STATISTICAL QUALITY CONTROL PROCEDURES

1. SUMMARY

Taguchi's Robust Design Approach

Taguchi's emphasis on instilling quality at the design stage has been important in a number of situations and deserves careful attention. His specific robust design approach has yielded good results in many instances, but recent studies indicate that more classical designs can serve the same purposes--sometimes, at least, doing so more efficiently, albeit less understandably for the technically unsophisticated. While some details of Taguchi's *method* as practiced in manufacturing may not be applicable in white-collar, public-sector, service-oriented activities, some of the Taguchi *philosophy* might be and might, for example, help to make the design of existing or future data collection, data analysis, and decision-making processes robust with respect to such factors as measurement biases (due, perhaps, to poor calibration or laboratory-to-laboratory variation), highly variable measurements, and missing data. Irrespective of incorporating a formal Taguchi approach, significant benefits can often accrue from improved calibration and sample size calculation, and from the use of better statistical techniques.

Systematic Approaches to Quality in the Planning for, Collection, and Use of Data

A careful, systematic approach to data collection should emphasize the planning steps, particularly a full specification of the problem, and should use teams of people with different skills to design data collection protocols and identify in detail what data are to be collected and how. The EPA's data quality objectives (DQO) process focuses on the earlier stages of this process. It deserves more extensive use, which would be facilitated by communication of the flexibility it can provide, and a clearer understanding of the extent to which it can use pre-existing information of whatever quality that may be available. To exploit a priori information, project managers and other decision makers need to assure that statistically based sampling schemes are used so that the associated sampled-data uncertainties can be quantified by the use of standard methods associated with probability designs. Explicit DQO guidelines can ensure that data collected from the field are of acceptable quality, and pre-set contingency plans can deal with data of unacceptable quality and with missing data. Total quality management principles could be applied by viewing each DQO process step as a subprocess involving customers and suppliers, with guidelines and metrics developed toward improving the performance of each subprocess.

Total Quality Management as a Foundation for Continual Improvement

Total Quality Management (TQM) ideas have been effectively applied in the production of goods and services, although success has been uneven. Applications to white-collar work such as that at EPA have only begun, and finding a model to follow will be difficult. It appears reasonably certain, however, that many of the essentials of TQM, such as driving responsibility downward, emphasis on teamwork, and continuous improvement, can play helpful roles in improving EPA management. Although at least some TQM experts would argue that one cannot apply TQM to some areas of operation and not to others, much improvement can be made in an organization's data collection, analysis, and decision-making activities even without the formal adoption of TQM as the foundation of an organization's overall management system. For instance, one possible TQM step would be to adopt quantitative performance metrics for DQO process implementation. Benchmarking DQO processes to comparable industry or government best practices would be another TQM activity worth study.

2. TAGUCHI'S ROBUST DESIGN APPROACH

This section briefly describes Taguchi's robust design approach (Taguchi, 1986, 1987) as it is currently applied in U.S. industry. A comprehensive review can be found in Kacker (1985); also see the article by Box et al. (1988) and the representative recent discussions of the Taguchi approach's comparative merits in Banks (1993), Condra (1993), Nair et al. (1992), Tsui (1992) Taguchi and Clausing, (1990) and Logothetis and Wynn (1989).

History and Description

The agricultural setting in 1920s England in which Fisher developed his ideas on experimental design (Fisher, 1935) was a nearly perfect one for their application because it satisfied three criteria for experimental trials that make systematic experimentation essential in order to gain useful information at reasonable expense in an acceptable amount of time. These criteria are that the experimental trials be costly, lengthy, and involve many uncontrollable aspects. It is not surprising that methods for the design of experiments should readily and beneficially translate to manufacturing and industrial engineering, since the same three criteria also apply there.

In the 1930s, investigators such as Tippett (1935) and Daniels (1938) realized the importance of using Fisher's ideas of design of experiments to improve quality and productivity in the cotton and woolen industries. In the 1940s, 1950s, and 1960s, other statisticians followed up with important research for applications in the chemical industry; an example is the response surface methodology (see, for instance, Box and Draper, 1987) that was used primarily in the 1960s and 1970s in "process" industries. Design-of-experiments methods were effectively and extensively applied in the chemical industry, but they did not penetrate as deeply into other industries for various reasons.

The now-renowned approach of W. Edwards Deming to improving quality (see, for example, Deming, 1986, 1993; Logothetis and Wynn, 1989; and Persico and McLean, 1994), which emphasizes "ceasing dependence on inspection to achieve quality," and "eliminating the need for mass inspection by building quality into the product in the first place," redirected attention from post-production performance testing to in-production continuous statistical process control. The Taguchi approach shifted attention even further "upstream" by emphasizing the design stage.

Prior to the 1980s, robust design in manufacturing was used principally in Japan as implemented by Genichi Taguchi.[1] (The concept of robustness as used here differs from that used in advanced statistical estimation.) In 1949, in order to substantially improve quality despite the severe constraints of little money and time, he began adapting existing design-of-experiments approaches to Japanese manufacturing, as well as incorporating original techniques. He focused on easy-to-learn and easy-to-use methods that could be utilized by all factory engineers, rather than on more advanced and subtle techniques that a theoretician might have deemed more suitable. His success has been attributed to his having taken an approach that both could be and was understood, appreciated, and widely applied in Japanese manufacturing (Nair et al., 1992). Although in retrospect the approach may perhaps not employ universally "proper" techniques, its

[1] Genichi Taguchi, who is now director of the Japan Industrial Technology Institute, has at four different times received the Deming Prize, and in 1989 received from the emperor of Japan MITI's Purple Ribbon Award in recognition for his contributions to Japanese industry.

widespread application in Japan helped produce dramatic improvements over previous Japanese manufacturing practice. However, this direction and the "follow-the-formula" aspects of the Taguchi approach also contributed to controversy when in the 1980s the methods began to attract attention in the United States. That was the period when many major U.S. industries went through a sequence of losing market share to other nations (particularly Japan); realizing that the key to regaining market share is product quality; convincing management to commit to quality and thus to a much wider use of statistical tools to achieve rapid quality improvements in quality; and lastly, regaining some market share as a consequence of becoming committed to improving quality (Tsui, 1992).

Taguchi methods are intended to instill in a company or organization a focus on quality—from the very design of both the product and its production system all the way through the "downstream" post-production use of the product—so that the performance of the products produced is, roughly speaking, consistent, reliable, and insensitive to most variations in the production process as well as to most subsequent adverse operating situations or conditions. That is, the products must entail and exhibit in their performance the characteristic of robustness. Robust design is thus one approach that could be used in an organization's efforts to institute total quality management or continuous quality improvement (see the section "Total Quality Management as a Foundation for Continued Improvement" below).

The overall Taguchi orientation involves defining quality by taking into account the loss that society incurs when quality is poor (that is, by assigning/recognizing a "quality loss function"); taking an active, exploratory approach to experimental design for off-line quality improvement; minimizing variability in production (in contrast to merely satisfying tolerance specifications); and distinguishing between factors that can be controlled, called design, (or control) factors or parameters, and those that cannot, called noise factors. Examples of noise factors include those due to manufacturing imperfections, environmental variation during product use, and component deterioration. The Taguchi philosophy seeks removal of the *effects* of the noise factors rather than the noise factors themselves, since removing noise factors frequently cannot be done or would be cost-prohibitive.

As part of his effort to address off-line quality improvement (Taguchi and Wu, 1980), Taguchi introduced a method called *robust* (or *parameter*) *design* for improving product and manufacturing process performance (Taguchi and Clausing, 1990; Lin et al., 1990; Logothetis and Wynn, 1989). It can be applied to new or existing products or processes.

The robust design approach aims to make product and system performance insensitive to noise factors by minimizing variation from the prescribed target (the desired result) by feeding back to the designer carefully gathered and analyzed information regarding how the product or process performance is affected by control parameters and by noise factors. Noise factors, control parameters, and product or process responses are often interrelated in unknown ways; such interactions among factors are also viewed as noise factors. However, some—or, in computer simulation, all—noise factors may be controllable during experimental trials conducted to study deviations of performance from design targets due to noise factors. Cost-effective controlled experiments run as part of the robust design approach help in identifying which control factor settings best dampen the effects of noise factors and thereby reduce unwanted variations in the desired quality of products and system performance.

The steps to implementing Taguchi's robust design method are (Tsui, 1992) the following:

1. State the problem and objective.
2. Identify responses, control factors, and noise sources.
3. Plan experiments to study how the responses are related to control factors and noise factors.
4. Run the experiments and collect and analyze the data to determine the control parameter settings that lead to improvement of the product performance or process design.

5. Run small experiments to confirm whether or not the control parameter settings obtained in Step 4 actually improve the product performance or process design. If they do contribute to improvement, adopt the new control settings and consider another iteration of Steps 2 to 5 to achieve further improvement.
6. If the control parameter settings do not improve product performance or process design, correct or modify the assumptions and go back to Step 2.

The American Supplier Institute began training U.S. engineers in the use of Taguchi methods in the early 1980s. Such major corporations as AT&T, Ford Motor Company, ITT, and Xerox have applied the ideas and reported significant improvements in product and manufacturing quality (Phadke et al., 1983). Many case studies are presented in the *Proceedings of the Symposia on Taguchi Methods* (American Supplier Institute, 1983-1992). See also Kacker and Shoemaker (1986), who reported a 60 percent reduction in undesirable product and process variation for an electronics-industry setting.

Several characteristics of the Taguchi methods distinguish them from other approaches to improving the quality of products and processes. For instance, what the product or process is delivering is viewed as a "signal" that should be maximally strengthened with respect to the effects of external (uncontrollable) noise factors, while internal (controllable) noise variables should be minimized. Thus the Taguchi methods focus on defining signal-to-noise ratios and maximizing them. With regard to selecting a set of experimental trials to analyze system or product performance (as an average effect due to changes in component parts or control parameters), the Taguchi approach emphasizes designing experiments through a product of inner (for process or product factors) and outer (for downstream noise factors) orthogonal arrays. The Taguchi approach to robust design characteristically emphasizes achieving consistency (defined as maintaining minimized variances in components) rather than achieving zero-defects. This characteristic reflects the principal that a consistent but off-target system can be adjusted onto target through the analysis of post-production performance data, whereas achievement of zero-defects (that is, falling within an allowed range of variation on specifications) will nonetheless lead to severely degraded post-production performance because of *cumulative* random and geometrically propagating poor interactions between the many "acceptable" deviations from optimal specifications. This emphasis on consistency view is coupled with a characteristic Taguchi belief that reducing post-production performance failures will concurrently reduce the number of defectives arising in production. Thus the above six steps to implementing a robust design approach can be re-expressed as follows (Taguchi and Clausing, 1990):

- Identify the target or objective.
- Identify both the signal and the attendant noise factors.
- Identify a suitably wide, representative assortment of possible settings for design parameters.
- Select a setting yielding the largest signal-to-noise ratio.

Naturally, it is crucial that the last selection be followed by a verification test to determine if the resultant product or system exhibits the desired level of robustness. If further improvement is needed, the verification test data along with additional analyses can be fed back into another iteration of this loop. The key to attaining robustness lies in identifying which factors (be they production inputs, transformations, or external influences) and operating conditions are of primary importance, and which are the uncontrollable factors to which the process must be made insensitive. Identified uncontrollable factors should be prioritized (among themselves), because it may cost too much to make a system robust with respect to all the uncontrollable noise factors.

Comparisons and Possible Statistical Research Opportunities

Taguchi's overall approach and philosophy to quality improvement have often been compared and contrasted with those of others, for example, with Deming's parallel--but technically different--approach to statistical process control (Logothetis and Wynn, 1989). The application of each approach is strongly linked to a (somewhat authoritarian) "package" emphasizing organizational and management philosophy. The relative merits and shortcomings of the statistical methods advocated by Taguchi versus other statistical techniques have been widely discussed (for example, see Banks, 1993; Condra, 1993; Nair et al., 1992; Tsui, 1992; and Lin et al., 1990). A few short examples of comparisons follow. For indications of possible statistical research opportunities, see Nair et al. (1992) and Tsui (1992).

Taguchi methods are sometimes described as being less rigorous than classical statistical methods (Condra, 1993). Further, there are realistic examples of situations where the use of certain Taguchi methods would be inappropriate; further, there are contexts where an approach advocated by Taguchi would be inferior to other known statistical approaches (for instance, in cases where design factors interact). See Nair et al. (1992) for some specific cases. Also, statistical improvements have been developed for various particular Taguchi techniques; Tsui (1992) provides a recent overview.

It has been claimed that Taguchi methods stress functional relationships and are more geared to the realities of engineering than are the stochastic models and "hypothesis testing" methods of traditional statistics (Lin et al., 1990). The Taguchi approach stresses modeling the real process rather than a hypothetical process (that is often the focus of statistics). However, it has also been pointed out that design for robustness has a significant history in statistics, and that a number of other statistical approaches can and have been successfully used for robust design, including some that surpass Taguchi techniques in cost-effectiveness or breadth of applicability (Nair et al., 1992). In a limited number of cases comparing the Taguchi approach with Fisherian experimental design, the Fisherian approach gave better information at lower cost (Welch et al., 1990). Fisherian designs (such as the combined array approach in which design and noise factors are used as a single homogeneous block of factors in a design of resolution at least IV) were often smaller than Taguchi orthogonal product designs while providing estimates of main effects that are clear of two-factor interactions, and permitting diagnosis (in terms of explicit interactions between design and noise factors) of the source of any improvement in signal-to-noise ratio (Welch et al., 1990).

Conclusions Regarding the Taguchi Approach

Reflecting the differences of opinion noted above, some members of the scientific community believe that the statistical methods proposed by Taguchi for implementing robust design are effective and valuable in improving product and process design in manufacturing, while others disdain his methods (Nair et al., 1992). Although some advocates of the Taguchi approach have probably overstated its value at times (as have some advocates of total quality management), even most critics would nevertheless agree that his formulations have been provocative and important (Banks, 1993). Thus far, robust design has been applied extensively only in the manufacturing sector, and it is not clear that a motivation exists outside the traditional manufacturing sector for using the Taguchi idea of variance reduction.

However, although some details of Taguchi's *method* as practiced in manufacturing may not be applicable in white-collar, public-sector, service-oriented activities, some of the Taguchi *philosophy* might be applicable and might, for example, help to make the design of existing or future data collection, data analysis, and decision-making processes robust with respect to such factors as measurement biases (due, for instance, to poor calibration or laboratory-to-laboratory variation), highly variable measurements, and missing data. It has been recognized that the same analytical and experimental techniques that can be used to design robust manufacturing processes can be applied in designing robust measurement procedures (Youden and Steiner, 1975) and robust service and work processes (Snee, 1993). Note, however, that irrespective of incorporating a Taguchi approach, significant benefits can often accrue from improved calibration procedures, improved calculation of what sample size is needed in the face of highly variable measurements, and the development and use of better statistical techniques for either multivariate censored data or cases where data are missing.

3. SYSTEMATIC APPROACHES TO QUALITY IN THE PLANNING FOR, COLLECTION, AND USE OF DATA

Many different data collection activities conducted in an organization are aimed at obtaining quality data to support reliable decision making and strategic planning. A systematic approach involving the use of modern statistical methods can greatly improve the quality of such data and thereby of the decisions and plans based on it. A report by the National Research Council's Numerical Data Advisory Board (NRC, 1988) described efforts to help the Environmental Protection Agency establish a sound quality assurance program during the 1980s. The present section discusses one standard systematic approach to field data collection and subsequent data use; it addresses only this setting and should not be assumed to pertain to any other contexts. It closes with some observations, based on visits to a very limited number of EPA sites, on the data quality objectives process developed by the EPA Quality Assurance Management Staff (QAMS).

One Systematic Approach

The importance of a systematic approach has been well demonstrated in various statistical investigations, including sample surveys (for example, Williams, 1978, Chap. 15) and design of experiments (Coleman and Montgomery, 1993). The basic steps in one systematic approach that has wide acceptance include:

1. Problem definition,
2. Planning,
3. Field activities,
4. Analysis, and
5. Reporting the results.

The first part of this section elaborates on the five steps of this approach. The process is then discussed as an expansion on steps 1 and 2.

Problem Definition

A key step in any investigation or study is problem definition. Its aim is to identify objectives, team participants, and the actions and information needed to achieve the objectives. The output of this step dictates all study activities, including the study's scope and direction. Problem definition is an iterative activity in which various hypotheses about the problem statement are proposed, evaluated, and modified.

An important part of this step is identifying a team of experts to participate in the study. A group effort is required because there are many issues or concerns (technical, social, political, financial, time, etc.) to be addressed at an early stage. At a minimum, the team should include the project manager, key technical people such as field and laboratory scientists, a statistician or person with appropriate experience in statistics and data issues, a quality assurance (QA) expert, and experts in other areas involved in the investigation. It is important to have all participants in the decision-making process involved early on in the planning. Many team members can be customers or suppliers of data used in later activities, so that their insight and recommendations can be obtained in advance for improved planning and scheduling.

Planning

After the questions have been specified and potential actions have been outlined, data have to be collected to enable answering those questions and making related decisions. So that appropriate sampling plans for data collection can be selected, the study's spatial and temporal boundaries must be determined. Also, formal decision rules or criteria for action together with appropriate inputs and measurements need to be drawn up.

A full-scale quality assurance/quality control (QA/QC) review should then be conducted. This review should determine measurement error as well as sampling and sub-sampling variability of the sample analysis techniques that will be employed. All aspects of the study—people, equipment, materials, and methods—should be reviewed. Simultaneously, the members of the team and their responsibilities should be specified. A formal work plan for communicating between team members and the individuals involved in field activities should document who, what, when, where, how, and why. It can also guide and help in reporting on the sampling design and sampling protocol implementations. Management and QA staff should review the plan before it is distributed to validate its accuracy and completeness. Contingency plans should also be outlined, since things may not go as planned, and any changes in planned field activities should be documented.

Various sampling designs can be evaluated statistically in terms of the probability of an error for different numbers of samples and laboratory analyses. By using all available information, including costs of sampling and analysis (provided by a cost analyst) and time constraints, various statistical sampling designs (all of which operate within the specified level of uncertainty) can be generated. Computer simulations can also be run to assess the sensitivity of the designs to increasing or decreasing the variability estimates. These runs will yield several candidate designs from which a suitable design can be selected. The selection of the design should be made by a team, optimally by the study project manager, a local manager (if applicable), a laboratory specialist, and a statistician working together.

Field Activities

Not all of the scientists and staff involved in field activities will have been members of the team that carried out the problem definition and planning activities. It is of utmost importance that formal documentation of the plans and procedures for the field activities be distributed to the field personnel who will collect samples. The local manager should have responsibility for assuring that sample collection proceeds as planned, as well as for seeing that collected samples are properly handled, stored, and transferred to the laboratory. Team members should review the organization's standard operating procedures and guidelines for tagging of samples and containers, chain of custody recording procedures, and other quality assurance procedures for field activities. If they are not followed, the samples should be declared invalid and more samples collected.

Quality assurance/quality control oversight of field activities should be on going. If local personnel modify any parts of the planned program (sample locations, etc.), these adjustments should be documented and justified as part of the report on field activities.

Analysis

Where applicable, laboratory analysis or measurements should be conducted on each physical sample. A standard protocol should be designed to assure that laboratory analysis procedures are accurate and consistent over the collection and analysis time period. Data on laboratory performance should be collected, since some of the most meaningful data in the study can be generated from a laboratory operations

QA/QC audit. Laboratory analysis results are the input for statistical data analysis by a statistician or a person with appropriate experience in statistics. The data analysis should be based on knowledge of the laboratory measurement processes.

Samples may arrive at the laboratory in stages and can thus be analyzed in stages. Following data review, the data collection procedure can be adjusted to permit any necessary re-sampling or re-analysis before all field activities at a location are completed, saving significant time and money. This sequential approach can improve understanding of changing local conditions and reveal unforeseen gaps in data.

Before a full-fledged data analysis is pursued, preliminary evaluations of the data should be performed to gain insight into the general descriptive properties of the data. When data samples are missing, many analytical techniques can still be used so long as the number of missing or lost cases is not too large. Some techniques require examination of initial assumptions regarding distributional properties of the data (for example, whether the data are normal or lognormal). An initial analysis can also determine if "outliers" (data that are significantly larger or smaller than the rest of the data) are present. By using histograms, scatter plots, probability plots, and so on, a visual assessment of data properties can be made; see, for example, Chambers et al. (1983). These statistical methods should be dictated by data characteristics. A good basic reference for environmental data is Gilbert (1987). Context specific factors (e.g., seasonal variation in media being sampled, or extreme variability in samples taken) must be considered when a sampling design, and field and laboratory procedures, are developed.

Investigations may yield data that consist of a series of measurements, either in time or space, for each sample collected. Further, each sample unit may have several measured variables yielding "multivariate" data. Modern statistical methods for design of experiments, survey sampling, and statistical quality control should be used to obtain the most helpful available information from multivariate data. Several sources (Cressie, 1991; Davis, 1973; MacLachlan, 1992; Pitard, 1985; Ripley, 1981, and NRC, 1991b) provide good discussions of methods for analyzing spatial data. If the data are amenable to these techniques, much benefit can accrue from incorporating them into statistical investigations.

Reporting the Results

Documents should be prepared as outputs for each of the preceding steps to aid in the overall communication between the various study participants. The final report will be, to a large extent, a compilation of these documents. Any organizational manuals and standard operating procedures outlining information that ought to be in the final study report should be adhered to. Appropriate graphical displays can be very effective for presenting analyses and results. Study results should be prepared in an accurate and timely fashion.

The findings of one study may function as "historical information" for a later study. Hence, every effort must be made to assemble and document all activities and data generated. The report could also contain potentially useful recommendations for successfully implementing future studies. Each study provides an opportunity to learn and improve. Documentation should be prepared to accurately communicate study findings and to successfully guide implementation efforts for other studies. All of the ultimate customers of a study's data and results (including the project manager, study team participants, state and local officials, and the public) must be considered in preparing the final report.

The Data Quality Objectives Process

All data have to meet scientific criteria regarding uncertainty in order to prevent endless challenges by affected parties. The Quality Assurance Management Staff (QAMS) of EPA has developed a systematic approach called the data quality objectives (DQOs) process that is designed to meet this requirement. The DQO process is a total quality management tool that facilitates the planning of data collection, data analysis, and decision making by focusing at the outset on the decision to be made, the decision criteria, and the level of uncertainty that a decision maker is willing to accept. (For related discussions, see NRC (1994), which addresses the analysis and reporting of sources of uncertainty in EPA risk assessments, and provides specific guidance on uncertainty analysis.)

In the previous subsection of this report, one systematic approach to data collection and analysis was discussed. The DQO process is not meant to replace that systematic approach but rather to elaborate on its Step 1 (Problem definition) and, especially, Step 2 (Planning). The DQO process consists of the following seven steps:

1. State the problem to be resolved.
2. Identify the decision to be made.
3. Identify the inputs to the decision.
4. Define the boundaries of the study.
5. Develop a decision rule.
6. Specify limits on the uncertainty.
7. Optimize the design for obtaining data.

The DQO process shares many features with systematic approaches in sample surveys and design of experiments. Issues such as defining the domain of the decision (population of interest), deciding up front on uncertainty constraints, and selecting the best design are common to all survey sampling. The DQO process is of importance in quantifying the level of uncertainty a decision maker is willing to accept in results derived from environmental data and in determining an appropriate balance between the resources available for action and the uncertainty in the data.

Step 1 of the DQO process is Step 1 (Problem definition) of the systematic approach discussed previously. Steps 2 through 7 of the DQO process are various stages of Step 2 (Planning) of the systematic approach. These seven steps (EPA, 1991a; Neptune and Blacker, 1990 and described below).

State the Problem to Be Resolved

A detailed description of the problem, relevant information, limitations, and available resources are identified. The need for and usefulness of new data in addressing the problem are evaluated by the planning team, which includes senior program staff, technical experts, and senior managers.

Identify the Decision to Be Made

A decision that addresses the problem is identified. This step involves sorting through initial ideas on approaches to resolving the problem, clarifying a range of actions that might be taken based on the data, specifying criteria for taking these actions (or specifying how such criteria will be established), and stating how the decision will address the problem to be resolved. The decision maker (most likely the project manager) is encouraged to be involved and provide guidance during this step.

Identify the Inputs to the Decision

A list of variables that can and should be measured is established. Assumptions about variables that may be important but cannot be observed are identified.

Define the Boundaries of the Study

A detailed description of the populations for which the decision will be made (people, objects, portions of media of interest) is given, so that it is clear what belongs in these populations and what the spatial and temporal boundaries of the populations are. If limitations prohibit an entire population of interest from being sampled, then inference should be limited to that part of the population that is measurable, or assumptions that allow inferences about the entire population should be identified.

Develop a Decision Rule

A statement that defines how the data will be summarized and used to make the decision is formulated. The decision rule should be a formal statement that discusses possible scenarios of study results and specifies how the decision will be made under different scenarios.

Specify Limits on the Uncertainty

Limits on the acceptable probability of making an incorrect decision based on the study findings are stated. These limits on uncertainty may sometimes be expressed as acceptable false positive and false negative error rates. The limits should be based on careful consideration of the consequences of incorrect conclusions, including (for example) economic, health, ecological, and political consequences. The decision maker should be an active participant in this step. QAMS has proposed an approach for developing and displaying limits on uncertainty based on a "design performance curve" or "discomfort curve."

Optimize the Design for Obtaining Data

Statistical techniques are used to evaluate various designs for the study. The "best" design for the study is selected from a group of alternative designs, all of which achieve the study goals. Here, "best" means "of lowest cost," with an attempt to take economic, health, ecological, and political costs into account. For example, EPA studies typically involve spatial considerations that might be taken into account in developing efficient sampling designs (Pitard, 1985).

Observations on a Small Sample of Examples of the DQO Process

A very limited series of visits to EPA headquarters and to offices of EPA Regions I and IV were conducted to observe how data quality concepts and total quality management have been integrated in a few EPA activities. The observations during these visits focused on the measurement methodology in use and the management systems then in place to ensure uniform application of best current practices in data quality efforts. This section presents observations based on these few visits and on other available information (for instance, Mathers, 1992; EPA 1988, 1991b; Neptune et al., 1990; and Roy F. Weston, Inc., 1989).

In Region VII, the DQO process has been used in the remedial design/remedial action at the Piazza Road dioxin site (Fairless, 1990; Ryti and Neptune, 1991). In Region IV, the DQO process has been used in two remedial investigations/feasibility studies and one Superfund site assessment. It was observed that the DQO process is sometimes perceived to be 1) of limited applicability, 2) difficult to apply without access to expert statistical help, 3) rigid, and 4) costly. In what follows, possible reasons for those perceptions are discussed and DQO process areas are outlined that might be adjusted to encourage its wider use.

It was observed that the DQO process is sometimes viewed as applicable only to studies involving large sites where a priori information is unavailable or limited. Such views might reflect some participants' assumptions that statistically based sampling plans are restricted to simple random sampling. However, the full scope of statistical sampling schemes encompasses much more than just random sampling. Schemes that take into account a priori knowledge, such as stratified sampling, with probabilities varying from stratum to stratum in the light of prior (possibly informal) knowledge, could be discussed and illustrated as part of the DQO process. To exploit a priori information, rather than using "purposive" or "judgment" sampling, project managers and other decision makers could be made aware that judgment sampling—although convenient—does not allow the associated sampled-data uncertainties to be quantified by the use of standard methods associated with random sampling. To quantify such uncertainties, a statistically based sampling scheme must be used.

It was also observed that the DQO process and "statistically valid samples" are perceived by some to be too costly. Two possible explanations are as follows: first, if users are not quantifying the risks associated with a study, then they do not know the uncertainty and may well be overestimating the degree of confidence associated with their results; second, it may be that information about the study based on subject matter expertise, judgment samples, observational data, and so on is not being incorporated into the DQO process. All parties involved in a study should understand that the scope of the DQO process is broad and that useful information from those sources can be incorporated into the decision making (Fairless, 1990). Given that each study is very expensive, useful information is far too costly to discard. The DQO process framework should be made flexible so as to not rely exclusively on sampled data. It could be further broadened by combining observational data with techniques for modeling and analyzing such data. For instance, see Cox and Piegorsch (1994) and NRC (1992a); also, compare NRC (1991a).

The DQO process may also be viewed as costly because it requires the use of statistical expertise. If the importance of statistical expertise is not widely appreciated, statisticians may be perceived as technical experts who are only needed to produce the right experimental design when, instead, they ought to be involved in a study from the outset. For their part, statisticians need to communicate better with other technical experts and with managers so that the role of statistics is clearly understood and appreciated. Most of the DQO process's guiding principles involve fundamental statistical principles, and so it is important that everyone involved in a data collection activity be aware of these principles.

To avoid it being viewed as rigid or inflexible, the DQO process should be presented as being able to be customized to a given situation. It is not mandatory that every element of a proposed design be followed in detail to the disregard of practical constraints. For example, at a study's outset, it may not always be possible or necessary to quantify in advance its associated uncertainties or errors. The important issue is to know the degree of uncertainty attained by a given study. If necessary,this degree can be quantified after the study has been completed, and the decision maker can be provided with this information at that time. Even in studies where such quantification, based on reasonable assumptions, has been carried out at the outset, additional data or other types of information may become available during the course of the study. Such additional information can and should be incorporated into the final evaluation.

In this admittedly limited series of site visits, it was observed that—despite its name—the DQO process did not appear to emphasize quality of data. Explicit guidelines could be incorporated for ensuring that data collected from the field are of acceptable quality. Contingency plans could also be prepared to deal with data of unacceptable quality and with missing data. Statistical methods used for data analysis should be clearly discussed, especially those that take the contingency plans into account.

Lastly, total quality management principles could be applied by viewing each step of the DQO process as a subprocess with customers and suppliers (see the section on total quality management below). Accordingly, guidelines and metrics could be developed toward improving the performance of each subprocess.

4. TOTAL QUALITY MANAGEMENT AS A FOUNDATION FOR CONTINUAL IMPROVEMENT

While total quality management (TQM) is just one of several current paradigms in modern management (others include "customer awareness," and "company-wide quality improvement"), the widely advertised success of its principles in some U.S. industries and in Japan provides strong motivation to explore its role in white-collar, non-routine, public-sector operations.

In the past few years, a number of books on TQM, many with case study examples, have appeared that point out its applicability to strategic planning (see, for instance, Galgano, 1994; Flood, 1993; Miller, 1993; Sashkin and Kiser, 1993; and Winchell, 1992). It should be noted that TQM is essentially a management approach (that uses well-done statistics where appropriate); an organization that is considering implementing TQM should consult organizational behavior experts to determine the suitability of TQM implementation for that organization. What is presented here is merely a brief overview of the principles and philosophy of TQM (see also the article with discussion Banks, 1993).

TQM originated in the manufacturing industry and, not surprisingly, uses the language of that industry. It should be noted first that the principles of TQM ought not to be blindly assumed to be transferrable without careful consideration; they may not apply in some contexts, and significant adjustments in them may be necessary for other non-manufacturing settings. When TQM is applied in other contexts, some terms need explanation. The TQM term "customer" means a party for whom value is being created. As an example, one might view EPA's customers as including other regulatory and enforcement agencies, lawmakers, industrial and government agencies being encouraged to clean up pollution, and the public in general. A "supplier" is a party that creates value for the producing industry or organization. For instance, EPA's suppliers might be thought of as other government agencies, contractors, consultants, testing laboratories, physicians, medical organizations, and even polluters involved in clean-up activities. However, certain EPA "suppliers" may have quite different relationships with EPA than an industrial supplier would have with a related industrial producer.

For example, many EPA suppliers are not rewarded or compensated by EPA, in contrast to the industrial setting relationship. Also, many of EPA's "suppliers" make information available in a "pool" from which various agencies and actors can draw; this relationship is quite different from the making of parts for an automobile. If products or services flow from A to B, then exactly the same products or services cannot also flow to C. This is not the case with information (unless there are barriers to, say, security or confidentiality). Products and services can "fan in" but not "fan out," while information can do both. Even suppliers supported by EPA to supply information have a different relationship than arises for suppliers of products or services. What impact these differences may have on TQM principles needs to be considered in any EPA effort to apply TQM.

In this section, the principles of TQM are presented, and best current practices and approaches to both setting and implementing TQM goals are discussed.

Principles of Total Quality Management

Total quality management (TQM) is a way of leading and managing an organization with ever-increasing efficiency and effectiveness to meet or exceed the needs of all the organization's customers. TQM involves major elements such as customer focus, process management and continual improvement, supplier partnerships, leadership, and participation by all affected parties. The fundamental principles of TQM are the following:

- Quality is defined by the customers.
- Quality happens through people.
- All work is part of a process.
- Decisions are based on data.
- Suppliers are an integral part of the organization.
- Quality improvement never ends.

In light of the last principle, the label "continuous quality improvement" (CQI) has replaced that of

TQM in some instances (Hogg, 1993). TQM can be applied to any organization that exists to create value for its customers. This includes all types of for-profit, professional, and educational organizations as well as government agencies, including regulatory agencies such as EPA, for example, (NRC, 1992b).

TQM begins with understanding the needs of the customers. These needs are translated back into the work of the organization, that is, the tasks or processes by which the organization creates value for its customers. The processes of the organization are in turn closely aligned and linked with their suppliers, and these suppliers are treated as an integral part of the organization. The entire value-creating chain from supplier to customer is managed and continually improved to be ever more efficient in resource consumption and maximally effective in creating value for customers.

In order to manage and continually improve the capability of an organization to create value for its customers, it is necessary to involve and lead the people of the organization. TQM asks the leaders of the organization to provide direction, empowerment, and support for the people who create value for the customers. Leaders do this by building unity of purpose and a compelling vision to motivate people, by providing clear and consistent communication, and by encouraging action. Leaders also establish shared values and behaviors to define how people work together. Leaders are role models for these values both in their own behavior and in the behavior they recognize and support. And, finally, leaders provide the necessary resources to help people learn and implement the principles and practices of TQM.

It is useful to think of TQM as having two dimensions, horizontal and vertical. The horizontal dimension is concerned with how value is created for customers. This dimension has three components. The first is customer focus. This involves understanding who the customers are, what they need and expect, and how well the organization is meeting those needs. It also involves translating customer needs into product, service, and process requirements so that value-creating tasks can be aligned to meet customer needs. TQM offers many tools and methods for listening to the voice of the customers, including "quality function deployment," which is methodology for cross-functional teams to translate the voice of the customer into product or service requirements.

The second component of the horizontal dimension is process management and continual improvement. A process is a set of interrelated tasks that has specific inputs from suppliers and produces specific outputs for customers. A process can be large and cross-functional or small and located within a single function. A central tenet of TQM is that all processes should have two outputs, value created for customers and information about how the processes can be performed more efficiently and effectively. TQM offers a powerful array of methods and tools for managing and continually improving processes. One of these, the best current practice approach, used by the Navy "Best Manufacturing Practices (BMP) Program," has had considerable success and has been well documented for dozens of its organizational components (see CSC, 1994; BMP, 1993; Navy, 1990, 1989).

The last component of the horizontal dimension of TQM is supplier partnerships; these are ways in which the organization aligns and works with its suppliers to create more value for its customers. Customers make no distinction between an organization and its suppliers. From the customer's viewpoint, all value comes from the organization itself. But a substantial amount of the value that comes from an organization is in fact created by its suppliers. These suppliers are critical to the success of the organization. TQM stresses the need for an organization to build new relationships with its suppliers, relationships based on cooperation, trust, and working toward the common goal of satisfying the organization's customers. Under TQM, suppliers are considered to be an integral part of the organization. The way in which suppliers manage their business becomes important. Organizations should assess the management systems of their suppliers to reduce the need for acceptance testing and inspection of the products and services of the suppliers and to help the suppliers improve. Joint quality improvement efforts with suppliers reduce costs and create new value for the organization's customers. By planning and working closely with their suppliers, organizations gain the benefit not only of the products and services of their suppliers but also of the knowledge and experience of their suppliers.

The vertical dimension of TQM is concerned with how one involves people in the success of the organization. The vertical dimension of TQM in many ways inverts the traditional organizational hierarchy. TQM challenges the leaders of the organization to provide clear purpose, vision, and direction and to translate these into specific goals and actions. Methods such as policy deployment (an organization-wide and customer-focused management approach aimed at planning and executing breakthrough improvements in an organization's performance) provide a systematic approach to accomplishing this. Policy deployment uses a top-down and bottom-up process known as "catchball" (a participative decision-making process based on communication of facts and analysis upward and downward in the organization) to determine organization-wide improvement objectives. Leaders must establish shared values and behaviors to guide the way people work together. These shared values and behaviors need to be reinforced in the reward systems that encourage growth and development of the employees in the organization.

Under TQM, work always has two aspects: "routine" tasks prescribed by the current processes, and work on improving the processes. The challenge to the leaders is to create a culture that recognizes these dual components of work. Leaders need to provide ongoing education and training for everyone in the organization to enable their involvement in continual improvement. Leaders need continually to assess and improve the management system of the organization. Careful thought must be given to what would be the impact of implementing a TQM approach, with the most critical issues being the manner in which a TQM approach is implemented and its relationship to existing procedures.

The PDCA Cycle and the BCP Approach

This section provides additional information on two methodologies, the Plan-Do-Check-Act (PDCA) cycle and the best current practice (BCP) approach, which are useful in implementing TQM.

The PDCA cycle is a standard paradigm for continual improvement in TQM. The PDCA cycle was first formulated by Shewhart in 1939 as a methodology for improvement based on the scientific method (Shewhart, 1986). As a result of having taken or observed various actions and based on some scientific theory of cause and effect, a plan (P) for action may be developed. The next step is to do (D) or execute the plan. Then one checks (C) the results of executing the plan against the results predicted on the basis of the theory with which one started. The final step is to take action (A) both on future plans as well as on the theory with which one started. The power of this methodology lies in the fact that it provides a rational structure in which one may take actions at all levels of an enterprise and also provides the opportunity for learning based on that improvement.

The BCP approach can be an effective means of establishing and implementing goals for improving key processes. A best current practice is one that is as effective and efficient as any comparable method or procedure throughout an industry or type of activity. The process of determining a BCP is called benchmarking. BCPs advance quality by:

- Promoting widespread use of proven successful methods,
- Offering documented methods for process improvement, and
- Reducing mistakes that result from untried methods.

The following are typical steps in developing a best current practice.

1. The process for which the BCP is desired is identified and the scope of the BCP is determined.
2. All customers (including all personnel responsible for implementation) of the BCP are identified.
3. Based on interviews with customers, project reviews, and industry and government standards,

customer requirements are developed.

4. Measures of process efficiency and effectiveness are established for the process for which the BCP is being developed.
5. A cross-organizational team develops a draft BCP using the information acquired in steps 1 to 4.
6. The BCP is implemented in a tailored fashion by each project manager. Support for implementing the BCP includes:
   - BCP guidelines and training, and
   - Consulting support.
7. The BCP is continually improved based on
   - Program reviews,
   - Continual benchmarking of comparable processes in other companies/and agencies, and
   - Feedback from project managers and customers.

Achieving Total Quality Management

TQM starts with the customer. The producing organization should identify its customers and then establish or continue dialogues with all of those customers to clearly understand and document their needs and expectations. The key processes by which work is done must then be oriented toward meeting those needs and expectations. All employees should clearly understand how the work they are doing contributes to satisfying customer needs. Mechanisms should be developed to collect regular feedback from both internal and external customers, and to monitor the alignment of processes with customer needs. Cross-functional teams provide a powerful tool for capturing the customers' voice and translating that voice into process and product requirements.

Most businesses and large producing organization are organized around managing functions rather than managing processes. This creates a strong hierarchical management structure with a lack of clear responsibility for creation of value and delivery of that value to the customer. The results are functional disconnects. Since key processes are almost always cross-functional, a focus on functional management alone greatly hinders the ability to manage and improve processes.

Many process defects have their roots with suppliers or in the linkage between suppliers and the producing organization. Integrating suppliers into the producing organization's management system requires a new paradigm for working with suppliers--one of cooperation, trust, and win-win thinking. The goal is to form long-term, stable partnerships with key suppliers based on total quality principles and the integration of a supplier's knowledge and experience (in addition to its products and services) into the producing organization's activities. In general, individual suppliers should be evaluated to determine which are capable of consistently providing quality products and services at reasonable prices, and more importantly, which are committed to working cooperatively with the producing organization.

One TQM planning approach to improving management systems (Juran, 1989) has eight components:

- Based on a long-term plan, set quality improvement objectives as part of the annual planning cycle.
- Identify methods or projects to achieve the objectives.
- Allocate resources to the plan.
- Provide specific training as required to carry out the plan.
- Define measures of success.

- Monitor the measures over time, intervening when necessary.
- Provide recognition, rewards, and sharing of successes based on the final measures.
- Compare measured results versus objectives used in the next planning cycle. This provides the loop through the PDCA cycle.

A management system based on total quality principles requires a new role for the leadership of the organization. It also requires the involvement of all the organization's employees in satisfying customers and improving processes. Under TQM, the organizational leadership is responsible for creating a shared vision of the importance of statistical planning and quality in the organization's data collection and analysis activities. A well-formulated mission and a consistently deployed vision in this area provide operational guidance and unity of purpose. In order for the mission and vision to be truly shared, and, therefore, motivating and aligning, representatives from all levels of the organization must be involved in developing them. Shared values and behaviors are perhaps the most effective means of improving how people work together throughout an organization. The means by which these values and behaviors are implemented by the leadership must be clear and visible. Rewards, recognition, training, education, and communication all need to be evaluated for consistency with these values and desired behaviors.

TQM relies heavily on the involvement of people and on pushing decision making to the lowest practical level. Active involvement occurs when people working in the key processes of the producing organization view their role as satisfying the needs of their internal and external customers, when middle management views its role as enabling the front-line workers to satisfy their customers, and when senior management views its role as enabling middle management, and thereby front-line workers, to satisfy customer needs with increasing efficiency and effectiveness. However, to achieve positive results from active involvement of all workers and managers, considerable education and training of people are required. While training is often defined as developing the capability of someone to perform a specific task, education is often defined as developing knowledge and understanding. Training, especially context-based training, is needed in basic skills required to perform a specific job, solve problems, or contribute effectively to team performance. Education, on the other hand, is required to communicate and to create understanding of the organization's strategic plans, mission, vision, values, and so on. Education enables everyone to understand where the organization is going, how it will get there, how each as an individual fits into these plans, and why new skills may be needed to carry out these plans effectively. It is a much more extensive endeavor than the traditional one-shot training program. It is also much more effective.

Teamwork is very important in TQM since no single individual has all the knowledge and skills required to solve complex problems. Teamwork does not occur naturally, but requires training and nurturing. There is a wealth of material available on team roles, meeting management, evaluating team effectiveness, and structuring education and training for teams. Cross-functional process management teams are often used to manage key processes that require several types of functional expertise. Teams are an effective means of reducing the "turf barriers" typical of most hierarchical management systems. The producing organization needs to use team structures that best fit its strategic plans and that help accomplish its goals most effectively.

Ideally, an organization should adopt total quality management in all of its operations and in the operations of its contractors. At least some TQM experts would argue that one cannot apply TQM to some areas of operation and not to others. However, practical exigencies might preclude such a comprehensive embracing of TQM throughout an organization. Much improvement can nevertheless be made in most organizational data collection and analysis and decision-making activities by merely employing the concepts and tools of TQM without formally adopting TQM as the foundation of the organizational management system. For instance, one white-collar, non-routine public-sector context to which the concepts of quality management readily apply is that of collecting and using data for decision making and strategic planning.

TQM and the DQO Process

Although any decision-making process involves potential associated errors, some decision makers might prefer to overlook the uncertainties associated with the decision making. However, when those decisions have major impacts and ramifications, they should not be made on an ad hoc basis but instead on the basis of quantifiable information. Decision makers need to assess trade-offs between different types of errors, study potential consequences, and then make a fully informed decision. In a situation where only an unreasonably large allocation of resources could further reduce the uncertainty level, it is better to know what achieving that would cost than not to know it. Quantifying the level of uncertainty is an essential step toward making fully informed decisions.

Based on this very limited number of observations, it appears that the data quality objectives (DQO) process allows quantification of the level of uncertainty and promotes responsible decision making. One possible improvement (in the TQM spirit) would be adopting quantitative performance metrics for DQO process implementation. These might measure, for instance, both resources consumed in acquiring and analyzing data and the accuracy of the decisions made based on those data. Whatever is the focus of such measures should provide sufficient information to guide the continual improvement of the data acquisition and analysis process. A cross-organizational TQM team for the DQO process might consist of, for example, one data acquisition and analysis expert from each region. A possible TQM approach might be for the Quality Assurance Management Staff (QAMS) to function as an information source, facilitator, and catalyst, while actual "ownership" of the DQO process could eventually rest with the project managers who implement it. Indeed, continual improvement of the DQO process might be accomplished by a best current practice approach, that is, by benchmarking comparable industry or government best practices. Problems with sampling, data quality, and data analysis that arise in EPA contexts may have much in common with those of the U.S. Bureau of the Census and, for this reason, the Bureau of the Census might be included in a comparison group for best statistical practices.

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