

EXHIBIT 18

THE DEFENSE PERSONNEL SUPPORT CENTER (DPSC)
QUALITY ASSURANCE PROGRAM

The Defense Personnel Support Center Quality Assurance Program consists of the following features:

Specifications and Purchase Descriptions: Maximum technical support is directed toward development of precise and definitive specifications for medical materiel. These specifications provide objective standards to measure and determine that quality products are procured.

Preaward Plant Surveys: The preaward facility survey is another significant feature in the Quality Assurance Program. Based upon the nature of the item and the known capabilities of the company, the Directorate of Medical Materiel of DPSC determines whether an inspection is required prior to the award of a contract. If a survey is needed, a Defense Contract Administration Service (DCAS) field inspector and/or a DPSC quality control specialist, experienced in the commodity, visit the plant to evaluate production capability, quality control procedures and housekeeping practices. Since this program was started on 1 January 1962, over 900 medical materiel manufacturers have been surveyed by government inspectors. A significant number of manufacturers have been rejected one or more times for failure to meet the DPSC quality control or sanitary standards.

Laboratory Analysis: The DPSC Medical Laboratory is equipped and staffed to accomplish chemical, physical and bacteriological tests. The laboratory tests preaward samples from prospective contractors to determine if the firm has the capabilities to produce an item which meets the applicable specification. The laboratory also analyzes samples of manufacturers' products before, during and after the production run, as well as samples submitted by hospitals and depots. The latter samples apply to stocks suspected of being unsuitable for further use and issue. Assistance is received from other Government, military and commercial laboratories when specialized testing is necessary.

Inspection Services: Inspection for medical contracts is the responsibility of DCAS. Due to the criticality of medical materiel, steps were taken to insure utilization of highly qualified personnel as medical inspectors. Qualification standards are established and two comprehensive training courses are required for all inspectors of drugs, chemical and blood grouping and typing reagents. Three instructional courses are required for inspectors of surgical and dental instruments, medical devices and equipment. The DCAS quality assurance representatives have been indoctrinated in product inspection as well as plant inspection, and they possess the capability to ensure that the materiel procured meets the specification requirements.

Depot In-Store Quality Control Program: The DPSC has an active In-Store Quality Control Program for the surveillance of depot stock. The basic objective of the program is to assure that medical materiel is "fit-for-issue". A detailed In-Store Quality Control Manual, first published in 1958 and subsequently revised, is used as a guide for periodic inspection and surveillance of depot stocks. If materiel is suspected of being unsuitable for use after visual inspection, depot stocks are suspended and samples of the suspected materiel are submitted to DPSC for laboratory analysis. In this manner, DPSC evaluates the condition of depot stocks to assure the suspension or destruction of unsuitable materiel and accomplish repairs or modifications of medical equipment.

Field Quality Control System: The DPSC actively solicits reports from military hospitals and other military medical treatment facilities concerning the adequacy of materiel being used. These reports are submitted independently by the user or obtained as a result of a visit to the installation through participation in the DSA Quality Check Program. This system permits DPSC to evaluate the condition and quality of medical materiel through the life of the items.

DSA Quality Check Program: This program is accomplished through visits by qualified technical personnel to using activities to obtain first-hand information regarding the quality, reliability, and maintainability of DPSC furnished materiel.