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British Standard (BS) 5750 – quality assurance?

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Abstract

BS5750 is the British Standard on "Quality Systems". Its equivalent in European Standards is EN29000 and in the International Standards Organisation ISO9000. This paper points out that these standards lay down formalised procedures and require documentation but do not *ipso facto* lead to quality assurance.

The author points to the Japanese post-war industrial success as being an example of Total Quality Management within the framework provided by the philosophy of Dr. W. Edwards Deming (1988 and 1993). This philosophy on the management of "systems" to provide high quality products and services is briefly outlined.

The author argues that improvement in prosthetic and orthotic services will not be reached through implementation of BS5750 but rather through radical rethinking and the adoption and application of the Deming philosophy.

Introduction

BS5750 has been promoted in the United Kingdom in parallel with its European (EN29000) and International (ISO9000) counterparts as a means of ensuring quality of products or services. The National Health Service, purchasing section has insisted that all orthotic and prosthetic companies trading in the UK must satisfy BS5750 or its equivalent, The standard has also found a place within the new European Medical Devices Directive (93/42/EEC) as forming part of the conformity procedure. This has placed a considerable bureaucratic and administrative burden on companies, many of which are small, but the actual benefit of this certification as a means of *ensuring* quality is, at the very least, questionable. This is not to say that the process gone through to attain BS5750 has not been of value to some orthotic and prosthetic companies. Many of these are small and had few formalised procedures; although this was found in larger companies as well. The process of formalising and documenting meant that the processes within the company were examined and perhaps altered which gave some semblance of improved quality by tighter control of procedures (this should have been carried out regardless of the need for BS5750, but was lacking generally in the orthotic and prosthetic industry). However, this article will detail where BS5750 fails in its objective of guaranteeing high quality services or products and will outline the preferred process whereby high quality is both *assured* and *improved*.

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The problem with BS5750

The main tenet of BS5750 is that by writing down, and adhering to, set procedures a high quality product or service will be produced. This unfortunately does *not* ensure quality, only repeatability and conformity to a standard. What is more, the standard is set by the host company or institution at a level of its choice. Rarely will anybody set a target or level that is unattainable as it would immediately invalidate their certification, so they set ones which are attainable. Having set these targets they are just required to reach them to maintain their certification which does not ensure anything other than the company or institution has met an attainable target yet again. To prove to the auditors that this level has been attained and

non-adherence has been rectified, a vast amount of documentation is produced which again does nothing to ensure a high quality product or service. It is just part of the audit trail required as part of the certification process.

There was a need within the industry for more formalised inspection of products and services which had a beneficial effect on the quality of the product or service but the dependence of a quality assurance system on mass inspection as the main process will not work. There is a commonly held belief that to have a high quality product or service requires lots of inspection. This however slows down the process, which reduces the profits and could, in the extreme, lead to cessation of trading. This is not the case if a proper Quality Assurance (QA) system is used, as improved quality will lead to a reduction in waste of materials, time spent on re-doing jobs, time spent correcting the "process" and management time. A sound QA system will lead to higher quality, lower unit costs and higher effective capacity (for all parts of the system including manufacture, ordering, sales, administration and management). In other words proper Total Quality Management (TQM). This aims to treat the whole of the company (or office or department) as one system and manage its processes with one common aim in mind; customer satisfaction. By adopting this attitude the whole system can be managed efficiently and with improving quality.

TQM, the alternative

These do sound like rather grand claims but all of these, and more, have been proved to be true if this fundamental change in the way in which the whole system (company, workshop, hospital, etc.) is viewed is adopted. To explain this, the background to a major international success story needs to be outlined as it sets the scene for the rest of this article. Just after World War II the Japanese industrial "machine" was devastated. As they needed to get back into effective production quickly a method was sought that would provide this. However, with great foresight they chose not to copy their old ways but to look for another system which would *ensure* that their output would be of such high quality that their products would be purchased in preference to those from more established companies and countries. In the 1940's and 50's they employed the services of Dr. W. Edwards Deming, a statistician by training. However, it was not mainly for his statistical prowess that they employed him but for his philosophy on the way to manage a "system" so that a high quality product or service would result. This management system is so designed that it involves everybody in the company or institution in working together towards a high quality product or service. This may sound naive but it works because people work *in* the system and with their help management works *on* the system to improve it continuously. Although some procedural systems, such as parts of BS5750, may form part of TQM, an emphasis on people rather than systems and procedures forms one of TQM's key features and distinguishes it from more restricted approaches to quality management which concentrate on a rigorous adherence to procedures.

The success of the Deming approach is there for everybody to see. Japan has made an enviable reputation for itself and one has to ask the question, "what have the Japanese got that others haven't?" Apart from a different work ethic, the answer is, of course, nothing. They found it easier to accept Deming's approach as it was in line with their attitude to work and the employer. But, by applying the Deming approach *any* company producing any product or service will benefit by a marked and continual improvement in quality, How can this be done? To answer this question some illustrations of the success and use of Deming need to be presented followed by the fourteen basic rules of management set out by Deming.

The train arriving late is now on time! and other stories

There are too many instances where numbers and statistics are manipulated to provide support for a policy or change. This occurs in Government, companies, hospitals, etc. and is so commonplace that we can be unaware of its use. Statistics should be used only to help to monitor and improve an aspect of manufacture or policy. Unfortunately, many people and organisations use statistics like a drunkard uses a lampost – for support rather than illumination. It is felt that rather than tackle the problem the statistics have revealed it is better to alter the way in which the statistics are collected or analysed to produce a false level of implied

quality. An example of this was to be seen in the Daily Mail on 16th July 1987 in which could be read "The train now arriving late is on time". This recounted the story that British Rail had considered trains which arrived within 5 minutes of their timetable schedule to be on time, but now this limit was to be extended to be within 10 minutes! This certainly made the system look better but did nothing to solve the underlying problem of late arrival of trains. In comparison, in Japan the trains are so reliable that a visitor to Japan who asked the ticket inspector to tell her when a certain station had been reached, as she could not read Japanese, was told "Don't worry, just get off the train at 10.46"!

More important than this trivial example is that of Hewlett Packard in the UK who, early in the 1980's had a component quality level (Acceptable Quality Level or AQL) of 1%. This was the worldwide industry norm and meant that, for example, in each moving message display of anything up to 15,000 light emitting diodes (LEDs) about 150 would be defective. To correct this all of the failed LEDS had to be unsoldered and replaced by hand, with the replacement LEDS being subject to the same quality level. This would usually mean a second process of replacement to make the final display work. By 1983, after applying the principles of Deming, the level of component failure had been reduced to 50 parts per million, ppm (1% AQL = 10,000 ppm). This meant that, using the example of the LEDS, the failure rate now represented one failed LED for every 200 moving message displays, with concomitant savings in replacement time and materials etc. However, there has been a reluctance to accept the principles of Deming in the western world due to the inability to readily accept that there is anything wrong. To many of us it is inevitable that some trains will run late instead of all being on time. Many of us accept that mistakes will be made that have to be corrected and we do not understand that developing systems for dealing with these mistakes, handling rework in all activities, not just manufacturing, but also administration and other services is hugely expensive. The first step is to get over the belief that what we are doing is right. The whole approach of management needs to be changed from the *Directive* or *Results Management* to what is called *Process Management.*

A definition of quality is contained in BS4778 as "the totality of features and characteristics of a product or service that bear upon its ability to satisfy stated or implied needs". Defined in this way, the assurance of quality relies upon effective management of all those affairs of an organisation which influence the satisfaction of customer need. This cannot be achieved if the customer is not part of the QA system as customer satisfaction is fundamental to the whole process. Yet how many orthotic/prosthetic companies actually involve their customers in their QA system? This does not mean that companies do not sometimes ask selected customers for their opinion but this is not the kind of total inclusion in the QA system which is envisaged by the Deming approach.

The fourteen fundamental ways (or "Obligations") in which this is brought about are listed below together with a brief outline. This is not a comprehensive list of how to employ Deming's theories but more of an introduction to his philosophy. One aspect of these which is very important is that of training which is considered as the single most important factor in actually improving quality. It is necessary to state that not all of what Deming mentions is new as some of these aspects are well accepted in existing management theory. What was, and still is to many, new is the totality of the approach.

Deming's fourteen points for management

1. Constancy of purpose
   Create constancy of purpose for continual improvement of products and service, allocating resources to provide for long-range needs rather than short term profitability, with a plan to become competitive, to stay in business and to provide jobs.
2. Implement the new philosophy
   Adopt the new philosophy. We are in a new economic age, created in Japan. We can no longer live with commonly accepted levels of delays, mistakes, defective materials and defective workmanship.
3. Cease dependence on inspection
   Eliminate the need for *mass* inspection as a way to achieve high quality by building quality into the product in the first place.

4. End lowest-tender contracts
   End the practice of awarding business solely on the basis of price tag. Instead require meaningful measures of quality along with the price; price has *no* meaning without a measure of the quality being purchased.
5. Constantly improve the system
   Improve constantly the system of planning, production and service, to avoid problems, to improve quality and productivity and thus constantly decrease cost.
6. Institute training on the job
   Institute modern methods of training, and retraining on the job for all, including management, to make better use of every employee.
7. Institute leadership
   Adopt and institute leadership aimed at helping people to do a better job. The responsibility of managers and supervisors must be changed from sheer numbers to quality. Improvement of quality will automatically improve productivity.
8. Drive out fear
   Encourage effective two-way communication and other means to drive out fear throughout the organisation so that everybody may work effectively and more productively for the company.
9. Break down barriers
   Break down barriers between departments and staff areas. People in different areas such as Research, Sales, Administration, etc. must work in teams to tackle and prevent problems that may be encountered with products or service.
10. Eliminate exhortations
    Eliminate the use of slogans, posters and exhortations for the workforce demanding zero defects and new levels of productivity, without providing methods. Such exhortations only create adversarial relationships; the bulk of the causes of low quality and low productivity belong to the *system*, and thus lie beyond the power of the workforce.
11. Eliminate arbitrary numerical targets
    Eliminate work standards that prescribe arbitrary numerical quotas for the workforce and numerical goals for people in management. Substitute aids and helpful leadership in order to achieve continual improvement of quality and productivity.
12. Permit pride of workmanship
    Remove the barriers that rob workers of their right to pride of workmanship. This implies the removal of the annual merit ranking (or performance appraisal) and of Management by Objective. The responsibility of managers, supervisors, etc. must be changed from sheer numbers to quality.
13. Encourage education
    Encourage education and self-improvement in everyone. People require, in their careers, more than just money; they need ever-broadening opportunities to add something to society, materially and otherwise.
14. Top management's commitment
    Clearly define top management's permanent commitment to ever-improving quality and productivity and their obligation to implement all of these principles.

Many of these points may read initially as idealistic and incapable of implementation. This is wrong as many companies outside Japan have now found to their great benefit. This is not a Japanese system but a system devised by an American and first implemented in a meaningful way in Japan. It can and does work and is encapsulated in Deming's "Chain Reaction" (Fig. 1).

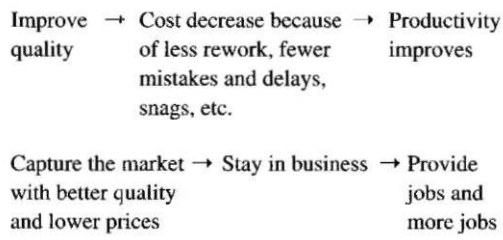


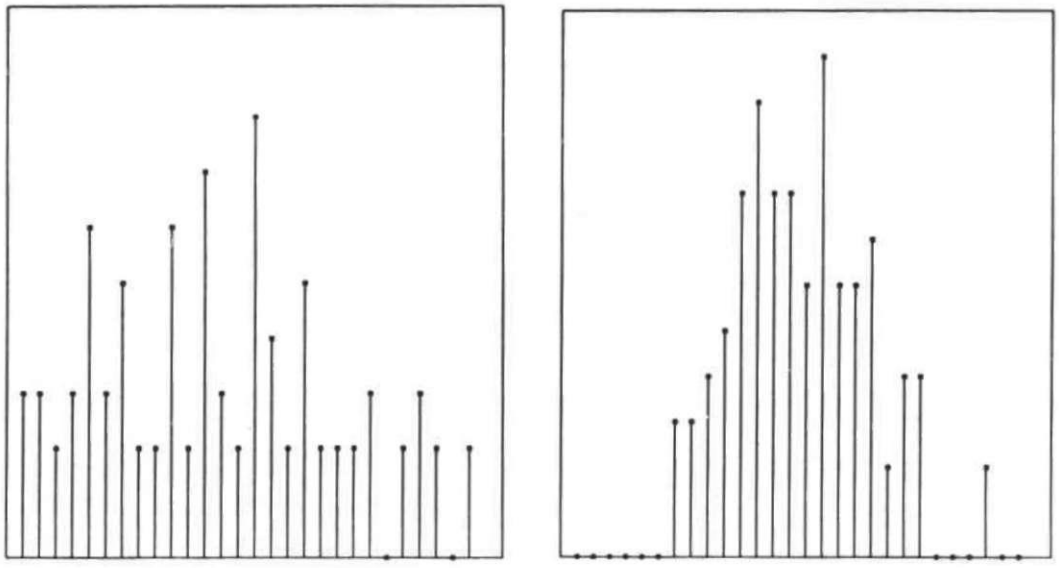
Fig. 1. Deming's "Chain Reaction"

To make the best use of the Deming points for management the use of Statistical Process Control (SPC) is vital. However, the blind use of statistics has already been shown to be useless. What is required is the targetted use of SPC to aid the Deming philosophy. Shewart (1986) was the first to recognise this and the combined value of Deming and Shewart is well

illustrated by the experience of many companies. Fundamental to the use of SPC is the understanding of variation. No two products or service elements will be exactly alike because any process contains sources of variability. The source of the variability is either common cause or special cause. The former of these is generally outside the specific control of the system but special cause variations are controllable. The monitoring of this variation and its time history with Control Charts will provide the necessary information to allow the system to be adjusted, when appropriate, to counter those effects which can be controlled and not to waste time trying to correct common cause variations. Without the proper use of Control Charts there is no way that the two causes of variation can be differentiated. The actual specifics of this are well outside the scope of this paper but are fundamental to effective TQM. However, a useful example of the waste of time, money and personnel on trying to "control" common cause variation can be illustrated by the experience of the Ford Motor Company.

The following is adapted from Scherkenbach (1986) and relates to the effort Ford put in to trying to control the turned diameter of transmission input shafts. They reasoned that if they installed an automatic compensation for the turning machine, when a shaft came out too wide the next one would be made smaller, and vice versa. This they hoped would produce more uniform shaft diameters and hence improve their quality. On the face of it this was a logical approach but it totally failed to recognise that the variation in shaft diameter was generally a common cause variation – due to aspects such as ambient temperature variations, cutting speeds, humidity, exact material properties of the stock metal, etc. There will be small variations in all of these which are essentially uncontrollable by the intervention of adjustment to the final diameters. Figure 2(a) shows the variation in shaft diameters with the automatic compensator in operation. No shaft is outside the limits but there is a random spread of diameters between these limits. Figure 2(b) shows the shaft diameters with the automatic compensator switched off – resulting in reduced variation. How could this be?

The answer is that the production process was already in statistical control. Without the compensation device the process was already exhibiting its lowest variability as only common



(a) (b)

Fig. 2. Shaft diameters
(a) Automatic compensation turned on.
(b) Automatic compensation turned off.

causes were present. Reduction of that variability could only be produced by improvements in the process itself, i.e. more stable temperatures, steadier cutting speeds, etc. The compensation device was not an improvement in the process but is an example of what Deming calls "tampering" with a stable process. The use of Control Charts and related SPC would have shown the lack of need for the compensation device.

This is a brief paper to outline why the path to quality improvement via BS5750 is fundamentally wrong and how a more proven way is via the Deming philosophy. The attitude of most managers, company executives, etc. about this approach, is that "we do not need to change – we are doing this right already". In reply to that kind of statement the following quote from Daniel Boorstin in The Discoverers is of value–

"The greatest obstacle to discovering the shape of the Earth, the oceans and the continents was not ignorance but the illusion of knowledge."

What this is saying is that, with respect to our orthotic/prosthetic products and services in this country, we too have a flat earth mentality. We cannot let go of the things that we believe to be correct. For us, therefore, it seems inevitable that our orthotic/prosthetic workshops will produce some percentage level of scrap and rework and that some devices will not be ready on time. The first step is to get over the belief that what we do is right.

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Editor's note: In July 1994 BS5750 was formally renumbered as BS EN ISO 9000.