be revised.

In order to fully resolve this Item of Noncompliance, Cotter Corporation must provide a copy of the procedures referenced in Cotter's May 23, 2002 response to this Item.

NOV Item 14 and Cotter's Response:

The deficiencies cited in Item 14 of the NOV indicate that the licensee is not performing annual In Vivo lung scans for workers who were routinely involved in operations with potential for inhalation of radioactive material if those employees are not employed in December. Cotter's response to this Item was unclear as to how Cotter Corporation will resolve this issue.

In order to fully resolve this Item of Noncompliance, Cotter Corporation must provide the technical data to demonstrate that no person who was exposed to airborne concentrations which would require the In-Vivo lung failed to have a annual In-Vivo lung scan.

NOV Item 16 and Cotter's Response:

The deficiencies cited in Item 16 of the NOV indicate that Cotter Corporation has not included both a test for removable contamination and fixed contamination in all weekly surveys. Procedure 2-4 does not distinguish between surveys for removable contamination or surveys for total alpha contamination and does not specify a different frequency for each type of survey.

In order to fully resolve this Item of Noncompliance, Cotter Corporation must commit to following their established procedures and/or revised procedures following NUREG/CR-3598 guidance. These procedures must be provided to this Department for review and approval.

Item of Concern A and Cotter's Response:

Item of Concern A indicates that Cotter Corporation has not resolved known program deficiencies which were identified during an independent ALARA audit conducted April 3-5, 2001 by Dr. Noel Savignac. Cotter's response to this concern did not include a copy of the written procedures needed to resolve known program deficiencies.

In order to fully resolve this Item of Concern, Cotter Corporation must provide a copy of the procedures referenced in Cotter's May 23, 2002 response to this Item of Concern. Cotter must also provide a listing of all items identified as deficiencies by Dr. Noel Savignac, corrective actions for each item to be addressed, and a schedule for completion of those corrective actions.

Item of Concern C and Cotter's Response:

Item of Concern C indicates that the number of deficiencies identified in Cotter's respiratory protection program may require that Cotter Corporation re-assess worker doses from exposure to airborne radioactive materials. Cotter's response to this concern did not demonstrate why Cotter's program was adequate to justify the use of respiratory protection factors in worker dose assessments.

In order to fully resolve this Item of Concern, Cotter Corporation must provide supporting documentation showing that Cotter's respiratory protection program was implemented sufficiently well as to permit the use of respiratory protection factors in worker dose assessments.

Item of Concern D and Cotter's Response:

Item of Concern D indicates that Cotter Corporation has not maintained an inventory system for documenting and tracking the receipt, storage, use/processing, transfer, burial, and disposal of radioactive materials. Cotter's response to this concern did not include a copy of the written procedures needed to establish an adequate inventory control program.

In order to fully resolve this Item of Concern, Cotter Corporation must provide a copy of the procedures referenced in Cotter's May 23, 2002 response to this Item of Concern.

Item of Concern E and Cotter's Response:

Item of Concern E indicates that Cotter Corporation uses irritant smoke at the site for fit-testing respirators. The National Institute for Occupational Safety and Health (NIOSH), NRC Reg. Guide 8.15, and NRC NUREG/CR-0041 no longer recommend this method for fit-testing. Cotter's response to this concern did not include a copy of the written procedures needed to establish an adequate fit-test program.

In order to fully resolve this Item of Concern, Cotter Corporation must provide a copy of the procedures referenced in Cotter's May 23, 2002 response to this Item of Concern. In addition, the use of a qualitative fit test, as you propose in your reply, has some obvious drawbacks that must be addressed. For instance, the results of a qualitative fit test are dependent on the subjects' response (as opposed to the objective response from a fit-testing machine). Subjects may respond inaccurately due to a misunderstanding of the test instructions or by a realization that a failed test might mean a change in work assignment or termination of employment. Also, depending on which challenge agent is utilized, some people may not be able to smell or taste it in the low challenge concentrations. One agent, isoamyl acetate (banana oil), will desensitize the olfactory nerves of a test subject if that subject is exposed to the vapors before the test is conducted. These concerns must be addressed. Please see NUREG/CR-0041.

Item of Concern F and Cotter's Response:

Item of Concern F indicates that Cotter Corporation has received alternate feed materials for which there appears to be no currently approved means for handling and processing those materials. Cotter's response to this concern referenced Cotter Procedure 1-7, pertaining to acceptance of materials for disposal. The Department intends to reevaluate Cotter's procedures for the acceptance of materials as part of the license renewal.

Item of Concern G and Cotter's Response:

Item of Concern G indicates that workers at the mill reuse filter cartridges for respiratory protection devices. A licensee should perform a test on the cartridges to detect damage that might have occurred during prior reuse. Cotter's response to this concern did not include a copy of the written procedures needed to establish a program for testing reused air filter cartridges. A visual inspection of used respirator filter cartridges, as you describe in your response letter dated May 23, 2002, does not meet the requirements of NUREG/CR-0041 or REG Guide 8.15. For example, REG Guide 8.15 states in section 4.9 "If the licensee's procedures allow for filter re-use beyond one day by the same person, or by other persons, such filters should be re-tested before re-use occurs. Such re-testing should include a penetration test using any appropriate aerosol and a pressure drop test." Further, NUREG/CR-0041 states in section 4.12.6 "It is the NRC's current position that aerosol penetration testing of filters and canisters by licensees should be performed with a testing protocol capable of detecting significant filter damage or deterioration. Licensees who wish to reuse replaceable facepiece filters as described in Reg Guide 8.15, Revision 1 may perform the required penetration test using corn oil aerosol, ambient dust particles, or any other aerosol for which a detection system is available. Aerosol penetration testing of filters prior to their reuse is necessary to detect damage, incurred during prior use, that may not be evident in a visual or pressure drop test."

In order to fully resolve this Item of Concern, Cotter Corporation must provide a copy of the procedures referenced in Cotter's May 23, 2002 response to this Item of Concern.

Item of Concern H and Cotter's Response:

Item of Concern H indicates that Cotter Corporation does not have a generic procedure to give guidance to plant personnel for receipt surveys. Cotter's response to this concern references a commitment to follow DOT procedures, but does not address general procedures for the receipt of radioactive materials. Instructions for the receipt of radioactive materials at the mill are covered in individual work plans. However, not all radioactive materials received at the mill are covered under such a work plan and, therefore, have no written procedures for completing and documenting receipt surveys.

In order to fully resolve this Item of Concern, Cotter Corporation must provide a written procedure to give guidance to plant personnel for generic radioactive materials shipments received at the mill.

Item of Concern J and Cotter's Response:

Item of Concern J indicates that Cotter Corporation should provide the Department with clear documentation demonstrating that all materials received for direct disposal are suitable for disposal. Cotter's response to this concern referenced Cotter Corporation Procedure 1-7, pertaining to acceptance of materials for disposal. The Department intends to reevaluate Cotter's procedures for the acceptance of materials as part of the license renewal.

Item of Concern K and Cotter's Response:

Item of Concern K indicates that portable survey instruments used to perform beta contamination surveys are not checked routinely with a beta check source to verify operability and detection efficiency. Cotter's response to this concern did not include a copy of the written procedures needed to address this issue.

In order to fully resolve this Item of Concern, Cotter Corporation must provide a copy of the procedures referenced in Cotter's May 23, 2002 response to this Item of Concern.

Item of Concern L and Cotter's Response:

Item of Concern L indicates that there are inconsistencies in the way personnel at the mill perform surveys. Cotter's response to this concern did not include a copy of the written procedures needed to address this issue.

In order to fully resolve this Item of Concern, Cotter Corporation must provide a copy of the procedures referenced in Cotter's May 23, 2002 response to this Item of Concern.

Item of Concern M and Cotter's Response:

Item of Concern M indicates that greater efforts could be made to reduce the levels of alpha contamination on employees prior to being released from the site. Table 5.1 in NUREG/CR-3598 suggests a target of "Nothing Detectable" for a personnel survey release level. A release level of 500 dpm/100 cm² is not considered ALARA because most contamination events in a Uranium mill could be resolved with either removal of contaminated clothing or simply washing the effected area with soap and water. Cotter's response to this concern did not include a copy of the written procedures needed to address this issue.

In order to fully resolve this Item of Concern, Cotter Corporation must provide a copy of the procedures referenced in Cotter's May 23, 2002 response to this Item of Concern.

Item of Concern N and Cotter's Response:

Item of Concern N indicates that potential problems exist with the storage of dosimetry badges and control badges. Cotter's response provided some technical data to support three storage options.

The storage options for dosimetry badges will be examined during the renewal of the license.

Item of Concern O and Cotter's Response:

Item of Concern O indicates that occupational dose calculations for TEDE and CEDE are not being completed on a quarterly basis. The lack of worker dose determination throughout the year prevents the licensee from identifying elevated worker doses and taking appropriate corrective actions. Cotter's response indicated that occupational air sampling data are reviewed on a quarterly basis. A review of air data is not the same as determining worker doses. The Cotter response did not address this concern and did not include a commitment to determine worker doses on a quarterly basis.

In order to fully resolve this Item of Concern, Cotter Corporation must provide the Department with a written commitment to determine worker doses on a quarterly basis.

Previously Listed SIGNIFICANT UNRESOLVED ITEMS:

1. At the time of the inspection, the licensee's occupational dose calculations and records were not completed for 2001. The adequacy of the dose determinations and compliance with occupational dose limits could not be verified. The 2001 dose determinations provided with Cotter's May 23, 2002 response to the April NOV contained many of the same errors and deficiencies identified Item of Noncompliance #1 in the April NOV. The Department acknowledges that progress is being made towards resolution of worker dose determinations. However, this Item remains unresolved. In order to fully resolve this Item of Noncompliance, Cotter Corporation must provide a complete re-assessment of worker doses for 2001. The reassessment of worker doses must be made in conformance with detailed written procedures approved by the Department, revised Excel spreadsheets which correspond to those written procedures; and technical data and analysis which supports the established procedures.

2. Public dose and NESHAPS assessment for 2001 were not completed at the time of the inspection. The adequacy of the methods and modeling assumptions used in making public dose determinations and the licensee's compliance with public dose limits could not be verified. Public dose and NESHAPS assessment for 2001 were provided to the Department in a report prepared by Shepherd Miller dated March 28, 2002. The report is currently under review by the Department. Department personnel have also met with representatives of Shepherd Miller to discuss the specifics of that report and additional information has been requested to clarify the assumptions and methods used in the calculations. Any remaining issues with the public dose and NESHAPS assessment for 2001 will be addressed when a final review of the report and supplemental data is completed. The resolution of this issue will be completed through separate correspondence. Cotter need not address this issue in future responses to this letter.
3. The licensee has added new buildings, processes, and radioactive materials at the Canon City facility. The adequacy of the existing financial assurance warranty to ensure site decommissioning could not be verified during the inspection. Cotter's response to this Unresolved Issue did not include a revised decommissioning cost estimate. In order to fully resolve this Item of Concern, Cotter Corporation must provide a detailed decommissioning cost estimate and establish a decommissioning warranty which is acceptable to the Department. In the interim, prior to completion of the conversion process, please submit an estimate for the current cost of decommissioning and projected costs for decommissioning once construction is completed. This estimate should be submitted by August 10, 2002.

In addition, three facility management issues were identified in the Department's April NOV. Cotter Corporation was to provide: 1) a detailed listing of all radiation safety issues that must be addressed under Cotter's license; 2) an estimate of the amount of time needed to address those safety issues; and 3) staff assignments and personnel shortfalls in the existing program. It is unclear from Cotter's response that adequate staffing and resources have been acquired to ensure the timely resolution of compliance issues and to maintain and operate an acceptable radioactive materials program.

The Department acknowledges Cotter's reorganization of the need for additional resources, and the commitment to implement recommendations from radiation protection consultants.

It appears from Cotter's May 23, 2002 letter that until a computer tracking system is in place, Cotter will be unable to accurately project the resources needed to maintain compliance. It is also noted that Appendix C did not include non-routine tasks requested, i.e., responses to compliance issues and licensing issues relating to routine operations, the renewal, and additional tasks that will be required as part of Cotter's attempt to receive alternative feeds and materials for direct disposal.

Cotter has committed to establishing and staffing the position of Assistant Radiation Safety Officer and using the services of a consultant. Please respond to the following:

1. What is the basis for the assumption that one position, together with the consultant, will provide sufficient resources for Cotter to achieve and maintain compliance? How has the time and duties of each been assessed?
2. We have been told that an existing radiation technician will be elevated to the position of Assistant Radiation Safety Officer. Will his/her position be backfilled? If not, demonstrate how the reallocation fits with Cotter's recognition of the need for additional resources.
3. An Assistant Radiation Safety Officer should have the training (formal and on-the-job) and experience to substitute as the Radiation Safety Officer in the absence of the Radiation Safety Officer. Provide the training and experience of the Assistant Radiation Safety Officer.

As Cotter proceeds with its computerized system to track tasks, the Department will review its progress and effectiveness during future inspections. In the final analysis, the adequacy of Cotter's resources, both the number of persons and their abilities, will be determined by Cotter's future compliance status.

The Department notes that many of the items identified in its April Notice of Violation are still not resolved. The Department is especially concerned about unresolved issues relating to doses to radiation workers – dose calculations, bioassay and respiratory protection. Ensuring worker protection is of paramount importance to the Department. It is recognized that since the Department's April 23, 2002 Notice of Violation, Cotter has met, and worked with staff to resolve these issues. It is also recognized that progress has been made. However, they are still unresolved issues. **In the interest of worker safety, Cotter shall suspend future receipt of radioactive materials, other than for laboratory analysis, for processing and/or for disposal until the Items of Noncompliance relating to dose (dose calculations, bioassay and respiratory protection) have been resolved, and can be documented to the Department's satisfaction.** The Department's staff will be available to help expedite the resolution of these issues.

Your written response to this letter must be submitted to the Department within 20 days from your receipt of this letter. If you have any questions regarding this letter please contact me at (303) 692-3036.

W. Jacobi, Program Manager
Laboratory and Radiation Services Division

CF: Patrick Mutz, Mill Manager
P.O. Box 751
Canon City, CO 81215-0751