

## **Standards for modular prostheses\***

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### **Introduction**

Inefficiency in administration and denigration of product or process quality can result from a purchasing agency (such as a Government) becoming too specific in issuing its requirements for a product or process. Inefficiency is associated with long, overly complex statements of specifications; these produce time-consuming efforts to comply and will, for compliance checking, require heavy investment by the purchaser.

Quality may be affected by the detail of a specification restricting innovation and change.

In limb prosthetics it should be acceptable to limit the standard to overall performance and durability requirements for hardware but to include the most important standards of all, those which establish the function of the assembled product and cover the people performing the service to the patient.

### **Specifications on hardware**

The United States Department of Defence has for many years used detailed specifications for nearly all of its purchases; only recently it considered some change in its philosophy on some standards. The Wall Street Journal of New York, in an article of September 22, 1978 pointed out that the Pentagon is trying to eliminate as nearly as possible all its very bulky statements of requirements for products and instead proceeding to buy items available in the commercial market. One example cited was Worcestershire sauce, for which a 20-page document was set down to cover acidity, colour and spice. Difficulty resulted in achieving

conformance; prices as a result were higher than when the Pentagon elected to suspend its specifications and purchase sauces that had demonstrated commercial market acceptability.

In another example the Wall Street Journal article points out that selling mouse traps to the military would require compliance with about 500 pages of specifications. When the military realized the problems associated with this particular acquisition, the standard for the mouse trap was reduced to less than a page; the requirement for the mouse trap was simply put in terms of the performance required, that of catching a mouse.

These examples (and there are many others) illustrate how over-zealous some government procurement agencies can become in trying to control the purchasing of hardware. The U.S. Veterans Administration some time ago learned that excessive restrictions on detailed prosthesis design would be inappropriate and that innovation would be impeded. Although the Veterans Administration has performance and durability specifications covering very common mass-produced hardware such as artificial hands, elbows, some knee mechanisms, and foot-ankle systems, it will not issue detailed specifications to cover the prosthesis. It is recognized that the quality and performance of the prosthesis (sometimes in spite of the hardware) are most dependent on the persons performing the fabrication and fitting.

### **Specifications on people**

Thus the quality of the prosthesis is related directly to the quality of the service, and the service provided in the delivery of artificial limbs is most dependent on the people providing that

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service. Specifics about their quality are based on knowledge and experience as determined by and as judged by their peers. The quality that should be required by purchasing organizations (such as the U.S. Veterans Administration) is that these people meet the highest standards of their profession and that their product meet the highest standards of their industry. Compliance with these are determined primarily in the VA clinics rather than in VA test laboratories where the minor aspects of compliance are determined only on components.

The requirements in the current Veterans Administration contract for procurement of prosthetic services reads as follows:

“The services provided under this contract should represent the highest quality standards of the industry in performing fabrication and

fitting. Prosthetic components purchased under the contract should meet VA's standards for quality and performance, wherever such standards exist. Enforcement of these standards, the compliance testing required, and the dissemination of results will be the responsibility of the VA. Materials and sundry hardware will be of the highest quality used by the industry and profession.”

To go much beyond the above would require an extraordinary and expensive capability for compliance testing. Standards which are detailed in terms of design would require persons to be employed to do quality checks to see if every detail of the specification was being met. Controlling the quality of people who supervise fabrications and perform the fittings is a much more sensible (and less expensive) approach.