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QA ROLE IN ADVANCED ENERGY ACTIVITIES

TOWARDS AN "ORTHODOX" QUALITY ASSURANCE PROGRAM: CANONIZING THE TRADITIONS AT FERMILAB

Mark W. Bodnarczuk
Chairman, Quality Assurance Committee
Fermi National Accelerator Laboratory (1)
Box 500
Batavia, Illinois 60510

ABSTRACT

After a brief description of the goal of Fermi National Accelerator Laboratory (Fermilab) this paper poses and answers three questions related to Quality Assurance (QA) at the Laboratory. First, what is the difference between "orthodox" and "unorthodox" QA and is there a place for "orthodox" QA at a laboratory like Fermilab? Second, are the deeper philosophical and cultural frameworks of high-energy physics accommodating or antagonistic to an "orthodox" QA Program? Finally, faced with the task of developing an institutional QA program for Fermilab where does one begin? The paper is based on experience with the on-going development and implementation of an institutional QA Program at Fermilab.

FERMILAB'S GOAL

Fermilab is a single purpose high-energy physics laboratory that houses and operates the highest energy particle accelerator in the world: the superconducting Tevatron. The best way to understand the goal of Fermilab is to view it in historical perspective. Fermilab is committed to the powerful concept of atomism, i.e., the ancient notion that the universe is composed of fundamental, indivisible constituents which interact with each other. The history of atomism is divided into a philosophical and a physical phase with a two hundred year transition period in between. The philosophical phase began when a fifth century BC Greek philosopher named Democritus first asserted that the universe was composed of indivisible atoms moving in a void. The philosophical phase ended when the 17th century philosopher Pierre Gassendi revived the atomistic doctrine after it had been exiled from the halls of Aristotelean Scholasticism for almost 1500 years. During the two hundred year transition period that followed, a variety of corpuscular and atomistic theories were postulated by individuals like Descartes, Newton, and Leibnitz. But the physical phase of atomism did not

1) Fermilab is operated by Universities Research Association, Inc. for the Department of Energy

begin until the 19th century scientist John Dalton applied the chemical investigations of Lavoisier to the "philosophical" concept of atomism, showing that atoms had an objective physical existence. But curiosity forced scientists to probe deeper in an attempt to determine whether the atom was indeed indivisible.

With Thompson's discovery of the electron, Rutherford's nucleus, and the mathematical formalisms of quantum mechanics and special relativity behind us, Fermilab continues to search for the fundamental building blocks of matter and the forces that cause them to interact. The present consensus of the high-energy physics community is capsulized in a "paradigm" called the Standard Model (See Figure below).

THE "STANDARD MODEL" OF ELEMENTARY PARTICLE INTERACTIONS

Force	Physical Phenomena	Relative Strength	Effective Range	Carriers of Force	Other Particles	Proposed Theory
Strong	nuclear bonds, fission,fusion	1	10^{-13}cm	gluons	quarks	quantum chromodynamics
Electromagnetic	electricity, magnetism, light	10^{-2}	infinite	photons	quarks,charged leptons	quantum electrodynamics
						unified electroweak theory
Weak	radioactive decay	10^{-5}	10^{-16}cm	W,Z, Higgs	quarks,leptons	beta decay theory
Gravity	planetary motion curved space-time	10^{-38}	infinite	graviton	all particles	Einstein's general relativity

At present, the universe is believed to be composed of fundamental particles called quarks and leptons. These particles interact according to the particle interactions displayed above. Fermilab scientists probe and measure various parameters and anomolies within the Standard Model which will hopefully lead to a more rigorous mapping between the quantum and macrocosmic realities of the universe and the mathematical formalisms we use to describe them. Towards this end, the superconducting Tevatron accelerator produces proton and antiproton beams with energies of nearly a trillion electron volts (TeV) each and collides them together in the center of huge sophisticated apparatuses like the Collider Detector at Fermilab (CDF) which cost over $60 million to build. During the last colliding beam run four experiments took data, while CDF accumulated a variety of events containing W and Z vector bosons. In addition, Fermilab is just completing a fixed-target physics run in which 1

TeV protons from the Tevatron were directed towards stationary targets providing beam for 18 experiments where the cost of experiments ranges between $1-8 million each. Located on 6,800 acres of land, 30 miles west of Chicago, with an annual budget of about $170 million and 2200 employees, Fermilab is a premiere high-energy physics laboratory which provides the highest energy particle beams anywhere in the world.

About a year ago, the Director's Office at Fermilab organized the Quality Assurance Committee and as Chairman, I was directed to create, develop, and implement an institutional QA program. Having written and implemented the Institutional QA Program, we are now involved in the on-going process of developing and implementing QA Programs in every Division and Section of the Laboratory. The goal is a total institutional plan. This endeavor has raised the questions which will be addressed in the remainder of this paper.

FRAMING THE QUESTIONS

Last September at a QA Forum sponsored by the Department of Energy (DOE-CH Operations) at Argonne National Laboratory, one of the speakers referred to something called "orthodox" Quality Assurance. He defined an "orthodox" QA program as one which is traceable to such documents as ANSI/ASME NQA-1 and the DOE's interpretation of that document which is called DOE Order 5700.6B (Quality Assurance). This raised a question in my mind about whether there were QA programs that were "unorthodox" or "heretical" and if so, what are the differences? When questioned, the speaker defined an "unorthodox" QA program as one which is not traceable to NQA-1 and DOE Order 5700.6B. This is an interesting and instructive distinction which deserves more careful reflection and is one of the driving forces behind what follows. This paper discusses three of the major issues that have helped forge the structure of an institutional QA program at Fermilab. First, what is the difference between "orthodox" and "unorthodox" QA and is there a place for "orthodox" QA at a laboratory like Fermilab? Second, are the deeper philosophical and cultural frameworks of high-energy physics accommodating or antagonistic to an "orthodox" QA program? Finally, faced with the task of developing an institutional QA program at Fermilab, where does one begin? We will address these questions in reverse order, beginning with experiences encountered in developing and implementing the QA program then drawing implications that will address the other two questions.

WHERE TO BEGIN

We began by adopting a QA philosophy that was not antagonistic towards the existing quality traditions of our researchers and recognized the fact that Fermilab had effective QA although it was "unorthodox". The best argument for this is the Laboratory's operating record. Fermilab has existed for about 20 years and up until last year had no "orthodox" institutional QA program. Yet the Laboratory has consistently produced world-class high-energy physics data, and among other things, designed, fabricated, installed, and is currently operating the highest energy superconducting accelerator in the world which is composed of about 1,000 superconducting magnets. This is "unorthodox" quality at its finest! I might add at this point that Fermilab is a sustaining member of the ASQC and has 2 ASQC certified quality engineers and 7 ASQC certified quality technicians that compose part of the Laboratory section that built the superconducting magnets which make up the Tevatron.

Researchers ask "why spoil a good thing"? Will an "orthodox" QA program really help the Laboratory or is it simply to comply with DOE Orders? When the QA guy comes around sermonizing about the "gospel" of salvation by "zero-defect" quality measures, or accusing researchers of not doing their jobs properly, they often feel like Socrates did when he said "I do not know what effect my accusers have had upon you gentlemen, but for my own part I was almost carried away by them; their arguments were so convincing. On the other hand, scarcely a word of what they said was true." (2)

So given a non-antagonistic philosophical stance, what kind of models does one use to begin approaching the issue of "orthodox" quality? We are using two models: the "therapy" model and the "medical" model. The "therapy" model is used primarily as a definitive tool; definitive in the sense that it helps define 1) the quality traditions that currently exist at the Laboratory and 2) people's attitudes toward QA. The "medical" model is used primarily as an analytic tool that lends itself more easily to quantifiable processes. We will describe each of them in turn.

In his book Quality is Free, Philip B. Crosby uses sex as a model that defines some people's attitudes towards QA. "In this regard, quality has much in common with sex. Everyone is for it. (Under certain conditions, of course.) Everyone feels they understand it. (Even though they wouldn't want to explain it.) Everyone thinks execution is only a matter of following natural inclinations..." and so on. (3) This is a useful illustration about identifying people's attitudes about what quality is, but it does not describe how to change those attitudes if they are inappropriate. Crosby moves a little closer to a model that both defines attitudes about quality and tries to change them with the stages that compose what he calls his "Quality Management Maturity Grid" (Uncertainty, Awakening, Enlightenment, Wisdom, and Certainty). The mechanism of change in this model is the confrontation of the individual with "quality standards" in such a way that his consciousness about quality issues is raised. This is the proper approach, but for our needs this model is too cumbersome. At Fermilab we have used a similar but more simple paradigm called the "therapy" model which both defines people's attitudes toward QA and offers possible solutions and ways to change or modify attitudes that are antagonistic towards "orthodox" QA.

What is the "therapy" model and how does it work? Telling a functioning adult that he has "emotional problems" and needs "therapy" is somewhat analogous to telling a successful high-energy physicist that he has "quality problems" and needs an "orthodox" QA program. Normally, the first reaction is resistance. But there are three major goals that the therapeutic process is designed to accomplish that can be used as a model for dealing with attitudes toward "orthodox" QA.

The first goal is self reflection. Examining the way one does their job and measuring that performance against some quantified measurable canon. In this case that standard is NQA-1 and DOE Order 5700.6B.

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2) The Last Days of Socrates, Plato, (Baltimore: Penguin Books, 1973) p 45.

3) Quality is Free, Philip B. Crosby, (New York: McGraw-Hill Book Company, 1979) p 15.

The second goal is an increased level of consciousness about what we do and why we do it. Most behavior modification plans start by asking an individual to log what he does and when he does it in order to raise the individual's consciousness about why he does these things.

The third goal is a long-term change in attitudes and feelings which eventually become changes in behaviors. The mechanism of change is heightened consciousness which comes from confronting quality standards. This does however, assume that the individual involved has a desire to seek a higher level of quality in his work. Compliance out of compulsion is certainly inferior to a desire to comply.

Beginning with a non-antagonistic philosophy and the "therapy" model, Fermilab made a commitment to QA from the Director's Office which fostered the formation of the Quality Assurance Committee (QAC). Each member of the committee was carefully chosen to represent a particular Division of the Laboratory. One of the criteria used in the selection was that the committee had to have organizational access to the Division Head at a level where QA issues could not be impeded. At Fermilab the ultimate responsibility for QA rests with the Division Head as a line function which the QAC independently audits. The Institutional QA Program mandates that each Division Head produce a QA program that complies with the Institutional QA program. Another important issue that was addressed was to remember who the experts were. Because each QAC member is a member of that Division or Section, he and the Division Head are the content experts about the operations and procedures of that section. In addition, it is important that the Division Head considers the QA program his own creation and something he can support honestly. If Division Heads "own" the QA program, they'll be much more likely to live by it.

But how does the "therapy" model work functionally? There are three steps. First, when working towards an "orthodox" QA program the initial step must be the canonizing or writing down of the QA traditions and procedures that already exist. It is imperative to quantitatively and carefully define where you are and what you have as far as quality traditions. This is related to the second goal of the "therapy" model i.e., an increased level of consciousness about what we do and why we do it. One of the best ways to modify a habit is by writing down a step by step record of what behaviors were performed before, during, and after the incident. Second, use such "orthodox" documents as NQA-1 and 5700.6b primarily as a standard against which existing QA traditions are measured. This component is related to the first goal of the "therapy" model, i.e. self reflection. By examining the way one does their job and measuring it against a quantified measurable standard, one understands what the measure of "normalcy" or "orthodoxy" is and gets a measure of the deviation from the standard. Before the existing QA traditions are written down and compared with NQA-1, one cannot quantitatively say that there are nonconformances with the 18 requirements. What can be said is that the QA program is "unorthodox", i.e., not traceable. This writing down process then becomes a heuristic probe which will identify, define, and quantify problem QA practices that have previously gone undetected. Third, modify practices or procedures that are non-conforming or else justify in writing why they have been ignored. If an individual begins to have an increased level of consciousness about how he does his job and agrees to use the "orthodox" QA documents as a standard against which to measure his procedures, a sincere modification of attitude toward the non-conforming procedures and possibly QA as a whole will probably follow. This relates to the third goal of "therapy", i.e., a long-term change in attitudes and feelings which eventually become changes in behaviors. If a person will not accept the "orthodox" criteria willingly, there will be no meaningful change of attitude, and conformance will come by compulsion. This is less than the ideal but may be the only avenue left. Finally, and maybe most importantly, the same goals of the "therapy" model used to examine the program side of the Laboratory must also be dialectically applied to the QA program itself. Is the QA program self reflective? Are they auditing strictly for compliance, or are they auditing for effectiveness? Are QA "types" trying to raise their own consciousness about what they do and why they do it? Is the QA organization trying to change inappropriate attitudes it may have towards program people in the same way that program people are asked to consider their attitudes about "orthodox" QA?

Although it has not been implemented at this time, the second phase of Fermilab's move towards an "orthodox" QA program will be driven by the "medical" model. In the early 1960's Avedis Donbedian, an MD and professor at the University of Michigan School of Public Health, postulated what has been called the Holy Trinity of quality measurement in medical care: structure, process, and outcome. "Structure meant a hospital that was clean, safe, and had all the right equipment filling its operating rooms and patient areas. Process meant that the doctor did all the correct things with that equipment. Outcome meant that the patient got well-or at least, got sicker no more quickly than he would have without the physician's intervention." (4)

It is important to note here that there are many conceptual and operational similarities between the services described above in reference to the medical profession and the services provided to the high-energy physics community by Fermilab. Because of time constraints, I cannot give all the details of the model but will give a few highlights. Fermilab provides a structure or facility which produces 1 TeV proton antiproton beams which can be converted to a variety of secondary and tertiary beams. Although the parameters of a beam can be changed slightly from beamline to beamline, an experimental proposal which is approved by the Physics Advisory Committee must be assigned a location for the experiment based on the parameters of the beam and the size constraints in the areas in which experimenters set-up their detectors and other equipment. The needs of the experiment are matched to the capabilities of Fermilab's structure much like the health needs of a patient (heart trouble, intensive care, etc.) are matched to the capabilities of a particular hospital. Although experimenters bring much of their own equipment and are often responsible for design, fabrication, installation, and operation of that equipment, the process of running an experiment is a mutual and reciprocal relationship between the Fermilab staff and individuals from universities around the world that compose the collaboration. They are allowed a specific number of hours of beam time in order to successfully make their measurements, after which they must remove their equipment to make room for the next "patient". But much like a patient unexpectedly may develop complications which demand that his hospital stay be extended even though he was scheduled for release, experiments are sometimes granted longer running periods because of unexpected complications in their apparatus or beam transport. The point is, that the process of running an experiment is not cut and dry and totally submissive to pre-designed schedules. Once an experiment has finished accumulating its data sample, the university professors, post-doctoral, and graduate students

4) "A Prescription for Change", Michael L. Millenson, in Quality Progress, May 1987, p 17ff.

set about the task of analyzing the data, with the outcome being new high-energy physics data that is published in a physics journal. As in the medical profession, peer review and the setting of standards and criteria are the most important components of this model. By using the model analytically, it will allow us to do a number of things. It will help to isolate and probe for unknown anomalies in the program that are not apparent by using the "therapy" model alone because it will define new criteria not currently in use at the Laboratory as opposed to defining what already exists. In addition, the "medical" model lends itself quite easily to the establishing of quantified standards and statistical analysis. Currently the mechanism for implementing the structure, process, outcome model is not in place. We are just beginning. The eventual goal is to use both models in an orchestrated dialectic that addresses the attitudinal and definitive aspects of QA along with an analytical approach which quantifies QA criteria within the paradigm of structure, process, and outcome of experiments.

PHYSICS AND "ORTHODOX" QUALITY

Having discussed Fermilab's QA philosophy and the "therapy" and "medical" models, this section will probe even deeper into the relationship between the high-energy physics community and "orthodox" QA and analyze some of the philosophical and cultural relationships between the two. Is it appropriate to refer to quality as a "cultural" phenomenon? Crosby describes his goal at ITT in this way, "So I embarked on a deliberate strategy of estalishing a cultural revolution-a cultural revolution that would last forever and become part of the corporate woodwork." (5) Although such a cultural revolution may have been necessary at ITT and in the manufacturing community as a whole, I would like to suggest that no such revolution is necessary in the high-energy physics community because the "scientific" culture is much more accommodating to some aspects of "orthodox" QA than the culture associated with the manufacturing community.

The remainder of the paper equates the high-energy physics community with the scientific community. This was done to narrow the scope of the arguments and because I am more familiar with "family life" in the high-energy physics community than any other branch of science. Although there are many historians and philosophers of science who have described the philosophical and cultural aspects of the scientific community, one of the most profound treatments was presented by Thomas Kuhn in his monumental book, The Structure of Scientific Revolutions. (6) According to Kuhn, an important distinguishing mark of the scientific culture is it homogeneity.

"A scientific community consists, on this view, of the practitioners of a scientific specialty. To an extent unparalleled in most other fields, they have undergone similar educations and professional initiations; in the process they have absorbed the same technical literature and drawn many of the same lessons from it...As a result, the members of a

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5) Quality is Free, Philip B. Crosby, (New York: McGraw-Hill Book Company, 1979) p 7.

6) The Structure of Scientific Revolutions, Thomas Kuhn, 2nd ed. enlarged (Chicago: University of Chicago Press, 1970).

scientific community see themselves and are seen by others as men uniquely responsible for the pursuit of a set of shared goals, including the training of their successors." (7)

Kuhn attributes this homogeniety to one major fact, namely a commitment to a set of shared theories and research traditions recorded in the physics textbooks with which students are initiated into the scientific community in which they will practice science. Kuhn claims that the combination of the textbook and research traditions become a "paradigm" to which a scientific community commits itself for a period of time. For high-energy physicists the theoretical side of the paradigm is the "Standard Model" discussed previously. These written traditions or paradigms (Classical Mechanics, or Relativistic Quantum Mechanics, etc.) are the true source of authority within the physics community at any given time. An individual physicist's "authority" is related to his level of comprehension of the paradigm theoretically and his ability to isolate and solve problems within the paradigm by designing detectors and apparatuses to test various anomolies which arise. Although these paradigms can be challenged by anomolies in the model and eventually overthrown if the anomolies are significant enough, the resolution of the mapping between theory and experiment remains the final authoritative court of appeal. Understanding the nature of this authority structure is paramount to understanding the nature of the "scientific culture", because Kuhn claims that it is "...one of the aspects of scientific work that most clearly distinguishes it from every other creative pursuit except perhaps theology." (8)

But other than the mathematical formalisms, theories, and experimental designs taught by the textbooks, are there hidden parameters of the paradigm that when isolated will provide additional insight into the training and cultural indoctrination of a high-energy physicist?

1. A sense of integrity in one's work where an experimenter purposely seeks out both theoretical and empirical anomolies
2. Extensive peer review of both experimental design and data
3. Theoretical structures that are based on mathematical formalism
4. A goal of rigor in measurement and elegance in the theory-experiment marriage

These are aspects of training that are built deeply into the framework of high-energy physics. In fact, having been a witness to the Behavioristic and Statistical Schools' demolition of Freud's theories, it is amusing to note how many of the "softer" sciences (and even some aspects of QA) have become victims of "physics" envy, i.e., the desire to reduce the foundations of their disciple to the kind of mathematical formalism and rigor found in physics. Most high-energy physicists have a fundamental commitment to assuring integrity in their work, a thing that is intrinsic to the scientific community as a whole. No doubt there are some scientists who have "fudged the data" or who are cludgers and scissors and tape people, but this type is the exception rather than the rule. In addition, if one of these

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7) The Structure of Scientific Revolutions, Thomas Kuhn, 2nd ed. enlarged (Chicago: University of Chicago Press, 1970) p 177.

8) The Structure of Scientific Revolutions, Thomas Kuhn, 2nd ed. enlarged (Chicago: University of Chicago Press, 1970) p. 136.

"data fudgers" is discovered by their peers, they are punished and ostracized from that scientific community. Nothing can ruin a physicist's reputation faster than a peer review that says "Oh Joe, yea, his numbers and calculations are always off by a factor of two or three." This type of "family-like" punitive mechanism used by the scientific community-and possibly the church-is not generally apart of the manufacturing culture. At the deepest level, I believe that the high-energy physics community and the quality community want the same things.

So what's the problem? Why have researchers been rumored to be so opposed to quality assurance? Part of the problem is explained by the way in which the physics community as a whole has and continues to evolve. "Physics has evolved and continues to develop without any single strategy. Careful refinements in measurement to uncover anomalous behavior, mathematical extrapolation of existing theory, critical re-examination of apparently obvious but untested presuppositions, argument by symmetry or analogy, aesthetic judgment, accident, and hunch all plays a role." (9)

It is important at this point to make the distinction between 1) the development of physics as mentioned above and 2) obtaining the tools with which to do that physics. These two issues meet at an interface and it is at that interface that physics and quality meet. With the advent of "Big Science", and $4 billion accelerators, the economics of designing fabricating and operating the tools for doing "Big Science" have come more and more into the center stage. (10) Because of this, scientists have been forced more and more to be fiscally accountable for the dollars they are given to do their research and they must also compete against other scientists who seek those same dollars. With the above distinction in mind, we can conclude that it is not the methods that scientists use to do physics that are at issue in QA, but the methods they use to procure, fabricate, and operate the tools they use to do physics.

In conclusion, I am convinced that integrity in one's work, rigorous peer review, and sophistication based on mathematical formalisms are intrinsically apart of the scientific community to a degree unparalleled elsewhere. Consequently, the basic philosophical and cultural framework of physics is not only accommodating to "orthodox" QA but in some senses its goals are identical. The issue is using the scientific integrity and rigor at the interface with the business world. This leads us to our final question about the place of "orthodox" QA in the Laboratory setting.

THE PLACE OF "ORTHODOX" QUALITY

There is most certainly a place for "orthodox" QA at a Laboratory like Fermilab. One must begin with a non-antagonistic QA philosophy where researchers accept the 18 requirements of NQA-1 as a valid standard against which to measure their procedures. As we move through the long process of writing down lists of existing procedures which increases our consciousness of what we already do, it is amazing to note how often the

9) Encyclopedia Brittannica, 15th Edition, vol 25, article on Physical Sciences, p 845.

10) "The Superconducting Supercollider", J. David Jackson, Maury Tigner and Stanley Wojcicki, in Scientific American, March 1986, p 66ff.

"unorthodox" procedures which have been done all along are in perfect compliance with the 18 "orthodox" requirements of NQA-1. This is so very important when beginning a QA program, because Division and Department Heads begin to realize that they've had a QA program all along, they just called it something else. When this happens the distinction between "orthodox" and "unorthodox" QA becomes nominal as a result of the actual differences being quantified. The 18 requirements of NQA-1 can then be viewed as a part of the peer review and procurement processes with scientific integrity and rigor being applied at the interface between the physics and business worlds. The most important thing here is accountability for one's work. As we have mentioned, this notion is built deeply into the fabric of the scientific community to start with so the foundations for a joining of forces between high-energy physicists and the QA community already exist.

Having begun with the "therapy" model in an attempt to canonize and compare existing QA traditions with the 18 requirements of NQA-1, and also to define and change attitudes towards QA by fostering self reflection and consciousness raising, we at Fermilab have begun to define who we are and what we do in relation to the quality community. This type of "self definition" is imperative when moving into the "medical" model where the Laboratory will be viewed according to its structure, process, and outcome. Once the "medical" model is implemented, the "therapy" model can be used to bring accountability to the analytic and statistical probes used to analyze the level of quality at the Laboratory.

Finally, and maybe most importantly, "The tail should never wag the dog". The QA program must be tailored to the individual needs of the Laboratory. "Orthodox" QA meets the most resistance when it generates massive amounts of bureaucratic paperwork and procedures. This is not necessary in order to have an effective program. The optimum program is a "less is more approach" where each part of the program is a living functioning piece of the overall framework. Applying the "therapy" model to the overall QA program can help assure that the "tail" remains what it is suppose to be; a monitor and indicator of how the dog is doing, not the other way around.