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## Qualitative Vs. Quantitative Methods

by Irena Ograjensek and Poul Thyregod

### In 50 Words or Less

- ▶ Statistics, while necessary for quality, are a frequently neglected component of quality management systems.
- ▶ This is not surprising since ISO 9000:1994 mentioned statistics only briefly and didn't link to statistical standards until 1999.
- ▶ The situation has improved with ISO 9000:2000, but organizational, national and international effort is still needed.

The use of statistical methods in certified quality management systems (QMSs) has been a frequently discussed topic ever since the total quality management (TQM) and ISO 9000 certification boom in the '70s and '80s.

By the '90s, many of the experts referenced at the end of this article were noting that statisticians frequently stood aside and watched the quality movement hype or overemphasize the qualitative aspects of quality management.

Although M.T. Czarnecki claimed the quality movement represents an impetus for measurement,<sup>1</sup> it is clear ISO 9000 certified companies focus primarily on TQM's philosophy without really embracing statistical methodology.

Thus, while concepts such as quality circles and W. Edwards Deming's 14 points have been widely accepted and used, statistical aspects of quality management have usually remained the neglected component of QMSs.

There are two reasons for this state of affairs: measurement difficulties and quantitative illiteracy of employees. Of the two problems, quantitative illiteracy is doubtless the more difficult to overcome.

Quantitative literacy includes not only statistical literacy (the ability to select, use and interpret the results of proper statistical methods to solve a problem), but also computer literacy (the ability to use the proper statistical software to solve a given problem) and online literacy (the ability to find and access data and information online).

European examples of problems created by statistical illiteracy abound. Slovenian companies lack personnel with formal statistical training and expertise.<sup>2</sup> An interesting study on the use of statistical methods in Swedish small and medium-sized companies presents clear evidence of poor utilization of statistical quality control in manufacturing.<sup>3</sup>

In his farewell Quality Progress "Statistics Corner" column in 1998, Bert Gunter bluntly said:

ISO-mania is symptomatic of an ever more pervasive decline in the quality profession ... : the retreat from quantitative methodology to soft quality ... [which] emphasizes human relations, personnel organization, communications procedures, meeting conduct and the like.



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I do not wish to dismiss this stuff as useless; some is both necessary and important. However, without the core quantitative disciplines that actually measure and effect real improvement, it ends up being mere fluff and distraction--all form and no substance. ... I believe that the flight from quantitative methodology in general--and statistical methodology in particular--is basically a capitulation. ...

It is a lot easier to send everyone through a class on how to hold better meetings or improve interdepartment communication than it is to learn SPC or experimental design. So by dismissing quantitative methods as inadequate and ineffective, one avoids having to expend that effort.<sup>4</sup>

**FIGURE 1****Clause 4.20 of ISO 9001:1994****4.20 Statistical techniques****4.20.1 Identification of need**

The supplier shall identify the need for statistical techniques required for establishing, controlling and verifying process capability and product characteristics.

**4.20.2 Procedures**

The supplier shall establish and maintain documented procedures to implement and control the application of the statistical techniques identified in 4.20.1.

It is no surprise quantitative methods have not been a priority. Older versions of the ISO 9001 standard address the issue of statistical analysis in just two brief paragraphs (see Figure 1), and the necessary links to international statistical standards weren't published until much later in ISO/TR 10017:1999, *Guidance on Statistical Techniques for ISO 9001:1994*.

**FIGURE 2****Clause 8.1 of ISO 9001:2000****8 Measurement, analysis and improvement****8.1 General**

The organization shall plan and implement the monitoring, measurement, analysis and improvement processes needed:

- a) To demonstrate conformity of the product.
- b) To ensure conformity of the quality management system.
- c) To continually improve the effectiveness of the quality management system.

This shall include the determination of applicable methods, including statistical techniques, and the extent of their use.

In ISO 9001:2000, a more process based structure has been introduced, together with an increased focus on continuous quality improvement and customer orientation. The new version stresses an evidence based approach to decision making and, accordingly, deals with issues of measurement, analysis and improvement in much more detail in its clause 8 (see Figure 2 for the general requirements in 8.1).

Apart from the general requirements provided in 8.1, clause 8 also includes guidelines on measurement of customer satisfaction, internal audits, and monitoring and measurement of both processes and products. The clause also addresses the control of measurement systems, nonconforming products and the issue of data analysis.

Despite the heroic effort to update the ISO/TR 10017:2003 guidance document to align it with ISO 9001:2000 clause by clause and despite an identification of need for quantitative data and appropriate statistical techniques associated with the implementation of the clauses, it is questionable whether this revision of the standard and the guidance document can result in rapid positive changes of attitudes toward the use of the statistical toolbox in companies with ISO 9001 certified QMSs.

Some may not consider this a problem because of awareness that companies whose production vitally depends on statistical trials (the chemical, pharmaceutical and food industries, for example) have not decreased their use of statistical methods.

Overall, however, the neglect of statistical methods at both micro (company) and macro (national and international) economic levels that started during the TQM and ISO 9000 certification boom has continued to this day.

### How To Change Things

This state of affairs needs to change at company, national and international levels. Among the ways at the company level are the following:

- ▶ Professional statisticians should participate in regular audits on the use of statistical methods in quality improvement processes at the company level. It is vitally important they not act as hostile evaluators but instead assume the role of friendly consultants, thus overcoming the employee aversion to the use of statistical methods.  
This idea was implemented by a leading U.S. pharmaceutical giant, and the results were impressive.<sup>5</sup> Friendly consultations can also be implemented in a business to business mentoring scheme, as shown in a report from the United Kingdom.<sup>6</sup>
- ▶ Top management's involvement in the process of integration of statistical methods into the quality system is critical, along with appointment of a statistical coordinator whose primary task is harmonization of statistical activities within a company.<sup>7</sup>
- ▶ Six Sigma, aimed at the near elimination of defects from every product, process and transaction, has found broad acceptance at the company level. Six Sigma is a disciplined quantitative approach for improvement of defined indicators (called metrics) in all types of business processes. Quality improvements are seen as leading to huge cost savings. Initially introduced by Motorola and widely used by giants such as General Electric, the initiative has a broad business character.

Other statistical activities and proposals at the micro level are scarce. Without the micro level initiatives, it is questionable whether significant progress in the use of statistical methods can be achieved at the national and international level.

Nevertheless, following are some possibilities:

- ▶ Quality associations such as the European Organization for Quality (EOQ) and its national counterparts could pay more attention to the use of statistical methods, lessening their focus on standardization alone.  
At its annual congresses in the past, EOQ usually dedicated only a single session to the use of statistical methods in QMSs. While sessions on statistics have recently increased, some of the congress's industrial character has been lost, with attention now shifted to topics such as quality in the service sector, customer satisfaction and customer loyalty.
- ▶ National and international societies and associations of statisticians should promote the use of statistical methods in quality improvement processes. The same could also be claimed for national and international statistical offices and agencies compiling statistical data, although they seem to have

- ▶ other priorities. Paradoxically though, they embraced the TQM philosophy and have been engaged in continuous quality improvement of their internal processes for the last few years.
- ▶ National chambers of commerce and similar organizations should become more involved. But initiatives such as the establishment of company awards for excellent achievements in integration of statistical methods into QMSs and for continuous employee training in proper use of statistical methods seem unrealistic and would probably only add to the already enormous bureaucratic strain on ISO 9001 certified companies. Additionally, in view of some recent studies of organizational learning, it seems clear that unless initiatives to use statistical methods in quality improvement processes originate from within the company, they will never be fully embraced by employees, much less carried out vigorously and energetically.<sup>8</sup>

### **A European Initiative**

Since European statisticians shared responsibility for such a state of affairs, it became vitally important to establish a professional network to connect theoretical and applied statisticians and statistical practitioners. The European Network for Business and Industrial Statistics (ENBIS) was founded in December 2000, and its mission, goals and accomplishments were described in a later article in *Quality Progress*.<sup>9</sup>

Functioning as a web based society, ENBIS connects members who believe statistics are vital for economic and technical development, and consequently, improved competitiveness of European companies.

Pro-ENBIS, the fundraising arm of ENBIS, obtained a grant from the European Commission, and ENBIS recently concluded its successful third annual conference. The conference's primary goal was to share examples of good practice in the use of quantitative methods to solve business and industry problems.

In the future, ENBIS and Pro-ENBIS will continue to support the systematic reaffirmation of the quantitative aspects of quality management by promoting the widespread use of sound and science driven applied statistical methods in European companies.

We believe an ongoing research project across countries and industries should be established to effectively address and evaluate whether the planned systematic reaffirmation of the quantitative aspects of quality management can be more easily achieved in companies with QMSs certified to ISO 9001 than in companies not limited by the standard.

Those interested in learning more about ENBIS and other initiatives to reduce quantitative illiteracy in business and industry are invited to visit [www.enbis.org](http://www.enbis.org).

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