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Risk Management & Organizational Uncertainty Implications for the Assessment of High Consequence Organizations

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RISK MANAGEMENT & ORGANIZATIONAL UNCERTAINTY IMPLICATIONS FOR THE ASSESSMENT OF HIGH CONSEQUENCE ORGANIZATIONS*

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ABSTRACT

Post hoc analyses have demonstrated clearly that macro-system, organizational processes have played important roles in such major catastrophes as Three Mile Island, Bhopal, Exxon Valdez, Chernobyl, and Piper Alpha. How can managers of such high-consequence organizations as nuclear power plants and nuclear explosives handling facilities be sure that similar macro-system processes are not operating in their plants? To date, macro-system effects have not been integrated into risk assessments. Part of the reason for not using macro-system analyses to assess risk may be the impression that standard organizational measurement tools do not provide hard data that can be managed effectively. In this paper, I argue that organizational dimensions, like those in ISO 9000, can be quantified and integrated into standard risk assessments.

1. PURPOSE

In using "organizational uncertainty" in the title, I refer to the doubt surrounding the measurement of how an organization is actually performing versus how the designers of the organization intend it to run.

In this paper, I develop the argument for incorporating organizational metrics into the measurement of macro system risk. I will look specifically at high-consequence industries such as nuclear weapons and nuclear power.

I will provide evidence that the most appropriate organizational dimensions for assessing system risk are already incorporated into the Code of Federal Regulations (CFRs) dealing with the Department of Energy (DOE). All that needs to be done now is for us to quantify these dimensions, and incorporate them into usable assessment tools.

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2. BACKGROUND

Productivity & Safety

There is consensus in the modern literature that organizational factors directly influence system safety. For example, see Perrow 1983; Presidential Commission 1986; Rasmussen 1990; Pate-Cornell and Bea 1992; Embrey 1992; Modarres et al. 1992; Sagan 1993; Jacobs and Haber 1994; and Davoudian et al. 1994a&b. As one might intuit by taking an historical perspective, the notion that organizational factors can influence human error and accidents is not new. See the two related papers: Pressman 1928 and American Engineering Council 1928.

The latter document is particularly interesting. The purpose of the study was to determine if there was a relationship between production efficiency (productivity) and accidents. It was comprehensive. Almost 14,000 companies and 2.5 million workers were examined. The following is from the Executive Summary:

"A physical accident must be looked at, not as a thing in itself, but as evidence of an inability to harness and control the forces of production. When industrial forces are brought under perfect control there will not only be a maximum of production, but the unexpected, that is accidents, will not happen..." (pg. 9)

The essence of the argument put forward in the previous quote centers on the phrase: "When industrial forces are brought under perfect control..." Unfortunately, what was left undocumented in the paper was how specifically to accomplish "perfect (organizational) control." The authors do hint that when all system activities are optimized, efficiency and safety are maximized. Again, from the Executive Summary:

"...The really significant relationship between safety and efficiency is not a direct relationship at all, but arises out of the fact that both are the result of a third factor, namely, a purposeful, powerful, dynamic and executive organization of the industry...It will be efficient, not through any special quality, but because it is functioning as it was meant to function; it will be safe not primarily because of special precautions, but because safety is a characteristic of an industry that is functioning properly."(p. 9)

Compare this with a quote from Marcus et al. 1990 in their conclusion of the relationship of various performance indicators and safety:

"Nuclear utility representatives argue that good performance using the INPO (Institute for Nuclear Power Plant Operations) overall performance indicators....reflect a well-managed plant with a higher margin of safety." (pg. 150)

What the authors of both of these documents seem to be grappling with is a total systems concept of an industry and its marketplace — and the relationship between safety and productivity. Such notions are clearly what we would call Total Quality Management (TQM).

In its current form, TQM advocates a business ethic different from the classical economics of Adam Smith (1776). See Bennett 1994a & b. In early formulations of capitalism, the sign of efficiency was profit, which was measured in money. The work of the American Engineering Council paralleled the neo-classical capitalism described by Keynes:

"The decadent international but individualistic capitalism in the hands of which we found ourselves after the war is not a success. It is not intelligent. It is not beautiful. It is not just. It is not virtuous. And it doesn't deliver the goods. (1936, emphasis added)

The contemporary, TQM ethic-base mandates that the interests of all stakeholders — owners, workers, and customers — be optimized (Bennett 1994b). Without question, this total systems approach to a marketplace was lacking in the early formulations of capitalism. But, perhaps what still haunts us is the American Engineering Council's phrase (1928), "When industrial forces are brought under perfect control,..." More about this later.

Productivity Metrics & Safety

The public has mandated that the nuclear industry — weapons and power — provide stewardship for the personal and environmental safety of the nation. This is a marketplace of sorts. The profits are nuclear peace and radiological safety. Its customers are the world's people. Its workers are those managing the nuclear stockpiles and power plants.

If we are to believe the American Engineering Council's conclusions concerning productivity and safety, then the nuclear power industry can achieve the public's mandate by simply bringing its "industrial forces under perfect control."

What tools do we have to achieve this? Well, first of all, we would need to operationally define what we mean by "perfect control." In doing so, we would develop the appropriate dimensions and metrics. In latter sections, I will present an approach for doing this. But, first, I will examine what attempts the Nuclear Regulatory Commission (NRC) has made in related areas.

Since the 1970's, the nuclear industry has relied on Probabalistic Risk Assessments (PRAs), sometimes called Probabalistic Safety Assessments, to assess hazards in nuclear power plants. See NUREG/CR-2300, PRA Procedures Guide 1983. The NRC has also examined various performance indicators for "trending the safety-related performance" of nuclear power plants (NUREG/CR-5241 1988; NUREG/CR-5568 1990). These later studies have been conducted under the premise that certain characteristics of management and organizational behaviors are associated with conditions under which plant accidents or incidents become more or less likely.

Some of the programs have met with more or less success. Others are still ongoing, but faced with problems. For example, there is a question of whether or not organizational influences on human error are captured in a PRA (Bley et al. 1992). All we know at this point is that organizational factors are not modeled explicitly in a PRA.

Despite such PRA shortcomings, the NRC is making a genuine effort to understand the effects, if any, of organizational influences on nuclear power plant system safety (Marcus et al. 1990; Haber et al. 1991; Jacobs and Haber 1994; and Davoudian et al. 1994a&b). The core of most of these analyses (except, as noted earlier, Marcus 1990) is based on the sociological theory of organizations developed by Mintzberg (Mintzberg 1979; Miller and Friesen 1984). The taxonomy of organizational factors reported in the NRC reports include: administrative knowledge, culture, decision making, and human resource allocation (Jacobs and Haber 1994).

These NRC efforts currently focus on measuring power plant organizational factors using the "Mintzberg-based," sociological metrics described above. Such organizational measurements are then used to influence PRAs. Future NRC work appears to be directed at correlating variations in these metrics (organizational performance) with changes in risk.

My contention is that the vendors of nuclear power should be interested not just in organizational performance, but total system performance, that is, productivity. The 1928 study by the American Council of Engineers did not correlate safety with organizational performance, but with production and efficiency. That is, they believed that unless they understood how the whole system was operating, then the exercise was fruitless.

What the American Engineering Council may not have realized, and certainly did not point out, is that at each level of safety, there was variability in terms of productivity. That is, some industries, with high levels of safety, may or may not be characterized by high levels of productivity (though on the average they were). The implication is that productivity alone does not explain all the variability in safety. That is, safety and productivity may be related causally, but that is only part of the reason why productivity is naturally related to safety. The American Engineering Council did not pursue this point.

If we assume organizational factors influence (or, at least correlate with) production, efficiency, and safety, then the NRC needs to develop metrics of the total output of the system. Simply put, if the NRC's intent is to optimize the interests of all stakeholders, the efficiency of each plant needs to be measured — and then correlated with risk or safety. If there are no measures of industrial productivity, then there will be no metrics to establish whether optimization is being approached. (Again, what I mean by optimization is that the interests of all the stakeholders in the nuclear industry — the public, the managers, and the workers — are treated equally.) To accomplish this, the focus should not be on organizational influences alone, but the development of metrics that reflect the quality of the whole system. At this point we will then be able to realize the American Engineering Council's vision of bringing "industrial forces under perfect control."

Purpose

During the course of this paper, I will discuss some of the basic aspects of technical and organizational uncertainty. Second, I will briefly review the characteristics of a High Reliability Organization. Third, I will analytically incorporate internationally recognized metrics of industrial performance into the metrics of High Reliability Organizations.

3. TECHNICAL UNCERTAINTY

Before I look at the measurement of organizational uncertainty, I believe it's important to look at how we measure technical uncertainty in general. If we can appreciate the problems in assessing doubt with such concepts as the physical constants, we may be able to better understand how to go about measuring organizations.

History of Uncertainty

Throughout this century, authors have documented the hazards with which we surround ourselves (American Engineering Council 1928; Pressman 1928; Herring 1989; and Schlager 1994). These selected compendia capture the failures in our science and technology— from the mundane to the catastrophic.

We assume, of course, that failures in technology were not intentional. Given this, I pose the question: What a priori certainty existed — in the minds of the designers and managers — that technology would not fail us? Surely, developers must have gone about some process to reduce the frequency and consequences of their system's failing.

In many cases, historians and analysts have in fact documented how scientists and policy makers dealt with certainty in technical knowledge. (For reasons of logic, it is uncertainty, rather than certainty, which must be analyzed. Throughout this paper, I will be dealing with uncertainty and failure rather than certainty and success.)

Academicians have written a number of excellent papers and books about technical uncertainty and the role it plays in policy analysis. See, for example, Morgan Henrion and Morris 1981; Clark 1984; Funtowicz and Ravetz 1984; Morgan, Morris, Henrion, Amaral, Rish 1984; Perrow 1984; Roberts 1990; Shrivastava 1992; Sagan 1993; and Shrivastava 1994. Many of the ideas in the following subsections have been synthesized from these authors.

Epistemology of Uncertainty

Before examining what role technical uncertainty plays in management sciences and policy analysis, I believe it is important to examine the fundamental nature of uncertainty. It is in the epistemology (the study of knowledge) of uncertainty that we can appreciate the subjective nature of our physical world — as well as the foundation for the quantification of subjective estimates.

As the aphorism goes, "The only certainty is that nothing is certain (Pliny the Elder, c. 23-79 AD)." However, with the modern age of science, we have become particularly arrogant concerning our knowledge about our physical world. We have even come to the belief that there are such truths as physical constants!

Some of the sciences, like physics and chemistry, have developed a list of concepts — the physical constants — which are said to exist in the physical world, independent of our subjective knowledge about them. See Landolt-Börnstein (1992) for the current list of physical constants.

Setting solipsism aside, the fact that physical constants exist may, or may not, be true. For some scientists, it would be a bitter pill to swallow if they had to acknowledge the impermanence of the physical constants:

"It would be disheartening to any real scientist to feel that an accepted value of any physical constant would never again be changed. The most characteristic feature of science — in general and particular — is its never-ending change. But what one must not overlook is the fact that it is the probable value of any given constant that changes, not its actual value. A belief in any significant variability of the constants of nature is fatal to the spirit of science, as science is now understood." (Birge 1942, pg. 90. Italics added for emphasis.)

It is clear in this quote from Birge's landmark treatise, that there was something heretical about acknowledging that variability exists in natural physical constants. Yet, in the decade following Birge's paper, one of mathematics' most influential statisticians, Sir Ronald A. Fisher, had another view of the problem:

"The obstacle to which I refer is the existence of variability in the natural world. Only one hundred years ago the inhibitory effect of this obstacle can be seen in many writers; for us today the obstacle does not exist. The familiar concept of a frequency distribution ... comes to our minds, and we recognize that by means of this device,... variability may be accurately specified, and its consequences calculated." (Fisher 1959, pg. 21)

Fisher's view of the physical constants probably represents the other extreme from Birge. And, as may be expected, there is a more moderate view which represents a compromise:

"*Strictly speaking, the actual error of a reported value* (of a constant) is usually unknowable. Limits to this error, however, can usually be inferred — with some risk." (Eisenhart 1968, pg. 1201)

This quote by a scientist from what is now the National Institute of Standards and Technology represents an aphilosophical position. Whether or not a physical constant exists should not deter us from going about the business of measuring nature — with some risk. The point is that whether or not physical constants exist in nature, uncertainty does exist about their true values because of the subjective nature of all measurements. That is, whether we are measuring the speed of light or the mass of an electron, some private, subjective experience must be exercised in the measurement process.

What role subjectivity played in creating the variability we observe in nature was not always so clear. In 1927, deBray (as reported by Birge 1942) seriously concluded, based on the historical trend, that c, the speed of light, was linearly decelerating at the rate of some four km/sec/year. At that rate, the speed of light would be zero in 75,000 years! Just a few years later, in 1934, Edmondson (again, as reported by Birge 1942) concluded that deBray's calculation was in error by demonstrating that c was not decreasing, but had a damped, sinusoidal period of approximately forty years.

Having roundly criticized deBray and Edmondson, Birge concludes his discussion of c with what was to be a bit of premature confidence:

"Thus, after a long and, at times, hectic history, the value of *c has at last settled down into a fairly satisfactory* 'steady' state. The same thing can now be said of the other important constants." (Birge 1942, pg. 101)

A mere nine years later, c had again shifted by more than 2.4 standard deviations of Birge's estimate of uncertainty (Eisenhart 1968).

It would take almost two more decades before a "solution" to the seemingly ever changing value of c was agreed upon:

"...This new definition (of c) has the effect of giving a fixed value to the speed of light:

c = 299,792, 458 m/s exactly,

...According to this definition, the speed of light can now no longer be measured." (Landolt and Börnstein 1992, pg. 3-49. Italics added for emphasis.)

What is glossed over is that the meter is measured with respect to how far light travels in one second. (Never mind that the second is measured in terms of how long it takes light to travel one meter.) In other words, the speed of light is defined in terms of the speed of light! Without a doubt, this has to be (to borrow from Islam) the "mother" of all scientific tautologies. Using different technologies, David Pritchard (as reported by Holden 1994) is taking an analogous approach in defining mass with respect to an "unchanging" standard.

Fortunately, there are some who have tried to clear the fog brought on by closed logic systems (Norman and Setterfield 1987). They argue:

"The behaviour of the atomic constants and the velocity of light, c, indicate that atomic phenomena, though constant when measured in atomic time, are subject to variation in dynamical time." (pg. 3)

The two types of cosmic time that Norman and Setterfield refer to are atomic time (based on the period taken for an electron to move around once in its orbit), and dynamical time (based on the period taken for the earth to make one complete orbit of the sun). Furthermore, they believe that the data show that "the two clocks measuring cosmic time are running at different rates" (1987, pg. 3). Briefly, to Norman and Sutterfield, if the Theory of Relativity is to be believed, then we must give up our cherished notions of the objective permanence of the physical constants.

The unsettling notion concerning the impermanence of the constants has even been extended to the subjectivity of the fundamental forces of nature. Those who have attempted to take the Theory of Relativity that one final step — quantumization of gravity, and its unification with the other forces — have found that the mathematics of space-time may bring us to a Kantian dead end — the subjectiveness of the cosmos.

"Ultimately, the biggest barrier to the construction of a theory of quantum gravity may not be the mathematics, but the interpretation of the mathematics...

"Veteran gravity theorist Chris Isham of Imperial College, London, sees even deeper issues starting to loom — issues long thought to be the preserve of philosophy. Perhaps most central of all is the question of whether space and time are merely constructs of our personal experience, as Immanuel Kant argued some 200 years ago.

"The mere suggestion that such fundamental concepts cannot be relied on in the construction of a theory would fill most physicists with horror. Yet those who dare to tackle the mystery of gravity are learning to live with such possibilities. As Isham puts it: 'The shadow of Kant is hanging over all of us.'" (Matthews 1994, pg. 32)

To conclude this section on the epistemology of uncertainty, and to justify the apparent diversion, I would like to briefly discuss two of what I believe to be the most interesting papers on the role of uncertainty and subjective judgment in the physical and social sciences.

Henrion and Fischhoff (1986)

Their paper, entitled "Assessing Uncertainty in Physical Constants," adequately demonstrates that scientists are consistently overconfident in their estimates of the physical constants, including the speed of light, Planck's constant, electron mass, Avogadro's number, as well as several others. Youden (1972), in an earlier and appropriately entitled paper, "Enduring Values," reported a similar phenomenon for the Astronomical Unit. In that paper, Youden showed that each of fifteen estimates, from 1885 to 1961, were outside the standard deviation of the immediately previous estimate. The overconfidence of the scientists in their own estimates is hardly something that one would expect to occur by chance alone.

What is the basis of this phenomenon? In any estimate of a physical constant, there are two sources of error — the first, called true or random error, is the difference between the measurement and the true or actual value, and is the result of unexplained measurement variability; and the second, called systematic error or bias, is the estimate of the amount of error introduced by specific, but unknown, experimental conditions. Experimenters generate systematic error when they make subjective estimates of their uncertainty about the true error.

Since we cannot know the true value of the physical constants, how are we to separate true error and bias? Müller (1979) contends we should not. I agree.

For example, let us assume we can never know the real value of random error. Furthermore, it is given that we do know the magnitude and direction of systematic error (because it was subjectively estimated by the scientist). Therefore, let us just deal with error as if it were systematic or biased only — that is, just make a single, albeit complex, estimate of our uncertainty. Henrion and Fischhoff (1986) and Youden (1972) have already shown that this is probably the case anyway.

Henrion and Fischhoff (1986) argue that while there are apparently limits on what we can do about the magnitude and direction of true error, there are at least some steps we can take in dealing with subjective error, i.e., uncertainty. Henrion and Fischhoff proceed to document carefully the literature describing how people make decisions in the face of uncertainty. (Some of this original literature will be discussed in later subsections.) Henrion and Fischhoff also specifically recommend how scientists can incorporate the uncertainty around subjective estimates of the physical constants.

What I argue here is that the errors, which occur when subjectively estimating the physical constants, also occur when estimating risk or uncertainty. Importantly, because we have some understanding about what influences our judgment in these settings, we should be able to minimize the magnitude and direction of the error.

Freudenburg (1988)

The thesis of Freudenburg's Science paper is that much of the difficulty in risk management occurs as the result of the perception that, on one hand, scientists identify "real," technical risks, and, on the other hand, the public perceives risk within an environment of misinformation and irrationalities.

However, the underlying theme of Freudenburg's paper is that judgments in the face of technical uncertainty, whether made by scientists or the public, will be influenced by known psychological and sociological factors. Furthermore, the factors which influence our estimates of uncertainty can be identified and controlled, at least to some extent.

Summary of Technical Uncertainty

In this section, I have presented a rather broad review concerning the nature of technical uncertainty in the physical sciences — and, to a lesser degree, the social sciences. I did this so that we may better appreciate the fact that the very process by which we measure the world around us is influenced by subtle subjective constraints.

I pointed out — using the physical constants as an explanatory vehicle — that measurement error (or, uncertainty) may have two sources. True error is the difference between the real value and the randomness introduced by our measurement tools. Bias or systematic error, the portion that always exists, is brought about by the subjective, perceptual, and cognitive nature of every measurement.

Henrion and Fischhoff (1986) and Freudenburg (1988) argued that we all use heuristics when we measure a physical process of nature or the organizational machinations of a group. Furthermore, subjective measurement heuristics follow behavioral rules that have been well documented over the last few decades. Both papers make persuasive arguments that we can limit the magnitude of error and affect the direction of uncertainty, by understanding the unavoidable, subjective nature of those measurements.

Conclusions of the classic papers concerning judgment under uncertainty (Kahneman and Tversky 1972, 1973, and 1974; and, Lichtenstein and Fischhoff 1977) have, for the most part, gone unchallenged. The reader is referred to the original papers for a complete discussion of judgment heuristics. Let us now turn to the uncertainty in measuring organizations.

4. THE NATURE OF HIGH CONSEQUENCE, HIGH RELIABILITY ORGANIZATIONS

High Consequence Organizations

Simply stated, high consequence organizations are those which, if they fail, would result in catastrophic environmental or human loss. The nuclear power and weapons industries are clear examples.

High Reliability Organizations

Strictly defined, High Reliability Organizations (HROs) are those that conduct tens of thousands of nearly error free operations (Roberts and Gargano 1989; Rochlin et al. 1987). Examples of such organizations would include air traffic control and international banking. There are several fine articles and texts describing the nature of High Reliability Organizations (Perrow 1984; Roberts 1990; and Sagan 1993).

There is another type of organization which I believe should be included under the rubric of HRO. Ones, which because of their very nature conduct relatively few operations—but because a failure in their operations—would be extremely hazardous, must operate nearly error free out of necessity. Nuclear weapons production would be an example.

5. QUANTIFYING HIGH CONSEQUENCE, HIGH RELIABILITY ORGANIZATIONS

Organizational and System Metrics

Early on in this paper, I contended that understanding organizational influences on safety needed to be extended beyond the American Engineering Council's correlation of productivity and accidents. I also argued that despite the fact that organizational factors contribute to accident rates, a focus on the sociology of organizations might not result in metrics with which managers can effectively deal.

Modarres et al. 1992 make an effective argument for beginning the process by incorporating NRC-like performance indicators into a quantitative assessment of the influence of an organization on its safety. Two types of indicators identified are Direct Performance Indicators (DPIs) and Indirect Performance Indicators (IPIs). The former includes events such as scrams and equipment-forced electric outages. The latter (IPIs) includes such events as maintenance overtime.

There are advantages and disadvantages to such an approach. A principal advantage is that these are measurable events. It minimizes the use of subject matter expert opinions — as well as the problems that go along with trying to quantify those opinions. A principal disadvantage is that the users must make certain a priori assumptions about the variables they select, and the relationship of those variables to the occurrence of accidents.

So, a case can be made for taking these quantitative measures of organizational performance (as opposed to expert opinion only) and incorporating them into the overall likelihood of success or failure or the system to meet its goals, that is its productivity. Later, I will suggest alternatives to the performance indicators suggested by Modarres et al. 1992.

Human Error Metrics

The very manner in which human error probabilities are incorporated into a PRA, condemn the analysis to be a meaningless predictive tool. Let us briefly look at the way in which a Human Risk Assessment (HRA) is computed.

A given activity is broken down into its subcomponents. Then, various error probabilities are assigned to the various tasks. The process is usually based on an analytic, and not empirical, decision. The probabilities are then multiplied or added depending on the assumption of independence. As a result, the computed error probability is only in part a function of the error rate. The probability is influenced by how many tasks into which the analyst has chosen to decompose the activity! Lots of little tasks might mean very low error rates. Few tasks might result in a high error rate.

The problem with HRA only begins with the way in which it is computed. Experts in the field of human error analysis have documented fundamental theoretical problems with the NRC process. In part because of these problems, the NRC requested the Human Factors Society to study the problems with human error assessment (NUREG/CR-2833 1982). They reported that "the application of such data (human error probabilities), under current conditions at least, is virtually impossible. The report went on to conclude that to improve the deficiencies in NUREG/CR-1278 (NRC's major contribution to HRA) "...while theoretically possible, practically infeasible."

Following this assessment, the NRC then asked the National Academy of Science to make an independent assessment (Moray and Huey 1988). The outcome of that assessment was anything but encouraging. Because of the inherent problems in the field, they concluded "...that research to further improve subjective estimates of human error should not receive a major emphasis in the future."

To mention one last NRC report, the authors of NUREG/CR-1420 1990, concluded that it was virtually impossible to determine if differences among HRAs computed by various analysts were the result of (a) different methodologies, (b) different experts, or (c) actual differences in error rates.

Based on these reports, it is clear that to examine the risk of organizational influences by means of human error probabilities will provide little information. This conclusion provides further support for using system metrics to examine risk and organizational productivity. Such an approach has the further advantage of focusing on the benefits of successful performance, rather than the outcomes of failure.

ISO 9000 Dimensions

The International Standards Organization (ISO) was founded in 1946 to promote the development of international standards. In 1987, the ISO published a series of five international standards to guide quality management compliance (ISO 9000, 9001, 9002, 9003, and 9004). Corporations, particularly in the European Economic Community, regularly require companies with which they do business to register with the ISO.

The ISO 9000 series has been adopted in the United States as the American National Standards Institute (ANSI) and American Society for Quality Control (ASQC) Q 90 series (Arter 1992; Golis and Kist 1993). The ISO 9000 document is summarized below in the list of ISO 9000 criteria.

Both ISO 9000 and Q 90 are highly structured, but generic in content, as a standard should be. Interestingly for us, they use most of the same requirements found in 10CFR50 Appendix B, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants," and ASME NQA-1, "Quality Assurance Program Requirements for Nuclear Power Plants."

ISO 9000 Criteria Identified

1. Management Responsibility
   a. The quality policy shall be defined, documented and understood.
   b. Responsibilities and authorities shall be defined.
2. Quality System
   a. Procedures shall be prepared.
   b. Procedures shall be implemented.
3. Contract Review
   a. Determine if contracts meet requirements.
4. Design Control
   a. The design project shall be planned.
   b. Design input parameters shall be defined.
   c. Design output shall be documented.
   d. Design output shall be verified.
   e. Design changes shall be controlled.
5. Document Control
   a. Generation of documents shall be controlled.
   b. Distribution of documents shall be controlled.
   c. Changes to documents shall be controlled.
6. Purchasing
   a. Potential suppliers shall be evaluated.
   b. Requirements shall be clearly defined.
   c. Effectiveness of suppliers quality assurance system shall be evaluated.
7. Customer Supplied Product
   a. Customer-supplied material shall be protected against loss or damage.
8. Product Identification & Traceability
   a. The product shall be identified and traceable by item, batch, or lot.
9. Process Control
   a. Production process shall be defined and planned.
   b. Production shall be carried out under controlled conditions.
   c. Special processes that cannot be verified after the fact shall be monitored and controlled throughout the process.
10. Inspection and Testing
   a. Incoming materials shall be inspected and verified.
   b. In-process inspection and testing shall be performed.
   c. Final inspection and testing shall be performed prior to release of finished product.
   d. Records of inspection and test shall be kept.
11. Inspection, Measuring & Test Equipment
   a. Equipment used to demonstrate conformance shall be controlled, calibrated, and maintained.
   b. Measurement uncertainty and equipment capability shall be known.
   c. Where test hardware or software is used it shall be checked before use and rechecked during use.
12. Inspection & Test Status
   a. Status of inspections and test shall be maintained for items as they progress through the process.
   b. Records shall show who released conforming product.
13. Control of Nonconforming Product
   a. Nonconforming product shall be controlled to prevent inadvertent use or installation.
   b. Review and disposition of nonconforming product shall be accomplished in a formal manner.
14. Corrective Action
   a. Problem causes shall be identified.
   b. Specific problems and their causes shall be corrected.
   c. Effectiveness of corrective actions shall be assessed.
15. Handling, Storage, Packaging & Delivery
   a. Procedures for handling, storage, packaging, and delivery shall be developed.
   b. Handling controls shall prevent damage and deterioration.
   c. Secure storage shall be provided.
   d. Packing preservation and marking process shall be controlled.
   e. Quality of product after final inspection shall be maintained.
16. Quality Records
   a. Quality records shall be identified, collected, indexed, filed, stored, maintained, and dispositioned.
17. Internal Quality Audits
   a. Audits shall be planned and performed.
   b. Result of audits shall be communicated to management.
   c. Any deficiencies found shall be corrected.
18. Training
   a. Training needs shall be identified.
   b. Training shall be provided.
   c. Selected tasks might require qualified individuals.
   d. Records of training shall be maintained.
19. Servicing
   a. Servicing activities shall be performed to written procedures.
   b. Servicing activities shall meet requirements.
20. Statistical Techniques
   a. Statistical techniques shall be identified.
   b. Statistical techniques shall be used to verify acceptability of process capability and product characteristics.

There is nothing particularly earth shaking in the documents describing ISO 9000, in that they outline basic, systems-analytic methods. In addition, these standards provide a framework and set of guidelines for measuring organizational processes. These dimensions can then be used to better understand accident rates and risk. Of course, what needs to be done first is to establish quantitative metrics for these dimensions. Such metrics might include observable organizational processes, and subject matter expert opinions concerning industry best practices.

As I pointed out earlier, many of the organizational metrics developed in ISO 9000 are already incorporated into some of the Federal controlling documents for the nuclear industry. As a result, the process of adapting them for DOE and NRC assessments of organizational reliability will be much less painful. In addition, by avoiding the generation of indicators on a theoretical, ad hoc basis, and by using performance indicators routinely followed by the industry will promote acceptance and the willingness to utilize the process.

6. CONCLUSIONS

There appear to be macro system metrics related to safety (American Engineering Council 1928; NUREG/CR-5568 1990; and Marcus et al. 1990). Global metrics that have been identified include productivity, return on assets, rates of production, and various organizational processes, like ability to learn and communication effectiveness.

However, little attention has been given to relating safety and risk respect to macro system measurements that follow from a TQM ethics-base. If such an ethics-base were to be followed, we would attempt to maximize the interests of all the stakeholders in the organization — the customer, the owners, and the workers. Such dimensions and metrics may be related to the processes that the American Engineering Council (1928) might be important in bringing an organization "under perfect control."

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