volve requirements which transcend those of some commercial products on the market. For example, military medical materiel is subjected to worldwide distribution under adverse conditions. Product stability is, therefore, a very essential element in assuring that the product is suitable when it is ultimately consumed. As a result, the standards described in DPSC specifications are at times more stringent than commercial standards in anticipation of adverse storage and transportation, and long-term storage.

It will be noted that the method of specification preparation is responsive to the rapidly changing need of the medical services. The division operates closely with the procurement personnel and obtains rapid feedback from industry on recent technological advances. Technical reviews and evaluations of such data permit updating and upgrading medical specifications. Valuable information is obtained via the complaint reporting system which involves evaluation of complaints, classification of the types of complaints, and determination of whether specifications require modifications in order to circumvent further complaints of a similar nature.

DPSC procures approximately 1,100 drug items, of which about 560 are monographed in the USP XVIII and NF XIII. About 50 percent of these items include standards that exceed those of the official compendia. Requirements specified include color limits for liquid products particularly for parenterals; expiration dates, refrigeration requirements for many items not required by the USP and NF; dissolution tests, animal tests, accelerated aging, and some clinical requirements. Also, special packaging is required for greater assurance of stability. These areas include inner and outer seals, leakage tests, special closures, label adhesion, tin plating, and vacuum packing.

In qualifying drug manufacturers, facilities of prospective contractors are inspected to determine the company's potential to produce a specification item under acceptable conditions of quality control and housekeeping. The DPSC drug standards are used as a guide in determining the acceptability of the firms. Disqualifications are usually in the areas of inadequate quality control, unacceptable housekeeping, or deficiencies in technology.

Preaward samples are requested in those instances where the capability of the firm to produce an item in conformance with the specification has not been established. Our medical laboratory performs the necessary analyses to determine compliance with specifications, and from these findings judges whether the manufacturer has the potential to produce the item specified. Other Government laboratories such as FDA and U. S. Army Medical Research Laboratory at Fort Knox are utilized to augment DPSC testing capability.

The medical laboratory is an essential segment of the total quality assurance effort. The laboratory represents an independent source of analyses by highly qualified, trained scientific personnel intimately acquainted with tests and standards of chemical, physical and bacteriological testing. The analyses performed on preaward samples, first articles, preacceptance samples and depot surveillance samples represent a critical part of the effort toward the quality objective. The laboratory also serves as a check point for inspectors when they wish to have company results verified independently.

During production, every drug product is inspected by a qualified chemist, pharmacist, or chemical engineer of the Defense Contract Administration Service of DSA. These personnel are specifically and formally trained for this function by DPSC. Inspection is performed against the applicable specifications and includes review of the laboratory analyses. The inspector may witness contractor testing or personally conduct check tests as necessary in the company laboratory.

Among the other features of the quality assurance program are: monitoring of inspection reports, participating in inspection operations, and maintaining a surveillance program over material in the system. Customer satisfaction with material supplied is evaluated by visiting depots, military hospitals and dispensaries. In this manner, DPSC maintains a direct line of communication with the medical/professional personnel with a view toward improving products and services wherever possible.

In offshore procurement of drugs further measures are taken to assure that plants and products comply with specifications. A specially trained medical service corps officer is assigned overseas for inspection of plants and surveillance of the inspection program. During production on DPSC contracts, a qualified inspector maintains residency at the plant. Prior to acceptance the active ingredients and finished product of each lot are forwarded for FDA testing in