UNITED STATES GENERAL ACCOUNTING OFFICE
WASHINGTON, D.C. 20548

HUMAN RESOURCES
DIVISION

B-206270

FEBRUARY 23, 1982

The Honorable Robert P. Nimmo
Administrator of Veterans Affairs

Dear Mr. Nimmo:

Subject: VA Needs To Improve Its Quality Assurance Program For Medical Supply and Equipment Items (PLRD-82-44)

The Veterans Administration (VA) Marketing Center in Hines, Illinois, is a national purchasing activity, providing 172 VA medical centers an opportunity to obtain supplies and equipment through a centrally managed national depot distribution system. The Marketing Center purchases about 650 different medical supply and equipment items for three VA supply depots located in California, Illinois, and New Jersey. It also is responsible for assuring product quality. In fiscal year 1981, VA medical centers obtained about $54 million of their medical supply and equipment items from these depots.

We made this review to assess the adequacy of VA's quality assurance program. (See enc. I for details on our objectives, scope, and methodology.) In summary, we found that the program does not consistently establish quality standards, nor does it have a dependable inspection program. In addition, since January 1980 the Marketing Center has been using informal purchase descriptions, rather than detailed specifications, to obtain medical supply and equipment items. However, the descriptions have not been coordinated with the users and suppliers. By changing to purchase descriptions, VA eliminated many of the standards that were previously available to assure that the items purchased met medical center needs. VA believed the use of purchase descriptions would result in the purchase of acceptable items from the commercial marketplace.

To test VA's quality assurance program, we examined items in the warehouse at Hines using a "common sense" usability approach. We found that items frequently were of poor quality or did not operate as intended. (A detailed listing showing the results of our examination is contained in enc. II.) Surgical instruments had defects, such as cracks, pits, or rough edges, that could prevent proper sterilization. Some did not close properly or failed to meet VA test standards. Furniture and

items used by patients sometimes had missing or broken parts and misalined components. We found suture removal kits, which were supposed to be sterile, in broken packages that contained dirt and flaking metal particles. We discussed our observations with VA officials and they agreed that quality defects of this type should not be tolerated.

VA's medical centers are aware of quality problems but are reluctant to report them because they believe the Marketing Center is indifferent to their needs. When complaints are registered, the Marketing Center often provides unsatisfactory responses that do not resolve medical center concerns.

QUALITY TESTING SHOULD BE IMPROVED

The Marketing Center has five marketing divisions that centrally manage specific types of depot-stocked commodities. In addition to its basic procurement responsibilities, each marketing division is responsible for having depot receipts inspected to assure that the required level of quality is maintained. Testing is done by depot inspectors, but the criteria are developed by the marketing divisions. Receiving inspections are limited to confirming quantities received and reporting apparent shipping damages. The contracting officers can and often do request quality testing of specific items, but they do not have guidelines or procedures for selecting items or for defining the specific product characteristics that should be tested. Furthermore, the tests often are incomplete.

According to contracting officers, tests sometimes were not requested because (1) the vendors had good performance records or (2) the officers forgot to request one. When tests were requested, the inspectors were asked only to assure compliance with VA's brief purchase description and/or the product sample. However, VA does not retain many of its product samples, and purchase descriptions offer little guidance for assessing product quality. Therefore, this level of inspection does not provide an effective means for evaluating the quality of depot-stocked items.

The Marketing Center has no control over, and little direct communication with, the depots' service and reclamation (S&R) division which performs the quality tests. As a result, the marketing divisions were not aware that requested evaluations frequently were not performed by depot inspectors. Test results show only whether the inspectors accept or reject the items and may lead the marketing divisions to believe that accepted items have met existing requirements.

The S&R division inspects products, but its specific duties are not defined. The division's main responsibilities are

maintaining and repairing technical equipment, such as x-ray tubes, microscopes, and surgical instruments. Product inspections are not included in the division's mission statement, and the inspectors have not received formal inspection training or instruction.

Normally, depot inspectors are requested to verify a product's compliance with its purchase description or sample. However, the inspectors frequently do not perform all the required tests. For example, sterility is not verified or tested, even though this characteristic is a part of the product's purchase description. The depot inspectors do not have the equipment needed for sterility analysis, and yet, they will certify product compliance on their inspection reports.

The purchase descriptions for surgical instruments also specify requirements that often are not verified by the inspectors. For example, the depot-stocked suture needle holder is tested for only one of the four quality requirements stated in VA's purchase description. The inspectors did not perform copper sulfate, boil, or carbide jaw hardness tests on the instruments in depot stock. And yet, the inspectors reported that these instruments complied with VA's purchase description requirements.

The inspectors told us that they (1) do not perform copper sulfate tests on expensive instruments which are supplied by a reputable manufacturer, (2) have not used the boil test for a long time, and (3) do not test the carbide jaw inserts since they would have to be removed and ground flat before their hardness could be determined. In our opinion, procedures are needed to determine when testing is desirable and to ensure that tests conducted are properly controlled.

USE OF PURCHASE DESCRIPTIONS

Another factor contributing to VA's ineffective quality assurance program is its use of purchase descriptions. By January 1980 VA had stopped using most detailed specifications to purchase medical supplies and equipment, including surgical instruments. This change was made in response to the Federal policy to purchase commercially available items. VA believed the use of purchase descriptions would result in the purchase of acceptable items available from the commercial marketplace. Because of this belief, VA discontinued many quality control measures that were previously required to assure product quality. It also discontinued using the quality product sample technique for surgical instruments.

In our opinion, VA applied the Federal policy improperly. The Office of Federal Procurement Policy requires that

commercial item descriptions be developed and used to buy commercial products. These descriptions are to be of sufficient detail and length to assure the items satisfy the user's needs. VA's purchase descriptions, however, were only one or two sentences long and contained little specific information to buy medical items. In addition, the marketing divisions, which developed the purchase descriptions, did not coordinate them with users and suppliers.

We believe the use of purchase descriptions without coordinating them with users and suppliers and the resultant abandonment of prior quality control measures have contributed to quality problems. For instance, historically, VA had a qualified products list for its surgical instruments and required stringent quality controls. Under this concept, surgical instruments had to pass the following three-stage test before being considered acceptable:

--The marketing division assessed overall quality.

--The depot inspectors performed technical tests.

--Medical centers provided professional opinions and assessments.

The vendors' accepted samples were retained and used as a standard, providing inspectors a basis for accepting or rejecting items that the supply depots later received. When VA discontinued using detailed specifications in early 1980, it also discontinued the three-stage test program, believing the program was contingent upon detailed specifications and therefore not applicable to VA's planned use of commercial item descriptions. Regardless of the type of specification used to procure surgical instruments, the three test stages mentioned above are necessary. Only the degree to which they need to be performed should vary.

GAO EVALUATION OF DEPOT STOCK

To test VA's quality assurance program, we evaluated the quality of 46 medical supply and equipment items that depot personnel pulled from inventory at our request. Generally, one unit of issue from each manufacturer was obtained for our examination. (See enc. II.) We selected 13 items because of medical center complaints or depot inspector concerns about the product. We also randomly selected 33 medical supply and equipment items to determine whether items that had not previously been identified as troublesome had quality deficiencies.

We determined that 17 of the 46 items would not function as required or had serious defects that could cause problems for the user. These items had annual sales of about $1.5 million. The three medical centers we visited generally were aware of the problems and, in most cases, were using alternative products.

Examples of defective depot stock included:

--A surgical forceps (used to clamp blood vessels) which had a clasp that would not properly engage, a cracked finger ring, and a rough instrument tip.

--An examination table that had uneven and scarred welding, a missing nut, scratched surfaces, and sharp, exposed edges. The table did not conform to the required dimensions and failed the stability test.

--Sterile suture removal kits with broken packages, dirty instruments, and flaking metal particles. Kits from a second supplier were assembled upside-down with instrument tips, rather than handles, being accessible to the user.

Our findings cannot be statistically projected to estimate the amount of poor quality items in VA depot stock. However, we believe they illustrate the kinds of quality problems which can occur under VA's existing quality assurance system.

VA NEEDS A BETTER SYSTEM FOR RESOLVING QUALITY COMPLAINTS

VA requires its medical centers to use depot-stocked items whenever possible. To assure user satisfaction with these items, VA has a formal system that allows a dissatisfied user to register a complaint with VA's Marketing Center. The Marketing Center, in turn, must promptly address and resolve these complaints.

However, the complaint system needs to be improved. Medical centers are not satisfied with depot-stocked items and often buy alternative products from other sources without filing a complaint. As a result, defective or poor quality stock is not brought to the Marketing Center's attention. When complaints are filed, the Marketing Center often does not take appropriate action to resolve the reported problem. This further discourages the medical centers from reporting additional complaints.

Reporting of quality complaints

The medical centers use VA's Quality Improvement Report (QIR) to file complaints about depot-stocked items with the Marketing Center. During fiscal year 1980, 478 QIRs were filed on medical supply and equipment items. The Marketing Center believes that several medical center complaints are unfounded and are filed as an excuse not to buy from the depot. On the other hand, the medical centers believe that the Marketing

Center is indifferent to their needs and does not properly resolve their reported problems.

We visited three VA medical centers to obtain their views on the complaint system. We also discussed 27 of the 46 depot-stocked items that we inspected, and the actions taken to resolve known problems with these items. Only 27 items were discussed because our audit work, at the time of the medical center visits, indicated that users may have problems with these specific items. At least one of the medical centers used 18 of the 27 items. The three centers had experienced problems with 13 of the items. Generally, the medical centers were aware of the same conditions that we observed while evaluating depot stock. However, they had filed QIRs for only two of these items--insulin syringes and surgeon gloves. The reasons for not filing QIRs varied, but basically the medical center personnel considered the QIR process to be time consuming and frustrating. In other instances, personnel were unable to explain why a QIR was not submitted to the Marketing Center.

Personnel at one of the medical centers acknowledged that they were unsatisfied with depot-stocked items, but rather than file a QIR complaint, they tolerated the items supplied. Another center had filed only one QIR in the past 18 months.

Marketing Center replies are not responsive

QIRs are sent to the Marketing Center so that potential problems can be properly identified, evaluated, and resolved. The Marketing Center should prepare and send a meaningful response to the medical centers. However, the replies we reviewed generally were not responsive to the identified problems. Since the marketing divisions that purchase the items are also responsible for responding to QIRs, they may not be able to objectively evaluate reported problems.

The nursing service at one medical center stated it took 9 months of paperwork to get rid of just one problem item. This inability to stimulate change is one reason medical center personnel do not submit QIRs.

We reviewed QIRs that were reported against the 46 depot items that we inspected. Most items did not have QIRs on file and the Marketing Center's responses to the complaints that were registered frequently (1) did not address the medical centers' stated problems, (2) did not provide the medical centers with clear resolutions, or (3) provided the medical centers with false assurances.

CONCLUSIONS AND RECOMMENDATIONS

We believe that VA has not properly emphasized its quality assurance responsibilities and needs to take action to improve the quality of items purchased for use by its medical centers.

We recommend that the Administrator of Veterans Affairs direct the Assistant Deputy Administrator for Procurement and Supply to:

--Develop a quality assurance program that provides for dependable independent testing of products purchased for depot stock. We are not implying that each medical supply and equipment item purchased should be subjected to quality testing or that all items should be subjected to the same level of testing. However, procedures are needed to determine when testing is desirable, to identify what product characteristics require testing, and to ensure that tests conducted are properly controlled.

--Discontinue using purchase descriptions until they have been coordinated with users and suppliers and modified to provide for adequate quality control.

--Assign responsibility for the quality complaint system to an entity that is independent from the marketing divisions and follow up to make sure that future medical center complaints are resolved promptly.

AGENCY ACTIONS AND COMMENTS

VA told us that it has taken several actions recently to improve the Marketing Center's quality control system. These include:

--Reestablishing a qualified products list for surgical instruments in July 1981.

--Developing inspection criteria in August 1981 which supplement the purchase descriptions and explain the tests to be conducted. The criteria are developed by the purchasing divisions in coordination with the Marketing Center; the Test and Evaluation staff; and the Hines Supply Depot, Service and Reclamation Division.

--Transferring the quality complaint responses from the purchasing divisions to the Marketing Center's Test and Evaluation staff in October 1981. This was done to improve the objectiveness and responsiveness of the quality complaint system.

VA advised that our audit contributed to the timely implementation of these changes. According to VA, the above changes and the ongoing conversion of purchase descriptions to commercial item descriptions will provide adequate quality control over medical supplies and equipment.

We commend VA's prompt initiation of corrective actions and agree that steps taken and planned should improve the quality of medical supply and equipment items. However, because of the Marketing Center's poor track record in developing purchase descriptions and testing for quality deficiencies, we believe that the Assistant Deputy Administrator for Procurement and Supply should closely monitor the implementation of the actions to strengthen VA's quality assurance program.

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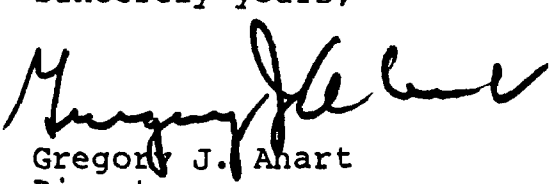
As you know, section 236 of the Legislative Reorganization Act of 1970 requires the head of a Federal agency to submit a written statement on actions taken on our recommendations to the House Committee on Government Operations and the Senate Committee on Governmental Affairs not later than 60 days after the date of the report and to the House and Senate Committees on Appropriations with the agency's first request for appropriations made more than 60 days after the date of the report.

We are sending copies of this report to the Director, Office of Management and Budget, and to the Chairmen, House Committee on Government Operations and on Veterans Affairs, Senate Committee on Governmental Affairs, and House and Senate Committees on Appropriations.

Sincerely yours,



Gregory J. Ahart
Director

Enclosures - 2

ENCLOSURE I

OBJECTIVES, SCOPE, AND METHODOLOGY

The objectives of our audit were to (1) evaluate the quality of medical supplies and equipment that are stocked in VA's supply depot system, (2) assess the Marketing Center's quality assurance practices, and (3) determine how the Marketing Center addresses and resolves medical center complaints concerning the quality of items obtained from VA's depot stock. We performed our audit in accordance with GAO's current "Standards for Audit of Governmental Organizations, Programs, Activities, and Functions."

We restricted our review to supply and equipment items that did not require a medical assessment of their quality, such as medical furniture, surgical instruments, and items that were in sterile packages or used by patients. We eliminated other items, such as casting compounds, hearing aids, compression bags, and nasal catheters because a medical evaluation would be needed to assess the quality of these items. Our final universe consisted of 207 of the 650 depot-stocked medical supply and equipment items and accounted for over $22 million in annual depot sales.

We tested the quality of the following items that accounted for large depot sales and were either the subject of medical center complaints or their quality was questioned by the depot inspectors.

	No. of items	Annual sales (thousands)
Surgical instruments	1	$ 164
Medical furniture	1	256
Patient items	6	2,190
Sterile items	5	1,843
Total nonrandom items	13	$4,453

We inspected active depot stock for each of these items and found that frequent quality problems did exist. We also randomly selected 33 medical supply and equipment items for review. The purpose of this selection was to determine whether randomly selected items also were experiencing quality deficiencies. Our random selection included the following items:

ENCLOSURE I

	No. of items	Annual sales (thousands)
Surgical instruments	11	$ 436
Medical furniture	7	233
Patient items	5	288
Sterile items	10	394
Total random items	33	$1,351

Our findings cannot be statistically projected to estimate the amount of poor quality items in VA depot stock.

Our examination of items selected from depot stock was based on a "common sense" usability approach. We compared such item characteristics as shape, size, and finish to the requirements in the purchase description. We visually inspected selected items for defects, such as rough or sharp edges, missing parts, and dents. When feasible, we tested the item to determine whether it could cause problems for the user. We performed copper sulphate and hardness tests on surgical instruments. We also performed any other tests that were required by the purchase description except for sterility. However, we did examine sterile items for dirt, flaking metal particles, and broken or unsealed packages, and tested some items for water tightness. We also discussed items with VA medical center personnel to obtain their views on apparent problem items.

We categorized the 46 items we examined in the review as follows:

--Defective - The item could not function or perform as required or had serious defects that could cause problems for its user.

--Uncertain - A potential problem was identified, but its significance could not be clearly verified or tested.

--Acceptable - No deficiencies were noted that could cause problems for its user.

We performed our review at the VA Marketing Center, the Hines Supply Depot, and three medical centers located in the Chicago area.

LISTING OF

DEPOT-STOCKED ITEMS INSPECTED BY GAO

	Random items	Unit price	GAO assessment Defective	Uncertain	Acceptable
	Surgical instruments:				
1	*5-3/4-inch scissors	$ 24.73	x		
2	*Towel forceps	1.89	x		
3	*Dressing forceps	3.42			x
4	Suture needle holder	15.82			x
5	5-1/2-inch scissors	4.90			x
6	*Gauze forceps	5.75	x		
7	*5-1/2-inch hemostatic forceps	5.87	x		
8	*Toenail nippers	7.59			X
9	*7-inch scissors	25.04			x
10	*5-1/2-inch scissors	22.07			x
11	*5-inch hemostatic forceps	2.33	x		
	Medical furniture:				
12	*Surgical stand	91.00	x		
13	Revolving stool	68.00			x
14	*Surgical table	135.00	x		
15	*Clinical chart holder	5.05	x		
16	Irrigation support rod	7.50		x	
17	*Examining table	286.89	x		
18	*Overbed table	62.00			x
	Patient items:				
19	*Medical warning necklace	1.13			x
20	Commode chair	208.62			x
21	Reusable bedpan	.68			x
22	Walking cane	2.18			x
23	Medical warning bracelet	1.16			x
	Sterile items:				
24	Intravenous stopcock	.56			x
25	Tubeculin syringe and needle	.04			x
26	Hypodermic needle	.03			x
27	Surgical knife blade - #15	.10			x
28	Surgical knife blade - #20	.13			x

		Unit price	GAO assessment		
			Defective	Uncertain	Acceptable
29	Tracheal catheter	$0.25	x		
30	Surgical drape	1.66			x
31	Urethral catheter - silicone	2.00		x	
32	Urethral catheter - rubber	2.30		x	
33	Blood recipient set	2.03			x
	Selective items				
	Surgical instruments:				
1	*5-1/2-inch scissors	5.33	x		
	Medical furniture:				
2	*Bedside cabinet	113.85	x		
	Patient items:				
3	Inflatable cushion ring	4.90			x
4	*Folding wheelchair	97.99		x	
5	*Aluminum crutch	16.20	x		
6	*Wood crutch	3.90	x		
7	*Invalid walker	14.30	x		
8	*Water pitcher	.15	x		
	Sterile items:				
9	*Insulin syringe and needle	.05		x	
10	*General syringe and needle	.05		x	
11	*Tuberculin syringe and needle	.08		x	
12	*Suture removal kit	.34	x		
13	*Surgeon gloves	.20			x

* Items discussed with VA medical centers.