Specifications Development And Compliance Testing

"Let us raise a standard to which the wise and honest can repair. The event is in the hand of GOD."

—GEORGE WASHINGTON

The Testing and Development Laboratory is organized and has the facilities to perform a number of activities for the Veterans Administration. The most important two are the development of specifications covering VA approved products, and the compliance testing of these items. This article will deal with these two functions. Some of the *other* activities of the Section can be briefly summarized as follows:

a. *Evaluations*—It conducts physical evaluations on various devices, inventions, new and modified products, new materials, etc., all submitted by interested parties with the aim of improving the lot of the disabled.

b. *Development*—Either on its own initiative or in cooperation with other sections of the Center, it develops and fabricates new devices, special test equipment, cycling machines, special jigs for new prosthetic techniques, experimental prostheses and braces, and other aids for the handicapped.

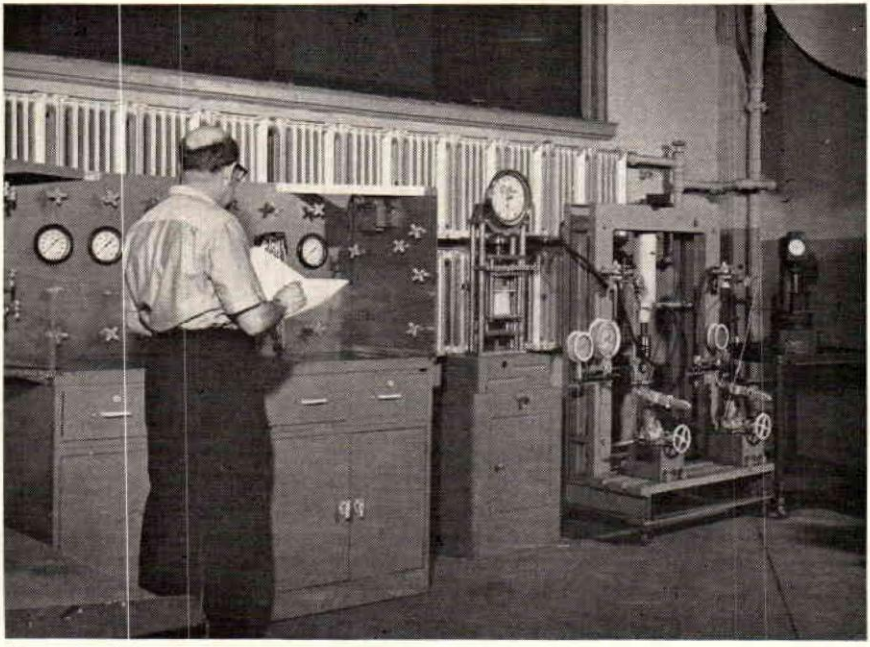

Figure 1. Physical test room. Left to right: Hydraulic test stand, Universal testing machine, another hydraulic tester, Rockwell hardness tester.

c. *Illustrations*—The Illustrations Unit of the Section serves the VA Prosthetics Center and the Prosthetics and Sensory Aids Service by supplying photographs and art illustrations for various publications and projects, such as technical reports, manuals, or special published articles (of which the illustrations appearing in this journal are an example). Charts, visual displays for exhibits, and slides for lectures are other services furnished.

Figure 2. Illustrator.

FACILITIES

The facilities of the Section consist of a well-equipped experimental Machine Shop which has been shown in a previous article, a welding, plating, and heat-treating room; a testing unit which contains accelerated testing machines and specialized equipment for testing of structures and materials (Fig. 1); and offices equipped for the engineering draftsmen and scientific illustrators (Fig. 2)

THE PHILOSOPHY AND BENEFITS OF SPECIFICATIONS

Specifications and standards have become fundamental requirements in all industrial and governmental activities. Standards have been used throughout history in isolated instances, but modern life would be almost impossible without them. What is the difference between a "Standard" and a "Specification"? Here are *some* definitions:

A *Standard* is that which is set up and established by authority as a rule for the measure of quality, weight, extent, value or quality (Webster).

A *Specification* is always the document that "specifies" the essential attributes of the subject matter. For differentiation, a standard is the item itself when it conforms fully to the specification.

These definitions should suffice. However, to confuse matters a bit, a specification that deals with a very *basic* item, such as screwthreads, is often called a "standard," and a *complex* product which is made according to a specification is not necessarily a standard. To be more specific, a specification (or, if you will, a standard) "defines a product, process, or procedure with reference to one or more of the following: nomenclature, composition, construction, dimensions, tolerances, safety, characteristics, rating, certification, testing and the service for which intended" (American Standards Association).

The most basic standards are standards of measurement: the meter, the pound, the volt, etc. They are the tools we build with. We cannot specify anything that we cannot measure. Neither can we reproduce it. So we see that basic standards are the building blocks which are used in specifications to construct more elaborate standards.

There are by now thousands of standards for such basic things as screws and nuts, gages, all kinds of materials, codes, symbols, etc. The use of approved standards in most cases is not mandatory, yet conditions in a highly civilized society like ours would be chaotic without them. Just

imagine things reverting to the "good old days": when you asked for an ell of cloth, you could get anything from 27 to 45 inches, depending on the locality. This example points up an important requisite of standards: the standards used must be well-defined and their accuracy suitable for the end result, otherwise the purpose of the specification is defeated. More precise standards are necessary, for instance, in pharmaceutical process specifications, where it may be necessary to measure to a few parts per million. Many examples could be given to show why our advancing technology needs ever more refined primary standards.

Specification is essential in procurement for several reasons. For one, the government's principles of purchase, which are based on obtaining a satisfactory material or item for the intended use at minimum cost, normally requires competitive bids. Secondly, specification is necessary so that prospective bidders will know the properties and quality of the material or items they must deliver, and thus enable them to make a reasonably close estimate of cost. Thus a good specification represents the lowest cost item that will do the job.

Thirdly, a specification describes the test method necessary to determine the properties and characteristics that are required. It is necessary to test each unit with the same method and apparatus so as to have a basis for ready comparison.

Fourth, a specification reduces waste by eliminating unnecessary sizes and types, costly manufacturing procedures, excessively expensive materials, or materials which may be inferior and cause premature failures thus increasing costs. Before specification, each manufacturer may have produced his own assortment of sizes and types, in variation with his competitors. This is not only confusing to the users, but also a nuisance and a bigger expense to distributors and retailers, because they have to carry much larger stocks, and parts of one manufacturer are usually not interchangeable with other makes. After agreement is reached through specification, the manufacturers' production lines can move faster and smoother, with longer runs and fewer changes, because there are fewer and simpler types to make. His set-up time, tooling, inspection, training of workers and raw materials requirements are all simplified. He is able to keep the factory busy in slack times by making standard parts for stock.

Finally, a specification establishes the limits and tolerances within which the product or process is acceptable. The concept of tolerance is based on the fact that variations *do* exist in all natural and manufactured materials. For the product to be economically feasible, the specification requirements must make allowance for some variation in the physical and chemical characteristics of raw materials and in the processing of these materials to the finished item. It then becomes necessary to decide how much variation can be permitted without lowering the standard. It usually resolves itself to the question of how much the buyer is willing to pay for quality, if no other determining factors are involved such as safety or reliability.

The ultimate benefits of standards have already been implied. Both industry and user achieve economies from well worked-out specifications, resulting in conservation of time, materials, labor and money. As in other industries, much waste results in the prosthetics business due to the great variety of manufactured products. Many types and sizes can not be justified from a sound economic standpoint. A majority of the varieties constitutes an unnecessary waste of materials, production facilities, and operating capital, needlessly increasing the cost to the consumer. Obvious ad-

vantages are to be gained by concentrating production on the varieties and sizes in greatest demand. One of the objectives of specification is "simplified practice" in accord with the foregoing.

Specification helps the manufacturer in other ways: (1) The standards tests enable a ready comparison between competitors' products. Thus, one finds out in what way his product is deficient compared to somebody else's and tries to improve it. This was the case with SACH Feet, for instance. (2) Specifications provide the necessary means of communication for the establishment of understanding between workers in the field of prosthetics. This helps to open to the research worker a knowledge of the work being done elsewhere, and so leaves their creative faculties free for the problems that are still unsolved. (3) Standards help designers to develop new products in such a way that they function better, and are attractive from the standpoint of cost and maintenance.

From the standpoint of the Veterans Administration, a major buyer of prosthetic items, specifications are of benefit to the taxpayer and to the disabled veteran, who is the ultimate user. Some of these benefits can be listed as follows:

a. The specifications and the tests performed in accordance with them, ensure the user of products made by proper techniques and from acceptable materials with known properties.

b. Product performance is uniform and predictable, and a number of manufacturers' products can be used interchangeably, from the standpoint of sizes and tolerances.

c. The availability of the product is increased, minimizing the need for the VA or one of its contractors to maintain large stocks.

d. When the Government buys in quantity under a bidding system, the product supplier with the lowest bid gets the contract for the specified product, thus saving the taxpayer money.

To sum up, the user of a specified product can look forward to a better product, better reliability, and better service, and the producer who complies with specifications will find himself in a more advantageous position with respect to a competitor who does not abide by the standard.

Perhaps a few words about general standards activities throughout the country are indicated. All nations have organizations for the development and preservation of standards. The primary source of standards in the United States is the National Bureau of Standards in Washington. Its works would fill many volumes, and its contributions to science and engineering are almost uncountable. They continue and increase with each passing month. In addition to the National Bureau of Standards, each major government agency develops and issues its own specification according to its needs. The Department of Defense to date has issued approximately 24,000 military specifications and standards. While their primary purpose is in the defense of the United States of America, these specifications and standards are of equal value to the daily pursuits and well-being of our people. The General Services Administration (GSA) promulgates the Federal Specifications and Standards which concern mainly commodities, supplies, materials and equipment which are purchased and used by all branches of the Federal Government. There are many other Government agencies whose daily pursuits involve standardization, but their work is more highly specialized, and directed to a narrower audience. One of these is the Veterans Administration which, of course, works for the benefit of all veterans, including the disabled.

Outside the Government, American industries and professional societies are continually developing standards to increase their abilities to specify. There are hundreds of these organizations. A few of them are:

American Society of Mechanical Engineers
American Institute of Electrical Engineers
American Society of Testing and Materials
American Standards Association
American Petroleum Institute
American Society for Metals
Society of Automotive Engineers
United States Pharmacopoeial Convention

A quite complete list can be found in reference (2).

The Development of a Specification

There are five major steps in establishing a VA specification on an orthotic or prosthetic item. Salient features of each are as follows:

a. *Request*—The request usually comes from the Prosthetics and Sensory Aid Service (PSAS) in Washington, D. C. to the VA Prosthetics Center. PSAS, which is a Service under the VA's Department of Medicine and Surgery, is usually contacted when a vendor wants to sell a new prosthetic or orthotic product to the VA. The Government's principle of purchase requires that, with some exceptions, competing vendors bid for a contract through a procurement document which has a specification attached. If a specification already exists on this commodity, (perhaps issued by a different Government agency), the Veterans Administration may adopt it for its own use. This was the case, for instance, with the specification for crutches, which was originally a Federal Specification. If it is a new product, or unique for veterans' use, and is acceptable, a specification has to be written. It is then that the request is sent on to the VA Prosthetics Center (VAPC) for development.

b. *Evaluation*—The item is first evaluated. Physical and physiological testing are performed by the Bioengineering Laboratory and clinical tests by the Orthopedic Shoe Section or Limb and Brace Section of the Center. In addition, the Research and Development Division of PSAS may possibly be involved with a national VA Field test. Sometimes comments are elicited from other interested sources. Or the job may be handled entirely by a VA contractor such as New York University. Depending on the complexity of the item, this investigation may consume a considerable amount of time. (In the case of the Hydra-Cadence hydraulic unit, VA field testing took about a year to complete.) When all the data are in, an evaluation report is written giving recommendations regarding possible future utility. Weighing all the factors involved, VA Central Office then decides whether the product has sufficient merit to be issued. If the decision is favorable, VAPC is asked to prepare a specification, which in large part employs methods and findings of the evaluation.

c. *Draft*—The vendor or manufacturer in the field of prosthetics usually has the skill and technique to make an acceptable product, but rarely has he the technical know-how to write the specification for it. As the writing of a specification is a cooperative venture between the vendor or a group of vendors and the government, a *draft* is usually written by experienced men in the Government. Requirements must be stated clearly and accurately; words and phrases should be simple and easily understood; Tables and graphs must be presented in an easily understandable form.

The structure of a Government Specification is usually composed of a heading and six numbered sections. The heading consists of the specification symbol, revision (if any), effective date, title, and preamble. The sections are titled as follows:

1. Scope
2. Applicable Documents
3. Requirements
4. Quality Assurance Provisions
5. Preparation for Delivery
6. Notes

Example

1. Scope

1.1 Description. This specification establishes the requirements for a prosthetic knee-ankle system with coordinated hydraulic swing control. The complete assembly (or system) consists of (a) the hydraulic mechanism, including the knee cap, fairing and foot attachments, hereafter referred to as the "unit," (b) the foot, and (c) the cosmetic cover with attachments.

1.2 Sizes. Ranges of sizes as specified in 3.5 and 3.12.

In section 2, all documents are listed which form part of the specification. These may be governmental or non-governmental specifications and standards, drawings, and other publications.

Section 3 states all essential requirements and descriptions applying to the design, material, or construction which the commodity must meet to be acceptable. The requirements should be worded so as to provide a definite basis of rejection in those cases where the quality and workmanship are such that the item is unsuitable for the purpose intended.

Example

3. Requirements

3.1 Materials

3.1.1 Materials shall be as specified on the detail drawings for each component.

3.1.2 Castings shall have no cracks or flaws, and shall be inspected for such before anodizing, by using a penetrating dye or by using black-light techniques.

3.2 Plating and Finishing. Those component parts or sub-assemblies formed from other than corrosion resistant materials and located externally shall be finished or plated to resist corrosion. For such parts, there shall be no rough spots, porosity, thin spots, or peeling evident in either the finishing or the plating.

3.3 Fastenings. The unit shall be assembled and fastened so that no fixed part or sub-assembly shall become loose, and no movable part or control be shifted in setting, position, or adjustment under extreme service conditions.

3.4 Effectiveness of Seals. There shall be no fluid leakage perceptible on the hydraulic assembly after any phase of testing under these specifications. (The normal film of fluid found on the piston rod is not to be considered as leakage).

3.5 Sizes

3.5.1 Units shall be furnished, or be adjustable, in the following lengths: When measured from the prosthetic knee axis to the bottom

of the attached, unshod foot, these sizes shall range from 16½ inches to 21½ inches in a maximum of 1 inch steps.

3.5.2 The foot shall be furnished, as specified, in left or right, and for any shoe size ranging from 6 to 13 inclusive. The foot shall be constructed so that when assembled to a unit, that the foot will be in a neutral position of valgus-varus.

3.6 Noise. There shall be no objectionable noise when the unit is tested or when it is being worn.

3.7 Swing Characteristics. The swing characteristic acquired by the unit is a function of the hydraulic resistance of the mechanism. This resistance shall range from a specified minimum to a maximum and shall be manually adjustable by setting the resistance range control. The hydraulic resistance shall be measured by the time it takes for a specified weight to drop through a certain height, when the weight is attached to the unit in the manner described in test 4.7. Using the apparatus specified in this test, the unit shall receive a drop-test at the minimum and at the maximum resistance settings, both in flexion and in extension (4 tests). The four drop-times shall be recorded as an average of at least 3 drops at each setting. There shall be no erratic reading when a drop is repeated within a setting. The weight shall be such as to produce a constant torque on the knee joint of 51.5 inch-pounds ± 0.1 inch-pounds (e.g. 10 lbs. 13.6 oz. for a pulley diameter of 9.5 inches). The height of the drop shall be adjusted so as to produce a knee flexion or extension of 65° ± 2°. Flexion shall be started from the initial position given in 3.9.2. Extension is a return to this initial position. The drop times shall be as follows:

1. Max. setting, flexion 0.7 to 1.2 sec.
2. Min. setting, flexion 0.35 sec. or less
3. Max. setting, extension 0.7 to 1.2 sec.
4. Min. setting, extension 0.35 sec. or greater

The time values shall be recorded on all units.

3.8 Workmanship—The assembly delivered shall be clean, well made, and free from any defects (such as flaws, burrs and rough edges) which may affect its appearance, impair its serviceability, or require preventive maintenance for the duration of the guarantee period stated in the contract. Workmanship and design shall be such that an unconditional guarantee for the stipulated period can be supplied, provided the hydraulic mechanism is not tampered with by the prosthetist or customer.

3.9 Interchangeability—Major component sub-assemblies, which may be considered to be expendable during the life of the unit, shall be manufactured with tolerances to permit easy replacement, as required in the maintenance of the unit, either in a local shop facility or at the manufacturing plant.

3.10 Identification Marking—Each unit shall be permanently marked on a main component with a serial number for identification. Such serial numbers need not be in sequence. The component selected for such marking should be one which will probably not require replacement during the life of the unit.

3.11 Storage Reliability—The units shall be shelf-stored in a horizontal position for at least one month and then reinspected for leakage.

In section 4.2 "Quality Assurance Provisions," procedures concerning sampling and inspection are given, test methods are described, and tests are differentiated (as between qualification tests and acceptance tests). Sam-

pling is an important factor in determining compliance with requirements. Sampling should be made on a rational basis so as to attain the greatest economy consistent with the required assurance of quality. Details of sampling will vary with the commodity. In complex mechanisms each unit is usually examined. Simple items, like stump socks, are sampled in random lots drawn from each shipment.

Descriptions of tests and methods of analyses shall appear in this section to insure that they will be properly conducted. Other information, such as description of testing apparatus shall also appear.

Example

4. Quality Assurance Provisions

4.1 Unless otherwise specified herein, the supplier is responsible for the performance of all inspection requirements prior to submission for Government inspection and acceptance. Except as otherwise specified, the supplier may utilize his own facilities or any commercial laboratory acceptable to the Government. Inspection records of the examinations and test shall be kept complete and available to the Government as specified in the contract or order.

4.2 Mechanical Inspection—Preliminary to performing the subsequent tests, each system shall be given a thorough visual and mechanical inspection to determine conformity with:

(1) the drawings listed under 2.1

(2) requirements 3.1, 3.2, 3.3, 3.5, 3.6, 3.8 and 3.10

4.3 Tests—Before performing the following tests, a) check hydraulic fluid level as per 5.1, b) hand cycle the unit through full extension and compression for a minimum of ten (10) cycles.

4.4 Alignment Check—Extend the knee fully. Invert the unit and set it with the knee casting resting on a horizontal plate. With a level and a plumb line check the requirements of 3.9.2. If not in the initial position as defined, make necessary adjustments until the requirements are met.

4.5 Manual Foot Flexion Control—With the unit in the initial position, check the requirement of 3.9.3 with the manual control knob, using a protractor to measure the angles.

4.6 Coordinated Knee-Ankle Flexion Ratio Test—Set the unit to the initial position. Flex the knee to 60 degrees and measure the dorsiflexion of the ankle with a protractor. Check conformity with the requirement 3.8.2.

4.7 Hydraulic Resistance Test—The hydraulic resistance of the mechanism shall be tested on the apparatus shown in Fig. 7. The unit shall be mounted as shown, and the weight specified in 3.7 shall be attached to the cable around the pulley. The procedure of 3.7 shall be followed.

4.8 Leakage and Flaws—Check for fluid leakage, adequacy of welds, existence of cracks and flaws in frame and all castings by using one of the techniques listed in 3.1.2. Requirements 3.1.2 and 3.4 to hold. This check shall be repeated after one month's storage for requirement 3.11.

4.9 Reports of Test—Tabulated results of the test data shall be recorded for each unit, showing quantitative results for all tests required by this specification.

The section "Preparation for Delivery" covers the applicable requirements for preservation, packaging, packing, and marking of packages and containers.

Example

5. Preparation for Delivery

5.1 Fluid Level—When delivered to the standards Laboratory or to the ultimate user, the unit shall be filled with the correct amount of hydraulic fluid as required for operation. When checked with a calibrated dip-stick, the level shall fall within the band marked thereon.

5.2 Alignment—The unit shall be delivered aligned to the initial position as defined in 3.9.2.

5.3 Wrapping—Units shall be wrapped in a dust-proof bag.

5.4 Shipping Container—Each unit shall be packaged and shipped in a carton secured to prevent accidental opening. Packing shall be accomplished in such a manner as to prevent marking or scratching of the unit. The carton shall contain sufficient cushioning material, corrugated liners, die cut pads, air cells, or other suitable material to prevent shifting or breakage of the unit.

Under "Notes," information of a general or explanatory nature is given. No requirements appear herein. This section contains information designed to assist in determining the applicability of the specification and in the selection of the appropriate type, grade, or class of commodity. Included are the following:

Intended use
Ordering data
Standard samples
Qualification (where required)
Suggested features to be included in the contract.
Miscellaneous notes

Example

6. Notes

6.1 Intended Use—These hydraulic units are intended for use by above-knee amputees to replace, to a limited extent, the functions of the knee and the ankle.

6.2 Ordering Data—Procurement documents should specify:

(a) Title, number and date of this specification

(b) Size of the unit and accessories and whether right or left.

6.3 Procedure before contract—Initially, and for any subsequent modification of the unit, the manufacturer shall supply two units that he wishes qualified. These units shall be submitted to the Standards Laboratory for qualification under these specifications. With the units submitted, there shall be included (1) a set of any special tools required for installation and maintenance of the units, (2) a general assembly drawing showing major sub-assemblies and the dimensions critical to installation in a prosthesis, (3) a schematic drawing showing principles of function with (a) a detailed description of the operational (functional) sequence of designed-in characteristics for one complete cycle, and (b) the accepted variation or tolerance range for the functional characteristics in one complete cycle, and (4) necessary instruction manuals for installation, maintenance, and use. The initial units and associated materials described in this paragraph when approved by the Standards Laboratory and agreed on by the manufacturer, will constitute Standards to be used for future compliance testing under these specifications.

6.4 Approval of Model—If and when approved under these specifications, the initial units shall be appropriately labeled. One unit will be retained by the Standards Laboratory as a Standard and the other re-

turned to the manufacturer to be used by him as a manufacturing reference.

6.5 Approval of units. Approval or disapproval shall be determined by the Standards Laboratory according to the maximum defect score allowable.

d. *Modification*—When the draft has been polished and edited, copies are sent to the interested manufacturers or vendors, and to others concerned, for their views and criticisms. Their comments are reviewed to determine the most satisfactory method of revision. If need be, a conference of manufacturers is called by VAPC, and the draft is revised and resubmitted for further consideration, the cycle being repeated until all problems have been resolved. It must be stressed that liaison between VAPC and the manufacturers is important to "iron out" all possible defects to develop a meaningful specification. The most effective form of cooperation exists where communications are kept straightforward and open between the Government and suppliers. VAPC must also be alert to feedback from VA clinics and other users because the most carefully worked-out specification is useless if the product does not satisfy the wearer.

e. *Acceptance*—The draft is finally adjusted to secure widest concurrence, and a tentative specification is issued, effective as of a certain date.

Why tentative? Although the draft has been worked out as carefully as possible, there is still no assurance that all the requirements are realistic, or even that all the requirements have been incorporated. After the first shipments have come in and the items have been gradually distributed, feedback is constantly coming back from the field. After a trial period of about 1 year, some changes will probably have to be made to the specification. The revised specification may be still tentative, or, if proven satisfactory, will be hopefully issued as the final version. New technologies, new concepts, changes in other ways may warrant the revision or amendment of a specification. Periodic review is, therefore, necessary to keep a specification from becoming obsolete. Of course, revisions are not made without a thorough investigation and the consent of all concerned.

Compliance Testing

After the specification of an item is put into effect, each manufacturer who wishes to be considered as a supplier to the VA or to the industry which serves VA beneficiaries, must submit production samples of his product for qualification testing to ascertain that the product complies with all requirements. Qualification tests are more severe and exhaustive than acceptance tests, which consist mostly of routine inspections and non-destructive tests. Qualification tests include all the acceptance tests, and in addition, the samples are subjected to endurance tests on accelerated testing machines, wear tests, strength tests, etc.; the samples may be tested for shrinkage, corrosion resistance, fungus resistance, water absorption, or whatever is stated as required. If a failure occurs, or a requirement is not met, the manufacturer is so notified. If he still wishes to qualify, he must submit improved samples, usually before a given deadline.

VAPC also uses sampling plans which depend on the kind of item, the quantities involved, and the character of the tests. Uusally a certain percentage is selected at random from each lot. If the item is complex, each unit may have to be checked. The samples are then submitted to the Testing and Development Laboratory for compliance testing, another term for specification checks or acceptance tests.

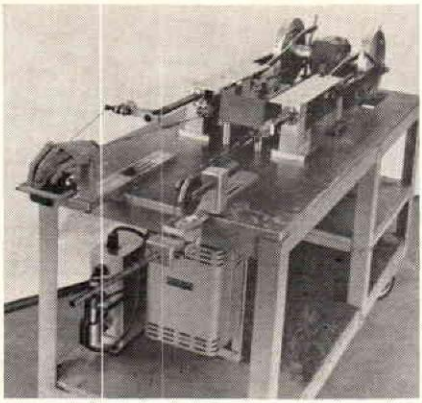

Figure 3. Two-station cycling machine originally designed by APRL.

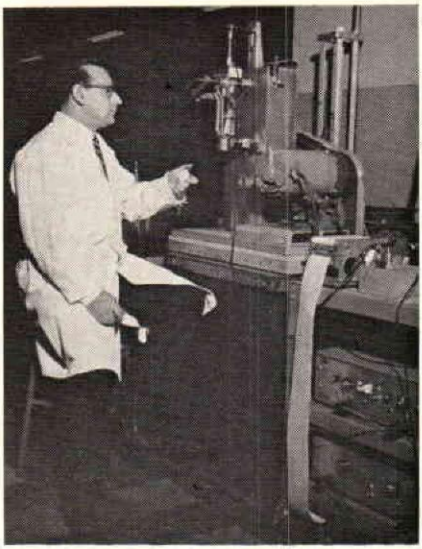

Figure 5. University of California knee testing machine

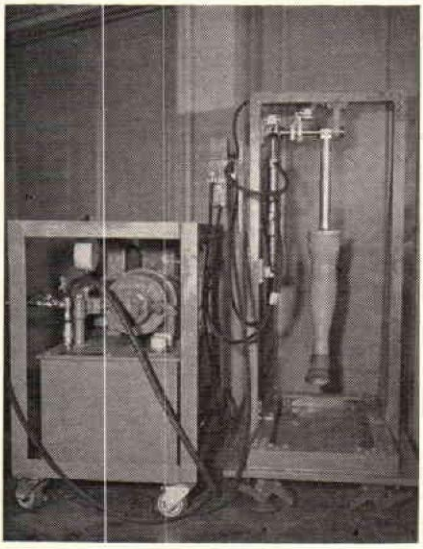

Figure 4. Dynamic knee tester.

As pointed out before, section 4 of the specifications explains all the test procedures and any *special* test apparatus needed. Most test and measuring equipment are standard and can be bought from many sources. Such equipment would include precision gages, precision weighing scales, force gages, all kinds of transducers, such as strain gages and accelerometers, universal testing machines for tension and compression testing (one is shown in Fig. 1), hardness testers, abrasion testers, and many others. Most transducers require electronic gear to amplify their signals and to record the results, usually on tape.

But often special apparatus is needed which cannot be purchased. It must then be designed and built. The Laboratory has a number of special purpose test machines. Fig. 3 shows a two-station cycling machine which is electronically controlled for variable speed. Shown mounted on this machine, originally designed by the Army Prosthetics Research Laboratory, is a prosthetic hand and an internal elbow, both being cycled simultaneously. The hydraulic test stand shown in Fig. 1 was built to check the static pressure of hydraulic knee units. It can accommodate 6 units at one time. The stand can also be used as a hydraulic power source for dynamic applications.

Fig. 4 shows a dynamic knee tester. The unit on the left is a hydraulic motor-pump. On the frame to the right, a knee system is set up for dynamic testing. With a programmed input to the stump, represented by the vertical tube, the prosthesis will be tested for swing reactions such as the angular acceleration of the shank. The electronic gear is not shown. The recorded result will be compared to an accepted standard knee characteristic curve.

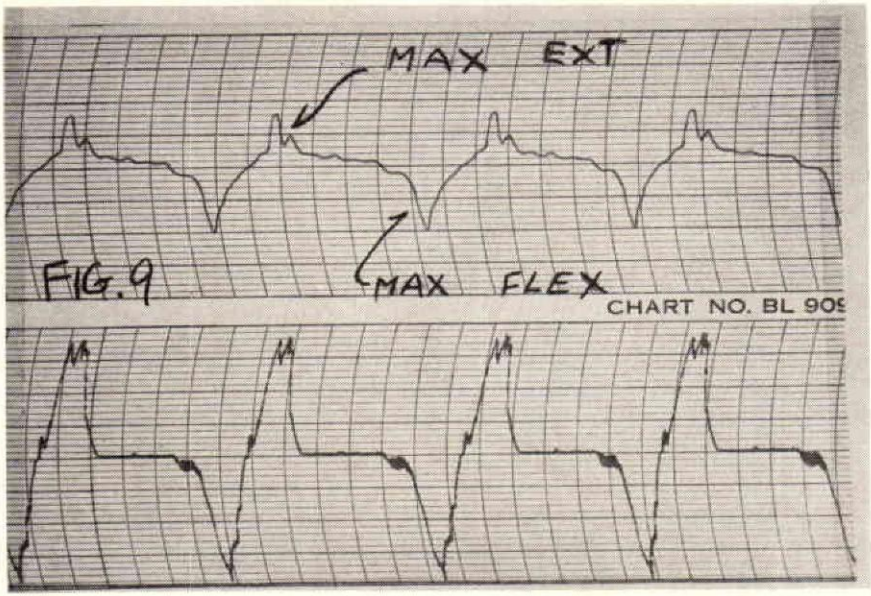

Figure 6. Force and velocity recordings from University of California knee testing machine.

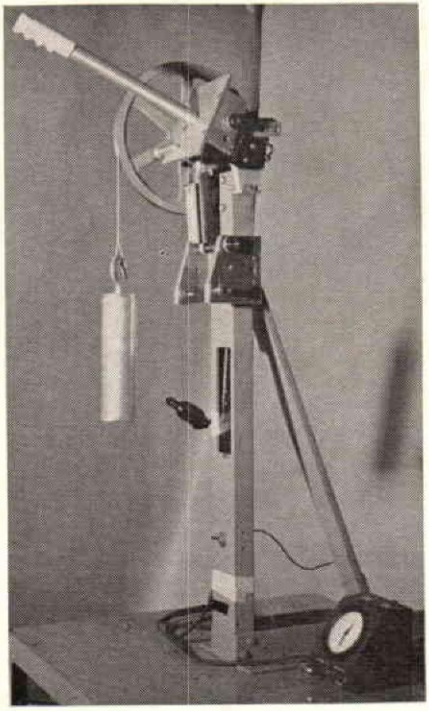

Figure 7. Drop tester.

Another dynamic cycling machine is shown in Fig. 5. This is an oscillating cycler for flexing and extending knee units with a forced input. Built by the University of California Biomechanics Laboratory, it has a strain gage element which measures the resistance of the unit to the flexing and extending forces. The amplifiers are in the lower compartments, and the oscillograph (with the paper tape output) is on top of the table. As most knee units have resistance adjustability, this machine is useful for checking resistance ranges particularly at different speeds and also for comparing the characteristics of different systems. Sample curves are shown in Fig. 6. The lower curve is that of input velocity and the upper curve is the corresponding resistance force measured in the rod producing flexion and extension.

A constant torque resistance test apparatus or drop tester used quite commonly for acceptance tests of hydraulic units is shown in Fig. 7. This unit was mentioned in the specification example given above.

Quality Control

Competition has been the way of life in our country ever since its inception—we seem to thrive by it. The system rewards that enterprise which can make its product a little better or market the same thing at a little lower price than its competitors. The secret of success can usually be summed up in two words: "quality control."

Quality control is a modern industrial concept which requires that every product be checked against established standards to make sure that nothing defective reaches the consumer. This concept also applies to the artificial limb industry as well as to other businesses. With a new product, where competition is absent, the VA sees to it that a standard of quality is established. The VAPC then acts like a quality observer to see that products abide by standards and prevents a shoddy product from reaching any disabled person.

Any supplier or manufacturer who neglects to practice quality control will eventually fall by the wayside. The things which will cause him to lose out may at first seem inconsequential to him—skimping on the thread count in stump socks . . . knee joints that are poorly assembled . . . a leak that develops in a hydraulic system . . . inferior workmanship in a SACH Foot . . . sloppy fits in a device . . . limb shop fitters who do their second best . . . substituting an inferior material because it is cheaper.

American orthotists and prosthetists and their suppliers have potentially the experience, competence, and ingenuity to do any job a little better than it is done now. This is a time when quality matters more than ever before, world conditions being as they are. The function of the Veterans Administration is to help the American industry along this path and to see to it that the words "Approved by the Veterans Administration" will always be a symbol of excellence and worth.

REFERENCES

1. "Industrial Specifications."—E. H. Mac Niece, John Wiley & Sons, N.Y.
2. "Standardization Activities in the United States"—A Descriptive Directory.—U. S. Department of Commerce, National Bureau of Standards.