Audit Report

OFFICE OF THE INSPECTOR GENERAL

ARMY USE OF RESULTS OF TESTS ON C2 FILTER CANISTERS

Report No. 96-076 February 23, 1996

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Acronyms

CK	Cyanogen Chloride
MSA	Mine Safety Appliances Company

INSPECTOR GENERAL
DEPARTMENT OF DEFENSE
400 ARMY NAVY DRIVE
ARLINGTON, VIRGINIA 22202-2884

February 23, 1996

MEMORANDUM FOR AUDITOR GENERAL, DEPARTMENT OF THE ARMY

SUBJECT: Audit Report on the Army Use of Results of Tests on C2 Filter Canisters (Report No. 96-076)

We are providing this audit report for review and comment. We conducted the audit in response to a complaint to the Inspector General, DoD.

DoD Directive 7650.3 requires that all recommendations and potential monetary benefits be resolved promptly. A draft of this report was provided to the Army Materiel Command, but no written comments were received. Management is requested to provide comments on this final report that conform to the requirements of DoD Directive 7650.3. We request that management provide complete comments to the final report by March 25, 1996.

We appreciate the courtesies extended to the audit staff. Questions on the audit should be directed to Mr. Terry L. McKinney, Audit Program Director, at (703) 604-9288 (DSN 664-9288) or Mr. Bruce A. Burton, Audit Project Manager, at (703) 604-9282 (DSN 664-9282). See Appendix E for the report distribution. The audit team members are listed inside the back cover.

Robert J. Lieberman

Robert J. Lieberman
Assistant Inspector General
for Auditing

Office of the Inspector General, DoD

Report No. 96-076 **February 23, 1996**
(Project No. 5CF-8020)

Army Use of Results of Tests on C2 Filter Canisters

Executive Summary

Introduction. This audit was performed in response to a complaint to the Inspector General, DoD, by Mine Safety Appliances Company. Mine Safety Appliances Company, which manufactures C2 filter canisters, alleged that results of tests on C2 filter canisters that Racal Filter Technologies, Limited, manufactured for the Army indicated that the C2 filter canisters, which are used in protective masks, did not provide required levels of safety protection from chemical-biological contaminants. The complainant also alleged that the Army has taken insufficient action to protect canister users.

In response to prior complaints to the Inspector General, DoD, by Mine Safety Appliances Company, the Army conducted health and safety testing of C2 filter canisters procured from all sources since 1988 to identify any nonconformances existing within the inventory. Such testing is normally completed 5 years after canisters are manufactured, but was expedited in response to the complaints. Based on the test results, the Army indicated that it would take appropriate action. The current contract for filter canisters, which was awarded in August 1995 to Racal Filter Technologies, Limited, is on hold pending a protest to the General Accounting Office by Mine Safety Appliances Company. The protest alleges that the Army determination that Racal Filter Technologies, Limited, was a responsible contractor was made in bad faith.

Audit Objectives. The overall objectives were to determine whether Army tests of C2 filter canisters disclosed significant defects in the canisters and whether appropriate action was taken to ensure the health and safety of personnel. This audit also assessed the adequacy of the management control program as it relates to the testing of canisters.

Audit Results. Army testing of C2 filter canister did not provide valid conclusions about the canister inventory. As a result, the Army can not know conclusively whether C2 filter canisters in its inventory are safe for use by military personnel. See the finding in Part I for details. We identified no weaknesses in management controls that we considered material. Recommendations, if implemented, could result in monetary benefits of $511,000. Appendix C summarizes the potential benefits of the audit.

Summary of Recommendations. We recommend that the Commander, Army Materiel Command, redetermine the safety and usability of the C2 filter canisters inventory based on a statistical plan that includes random sampling techniques and gives each canister in inventory an equal chance of being included in the sample for surveillance testing. In addition, C2 filter canisters for suspended lots should be reinstated if those lots pass reevaluation. We also recommend that the sample size for surveillance testing be increased and that management controls be assessed.

Management Comments. We issued a draft of this report to management on December 13, 1995. No written comments were received. We request that the Commander, Army Materiel Command, provide comments to the final report by March 25, 1996.

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Part I - Audit Results

Audit Background

This audit was conducted as a result of a contractor complaint to the Inspector General, DoD. In August 1995, Mine Safety Appliances Company (MSA) requested that the Inspector General, DoD, review the Army's testing of C2 filter canisters. The C2 filter canisters are used in protective masks to filter chemical and biological contaminants from the air that soldiers must breathe during combat. MSA expressed concern that the Army allowed C2 filter canisters, manufactured by Racal Filter Technologies, Limited (Racal), to remain in inventory even though the filters failed Army testing for minimum levels of safety and presented a life-threatening risk to the user. Specifically, MSA alleged that Army test results showed that, "Hundreds of thousands of Racal C2 canisters did not provide minimum levels of safety protection from chemical and biological contaminants," that Racal canisters were degrading over time, and that the Army "failed to exercise its contractual rights and reprocure to remedy this safety problem."

Since 1988, eight contracts have been awarded for 8.9 million C2 and C2A1 canisters at a total cost of $62.8 million. A ninth contract was awarded to Racal in August 1995 for approximately 0.5 million canisters costing approximately $3.4 million. However, that contract is on hold pending a protest to the General Accounting Office by MSA. That protest is based on allegations that the decision that Racal was a responsible contractor was made in bad faith. Table 1 shows the number of canisters produced by MSA and Racal from 1990 through 1994.

Table 1. C2 Filter Canisters Procured from MSA and Racal From 1990 Through 1994

Year	MSA	Racal
1990	274,734	868,504
1991	1,234,069	887,325
1992	638,561	2,206,279
1993	0	1,458,519
1994	0	524,101
Total	**2,927,364***	**5,944,728**

*Includes 780,000 canisters that another Army command procured from MSA.

Audit Objectives

The audit objectives were to determine whether Army tests of C2 filter canisters disclosed significant defects in the canisters and whether, as a result, appropriate action was taken to ensure the health and safety of personnel. We also reviewed the management control program as it related to the other audit objectives. See Appendix A for the audit scope and methodology and details of our review of the management control program. Appendix B summarizes prior audit coverage.

Army Surveillance Testing

Some information that the Army considered when it determined that its C2 filter canisters were safe was not valid for reaching conclusions about the canister inventory. Results of tests that the Army used to make its determination were not projectable to the universe because the samples on which the tests were performed were not selected randomly. In addition, the Army used small surveillance samples, which rendered results unreliable and increased the stringency for acceptance of surveillance criteria. As a result, the Army can not know conclusively whether C2 filter canisters in its inventory are safe for use by military personnel.

Decision Regarding C2 Filter Canisters

The Army determined that the C2 canisters in its inventory did not pose a life-threatening risk to soldiers. The Army made that determination based in part on results of surveillance tests. Surveillance tests are done to determine the serviceability of the canisters 5 years after canisters are manufactured. The surveillance tests involved gas-life protection against a blood agent, cyanogen chloride (CK) and did not disclose any life-threatening deficiencies.

Tests were done on a sample group of canisters, and test results were compared with criteria that the Army had developed for safety. However, neither the test results nor the surveillance sample size should have been relied upon.

Sampling Methodology

Selection of Canisters. Quality assurance representatives selected canisters for acceptance testing (testing done during production) and for later surveillance testing from each production lot produced by Racal and MSA using a haphazard, nonrandom sampling approach. The quality assurance representatives stated that the samples were selected in such a manner because time did not allow the quality assurance representatives to develop and implement a more statistically valid approach.

The purpose of acceptance sample testing is to enable a decision to be made as to whether or not the production lot (total population) has met the contractually agreed-upon lot tolerance percent defective* without the burden of testing every item in the lot. Both acceptance tests and surveillance tests, whether in the

*Lot tolerance percent defective is the percent of items in the lot that can be defective and still be accepted by the Government.

commercial realm or using Military Standards, are based on the computation of probabilities from the hypergeometric probability distribution. That distribution provides a statistically valid approach for evaluating sample results.

Both acceptance testing and surveillance testing result in acceptance numbers and rejection numbers based on:

o assumptions about the number or percent of defective parts that can be tolerated in the production lot,

o the possible true percent defectives in the lot,

o the lot size or number of items produced,

o the sample size, and

o the requirement that the sample be drawn in such a way that each item in the production lot has an equal chance of being selected (in other words, random selection using an accepted technique such as a random number generator or a random number table).

Random Sample. To make decisions using only a subset of a production lot, the subset (or sample) must be randomly selected--not haphazardly selected, not "grab" sampled, and not sampled for convenience of access. Only the random selection process can ensure a sample that represents the total population of the production lot. Only a random sample can have its results applied directly to the appropriate probability distribution for valid inference about the entire lot quality. Failure to use an acceptable random process for selection of a sample renders the results and the inference to the total quality of the lot population suspect and exposes the results to potential bias. That is, the acceptance and rejection numbers for the production lot have no meaning if the sample is not randomly selected.

The exposure to potential bias in the results of samples being taken by Government representatives means that the Government "can't tell" what the lot quality is likely to be on any of the lots so sampled for surveillance. Because the quality assurance representatives' haphazard sampling was also used at the acceptance phase, the Government representatives may not have accurately determined the lot quality at that phase either.

A random sampling methodology for the selection of canisters for surveillance tests should be implemented. Random selection will ensure that each canister is given an equal chance of being included in the sample, which will permit objective measurement of the reliability of the results. We also believe that a random selection program, when implemented, should include a reevaluation of the usability and acceptability of the suspended lots. If the currently suspended lots pass the reevaluation, reinstating the canisters now in the suspended lots would make approximately $511,000 available for uses to the Government other than procuring replacement canisters.

Stringency of Criteria

The criteria with which test results were compared should not have been relied on because the criteria were too stringent.

Sample Size. Surveillance testing criteria established by the Army require a sample size of seven canisters per lot to be tested for CK gas life. Acceptance testing criteria require 20 canisters per lot. The number of canisters in a lot varies with each company. A Racal lot averages approximately 30,000 canisters, and an MSA lot averages between 10,000 and 12,000 canisters. A "lot" of C2 canisters fails both surveillance testing and acceptance testing if the calculated gas life is less than 30 minutes. Because sample sizes that were used in calculating the gas life were smaller for surveillance testing than for acceptance testing, surveillance testing requirements were, in effect, more stringent than the requirements for production testing. That occurred when a statistical factor was applied to the test results so that the results would provide a certain level of confidence that a specified percent of the canisters in the universe exceeded the calculated minimum gas life. The statistical factor becomes larger as the sample size gets smaller.

The Army surveillance test results showed that because of the manner in which factors were applied, some canisters that had passed acceptance testing would have failed had the surveillance testing criteria been used. The Army applied surveillance testing criteria to test data from 124 production lots that had passed acceptance testing. As a result, 24 production lots, equating to more than 19 percent of the total lots produced, including some MSA lots, would have been rejected using the surveillance testing criteria. The Army is currently evaluating whether it should increase the surveillance sample size.

We strongly question the use of so small a sample and believe that the Army should increase the number of C2 filter canisters in its sample for surveillance testing. In Military Standard 105E, "Sampling Procedures and Tables for Inspection by Attributes," a lot of 1000 or more items with an actual quality level of 2.5 percent defective would use a sample size of seven only under special circumstances where, according to Military Standard 105E, "Large sampling risks can or must be tolerated." Furthermore, if the lot tolerance percent defective agreed upon in the contract was 2.5 percent defective, but the actual quality level was 10 percent defective, the plan used for the canisters with a sample size of seven would still accept such a lot 43 percent of the time. In fact, it would take an actual quality level of 20 percent defective items or more in the lot to make a sensitive discrimination and correctly reject such a lot most of the time. The larger the sample:

o the less likely a product that does *not* meet contractual specifications will be accepted and

o the less likely a product that does meet contractual specifications will be rejected.

The statistician for the Inspector General, DoD, stated that at some point a sample size will allow reasonable control of decision risks without involving excessive costs. He believes that the point requires a sample size of 20 or more.

Similar Canisters. Canisters generally degrade over time; that is, they become less effective. Criteria for the C2 canisters did not consider degradation. The Army stated that some degradation of canisters is anticipated over time and that surveillance criteria for other types of filter canisters have taken that into consideration in establishing gas-life requirements for surveillance testing. The Army supported that argument by citing comparisons to similar gas mask canisters that showed decreased CK gas-life requirements for surveillance testing. Table 2 shows the reduced CK gas-life requirements of the similar canisters and that the requirements for C2 canisters are not adjusted.

Table 2. Reduced CK Gas-Life Requirements for Canisters

Filter Canister Type	CK Gas-Life Acceptance Requirements	CK Gas-Life Surveillance Requirements	Percent Decrease Between Acceptance and Surveillance Testing
C2	30 minutes	30 minutes	0.0
M10A1	40 minutes	15 minutes	62.5
M11	30 minutes	15 minutes	50.0
M13A2	7 minutes	5 minutes	28.6

The C2 filter canister is the only canister in which the criteria did not allow for degradation in the requirements from production to surveillance. The other canisters allowed for substantial amounts of degradation.

The Army had no explanation as to why the surveillance criteria for the C2 canister maintained the 30-minute requirement for CK gas-life protection for both acceptance testing and surveillance testing. The 30-minute requirement represented a 300-percent margin of safety to the user using the Joint Service Operational Requirement for CK gas-life protection. The Joint Service Operational Requirement required only a minimum CK gas life of 10 minutes based on two attacks at a CK concentration of 4000 milligrams per cubic meter. The 30-minute production requirement provided a safety factor to ensure that canisters would provide adequate protection, not only at the time of production but in future years as well, even if some degradation of the canisters were to occur. Because the Army is evaluating the surveillance requirement to determine whether it should be relaxed, no recommendations on this matter are being made.

Results of Surveillance Testing

In late 1993, the Army did surveillance testing of 34 lots of MSA canisters and 20 lots of Racal canisters and found that all of the canisters provided a level of protection well above the amount required by the Joint Service Operational Requirement for gas threat protection. The lowest value for an MSA canister tested was 30.1 minutes, and the lowest value for a Racal canister tested was 24.2 minutes. However, the Army failed five Racal lots because those lots did not meet the Army's preestablished CK gas-life surveillance criteria of 30 minutes. The Army stated, however, that the 30-minute protection was excessive and that the canisters were not life-threatening. To be conservative and to fully consider soldier safety, the Army pulled the five lots that were questionable from inventory until it could further evaluate surveillance test procedures. Additional testing was done from 1993 through 1995 on 45 lots of MSA canisters and 31 lots of Racal canisters. Those tests resulted in five additional Racal canisters failing to meet the CK gas-life surveillance criteria. The Army did not remove those canisters from inventory, even though the earlier failed lots were still suspended.

Although 10 of the Racal lots failed the testing for CK gas life, the Army determined that the canisters provided adequate CK gas-life protection and failed the testing only because the surveillance criteria were too stringent, requiring excessive protection.

Management Controls Over Quality Assurance

The Quality Evaluation Division was transferred from the Army Armament, Munitions, and Chemical Command to the Armament Research Development Command in October 1994. Since the transfer, no risk assessments or reviews have been performed. DoD Directive 5010.38 requires that a risk assessment be performed once every 5 years and as major changes occur. The Quality Evaluation Division should perform risk assessments using the Armament Research Development Command criteria and should conduct management control reviews.

Summary

MSA alleged that many Racal-manufactured C2 filter canisters posed life-threatening risks to the user and that the Army failed to take corrective action. Because the canisters tested were not statistically selected, the results of the testing could not be projected to the universe. However, testing of canisters revealed that for the canisters tested, minimum safety levels were attained and failures occurred because of stringent surveillance testing criteria.

Recommendations for Corrective Actions

We recommend that the Commander, Army Materiel Command:

1. Redetermine the safety and usability of the C2 filter canisters inventory including the suspended lots. Specifically:

a. Implement a statistical plan to include random sampling for surveillance testing of the C2 filter canister inventory and for acceptance testing for future lots.

b. Reinstate C2 filter canisters from suspended lots if those lots pass reevaluation.

c. Increase the sampling size for C2 filter canisters undergoing surveillance testing.

2. Instruct the Quality Evaluation Division to perform new vulnerability assessments and conduct management control reviews.

Management Comments Required

The Commander, Army Materiel Command, did not respond to the draft of this report. We request that the Commander, Army Materiel Command, provide comments on the final report.

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Part II - Additional Information

Appendix A. Scope and Methodology

Scope

Since 1988, the Army Armament and Chemical Acquisition and Logistics Activity has awarded and administered nine contracts with a value of $66.1 million for the C2 filter canister. Of the contracts, six contracts, totaling $44.1 million, have been awarded to Racal Filter Technologies, Limited, and three contracts, totaling $22 million, have been awarded to Mine Safety Appliances Company.

We reviewed documentation from FYs 1992 through 1995 related to the evaluation of the best value acquisition plan performed in 1992 and contract DAAE20-95-C-0368, valued at $3.3 million. Seven contracts, valued at $56.2 million, were evaluated during a previous Inspector General, DoD, audit of C2 filter canisters. Also reviewed were test results of canisters procured under past contracts. Specifically, we evaluated the testing criteria used for the C2 filter canister as compared with other filter canisters.

We performed this program audit in September 1995 in accordance with auditing standards issued by the Comptroller General of the United States as implemented by the Inspector General, DoD. We included tests of management controls considered necessary. We did not use computer-processed data or statistical sampling procedures for this audit. Appendix D lists the organizations we visited or contacted.

Members of the Quantitative Methods Division of the Analysis, Planning, and Support Directorate, Office of the Inspector General, DoD, provided assistance in analyzing sample data and preparing the sampling narrative of our report. In addition, an Inspector General, DoD, evaluator with a chemical and biological background assisted us with the review of canisters and gas lives.

Management Control Program

DoD Directive 5010.38, "Internal Management Control Program," April 14, 1987, requires DoD organizations to implement a comprehensive system of management controls that provides reasonable assurance that programs are operating as intended and to evaluate the adequacy of the controls.

As far as we could determine, management controls were adequate, in that we identified no material management control weaknesses. The problems discussed in this report were related to statistical procedures and not to the management control program. However, we noted that no assessments or management control reviews had been done since the Quality Evaluation Division was transferred from the Army Armament, Munitions, and Chemical Command to the Armament Research Development Command in October 1994.

Appendix B. Prior Audits and Other Reviews

Three reports related to this audit have been issued by the Office of the Inspector General, DoD.

Report No. 95-021. Inspector General, DoD, Report No. 95-021, "Defense Hotline Allegations Regarding DoD Fielding of Chemical Protective Masks," was issued on November 2, 1994. The Hotline allegations mentioned problems with fielded chemical protective masks, the design and production problems of the replacement masks (M40 and M42), and depot inspection intervals occurring after the warranty expired. The allegations were valid and the report recommended that the Army establish a DoD-wide chemical protective mask cyclic testing program and facility. It also recommended that the Army develop and implement a plan of action to correct outstanding design and production deficiencies for the M40 and M42 masks. In addition, it recommended that the Army require acceptance testing for the drink tube quick disconnect for leakage and establish training guidance for nuclear, biological, and chemical leaders to teach preventive maintenance checks and services and to provide command-level inspections to ensure maintenance of chemical equipment. The Army concurred with the recommendation to establish training guidance and to teach preventive maintenance checks.

Report No. 94-154. Inspector General, DoD, Report No. 94-154, "Quick-Reaction Report on the Reliability of the M17 Series and M40 Chemical Protective Masks," was issued on June 30, 1994. The report addresses a readiness issue on the condition of M17 series and M40 chemical protective masks. The audit results in the report are classified.

Report No. 94-011. Inspector General, DoD, Report No. 94-011, "Procurement of C2 Filter Canisters by the Army Armament, Munitions, and Chemical Command, Rock Island, Illinois," was issued on November 2, 1993. The subject report states that the Army procured the C2 filter canister in accordance with the Competition in Contracting Act. Both contractors, as well as other bidders, were given the same solicitation package and were provided the same opportunity to bid and win C2 filter canister contracts. Although Racal delivered C2 filter canisters with minor nonconformances, the Army Armament, Munitions, and Chemical Command took appropriate action and held Racal to the same specifications and standards as MSA.

Appendix C. Summary of Potential Benefits Resulting From Audit

Recommendation Reference	Description of Benefit	Amount and Type of Benefit
1.	Program Results, Economy and Efficiency. Results in a representative sample of canisters from which projections to the universe can be made and obtains a higher confidence level that test results are reflective of the universe.	$511,000 available for uses other than obtaining replacement canisters for those on hold.
2.	Management Controls. Improves management controls by reassessing risk of the Quality Evaluation Division.	Nonmonetary.

Appendix D. Organizations Visited or Contacted

Department of the Army

Armament and Chemical Acquisition and Logistics Activity, Rock Island, IL
Armament Research Development Command, Rock Island, IL
Edgewood Research, Development and Engineering Center, Aberdeen Proving Grounds, MD
Pine Bluff Chemical Activity, Pine Bluff Arsenal, AR

Defense Organizations

Defense Contract Management District Northeast, Boston, MA
Defense Contract Management District South, Atlanta, GA
Defense Contract Management Area Operations Ottawa, Defense Contract Management Command International, Ottawa, Ontario, Canada

Non-U.S. Government Organization

National Defence, Canadian Forces Quality Assurance Region, Ottawa, Ontario, Canada

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House Subcommittee on National Security, International Affairs, and Criminal Justice, Committee on Government Reform and Oversight
House Committee on National Security

Audit Team Members

This report was prepared by the Contract Management Directorate, Office of the Assistant Inspector General for Auditing, DoD.

Paul J. Granetto
Terry L. McKinney
Bruce A. Burton
Dr. Frank M. Ponti
Harold E. Lindenhofen
Steven I. Case
Billy J. McCain
LaNita C. Matthews
John A. Seger
Robert E. Bender
Christopher R. Clemens
Ana M. Myrie

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