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INTEGRATING QUALITY ASSURANCE AND RESEARCH AND DEVELOPMENT

John J. Dronkers

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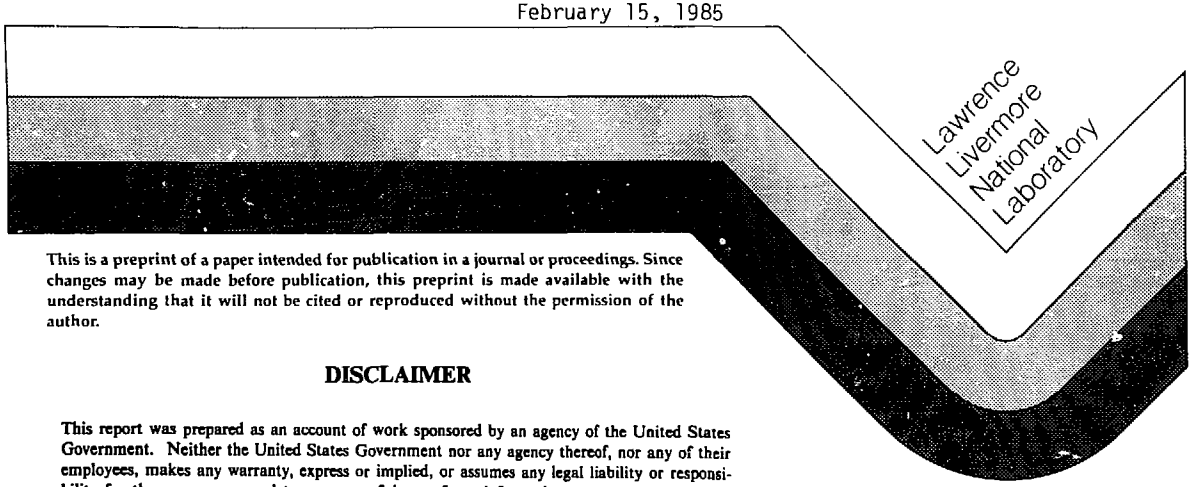

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Integrating Quality Assurance and Research And Development

John J. Dronkers, CQE; Quality Assurance Specialist, LLNL, Livermore, CA

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Abstract

Quality assurance programs cannot be transferred from one organization to another without attention to existing cultures and traditions. Introduction of quality assurance programs constitutes a significant change and represents a significant impact on the organizational structure and operational mode. Quality assurance professionals are change agents, but do not know how to be effective ones. Quality assurance as a body of knowledge and experience can only become accepted when its practitioners become familiar with their role as change agents.

Introduction

There can be no doubt that management by quality assurance is increasingly gaining the attention and respect of America's executives. A good indication of this is not so much what the quality assurance journals write, but what the business or even popular press writes. In spite of this new found popularity, or perhaps because of it, close reading of what is actually taking place leaves one with the distinct impression that all is not well. Quality assurance programs that worked wonderfully well in one organization, fail miserably when implemented elsewhere. Overall success of quality assurance programs is spotty at best and there are many, many disappointments.

The implementation of quality assurance programs in organizations that did not have such programs before, or had different ones, constitutes an organizational change of significant magnitude. To be successful, such changes must be given time in order to take effective hold. During this transition period the quality assurance professional is perceived as the principal change agent by the rest of the organization. This paper takes the position that one of the reasons for the uneven success of newly emplaced quality assurance programs is that most quality professionals do not know how to be effective change agents. They were never trained to be. In order to become effective change agents, quality professionals will have to pay closer attention to the basic tenets of organizational behavior and in particular those dealing with organizational change and learning processes.

The point is perhaps made clearer with an example. A friend and valued colleague recently changed employers. He has many years of experience and fine credentials as a quality professional. His new employer never had a formal quality assurance program and was just beginning to become aware of some of the implications of implementing such a program. When my friend reported for work, this experienced professional sat down and in a few weeks wrote a complete quality program based on knowledge and experience gained elsewhere. The program was written without an understanding of the cultures and traditions that existed in his new organization. There was not even an attempt to learn the organization's language. The plan was quietly shelved. It was probably misunderstood and held to be not applicable to the organization.

This point bears emphasizing. Quality assurance programs imported from outside the organization and imposed without regard to existing organizational cultures and traditions, will very likely fail... indeed, they should be expected to fail. Quality assurance programs are environment dependent.

Nowhere is the problem of trying to cause change, but not knowing how, more visible than in the application of quality assurance to research and development activities. Here a legitimate concern arises. Is the profession able to transfer its knowledge to a field of which it knows little? The vast body of knowledge and experience that the profession has accumulated since Dr. Shewhard have been obtained from applications in manufacturing. The profession's current renaissance is the result of an attempt to reestablish America's competitive edge in manufacturing. These constant stress systems, in which repetitive operations easily lend themselves to quantitative analyses, continue to be a rich lode from which valuable lessons are constantly mined. Very carefully these lessons are applied in non-manufacturing environments. The service sector, notably banking and insurance, is using quality assurance with some success. Even there, however, applications are characterized by quantification of routine functions and subsequent application of traditional principles. Ask any quality assurance professional what his job is and the reply will be the control of variables.

Quality assurance has come to research and development. This is not a constant stress system. The variables do not fit the binomial distribution. New lessons must be learned. Previous applications are suspect. Basic questions must be answered, first about managing research and development activities in general, then about managing research and development activities by quality assurance.

Research and Development

Research and development (R&D) activities range over the largest possible of management domains. They may involve one scientist for one or two months at a cost of $25,000, or they may involve a thousand scientists and engineers for several years at a cost of several hundreds of million of dollars, or anything in between. Nor is the dividing line clearly drawn between that which constitutes research and that which can be considered development. Research drives the development, but also development drives the research.

An enduring fallacy regarding the application of quality assurance to R&D is usually expressed this way. R&D has a product, data, which is the result of a process. Therefore, the process can be treated like any other process that results in a product. Ergo, traditional quality assurance. Aside from the sheer banality of its sentiment, this fallacy ignores the simple truth that the result of a process reflects the process. The process and its

result cannot be viewed as separate. To equate the end result of an R&D process with the end result of say, a manufacturing process, is to ignore the attendant organizational aspects of R&D processes. In addition, data, the end result of an R&D process, have different quality characteristics than a manufactured piece of hardware, the end result of a manufacturing process. The quality characteristics of data are generally considered to be validity, integrity, reliability, preservation, and retrievability (Ref. 1).

Consider the organizational aspects of R&D processes. Work on many R&D projects is characterized by matrix assignments. That is, technical specialists from different organizational entities are brought together in one project to do work toward one specific goal. Once the goal is reached the team disbands and the people return to their "home" organizations. Not all people work on the project full time. Some may work on several projects at once and hence only part time on any one. Others will work full time, but only for a short time, after which their specific expertise is no longer required and they move on. The picture being sketched here is one of a fluid organization, temporarily put together to reach a goal and that will make the effort only once.

The top two management levels of the project are usually stable. Here are the Project Leader and his Deputies or Assistants. They are typically scientists themselves, but whose primary job now is to hold the project together and to manage it. They are to provide the management plan and maintain the structure by which work toward the goal of this temporary organization can proceed. The scientists and engineers who work under the top two levels are usually given a great deal of discretion. They work under some guidelines as to general direction, but the particulars do not evolve until experiments are done, results analyzed, and the project goal is in clearer focus. They are likely to be experts in the field of science under investigation and sometimes there are few as expert in the field as they. Lines of communication and authority are rarely formal and the organization is as nearly horizontal as one is likely to encounter in the real world.

To this loose and informal coalition is introduced one of the more formal management methods, management by quality assurance. There is no doubt that R&D efforts can benefit from using quality assurance. How to realize those benefits is the problem.

Quality Assurance in Research and Development

As an example consider an R&D project consisting of several tasks, divided into subtasks, engaging about 50 scientists and engineers, having an anticipated duration of several years, and costing about $12 million per year. The project is to research and develop something never done before, namely the selection of a nuclear waste repository.

The nuclear waste repositories under consideration are geologic repositories. There has never been, anywhere nor any time in the history of the world, a geologic repository for high level nuclear waste. There is no previous experience on which to proceed. There are no data to predict how a geologic site behaves over thousands of years with active nuclear waste buried in it. The data must be developed on a small scale experimentally in laboratories. The site's behavior must be modeled on very powerful computers. The complexities of the effort boggle the mind. It is a perfect example for a research and development project.

The effort is still at the research stage, but the quality assurance requirements are the same that are required when a utility wishes to build a nuclear power plant. To make it clear, the scientific research needed to characterize whether a site is suitable for the construction of a waste repository is done with quality assurance requirements that were originally written for the construction of nuclear power plants (Ref. 2). Here is a good example of quality assurance requirements written for one effort, being imposed on a completely different effort.

Levels of Authority

Two aspects of the R&D organization previously described now need a closer look. One is that the scientist or engineer is given a great deal of discretion. The other pertains to the assertion that R&D organizations are as near to the theoretical horizontal model as one is likely to encounter in the real world. These two collectively result in a higher organizational level at which work is done than is usually the case. Quality assurance is therefore integrated at a higher decision level. Indeed, it may very well occur that planning decisions are made at the working level, a situation that rarely exists in traditional hierarchical organizational structures.

The quality program that governs the construction of nuclear power plants, requires that all activities that could affect quality are done in accordance with written and approved procedures. Deviations from the procedures are not allowed. Changes to approved procedures must first undergo the same review as the originals. There also must be verification to assure that work is done in accordance with the approved procedures. The pouring of concrete, the welding of pipe, the wiring of controls, the receipt of building materials, all are accomplished in accordance with approved procedures that not only prescribe what has to be done, but also how it has to be done. Once done it is verified to make sure that it was done right.

Over the years the construction of nuclear power plants has become a known activity. Over the years the procedures governing that construction have evolved into rigidly applied prescriptions of how to do work. Contrast that with the selection of a nuclear waste repository site. What does one look like? What is the effect of nuclear radiation on rock? groundwater? What kind of material should be used to encase the nuclear waste? How fast will the material corrode? types of corrosion? The list of questions that must be answered is almost infinitely long. And yet there is that requirement. "All activities that affect quality..." What activities would affect quality? For that matter, what activities are required to first select a site and then construct a repository on it? Of all the activities that are now taking place, which ones will finally turn out to be those that can to be used to obtain a construction permit? No one knows. Make a best guess. Now write procedures. Who will write them? The investigating scientist who is experimenting with an activity writes the work procedure. He is the only one who knows how. That scientist will also determine whether the procedure works. Who approves the procedure? Management at least one level higher

than the scientist and, of course, quality assurance. What happens when the scientist finds that the procedure does not work, that a small change is required? Write and send out a revised procedure for approval and wait for the approval.

Not too long ago there was an audit that found that scientists "were working with unapproved procedures". During a subsequent informal discussion concerning the infraction, one of them expressed surprise. He had been hired to conduct certain studies. As part of his work he wrote procedures on how to conduct the studies. He thought that the approval was a mere formality, because who would disapprove? Who would know enough about the studies to disapprove? In addition the approval generally took over six weeks and was he supposed to suspend work until then? What would happen if he needed to make changes as he went along? Would he have to stop work each time he wanted to make a change and wait until the change was approved?

The answer to all those questions is to write procedures that allow discretion on the part of the scientist, who is at the working level. Changes must be allowed at the working level. The point of the example is, that the quality professional who imposed the requirement did not realize that the nature of R&D work and the discretionary level at which such work takes place is markedly different from anything in his past experience. And the profession suffered some loss in credibility.

Test versus Experiment

There is an element in the nuclear quality program that calls for test control. Test are to be prescribed, reviewed, approved, have hold points, acceptance criteria, specified documentation, etc. There is nothing out of the ordinary about that. When this element was first translated into repository quality assurance requirements, a curious phrase appeared. It effectively said that experiments were to be controlled in the same manner as tests. In other words there is no difference between a test and an experiment.

There is indeed a difference between a test and an experiment. In an experiment the goal is the understanding of a phenomenon. It is the search for an understanding of a cause and effect relationship. The results of an experiment are not determined a priori. In an experiment one manipulates external variables in order to ascertain their relative importance as causative factors. Although quantitative measurements are desired, initial emphasis is on the qualitative relationship between cause and effect. An experimental procedure consists of a question and a goal. For example, are there any effects of gamma irradiation on the corrosion properties of austenitic steels in water? The goal is to determine if there are any effects, the cause of the effects, and what tests can be devised to demonstrate the suitability or unsuitability of austenitic steels for a desired application.

A test, on the other hand, is a quantitative measurement to evaluate the magnitude of an effect. Where possible, test variables should be anticipated and controlled. The what and the how of a test should be known and written in a procedure before the test is run. The technician running the test has an a priori understanding of the direction and the magnitude of the effect to be measured. Using the same example as above, a test procedure would first measure and then compare the effects of gamma irradiation on the corrosion rates of austenitic steels in irradiated water relative to corrosion rates in non-irradiated water. The fact that there are effects was determined by the experiment.

Experimental design is highly dependent on the knowledge, experience, and intuition of the scientist to whom it is assigned. Different scientists use different approaches. An adequate test is dependent on the experience of the technician using well written procedures (Ref. 3).

Again, the point of the example is to show that what works well in one environment, may not be transferable to another without some thought. But there is something else. There is a tendency for quality assurance professionals to apply controls to every level of activity. The phrase "judicious use" is not very well applied in practice. Full blown closed loop controls are applied to areas where they serve no purpose. There is no need to control experiments to the extent that tests need to be controlled. Experiments result in tests and tests result in design data. The latter is important and should be able to be traced to the test. No need to go back to the original experiment. In the nuclear power plant environment excessive application of quality assurance controls results in the addition of "approximately one year to the overall schedule in the form of stretched out design and construction schedule and adds 30 to 35 percent of overall plant costs." (Ref. 4).

Calibration

In a description of an experiment the following two sentences appeared. "A Beckman CEL-K1 conductivity probe will be used to monitor conductivity in the corrosion cells and to act as a depth probe to monitor the water level in each corrosion cell. Only conductivity changes will be determined using this cell so an absolute calibration is not planned" (Ref. 5). Calibration is one of the profession's most sacred cows. All quality assurance standards contain requirements for calibration control. All auditors include calibration on their lists of things to audit. Here is a scientist who states that "absolute calibration" will not be done. What does he mean?

Calibration of measuring and test equipment is vital when "measured values [are] used directly in establishing design specifications or reported as absolute values to [customers]" (Ref. 6). Calibration of measuring equipment is also vital when one manufactures or constructs from specifications. How important is it to calibrate measuring and test equipment in a research phase of an R&D effort? To paraphrase an opinion once heard, human knowledge increases incrementally and who cares where zero is. Recall the previous discussion on tests versus experiments. In an experiment one searches for an understanding of a cause and effect relationship. It is relative in the sense that one needs to determine that an effect has indeed occurred, not necessarily the extent of the effect. For experimental work it may be sufficient to have relative data. That is what the scientist meant when he wrote that absolute calibration is not planned. His interest was in determining whether or not conductivity had changed and he may have had a secondary interest in how much conductivity changed, but it was not important.

Few quality assurance professionals will accept the notion that relative measurements suffice in many of the research activities. Audit after audit finds that calibration of measuring and test equipment lacks control systems with the independent verification so dearly loved by quality assurance professionals. A story is told about a prestigious research institution that was audited. The auditors had found that some of the equipment bore calibration stickers that were 15 years old. The incredulity of that discovery was told with much glee. A telephone call to the organization revealed that the equipment was no longer used for absolute measurements, it was used to reveal deviations from the expected, i.e., to make relative measurements.

That is not to say that 15 year old calibration stickers on measuring equipment is a good thing. On the contrary. If an organization has a two tiered calibration program, one for absolute measurements and another for relative ones, then it must keep the two apart. There must be controls that prevent the inadvertent use of experimental measuring equipment to make absolute measurements. The solution is not to insist on a program to control the calibration of all measuring and test equipment regardless of use. Such programs are inefficient, expensive and not necessary.

Management By Quality Assurance

The three examples discussed in the previous section were instances where well intended and traditional actions on the part of quality assurance professionals resulted in misunderstandings. Instances like those are legion and do not just occur when quality assurance and R&D meet. Any time quality assurance professionals gather, tales of woe dominate the conversation. They usually have a common thread, the universal misunderstanding of the good intentions. Colleagues usually have had similar experiences and can offer advice, or at least cite a worse example. The problem with R&D task organizations is that they may sound like something heard before which implies that therefore somebody has experienced a solution, but in truth the problems are far more fundamental.

R&D task teams, coalitions for applied scientific research, present problems from an organizational theory point of view as well. The relationship between scientist and administrator, the relationship between scientist and sponsor, the relationship between science and government, and finally the relationship between science and society, all are ill defined and all are the subject of academic investigation. When R&D efforts grow into the gigantic engineering projects with which this nation has become familiar only since WWII, the problem becomes a very practical one. How does one efficiently organize such efforts? Matrix organizations? Projected Organizations? Coordinator Organizations? Expediter Organizations? (Ref. 7) All these have been tried with various modifications. All will more or less work depending on the circumstances. R&D organizations are justified in asking why quality assurance would organize them any better.

One thing that will not work is the overlay of monolithic quality assurance programs on existing management structures. One does not apply quality assurance. One integrates quality assurance so that its requirements are met as a result of a management process designed to accommodate as much as possible of the informal structures that already exist in all organizations.

Consider one last time the quality assurance requirements mandated for the research needed to characterize a waste repository site. That program has a total of 18 elements, which, according to its authors, collectively constitute a complete and sufficient set to assure the quality of a nuclear power plant. These elements represent a reduction of an industrial experience to procedures. The end result is a safe and operational structure. Of those elements, only a few, at most four, can be made to apply directly to an R&D effort. For the latter the result is data. The constituent parts that make up the end result are experiments and tests. The question is not: "How does one fit an industrial experience into an R&D effort?", but "how does one manage experiments and tests to assure the quality of their data?" Quality assurance, along with other management approaches, has a contribution to make in the search for an answer. Its practitioners, however "must learn to think without making use of the patterns and models taken for granted by most of the textbooks." (Ref. 8).

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Biography

John J. Dronkers, CQE
Lawrence Livermore National Laboratory
P.O. Box 808, L-204
Livermore, CA 94550

John Dronkers is a Quality Assurance Specialist. From 1972 to 1979, he was with the Quality Assurance Division of the General Services Administration, from 1979 to 1982, he was with the U.S. Department of Energy. In 1982, he joined the Lawrence Livermore National Laboratory where he is currently engaged in the Nuclear Waste Management Projects. He is a Senior Member of the ASQC and an ASQC Certified Quality Engineer. He is a founding member of the Golden Gate Section of the ASQC.

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