Audit Report

OFFICE OF THE INSPECTOR GENERAL

HOTLINE ALLEGATIONS CONCERNING THE PROCUREMENT OF VENTILATORS

Report No. 95-152

March 21, 1995

Department of Defense

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Acronyms

DMSB	Defense Medical Standardization Board
DPSC	Defense Personnel Support Center

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

March 21, 1995

MEMORANDUM FOR ASSISTANT SECRETARY OF DEFENSE (HEALTH AFFAIRS)
ASSISTANT SECRETARY OF THE NAVY (FINANCIAL MANAGEMENT)
ASSISTANT SECRETARY OF THE AIR FORCE (FINANCIAL MANAGEMENT AND COMPTROLLER)
DIRECTOR, DEFENSE LOGISTICS AGENCY
AUDITOR GENERAL, DEPARTMENT OF THE ARMY

SUBJECT: Audit Report on Hotline Allegations Concerning the Procurement of Ventilators (Report No. 95-152)

We are providing this audit report for your review and comments. The report discusses DoD Hotline allegations related to the procurement of ventilators. Management comments on a draft of this report were considered in preparing the final report.

We have renumbered two recommendations and redirected one recommendation from the Staff Director, Defense Medical Standardization Board, to the Chairman, Defense Medical Standardization Board. Comments of the Defense Medical Standardization Board did not meet the intent of Recommendation 2. DoD Directive 7650.3 requires that all recommendations be resolved promptly. Therefore, we request that the Defense Medical Standardization Board provide comments on the unresolved recommendation by May 22, 1995.

The courtesies extended to the audit staff are appreciated. If you have questions on this audit, please contact Mr. Charles F. Hoeger, Audit Program Director, or Mr. Terrance Wing, Audit Project Manager, at (215) 737-3881 (DSN 444-3881). The distribution of this report is in Appendix C. The audit team members are listed on the inside back cover of this report.

David K. Steensma

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Office of the Inspector General, DoD

Report No. 95-152 **March 21, 1995**
(Project No. 4LD-8012)

HOTLINE ALLEGATIONS CONCERNING THE PROCUREMENT OF VENTILATORS

EXECUTIVE SUMMARY

Introduction. We performed this audit in response to DoD Hotline allegations. The initial allegation stated the Defense Medical Standardization Board inappropriately interfered in the Defense Personnel Support Center (DPSC) procurement of 1,957 portable ventilators (contract DLA120-92-C-8533). The October 1992 contract was valued at $4.9 million. Ventilators are medical equipment that assists patients in breathing. The essential characteristics of the ventilator were developed by the Defense Medical Standardization Board, a joint DoD organization that manages the clinical and technical aspects of medical materiel and deployable medical systems. In response to the initial Hotline allegation, the Defense Medical Standardization Board alleged that systemic problems existed in the DPSC medical equipment procurement process.

Objective. The audit objective was to evaluate the DPSC procurement of the ventilators and the validity of the Hotline allegations.

Audit Results. The audit showed that the allegations generally had merit. The ventilator contract was not properly managed or administered. As a result, DPSC procured $1.1 million of ventilators with no existing requirements (see Part II). The systemic problems in the procurement process are discussed in Part I, Other Matters of Interest. During our audit, management took actions to improve the medical equipment procurement process (see Appendix A).

Internal Controls. The audit identified no material internal control weaknesses. Part I describes the controls assessed.

Potential Benefits. We could not quantify the potential monetary benefits. However, implementing the recommendations should enhance the medical equipment procurement process and improve the coordination between the Defense Medical Standardization Board, the Military Departments, and DPSC.

Summary of Recommendations. We recommend that the Defense Medical Standardization Board and DPSC establish procedures for classifying medical devices as military unique. We recommend that the Defense Medical Standardization Board establish formal procedures to contact the Military Departments, not the contracting

office, when concerns arise about the Military Departments' requirements. We further recommend that DPSC establish controls to terminate contractual requirements when requisitions are canceled and that the approval of first articles are properly coordinated.

Management Comments. The Assistant Secretary of Defense (Health Affairs) concurred with the finding and recommendations. The Director, Defense Logistics Agency, partially concurred with the finding and concurred with all recommendations, except the recommendation to establish controls over medical equipment procurements to terminate contractual requirements when requisitions are canceled. The Director stated that the Defense Personnel Support Center made a decision not to terminate contractual requirements for the canceled ventilator requisition because it believed it would be able to sell the ventilators; however, it failed to document the decision and the supporting rationale. The Defense Medical Standardization Board members provided a majority and minority opinion on the finding and recommendations. In the majority opinion, the Air Force, Navy, and Marine Corps board members nonconcurred with the finding and concurred with all recommendations, except the recommendation that the Defense Medical Standardization Board establish procedures to contact requisitioners not the Defense Personnel Support Center when it has concerns about the materiel being procured. Those members stated that at no time did the Defense Medical Standardization Board inappropriately interject itself into the ventilator procurement process. In the minority opinion, the Army board member concurred with the finding and all recommendations. A discussion of management comments and audit responses to those comments are in Part II of the report. The complete texts of those comments are in Part IV of the report.

Audit Response. We renumbered two recommendations and redirected one recommendation. The Assistant Secretary of Defense (Health Affairs) comments were responsive. The Director, Defense Logistics Agency, comments were generally responsive and met the intent of our recommendations. We disagree with the Defense Medical Standardization Board majority opinion comments that the Defense Medical Standardization Board did not inappropriately interject itself into the ventilator procurement process. Accordingly, we request that the Defense Medical Standardization Board reconsider its position and provide comments on the unresolved recommendation by May 22, 1995.

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This report was prepared by the Logistics Support Directorate, Office of the Assistant Inspector General for Auditing, Department of Defense.

Part I - Introduction

Background

Allegations Concerning the Procurement of Ventilators. On August 13, 1993, an anonymous caller advised the DoD Hotline that the Defense Personnel Supply Center (DPSC) had awarded a contract with a manufacturer for 1,957 ventilators that should save the Government more than $5 million. The caller stated that the Defense Medical Standardization Board (DMSB) had inappropriately requested that DPSC terminate the contract for convenience, and that DPSC award a contract for the ventilators to another manufacturer. This action would result in increased costs of $1,100 per ventilator. The DoD Hotline referred the allegation to DMSB for its review.

On January 31, 1994, DMSB responded to the allegation, stating it was unaware of any inappropriate organizational or individual actions imposed on DPSC for the ventilator procurement. The DMSB had attempted to cancel the ventilator contract because it believed the Government would waste nearly $5 million by procuring ventilators that did not satisfy contingency mission requirements. The DMSB response raised additional allegations concerning systemic problems in the DPSC procurement process for medical equipment. The problems primarily related to improper technical evaluations and coordination, and DPSC contracting methodologies.

On March 1, 1994, the DoD Hotline referred the allegations to the Inspector General, DoD, Assistant Inspector General for Auditing, for evaluation.

Function of Ventilators. Ventilators provide controlled ventilation to nonbreathing patients and provide assist ventilation to spontaneously breathing patients. A compressor or bottled gas is used in conjunction with the ventilator to provide air to the patient. Ventilators are used in hospitals, ambulances, battlefield medical units, and military patient evacuation aircraft.

Assistant Secretary of Defense (Health Affairs) Responsibilities. The Assistant Secretary of Defense (Health Affairs) is responsible for reviewing the Military Departments' procurement programs to ensure the maximum standardization of deployable medical systems. He is also responsible for approving deployable medical systems that have been developed under the direction of the DMSB. Deployable medical systems are facilities (contingency hospitals) and equipment that can be used in a national emergency, contingency, or war operation.

DMSB Responsibilities. DoD Directive 6430.2, "Defense Medical Standardization Board," June 21, 1984, established the DMSB, composed of the Surgeons General of the Army; Navy; and Air Force, or their designated alternates, as a joint DoD organization. The directive states that the DMSB shall:

o direct the development of deployable medical systems that are standardized to the maximum extent consistent with the distinct missions of the Military Departments;

o determine items for which sources of supply shall be limited to selected manufacturers of the items to meet Military Department clinical and logistics support requirements, and designate acceptable sources of supply;

o provide advice to the Defense Logistics Agency for carrying out the clinical and technical medical materiel functions assigned to it; and

o be the preparing organization for medical standardization documents and all other medically related items and review specifications covering medical materiel to determine conformity with essential characteristics. Essential characteristics are the design, construction, composition, and performance qualities of a professional, technical, military, or therapeutic nature required to meet the minimum needs of the Government.

DPSC Responsibilities. DPSC, a Defense Logistics Agency inventory control point, is the DoD integrated materiel manager for medical items. As the materiel manager, DPSC receives and processes requisitions for customers, initiates contracts for medical items, and administers the contracts to ensure that the items procured are delivered in accordance with contractual requirements. DPSC also acts as the DMSB agent to convert essential characteristics developed by the DMSB into standardization documents.

Chronology of Events. The following is a chronology of events for the ventilator procurement.

o On July 12, 1989, the DMSB established the initial essential characteristics for a portable ventilator. The ventilator (national stock number 6530-01-292-1049) is not stocked in the supply system.

o In April 1991, the Navy requisitioned DPSC for 446 ventilators.

o In July 1991, the Army requisitioned DPSC for 1,511 ventilators.

o In December 1991, DPSC classified the ventilator as military unique.

o On January 28, 1992, DPSC issued a procurement solicitation for 1,957 ventilators.

o On July 21, 1992, the DMSB revised the ventilator's essential characteristics to change the dimensions of the ventilator and require that the manufacturer be capable of offering a compressor to work with the ventilator.

o On October 7, 1992, DPSC awarded a contract (DLA120-92-C-8533) for 1,957 ventilators. The contract used the July 12, 1989, essential characteristics.

o On October 16, 1992, a nonselected manufacturer filed a protest of the ventilator contract award with the General Accounting Office.

o On October 21, 1992, the DMSB contacted DPSC and requested termination of the contract because the contract did not meet the revised essential characteristics.

o On November 18, 1992, the Navy canceled its requirements for 446 ventilators. DPSC did not modify the ventilator contract to cancel the Navy's requirements.

o On March 17, 1993, the General Accounting Office dismissed the nonselected manufacturer's protest.

o On September 14, 1993, DPSC approved the first article testing of the ventilator.

o In October 1993 and March 1994, the ventilators were accepted by the Government and shipped in place (accepted as Government property and stored at the manufacturer's plant) until aeromedical certification was completed.

Objective

The audit objective was to evaluate the DPSC procurement of ventilators and the validity of the Hotline allegations.

Scope and Methodology

We reviewed DPSC official contract files for contract DLA120-92-C-8533. We also held discussions and evaluated documents and correspondence related to the Hotline allegations with personnel from the Office of the Assistant Secretary of Defense (Health Affairs), Defense Logistics Agency, the DMSB, DPSC, the Food and Drug Administration, and the Military Departments. We also held discussions with the nonselected manufacturer involved in the contract award protest. The documents and correspondence we evaluated covered the period from July 1989 through September 1994.

We performed this economy and efficiency audit from April through September 1994 in accordance with auditing standards issued by the Comptroller General of the United States, as implemented by the Inspector General, DoD. Accordingly, we included such tests of internal controls as we considered necessary. We did not rely on computer-processed data to perform the audit. Appendix B lists the organizations visited or contacted during the audit.

Internal Controls

Controls Assessed. We evaluated the adequacy of internal controls relating to compliance with regulations and procedures governing the award and the administration of DPSC contract DLA120-92-C-8533. We evaluated the controls by reviewing correspondence and contract files related to the ventilator contract. We also made a limited review of the medical equipment contracting process, but curtailed our efforts based on the results of a concurrent DPSC review and development of a corrective action plan (see Appendix A).

Internal Control Weaknesses. The audit identified no material internal control weaknesses.

Prior Audits and Other Reviews

Inspector General, DoD, Office of the Assistant Inspector General for Inspections, issued a report, "Defense Medical Standardization Board Program Evaluation," on December 29, 1992. The report stated that the memorandum of understanding between the Defense Logistics Agency and the DMSB regarding the Defense Standardization and Specification Program had not been adhered to, was incomplete and outdated, and resulted in procurement delays and possible unwanted procurements. The report recommended that the Defense Logistics Agency and the DMSB review the memorandum of understanding for accuracy and completeness every 3 years, and revise the memorandum of understanding to require the participation of DMSB clinical experts at first article tests. The report also recommended that the DMSB research all deviations to the memorandum of understanding and revise internal procedures to prevent similar deviations.

The memorandum of understanding had not been updated. However, during our audit, the Defense Logistics Agency and the DMSB initiated actions to review and update the memorandum of understanding, and they anticipate that the memorandum will be finalized and signed by May 31, 1995. Because management is addressing this issue, we are not making a separate recommendation in this report.

Inspector General, DoD, Report No. 91-085, "Audit Report on the Procurement of Medical Material and Equipment," May 30, 1991, stated that increased use of Federal Supply Schedules for direct vendor delivery of small purchase procurements could save an estimated $1.4 million annually. The report recommended that DPSC increase the use of Federal Supply Schedules in procuring items for direct vendor delivery. DPSC concurred with the recommendation and stated that it would use an automated system to increase the use of Federal Supply Schedules. Problems with the DPSC use of Federal Supply Schedules were also addressed in a DPSC review of the quality of contracting in its Medical Directorate in June 1994, and actions are being taken to address the use of Federal Supply Schedules (see Appendix A).

Other Matters of Interest

In response to the initial Hotline allegation, the DMSB alleged that there were systemic problems in the process used by DPSC to procure medical equipment. The problems primarily related to improper technical evaluations, coordination between DMSB and DPSC, and DPSC contracting methodologies. Personnel from DPSC also informed us that they believed that the DMSB was inappropriately interjecting itself into the medical equipment procurement process. Our audit documented a history of correspondence indicating longstanding serious problems between the two organizations in coordinating procurements of medical equipment.

The initial allegation was substantiated and is discussed in detail in Part II. The DMSB allegation that there were systemic problems in the DPSC medical equipment contracting process was also substantiated. In June 1994, the DMSB and DPSC initiated actions that addressed some of the problems between the two organizations, which should improve the medical equipment procurement process (see Appendix A).

Part II - Finding and Recommendations

Ventilator Procurement

The DPSC contract DLA120-92-C-8533, for the procurement of ventilators, was not properly managed or administered and improvement was needed in the coordination between the Defense Medical Standardization Board and the DPSC. The conditions occurred because coordination procedures were lacking to classify medical devices as military unique and to ensure that the ventilator procurement was properly coordinated between the Defense Medical Standardization Board and DPSC. Also, there were inadequate controls to terminate the ventilator contract for unneeded requirements and to approve the ventilator first article test acceptance. As a result, DPSC procured $1.1 million of ventilators with no existing requirements.

Ventilator Procurement Process

The DPSC contract for ventilators was not properly managed or administered. Additionally, improvement was needed in the coordination between DPSC and DMSB. Specifically,

o DMSB and DPSC did not properly coordinate classifying medical devices, such as the ventilator, as military unique.

o DMSB inappropriately interjected itself in the DPSC ventilator procurement process.

o DPSC did not modify the contract when the Navy canceled its requisition for $1.1 million of ventilators.

o DPSC approval of the ventilator first article was not properly approved by the DMSB.

As a result, DPSC procured $1.1 million of ventilators with no existing requirements.

Military Unique Medical Devices. The DMSB and DPSC did not properly coordinate classifying medical devices, such as the ventilator, as military unique. This occurred because there was no written criteria or procedures to classify medical devices as military unique. Additionally, there were significant differences between the DMSB and DPSC as to what medical devices should be classified as military unique and what organization had the responsibility to classify devices as military unique.

Inaccurate classification of items as military unique or commercially available could result in noncompliance with the Food and Drug Administration procedures, which could affect the competitive base of vendors bidding on medical equipment procurements. The classification of a medical device as

military unique or commercially available affects the requirements that manufacturers must meet to bid on Government contracts. DMSB defines military unique as an item manufactured, fabricated, assembled, or produced primarily for military use and not commonly available in the commercial marketplace.

Food and Drug Administration procedures require that manufacturers seeking Government contracts for medical devices obtain Food and Drug Administration approval for the device 90 days before bidding for the contract. In November 1992, DPSC requested that the Food and Drug Administration grant DPSC an exemption to the 90-day criterion for manufacturers bidding on solicitations for military unique medical devices, to promote competition. In December 1992, the Food and Drug Administration granted DPSC the exemption and required that the successful offeror have Food and Drug Administration approval before shipping the medical device to the Government. The exemption was conditioned on DPSC advising the Food and Drug Administration whenever DPSC used the exemption, so the Food and Drug Administration could provide any relevant information.

The DPSC classified the ventilator as military unique over the objections of DMSB. The DMSB position was that the ventilator was commercially available and therefore should not have been classified as military unique. DPSC lacked procedures identifying the criteria to be used to classify the ventilator or any medical devices as military unique. On June 17, 1994, the Food and Drug Administration notified DPSC personnel that DPSC had not properly notified the Food and Drug Administration that the ventilator was classified as military unique.

Because of the lack of procedures, the differences of opinion, and the concerns of the Food and Drug Administration about the issue of military unique medical devices, we believe that DMSB and DPSC should coordinate their resources to establish standard criteria for classifying medical devices as military unique and develop a list of military unique devices. The DMSB and DPSC should refer any differences of opinion to the Assistant Secretary of Defense (Health Affairs) for mediation and resolution.

DMSB Authority. The DMSB inappropriately interjected itself into the DPSC procurement of the ventilators. This occurred because the DMSB had inadequate coordination procedures between itself and DPSC and itself and the Military Departments.

On October 7, 1992, DPSC awarded a contract for ventilators based on July 12, 1989, essential characteristics. The ventilators were not stocked in the supply system and were specifically procured for Army and Navy requirements. On October 21, 1992, DMSB contacted DPSC and inappropriately requested that DPSC terminate the ventilator contract for technical merit because the ventilator being procured by DPSC did not meet revised essential characteristics. The essential characteristics for the ventilator changed in July 1992 after DPSC solicited bids for the ventilator, and DPSC did not revise the solicitation to include the new characteristics. DPSC informed us that it did not revise the solicitation because the revision would have required a new

solicitation that would have delayed the procurement. DPSC did contact the Army, which stated that the ventilator being procured under the older characteristics met its needs. The Navy canceled its requirements because of concerns that the ventilator was not aeromedically certified.

This was not an isolated attempt by the DMSB to inappropriately contact DPSC to request that DPSC cancel Military Department requisitions. A March 20, 1992, Army memorandum to DMSB addressed another procurement of deployable medical systems equipment that DMSB attempted to have DPSC cancel. The Army informed DMSB that requisitions are placed by the U.S. Army Medical Materiel Agency for the Army's deployable medical systems project, and only the U.S. Army Medical Materiel Agency has the responsibility and authority to cancel Army requisitions. Instead of going directly to DPSC, the Army told DMSB to notify either the U.S. Army Medical Materiel Agency or the Office of the Army Surgeon General of the need to immediately change the essential characteristics of an item in procurement.

The DMSB action was inappropriate because the DMSB does not have the authority to cancel Military Department requisitions submitted to the DPSC. DMSB can recommend cancellation of DPSC procurement actions to the Military Departments, but only the Military Departments have the authority to request cancellation.

Termination of Navy Requirements. DPSC did not terminate contractual requirements for 446 ventilators, valued at $1.1 million, even though the Navy requested that its requisition for the ventilators be canceled. This occurred because of inadequate controls to ensure that procurement actions were modified to terminate unneeded requirements.

On October 7, 1992, DPSC awarded a contract for 1,957 ventilators based on requisitions from the Army for 1,511 ventilators and from the Navy for 446 ventilators. On November 18, 1992 (42 days after award), the Navy requested that DPSC cancel its requisition for the 446 ventilators. DoD Regulation 4140.1-R, "Materiel Management Regulation," January 1993, states that after contract award, if inventory management reviews disclose that requirements under contract have been reduced, termination actions by the contracting officer shall be requested.

DPSC did not modify the contract to terminate the Navy's requirement and advised us that the management decision not to modify the contract was based on the DPSC belief that it would be able to sell the ventilators to other customers or that the Navy would reorder the ventilators. No documentation supported the management decision or showed the cost benefits of not modifying the contract. Further, on June 21, 1993, in response to a congressional inquiry, DPSC stated that if the Navy decided not to reinstate its requirements for the ventilators, DPSC would issue a partial termination for convenience.

Had DPSC canceled the Navy requisition and modified the contract, it would have minimized termination costs to the Government. The contract stated that the manufacturer was solely responsible for all costs incurred to produce the

ventilator if the order was canceled before first article approval. The first article approval for the ventilator occurred on September 14, 1993, approximately 10 months after the Navy requested cancellation of its requisition. In December 1994, the Navy subsequently requisitioned 96 of the ventilators that DPSC had procured with no requirements.

First Article Approval. The DPSC approval of the ventilator first article was made even though DMSB had not provided prior approval. This occurred because DPSC lacked the controls to ensure compliance with prescribed procedures. DoD Directive 6430.2 states that the DMSB will evaluate and approve or disapprove requests for and deviations from essential characteristics of medical materiel and that no medical materiel that deviates from its established essential characteristics may be procured without prior approval of DMSB.

DPSC conducted the first article test for the ventilator on June 7, 1993, with DMSB and Military Department representatives present. At that time, the manufacturer requested deviations from the ventilator's essential characteristics. The deviations related to digital displays, battery voltage, and the high pressure alarm. The Chief of the DPSC Directorate of Medical Materiel Quality Assurance Division conditionally approved the deviations. The deviations either had no adverse effects or enhanced the ventilator's performance; therefore, DPSC accepted the first article, including the requested deviations, on September 14, 1993.

Between the conditional approval and final approval, the Staff Director, DMSB, notified DPSC that the technical panel members assisting at the first article test did not have the authority to authorize procurement of equipment not meeting essential characteristics. DMSB further stated that recommended essential characteristic changes must be coordinated with the Military Departments' speciality advisors and consultants, who consider changes in light of interoperability, maintainability, and transportability. We agree with DMSB. Formal processes should be followed when deviations from essential characteristics are required.

Conclusion. The Hotline allegations generally had merit. The ventilator contract was not properly managed and administered. Additionally, the audit documented a history of correspondence indicating longstanding serious problems between the DMSB and DPSC in coordinating procurements of medical equipment.

Management Comments on the Finding

Assistant Secretary of Defense (Health Affairs) Comments. The Assistant Secretary of Defense (Health Affairs) concurred with the finding.

Defense Logistics Agency Comments. The DLA partially concurred with the finding. DLA concurred that inadequate controls were implemented for first

article tests and that coordination procedures were lacking to classify medical devices as military unique. DLA nonconcurred that DPSC procured $1.1 million of ventilators with no existing requirements because of mismanagement of the ventilator contract. DLA stated that DPSC made a purposeful decision not to partially terminate the ventilator contract but failed to document the decision it made and the supporting rationale. DPSC has taken actions to ensure that decisions not to terminate canceled requirements are properly documented and approved.

Defense Medical Standardization Board Comments. The DMSB concurred that the DMSB and DPSC did not properly coordinate classifying medical devices as military unique. However, the DMSB board members disagreed among themselves on whether the DMSB inappropriately interjected itself into the procurement process. The Air Force, Navy, and Marine Corps board members (majority opinion) nonconcurred with the finding, while the Army board member (minority opinion) concurred. See the DMSB comments on Recommendation 2. for details on the disagreement.

The DMSB majority opinion suggested that we include additional data in the background section of this report and that we contact two retired members of the DMSB who were involved in the ventilator procurement for more detailed information on the procurement. The DMSB majority opinion further stated that we ignored its recommendation to discuss the audit with members of the DMSB and to not interview the members is to ignore official Service input.

Audit Response. Despite the nonconcurrence, the DPSC actions address the condition noted in the finding. As DLA stated, no documentation was available to support the DPSC rationale for not terminating the canceled requirements.

The DMSB majority opinion stated that it did not inappropriately interject itself in the ventilator procurement process. We disagree with those comments. See the audit response to the DMSB comments to Recommendation 2. for the reasons for our disagreement.

Regarding the comments of the DMSB majority opinion to include additional data in the report and to contact retired DMSB members, we believe the background data in the report provide ample information to explain the ventilator procurement. We disagree that we ignored its recommendation to discuss the audit with Navy and Air Force DMSB members, and by not interviewing those members we ignored official Service input. During the audit, we informed the Staff Director, DMSB, that, if necessary, we would like to discuss the audit with the DMSB members. The Staff Director stated that he could arrange the meeting. After evaluating the data collected and discussing the procurement with responsible management officials and operating personnel, to include DLA; the Services; the Staff Director; and other personnel of the DMSB, we believed we had sufficient information to adequately address the Hotline allegation. Therefore, it was not necessary to discuss the audit with the DMSB members. At no time during the audit, did the DMSB members request to meet with us.

Recommendations, Management Comments, and Audit Response

Renumbered and Redirected Recommendations. We renumbered draft Recommendation 1. to Recommendation 3. and Recommendation 3. to Recommendation 1. Recommendation 1. has been redirected from the Staff Director, Defense Medical Standardization Board, to Chairman, Defense Medical Standardization Board.

1. We recommend that the Director, Defense Logistics Agency, and the Chairman, Defense Medical Standardization Board, jointly develop procedures and criteria for classifying medical equipment as military unique. The process should be included in the memorandum of understanding being developed by the two organizations. Any disagreements concerning military unique classifications should be mediated by the Assistant Secretary of Defense (Health Affairs).

Assistant Secretary of Defense (Health Affairs) Comments. The Assistant Secretary of Defense (Health Affairs) concurred with the recommendation and stated that the recommendation should be directed to the Chairman, Defense Medical Standardization Board, instead of the Staff Director, Defense Medical Standardization Board. See Part IV of this report for a complete text of the Assistant Secretary's comments.

Defense Logistics Agency Comments. The DLA concurred with the recommendation and stated that DPSC and the DMSB are jointly developing procedures and criteria for classifying military unique medical equipment. They have also initiated action to review and update the memorandum of understanding between DLA and DMSB. The estimated completion date is May 31, 1995. See Part IV of this report for the complete text of the DLA comments.

Defense Material Standardization Board Comments. The DMSB concurred with the recommendation and stated that DPSC agreed to coordinate with the DMSB on proposed military unique determinations. Moreover, the DMSB and DPSC are close to finalizing the memorandum of understanding referenced in the recommendation. The estimated completion date is May 31, 1995. See Part IV of this report for the complete text of the DMSB comments.

Audit Response. Comments from the Assistant Secretary of Defense (Health Affairs), DLA, and DMSB and the planned actions are responsive. As suggested, we redirected the recommendation to the Chairman, Defense Medical Standardization Board.

2. We recommend that the Staff Director, Defense Medical Standardization Board, establish formal procedures to contact the customers ordering medical equipment, not the Defense Personnel Support Center, when the Defense Medical Standardization Board has concerns about the customer requirements being procured.

Assistant Secretary of Defense (Health Affairs) Comments. The Assistant Secretary of Defense (Health Affairs) concurred with the recommendation.

Defense Medical Standardization Board Comments. The Defense Medical Standardization Board members provided a majority and minority opinion on the recommendation. The majority opinion (Navy Air Force, and Marine Corps) nonconcurred that the DMSB inappropriately interjected itself into the procurement process. The majority opinion stated that the finding is based on the premise that the DMSB requested cancellation of the Army and Navy ventilator requisitions placed with DPSC. This is not true. The DMSB requested that DPSC cancel the contract and resolicit using the new essential characteristics. The DMSB avoided the issue of the Army and Navy requisitions, preferring to let the Services act on their own behalf. The decision to recommend contract termination and resolicitation was made at the request of the Services and with their full knowledge and concurrence. Additionally, in conducting the procurement in the manner they did, DPSC defeated the Services attempt to standardize medical equipment.

The minority opinion (Army) concurred with all recommendations. The minority opinion stated that it strongly nonconcurred with the majority opinion response to the audit report. The DPSC correctly pursued the Army's need for a hospital ventilator and the DMSB did not have the authority to unilaterally cancel contracts without the concurrence of the requisitioning Service.

Audit Response. Comments from the DMSB majority opinion comments did not meet the intent of the recommendation. As the DMSB minority position stated, the DMSB did inappropriately interject itself in the ventilator procurement process. We understand that the DMSB has a significant role in the medical equipment procurement and standardization processes. Our point is that if the DMSB has concerns with the medical equipment that the Services procure, it should discuss its concerns with Services, not the contracting office, and resolve any differences before the Services requisition the material or before the contract is awarded. DPSC, the contracting office, provided a contracting service to requisitioners, and did not have the authority to cancel requisitions without direction from requisitioners.

The DMSB was unable to convince the requisitioners of the need to go through another acquisition cycle to wait for the newer ventilator. The Army and subsequently the Navy, both aware of the DMSB concerns, decided to use the ventilators that DPSC procured. As noted in a July 30, 1993, memorandum from Acting Deputy Surgeon General of the Army to the Chief of the Air Force Medical Corps, "The Army has valid requirements of an essential nature within its hospital structure that are currently under-resourced. This procurement was specifically designated for our hospital requirement and was not originally intended to be a transport ventilator. The need in our hospitals is too critical to forego receipt of these ventilators in hopes of procuring a "better" ventilator 18-24 months latter." We request the DMSB to reconsider its position and to provide comments on the recommendation in response to the final report.

3. We recommend that the Director, Defense Logistics Agency, establish controls over medical equipment procurements to provide that:

a. contractual requirements are terminated when requisitions are canceled or the decision not to terminate the canceled requirements is properly documented and

b. first article approvals and changes to essential characteristics are properly approved by the Defense Medical Standardization Board.

Assistant Secretary of Defense (Health Affairs) Comments. The Assistant Secretary of Defense (Health Affairs) concurred with the recommendation.

Defense Logistics Agency Comments. DLA nonconcurred with Recommendation 3.a., and stated that DPSC made a purposeful decision not to terminate the canceled requirements because DPSC believed it would be able to subsequently sell the canceled ventilators. The DPSC problem was its failure to document the decision it made and the supporting rationale. However, to reinforce existing controls, DPSC has directed its staff to terminate contractual requirements when requisitions are canceled or document the decision not to terminate the canceled requirements. DLA concurred with Recommendation 3.b., and stated that procedures and criteria concerning first article tests and essential characteristics are being developed. The estimated completion date is May 31, 1995.

Audit Response. Although DLA nonconcurred with Recommendation 3.a., the DPSC actions fully address the intent of the recommendation and are responsive. The DLA comments and planned actions for Recommendation 3.b. are also responsive.

Part III - Additional Information

Appendix A. Medical Equipment Contracting Initiatives

Recognizing the longstanding problems in coordinating procurements of medical equipment, DMSB and DPSC began joint actions in June 1994 to address the coordination problems. Additionally, in June 1994, DPSC initiated a review of the quality of contracting in its Medical Directorate.

Memorandum of Understanding. DMSB and DPSC have held discussions to revise and update the memorandum of understanding between them, which should enhance the medical equipment procurement process by addressing the responsibilities and roles of each in the procurement process. A new memorandum of understanding should be signed by the May 31, 1995.

Contracting for Medical Equipment. In June 1994, DPSC initiated a review of the quality of contracting in its Medical Directorate. The significant findings and recommended actions follow.

Significant Findings. Customer requirements, particularly for medical equipment items, were not being processed timely, and communication with the customers was inadequate to promote customer satisfaction. Additionally, the contract files reviewed reflected inattention to detail, a lack of personal responsibility for quality contracting, and insufficient management oversight.

Recommended Actions. The Medical Directorate has developed a corrective action plan, and the quality of contracting will be reevaluated in 6 to 9 months after the corrective action plan is implemented to ensure that acceptable progress is being achieved. Some of the recommended actions follow.

o Increased management oversight, including the monitoring of procurement milestones, is required to improve the timeliness of medical acquisitions.

o Solicitations and contracts distributed to customers should be accompanied with a card to be returned to DPSC acknowledging receipt. If the receipt card is not returned, DPSC should follow up by telephone until receipt is assured.

o Quantity and technical requirements, for equipment items at a minimum, should be confirmed from requisitioners for all large purchase before solicitation issue, every 6 months thereafter, and immediately before contract award.

o All pre-award actions over $100,000 for medical equipment must be approved by the Contracting Chief.

o All contracting and management position descriptions should be modified to include the quality of acquisition actions as a critical element.

o All acquisitions should document whether the item is available on the Federal Supply Schedule, the Federal Supply Schedule price, and why it is advantageous to award a DPSC contract for an item available under the Federal Supply Schedule.

Appendix B. Organizations Visited or Contacted

Office of the Secretary of Defense

Assistant Secretary of Defense (Health Affairs), Washington, DC

Department of the Army

U.S. Army Medical Materiel Agency, Ft. Detrick, MD

Department of the Navy

Naval Medical Logistics Office, Ft. Detrick, MD
Fleet Hospital Program Office, Alexandria, VA

Department of the Air Force

Air Force Medical Logistics Office, Ft. Detrick, MD

Defense Agencies

Headquarters, Defense Logistics Agency, Alexandria, VA
  Defense Personnel Support Center, Philadelphia, PA
Defense Medical Standardization Board, Ft. Detrick, MD

Non-Defense Federal Organizations

Food and Drug Administration, Rockville, MD

Non-Government Organizations

Impact Instrumentation Corporation, West Caldwell, NJ

Appendix C. Report Distribution

Office of the Secretary of Defense

Under Secretary of Defense (Comptroller)
Assistant Secretary of Defense (Health Affairs)
Assistant to the Secretary of Defense (Public Affairs)

Department of the Army

U.S. Army Medical Materiel Agency
Auditor General, Department of the Army

Department of the Navy

Assistant Secretary of the Navy (Financial Management)
Naval Medical Logistics Office
Fleet Hospital Program Office
Auditor General, Department of the Navy

Department of the Air Force

Assistant Secretary of the Air Force (Financial Management and Comptroller)
Air Force Medical Logistics Office
Auditor General, Department of the Air Force

Defense Organizations

Director, Defense Contract Audit Agency
Director, Defense Logistics Agency
  Commander, Defense Personnel Support Center
Defense Medical Standardization Board
Director, National Security Agency
Inspector General, Central Imagery Office
Inspector General, Defense Intelligence Agency
Inspector General, National Security Agency
Director, Defense Logistics Studies Information Exchange

Non-Defense Federal Organizations

Office of Management and Budget
National Security and International Affairs Division, General Accounting Office
Technical Information Center
Defense and National Aeronautics and Space Administration Management Issues
Military Operations and Capabilities Issues

Chairman and Ranking Minority Member of Each of the Following Congressional Committees and Subcommittees:

Senate Committee on Appropriations
Senate Subcommittee on Defense, Committee on Appropriations
Senate Committee on Armed Services
Senate Committee on Governmental Affairs
House Committee on Appropriations
House Subcommittee on National Security, Committee on Appropriations
House Committee on Government Reform and Oversight
House Subcommittee on National Security, International Affairs, and Criminal Justice, Committee on Government Reform and Oversight
House Committee on National Security

Part IV - Management Comments

Assistant Secretary of Defense (Health Affairs) Comments

Final Report Reference

THE ASSISTANT SECRETARY OF DEFENSE

WASHINGTON, D. C. 20301-1200

HEALTH AFFAIRS

DEC 30 1994

MEMORANDUM FOR INSPECTOR GENERAL, DEPARTMENT OF DEFENSE
ATTENTION: Logistics Support Directorate

SUBJECT: Audit Report On Hotline Allegations Concerning The Procurement Of Ventilators (Project No. 4LD-8012)

Reference: Draft Audit Report, Project No. 4LD-8012, Subj: HOTLINE ALLEGATIONS CONCERNING THE PROCUREMENT OF VENTILATORS

In reply to the reference, I concur with your findings and recommendations for corrective actions.

Revised and Renumbered Recommendation 1.

Recommendation number 3, however, should cite either the Director, DLA and the Chairman, DMSB, or the Director, Defense Personnel Support Center, Medical Directorate and the Staff Director, DMSB.

My point of contact for this report is CDR Jon Sherman at DSN 224-4157 or (703) 614-4157.

Edward D. Martin /for
Stephen C. Joseph, M.D., M.P.H.

Defense Logistics Agency Comments

DEFENSE LOGISTICS AGENCY
HEADQUARTERS
CAMERON STATION
ALEXANDRIA, VIRGINIA 22304-6100

26 JAN 1995

IN REPLY REFER TO DDAI

MEMORANDUM FOR THE ASSISTANT INSPECTOR GENERAL FOR AUDITING, DEPARTMENT OF DEFENSE

SUBJECT: Hot Line Allegations Concerning the Procurement of Ventilators (Project No. 4LD-8012)

This is in response to your 7 November 1994 request.

4 Enclosures

JACQUELINE G. BRYANT
Chief, Internal Review

cc:
AQP
DPSC - DI

TYPE OF REPORT: Audit

PURPOSE OF INPUT: Initial Position

AUDIT TITLE & NO: Hotline Allegations Concerning the Procurement of Ventilators (Project No. 4LD-8012)

FINDING: The DPSC contract DLA120-92-C-8533, for the procurement of ventilators, was not properly managed or administered and improvement was needed in the coordination between the Defense Medical Standardization Board and the DPSC. The conditions occurred because there were inadequate controls to terminate the ventilator contract for unneeded requirements and to approve the ventilator first article test acceptance. Also, coordination procedures were lacking to ensure that the ventilator procurement was properly coordinated between the Defense Medical Standardization Board and DPSC and to classify medical devices as military unique. As a result, DPSC procured $1.1 million of ventilators with no existing requirements.

DLA COMMENTS: Partially concur.

We nonconcur with the finding that DPSC procured $1.1 million of ventilators with no existing requirements because of mismanagement of the ventilator contract. Although the Navy cancelled its requirement for 446 each, DPSC management made a purposeful decision not to do a partial termination as an outcome of the cancelled requirements. Their decision was based on the fact that the ventilator is not only a Deployable Medical Systems (DEPMEDS) item but can also be used in peacetime settings (i.e., military hospitals). As the ventilators were provided by a highly reputable contractor at a price significantly below comparable commercial products, DPSC believed it would sell the 446 ventilators to peacetime customers. DPSC is marketing these ventilators to peacetime customers through advertisement in DPSC Medical's Customer Assistance Bulletin, Lifeline. Also, the Navy has already requisitioned 96 of the 446 ventilators previously cancelled. DPSC's decision not to terminate is allowable under the guidance in DoD 4140.1-R, the DoD Materiel Management Regulation. The mismanagement on DPSC's part was their failure to document the decision made and its supporting rationale.

We nonconcur with the finding that there were inadequate controls to terminate the ventilator contract. DoD 4140.1-R, the DoD

Final Report Reference

Materiel Management Regulation, clearly delineates appropriate actions to be taken in regard to termination when requirements are cancelled. DPSC complied with the guidance by evaluating whether partial termination based on cancelled requirements was in the best interests of the Government and making a rationale decision that it was not. DPSC failed to follow the controlling guidance by not documenting their decision. DPSC has taken certain actions to reinforce the existing control, which are described under Recommendation 1.

Renumbered Recommendation 3.

We concur with the finding that there are inadequate controls for approval of first article tests for DEPMEDs items. General guidance in Federal Acquisition Regulation 9.307(b) states that the Government laboratory or other activity responsible for first article testing or evaluation shall inform the contracting office whether to approve, conditionally approve, or disapprove the first article. Based on this guidance, DPSC Medical Technical/Quality has the responsibility for evaluating first article tests for its acquisitions, and therefore, has the ultimate authority to technically approve the first article (via contracting office notice to the contractor). DMSB's role, as recommended in the 29 December 1992 IG Report titled "Defense Medical Standardization Board Program Evaluation", is to participate as a clinical expert at the first article tests. We believe the above describes appropriate lines of authority whenever the first article does not deviate from essential characteristics. However, when the first article does deviate from essential characteristics, approval of the deviations by DMSB should be obtained prior to DPSC Medical Technical/Quality proceeding with approval of the first article test. This conclusion is based on guidance in DoD Directive 6430.2 (titled DoD Medical Standardization Board), paragraph F. 2.k., which states: "The DMSB shall evaluate and approve or disapprove requests for waivers and deviations from essential characteristics. No item of medical materiel that deviates from its established essential characteristics may be procured without prior approval of the DMSB." The only guidance at DPSC addressing first article evaluation of DEPMEDs items is Standard Operating Procedure (SOP) "First Article Testing of DEPMEDS/ Shared Procurement of Medical Equipment Items Requiring Provisioning or Having Special Electrical Characteristics" dated 10 May 1990. According to the SOP, DMSB's role is to observe the subject first article test and advise of any deficiencies seen. The SOP allows DPSC Quality Representatives to approve or disapprove waivers or deviations but is silent on whether these

waivers and deviations are to essential or nonessential characteristics. We recommend that DPSC and DMSB, as part of their joint effort, develop clear guidance of the roles of both agencies in first article tests, including first article evaluations involving deviations to essential characteristics. We further recommend that the guidance define the coordination process between the two agencies and include time frames for actions to be taken.

In approving the First Article without first obtaining DMSB's approval on deviations to essential characteristics, DPSC Medical did not strictly comply with the DoD Directive 6430.2. However, DPSC Medical took this action only after coordinating the deviations with DMSB, indicating clearly a belief that the changes should be approved (i.e., using wording "conditional approval") because they would have no adverse effects and actually result in enhancements, waiting a reasonable time (2 and 1/2 months) overall for DMSB's determination, being provided approval by DMSB to proceed and then having that approval retracted, not taking any action until DMSB had the full time period it requested to complete a review by the Military Services' Specialty Advisors/Consultants and Joint Services Clinical Review Group, and being advised verbally that DMSB would not provide a determination. Although a coordination process is not clearly defined in DPSC's SOP, in practice DPSC routinely coordinates with DMSB on all first article tests. In this case, DPSC Medical initiated and followed through on the coordination process. DPSC's approval of the first article without DMSB's prior approval of deviations from essential characteristics appears to have resulted from DMSB's abdication of its role. Further delay in taking action would have put DPSC at risk of contractor claims for equitable adjustment for failure to comply with the specified Government evaluation period in the contract.

Chapter 2.2.6.a.(3) of the 1994 Federal Standardization Manual requires that the preparing activity assure (when preparing new or revising existing documents) that requirements are specified in a form permitting maximum competition and innovation and avoiding restrictive features that would limit competition unless these features are essential to satisfy the user's needs. Application of this citation to DMSB would require that DMSB provide essential characteristics without restrictive features. DPSC Medical determined that several of the changes were to design features of the original producer of the item that should appropriately be changed to performance requirements as part of

the continuing specification development process. Insistence on continued use of design features of one manufacturer when change to performance features would not have any adverse effect (and actually result in product enhancement) would inappropriately restrict competition. DPSC strongly believed that the changes to essential characteristics should be made because they had either no adverse effect or enhanced performance and to do otherwise would unnecessarily restrict competition. DPSC's action in approving the changes to essential characteristics complied with the requirements of the 1994 Federal Standardization Manual. We suggest any guidelines developed for evaluating essential characteristics contain this language from the 1994 Federal Standardization Manual.

We concur with the finding that coordination procedures were lacking to classify medical devices as military unique.

We concur with the finding that improvement is needed in the coordination between DMSB and DPSC. During the ventilator procurement, the relationship between the DMSB and DPSC was severely strained because actions taken by the DMSB on several procurements gave the appearance of directing the procurements to favored contractors. The situation was so serious that a referral was made in July 1993 to DCIS (Enclosure 1). To date, DCIS has not declined the investigation.

The Director of Medical Materiel, DPSC and the Staff Director, DMSB have met and are committed to resolving the problems identified in this audit. Also, DPSC's Directorate of Medical Materiel reorganized in May 1994 into the Pharmaceuticals, Devices and Equipment Products Groups. Under this organizational structure, all the resources and functions associated with acquiring medical equipment were assembled into a single entity reporting to a Product Group Director. This structure enhances oversight and management of all aspects of medical equipment acquisitions and facilitates proper administration.

INTERNAL MANAGEMENT CONTROL WEAKNESSES:
(X) Nonconcur (regarding: inadequate controls to terminate contract requirements)
(X) Concur; however weakness is not considered material (regarding: coordination procedures regarding First Article Testing and defining military unique items)
( ) Concur; weakness is material and will be reported in the DLA Annual Statement of Assurance

ACTION OFFICER: Martha King/AQPLD/X47936
PSE REVIEW/APPROVAL: Margaret J. Janes, Assistant Executive Director, (Procurement Policy) AQPL, 19 Jan 95
COORDINATION: Tom Ridgway, MMSLP, Investments Programs Team
E. Walker, MMSLP, Product Conformance Team
Amy Sajda, AQPLC,
E. Sanchez, FOE, 20 Jan 95
D. Stumpf, DDAI, 20 Jan 95
Enclosure J. Bryant DDAI, 20 Jan 95

DLA APPROVAL:

22 JAN 1995

DEFENSE LOGISTICS AGENCY
DEFENSE PERSONNEL SUPPORT CENTER
2800 SOUTH 20TH STREET
PHILADELPHIA PENNSYLVANIA 19101 8419

50

REPLY TO
DPSC-G

20 July 1993

Mr. James Hagen
Special Agent in Charge
Defense Criminal Investigative Service
150 East 7th Street
Chester, PA 19013-6033

RE: Suspected
* Violation of the Procurement Integrity
Act/Standards of Conduct Regulations

Dear Mr. Hagen:

I am referring for investigative consideration a matter wherein
* , is suspected of engaging in conduct
violative of the Procurement Integrity Act and the applicable Standards
* of Conduct regulations. is assigned to the Defense
Medical Standardization Board (DMSB) at Fort Detrick, Frederick,
* Maryland. As a result of his assignment, has access to confidential
procurement information and has authority to impact on DPSC
solicitations and contract awards. I have enclosed a report dated June
16, 1993 wherein a number of incidents are reported which describe
* highly improper conduct on the part of Although
* motives are unknown, it seems fairly clear that conduct is intended
to favor a small number of DPSC contractors.

I have also enclosed a copy of the current standards of conduct regulation, and the preceding regulation dated February 24, 1988. If you are in need of additional information, I can be reached at (215) 737-5305.

Very Truly Yours,

WALTER F. RIESS, JR.
Assistant Counsel, Fraud

Copy to File

* Deletions made by the Defense Logistics Agency.

Final Report Reference

TYPE OF REPORT: Audit

PURPOSE OF INPUT: Initial Position

AUDIT TITLE & NO: Hotline Allegations concerning the Procurement of Ventilators (Project No. 4LD-8012)

Renumbered Recommendation 3.

RECOMMENDATION 1: Recommend that the Director, Defense Logistics Agency, establish controls over medical equipment procurements to provide that:

a. contractual requirements are terminated when requisitions are canceled or the decision not to terminate the canceled requirements is properly documented and

b. first article approvals and changes to essential characteristics are properly approved by the Defense Medical Standardization Board.

DLA COMMENTS:

Renumbered Recommendation 3.a.

1.a. Nonconcur. See discussion under finding. To reinforce existing controls, the Director of DPSC's Equipment Product Group directed staff to either terminate contractual requirements when requisitions are cancelled or document the decision not to terminate the cancelled requirements. Senior level staff were provided this instruction verbally and all staff were provided this instruction in writing (Enclosure 2).

The ventilator contract reviewed under this audit was a Firm Fixed Price (FFP) contract, which commits to purchase of the entire quantity under the contract. With FFP contracts, cancelled requisitions can result in partial terminations. DPSC's current business strategy is to use Indefinite Quantity Contracts (IQCs), which only commit to purchasing a minimum quantity. Use of IQC's dramatically reduces the risk of partial terminations because of cancelled requisitions.

Renumbered Recommendation 3.b.

1.b. Concur. See discussion under the findings. Procedures and criteria concerning first article test and essential characteristics are being developed. As stated in our response to the Finding, first articles approvals (with exception of waivers to essential characteristics in first articles) are the responsibility of DPSC, whereas approval of essential characteristics is the responsibility of DMSB.

Final Report Reference

DPSC is currently using best value buying procedures for medical equipment items that were not used in the ventilator procurement that is a subject of this audit. Under best value buying procedures, an offeror must submit a comprehensive technical proposal which is evaluated in conjunction with a business proposal. Representative from the DMSB and the Services are participating in technical evaluation panels that review and evaluate technical proposals. This more extensive evaluation of technical aspects at an early stage in the acquisition process should enhance the ability of DPSC and DMSB to successfully resolve technical issues and result in a source selection decision of the product with the most value to customers.

DISPOSITION:
(X) Action 1.b. is Ongoing. Estimated completion Date: 31 May 95
(X) Action 1.a. is Considered Complete.

Renumbered Recommendation 3.a. an 3.b.

INTERNAL MANAGEMENT CONTROL WEAKNESSES:
(X) Nonconcur (regarding: 1.a.)
(X) Concur; however weakness is not considered material (regarding: 1.b.)
( ) Concur; weakness is material and will be reported in the DLA Annual Statement of Assurance

Renumbered Recommendation 3.a. an 3.b.

MONETARY BENEFITS:
DLA COMMENTS:
ESTIMATED REALIZATION DATE:
AMOUNT REALIZED:
DATE BENEFITS REALIZED

ACTION OFFICER: Martha King/AQPLD/X47936
PSE REVIEW/APPROVAL: Margaret J. Janes, Assistant Executive Director, (Procurement Policy) AQPL, 19 Jan 95
COORDINATION: Tom Rigdgway, MMSPL, Investments Programs Team
E. Walker, MMSPL, Product Conformance Team
Amy Sajda, AQPLC
E. Sanchez, FOE, 20 Jan 95
D. Stumpf, DDAI, 20 Jan 95
Bryant, 25 Jan 95, DDAI

DLA APPROVAL:
[illegible] JAN 1995

ATTACHMENT

DEFENSE LOGISTICS AGENCY

Inter-Office Memorandum

IN REPLY REFER TO

DPSC-MQ

12 January 1995

SUBJECT: Terminating Contract Requirements

TO: ALL DPSC-MQ SECTION/BRANCH CHIEFS AND CONTRACTING STAFF

1. Reference: DoDIG Draft Proposed Audit Report (Project No. 4LD-8012), Hotline Allegations Concerning the Procurement of Ventilators, 7 November 1994.

2. In light of the referenced report, I want to reaffirm our policy regarding procurement actions when requisitions are cancelled.

> When requisitions are cancelled, contract requirements shall either be terminated or the decision not to terminate the cancelled requirements shall be documented in the contract file. Decisions not to terminate cancelled requirements must be approved by the Director, Medical Equipment Product Group.

3. Please insure this policy is maintained.

NEIL S. KOVNAT
Director, Medical Equipment Group
Directorate of Medical Materiel

cc
DPSC-MP

DLA FORM 111 JUL 82 PREVIOUS EDITION MAY BE USED UNTIL EXHAUSTED

Final Report Reference

TYPE OF REPORT: Audit

PURPOSE OF INPUT: Initial Position

AUDIT TITLE & NO: Hotline Allegations concerning the Procurement of Ventilators (Project No. 4LD-8012)

RECOMMENDATION 3: Recommend that the Director, Defense Logistics Agency, and the Staff Director, Defense Medical Standardization Board, jointly develop procedures and criteria for classifying medical equipment as military unique. The process should be included in the memorandum of understanding being developed by the two organizations. Any disagreements concerning military unique classifications should be mediated by the Assistant Secretary of Defense (Health Affairs).

Revised and Renumbered Recommendation 1.

DLA COMMENTS: Concur. DPSC and DMSB are jointly developing procedures and criteria for classifying military unique medical equipment and have initiated actions to review and update the Memorandum of Understanding (MOU) between DLA and DMSB.

A military unique designation allows the offer of products being developed. The FDA must provide a premarket approval on these items prior to their delivery to the customer. As the FDA process can be lengthy, customers are concerned about the military unique designation, which allows consideration and possible award of developing products whose delivery could be delayed. DPSC is planning a revised acquisition strategy using best value buying procedures that will address customers' concern. An technical evaluation factor for rating products already available on the market more highly than products that are still in development will be used. This strategy supports competition while addressing legitimate customer concerns.

DISPOSITION:
(X) Action is Ongoing. Estimated completion Date: 31 May 95
( ) Action is Considered Complete.

INTERNAL MANAGEMENT CONTROL WEAKNESSES:
( ) Nonconcur
(X) Concur; however weakness is not considered material
( ) Concur; weakness is material and will be reported in the DLA Annual Statement of Assurance

MONETARY BENEFITS:
DLA COMMENTS:
ESTIMATED REALIZATION DATE:
AMOUNT REALIZED:
DATE BENEFITS REALIZED

ACTION OFFICER: Martha King/AQPLD/X47936
PSE REVIEW/APPROVAL: Margaret J. Janes, Assistant Executive Director, (Procurement Policy) AQPL, 19 Jan 95
COORDINATION: Tom Ridgway, MMSLP, Investments Programs Team
E. Walker, MMSLP, Production Conformance Team
Amy Sajda, AQPLC
E. Sanchez, FOE, 20 Jan 95
D. Stumpf, DDAI, 20 Jan 95
Joint DDAI 20 Jan 95

DLA APPROVAL:

Defense Medical Standardization Board Comments

CHAIRMAN
DEFENSE MEDICAL STANDARDIZATION BOARD

FORT DETRICK
FREDERICK, MARYLAND, 21702-5013

REPLY TO
ATTENTION OF:

Code 01

17 February 1995

From: Chairman
To: Mr. Robert J. Lieberman, Assistant Inspector General for Auditing, 400 Army Navy Drive, Arlington, Virginia 22202-2884

Subj: AUDIT REPORT ON HOTLINE ALLEGATIONS CONCERNING THE PROCUREMENT OF VENTILATORS (PROJECT NO. 4LD-8012)

Ref: (a) DMSB Code 181 ltr of 3 Feb 1995, subject as above
(b) DMSB Meeting 1-95 of 13 February 1995
(c) PHONCON DMSB CAPT Houk/DoDIG Mr. Charles Hoeger of 14 Feb 1995

Encl: (1) Executive Summary of 30 January 1995, subject as above
(2) MCMR-ZA Memorandum of 10 Feb 1995, subj: Audit Report Concerning the Procurement of Ventilators

1. This letter and its enclosures are submitted to correct the record and forward the majority and minority opinions of the Defense Medical Standardization Board (DMSB). Reference (a) was erroneously forwarded to your office representing a unanimous opinion of the DMSB.

2. In reference (b), the DMSB Members agreed to resubmit the DMSB review of the subject Audit Report containing the majority opinion of the Navy, Marine Corps, and Air Force representatives of the DMSB and include for the record the minority opinion of the Army Representative of the DMSB. The Army non-concurs with enclosure (1) and concurs with the DoD IG report findings and recommendations as detailed in enclosure (2).

3. As advised in reference (c), this letter updates reference (a). The DMSB point of contact is the undersigned at DSN 343-2001/Commercial (301)619-2001.

W. M. HOUK
CAPT, MC, USN
By direction

Copy to:
Mr. Charles Hoeger
Army Member, DMSB
Navy Member, DMSB
Air Force Member, DMSB
Marine Corps Member, DMSB

30 January 1995

Comments, DoDIG Draft Report, Audit Report on Hotline Allegations Concerning the Procurement of Ventilators (Project No. 4LD-8012)

EXECUTIVE SUMMARY

POTENTIAL BENEFITS: Insert in second sentence between Defense Medical Standardization Board and DPSC "the Military Services."

COMMENTS: In the Executive Summary it is important that we identify who the real customer is... the four Services.

SUMMARY OF RECOMMENDATIONS: Recommend deletion of the second sentence, "We recommend that the Defense Medical Standardization Board establish formal procedures to contact the Military Departments, not the contracting agency, when concerns arise about the Military Departments' requirements."

COMMENTS: Do not concur with the statement. First, it is made on the premise that the DMSB addressed the service requisitions placed with DPSC. This is not true. The DMSB (Staff Director) 21 October 1992 letter does not address service procurement requisitions. It does address service clinical and operational requirements encompassed in the Essential Characteristics produced jointly with the four military services. The DMSB requested that DPSC cancel the just awarded contract and resolicit using the new Essential Characteristics. The letter in no way requested that DPSC cancel service requisitions. In fact the DMSB scrupulously and totally avoided the issue of Service requisitions, preferring to let the Services act on their own behalf. Second, the issue in the case of the ventilator procurement and other acquisitions is standardization. In conducting the procurement in the manner they did, DPSC totally defeated the Military Services' attempts to standardize. The ventilator procurement was symptomatic of systemic problems in the DPSC contracting process that is in the process of being addressed by all parties concerned; DPSC, DMSB, and the Military Services.

PART I - INTRODUCTION

CHRONOLOGY OF EVENTS (Page 3): Several more important event items should be included in the Chronology of Events. This log should include the following letters:

As mentioned above, the 21 October 1992 Letter from Staff Director, DMSB, to Medical Directorate, Defense Personnel Support Center.

In March 1993, DPSC declares the ventilator a Military Unique item in order to bypass the normal requirement for non-developmental equipment to already have FDA "510K" approval for clinical application.

25 June 1993 Letter from BG Charles H. Roadman, USAF, MC, SFS, Air Mobility Command and Transportation Command Surgeon, who expressed concern over the procurement of the ventilator product and the acquisition process. He recommended that the procurement be investigated to determine if the product met Aeromedical Evacuation requirements before a contract award or production decision was exercised.

30 July 1993 Letter from Major General Thomas Tempel, DC, USA, Deputy Surgeon General of the Army, to BG Peter C. Bellisario, USAF, MSC, addressing concerns that the Air Force community had with the procurement of the transport ventilator.

3 August 1993 Letter from Major General William Moore, MC, USA, Commander U.S. Army Medical Department Center and School, requesting support from DMSB for the cancellation of present ventilator contract.

PART II - FINDINGS AND RECOMMENDATIONS

VENTILATOR PROCUREMENT PROCESS (Page 8): "DMSB inappropriately interjected itself in the DPSC ventilator procurement process."

NON CONCUR: At no time did the DMSB inappropriately interject itself into the procurement process. The DMSB's purpose is to assist and represent the Services in their efforts to standardize their medical material requirements. Over the years, procurements have been made without consideration of Service standardization requirements resulting in awards of contracts that provided less than acceptable equipment, and/or contracts that went unused by the Services. The major problem is that the standardization actions, which reflect clinical and technical requirements defined by the DMSB and the Services, have not been adhered to, or have not been thoroughly considered during the procurement process. The decision to recommend contract termination and resolicitation was made at the request of the Services and with their full knowledge and concurrence.

The DMSB Staff Director letter dated 21 October 1992 explained the history, reasoning, and solutions to the ventilator procurement action. This letter was coordinated through all four Services before distribution. After over two years, the customer is still asking for the DMSB's help.

2

Final Report Reference

VENTILATOR PROCUREMENT PROCESS (Page 8): "DMSB and DPSC did not properly coordinate classifying medical devices such as the ventilator as military unique."

CONCUR WITH COMMENT: DMSB discovered in March 1993 that DPSC had declared the ventilator as "Military Unique" in order to bypass the normal requirement for non-developmental equipment to already have FDA "510K" approval for human use. The DMSB has never considered the Portable Ventilator as being Military Unique and still does not. When declaring an item Military Unique, we are in effect setting aside the requirement for an item to have a proven clinical track record.

Revised Page 13 and Renumbered Recommendation 1.

RECOMMENDATIONS FOR CORRECTIVE ACTION (Page 12): "3. We recommend that the Director, Defense Logistics Agency, and the Staff Director, Defense Medical Standardization Board, jointly develop procedures and criteria for classifying medical equipment as military unique. The process should be included in the memorandum of understanding being developed by the two organizations. Any disagreements concerning military unique classifications should be mediated by the Assistant Secretary of Defense (Health Affairs)."

CONCUR WITH COMMENT: On 9 August 1994, DPSC agreed that they would coordinate with the DMSB on both proposed "Military Unique" determinations and changes to specifications and Essential Characteristics. Moreover, DPSC and DMSB are close to finalizing the referenced memorandum of understanding (MOU). DMSB comments on the memorandum were provided to DPSC on 6 December 1994 and included, in part, the following:

"DMSB and DPSC will work closely together to ensure the procurement process provides material that meets Essential Characteristics based on clinical, therapeutic, technical, regulatory, and/or medical readiness requirements."

ADDITIONAL COMMENTS:

a. As originally recommended during conduct of the audit, the DMSB again recommends that the Inspector General staff speak directly to the cognizant flag and general officers who have knowledge and provided guidance during different phases of the procurement cycle of the ventilators. They are Rear Admiral Hugh P. Scott, MC, USN, and Major General Robert Buethe, USAF, MC. Both served as DMSB Chairman and are now retired. They were both actively involved with the purchased ventilators from January 1991 to September 1994. All issues were discussed and tracked by both, and direction was provided every step of the way. Moreover, these flag and general officers were the executive service representatives of the Navy and Air Force. To not interview them as part of this IG is to ignore official Service input.

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b. Incidently, it should be noted that Navy input to this Inspector General report was solicited from the Naval Medical Logistics Command. The cognizant Navy activity concerning DEPMEDS issues has been and remains the Fleet Hospital Program Office, a Naval Supply Systems Command Activity. This report and all queries should be directed to that agency.

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DEPARTMENT OF THE ARMY
U.S. ARMY MEDICAL RESEARCH AND MATERIEL COMMAND
FORT DETRICK, MARYLAND 21702-5012

REPLY TO ATTENTION OF:

MCMR-ZA (70b)

10 FEB 1995

MEMORANDUM FOR DIRECTOR, DEFENSE MEDICAL STANDARDIZATION BOARD, FREDERICK, MD 21702-5013

SUBJECT: Audit Report Concerning the Procurement of Ventilators

1. The Army strongly nonconcurs with the proposed Defense Medical Standardization Board (DMSB) reply to the subject Department of Defense Inspector General (DoDIG) audit. In paragraph 1 of the proposed letter, please strike the sentence that mentions your comments represent the sincere concerns of all the Services. Instead, the Army concurs with the findings and recommendations of the DoDIG report.

2. The reasons for my nonconcurrence to your proposed memorandum follow:

a. The Army used a Deployable Medical Systems (DEPMEDS), DMSB approved specification for the procurement, and Defense Personnel Support Center (DPSC) correctly pursued the Army's need for a hospital ventilator.

b. Although the DMSB's desire for a single standardized ventilator for all missions to include air evacuation (i.e., a seamless ventilator system) was well intended, it was flawed in that it was not operationally or financially feasible. It was nonprocurable at the time the specifications were written and to our knowledge may still be so today.

c. The DMSB did not have the authority to unilaterally cancel contracts without concurrence of the requisitioning Service. The DMSB's narrow use of MG Moore's memorandum is an incomplete display of the Army position. The DMSB was instructed that the Army Medical Department Technology Committee (consisting of senior Army Medical Department General Officers) had decided to continue with the older specification.

d. We question the DMSB's ability to determine military uniqueness. The DPSC is the Agency with visibility as to the willingness of firms to bid with commercially available items. The true fault lies in whether DPSC properly challenged the Services and the DMSB on those specifications that made the item military unique.

MCMR-ZA
SUBJECT: Audit Report Concerning the Procurement of Ventilators

3. My point of contact for this action is COL R.I. Donahue, extension 7378.

RUSS ZAJTCHUK
Brigadier General, MC
Army DMSB Member

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