

Senator NELSON. Do you have evidence that that is more effective therapeutically?

Captain PFLAG. Yes, sir; to this extent, sir. We have found that as penicillin injectible ages, that there is an increase in yellow color, or it darkens, and, therefore, since we purchase some of this for long-time storage, it seems prudent to get the lowest color value that one possibly can, so that as it ages there would be less color, and, therefore, less degradation. The color is synonymous with degradation. Generally, where there is a color change, it is generally associated with degradation of the product.

Senator NELSON. All right, go ahead.

Admiral ETTER. 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 specifications 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 checkpoint 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.

Senator NELSON. May I ask a question here. I think I could cover these next few pages.

Do DOD personnel inspect the plants of all suppliers?

Admiral ETTER. Of all the prospective suppliers, they inspect all plants of those with whom we have contracts, sir.

Senator NELSON. Those with whom you have direct contact. You aren't referring to purchases made at the local level?

Admiral ETTER. No, sir.

Senator NELSON. What is the qualification of your inspectors? What are their technical qualifications?

Admiral ETTER. They all undergo training in DPSC, and they have all—I think I am correct, Captain Pflag—a baccalaureate degree, usually in one of the sciences.