

10040 COMPETITIVE PROBLEMS IN THE DRUG INDUSTRY

Information Required by Senator Nelson
from Department of Defense

16. ANSWER: (Cont'd)

A Pre-Award Survey required in-depth knowledge of various technical areas in order to derive the necessary professional judgments regarding the bidder's capability to perform in accordance with the terms and conditions of proposed contract. The Pre-Award Survey involves expertise in such areas as finance, development and production operations, production engineering, specialized engineering, quality control, accounting, industrial management, industrial property management and disposal, commodity specialist and purchasing activity representatives. In addition, assistance frequently may be required from legal, small business and industrial labor relations specialist. Consideration is given to utilization of available DCAS experts and likewise to those technicians and specialists available from purchasing activities. Each team member contributes his specialized knowledge and professional judgment under and with the overall guidance of the team coordinator and Pre-Award Survey Monitor. The monitor, in turn, is responsible for submitting the integrated results of the survey to the chairman of the Pre-Award Survey Board for approval and transmittal to the purchasing office. The survey report and recommendations are then forwarded to DPSC where the report is reviewed and evaluated by personnel in the Quality Assurance Branch. A summary of technical findings, which required approval by the Chief of the Branch, is prepared together with a recommendation to the contracting officer.

(c) DPSC utilizes the DPSC Drug Standards; Federal Standards on Tablets, Capsules and Parenteral Preparations; Military Inspection System Specification, and any other specific specifications contained in the procurement solicitations.

(d) Inspection is done in the plant for the procurement item to determine compliance of plant and product to requirements. Violations may contribute to the contamination of the product.