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Defining a Doctrine for QA in Government Funded Basic Research *

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Defining a Doctrine for QA in Government Funded Basic Research[1]

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For all its quantifiable certainty and mathematical rigor, the *sociological* aspects of pure research remain somewhat of an enigma to most people outside the scientific community. Based on a tightly-knit culture of peers, the origins of which are traceable to 17th and 18th century natural philosophers like Robert Boyle, Isaac Newton, and the early days of the Royal Society, few outside the scientific disciplines have been able to successfully characterize the nature and sociological structure of scientific activities. This has important ramifications when a funding agency attempts to impose an institution-wide quality philosophy that may be at odds with the established culture as practiced in scientific environments.[2]

In the days when table-top experiments were financed by a single university, these issues had yet to arise because the scope and complexity of experiments were more modest and no outside funding agency was involved. The scientists knew what they were doing and that's all that mattered. But in a time when basic scientific knowledge costs upwards of 2 billion dollars to obtain, like the high-energy physics data produced at powerful particle accelerators like Fermilab, new questions have arisen about the role that quality assurance and QA professionals should play in government funded basic research.

The problem is that basic researchers, QA professionals, and government funding agencies have yet to define a workable "doctrine" for basic research QA that is acceptable to all parties involved.[3] An important distinction turns on the

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[1] Fermilab is operated by Universities Research Association, Inc. under contract with the United States Department of Energy. Fermilab is also a Sustaining Member of ASQC.

[2] It should be noted that ANSI/ASME NQA-1 is required of all DOE contractors, even non-nuclear basic research laboratories, even though the applicability statement of NQA-1 excludes such facilities by virtue of being non-nuclear. I discuss this issue at some length elsewhere, see Mark Bodnarczuk, "QA At Fermilab; The Hermeneutics of NQA-1", published in the *Proceedings of the Twenty Ninth Annual Meeting of the Institute of Nuclear Materials Management*, June, 1988, pp 413-416, (Fermilab-Conf-88/55) and *New Directions for QA in Basic Research: The Fermilab/DOE-CH Experience*, presented at the DOE Quality Assurance Workshop, Department of Energy Idaho Operations Office, Idaho National Engineering Laboratory, Idaho Falls, October 3-4, 1989, (Fermilab-Conf-89/194)

[3] Some of the first attempts at defining a workable doctrine were developed at Los Alamos National Laboratory, see "A New Approach to Quality for National Research Labs", Peter L. Bussolini; Alvin H. Davis; and R. Ronald Geoffrion, in *Quality Progress*, January 1988, pp 24-27, and in a Department of Energy sponsored document authored by Ames Laboratory, Argonne National Laboratory, Brookhaven National Laboratory, Fermi National Accelerator Laboratory, Princeton Plasma Physics Laboratory, and the Solar Energy Research Institute, see *Institutional Quality Assurance at DOE-CH Laboratories; A Partnership*, published by the U.S. Department of Energy Chicago Operations Office, June 1988.

two components of the word "doctrine;" orthodoxy and orthopraxy. Orthodoxy is right belief, while orthopraxy is simply right practice. While government funding agencies have interfered little with the "orthodoxy" of basic research (the scientific knowledge produced), they have increasing interfered in the "orthopraxy" of basic research (the mechanics of how the research is obtained). At the heart of the issue lies many misconceptions about the primary mechanism used to assure quality in basic research for the last 300 years; peer review. This article focuses upon three of the major issues related to peer review and QA in basic research environments, using examples which come from the design and implementation of an institution-wide QA program at Fermilab.

Basic Research and Fermilab's Mission

It is important to define exactly what basic research *is* in regard to the other types of research missions. The goal of applied research (R&D) is to exhaustively investigate important aspects of the physical world that can be used for practical or technologically definable purposes. The role of QA in these types of environments has been skillfully described by George Roberts in his book *Quality Assurance in Research and Development.*[4] In contrast, the goal of basic research is to more clearly define or create new laws of physics and consequently constitutes the starting point for new knowledge about the physical world and future applied research endeavors. As such, it is a natural extension of the training done at universities. The distinction between applied and basic research is vital to understanding the role that QA and peer review plays in such environments because the cutting-edge nature of the science dictates who it is that can assure the quality of such data.

Fermilab's mission is confined to doing basic research in high-energy physics. The Laboratory explores and defines the fundamental parameters of the universe. This includes studies of the constituents of the matter (quarks and leptons) and the forces by which they interact (weak, strong, electromagnetic, and gravitational forces). Fermilab's sole product is PhD physicists and journal articles about high-energy physics parameters measured at the Laboratory. The tools with which this basic research is carried out are one-of-a-kind particle accelerators and detectors designed and built by international high-energy physics collaborations in cooperation with Fermilab. How does one approach this scenario with the standard tools of the QA profession? One approach is to understand the peer review process, i.e., the process by which basic researchers assure the quality of the data that eventually become formulated into new physical laws.

The Nature and Function of Peer Review

There are two aspects to understanding the nature and function of peer review. The first is determining what it means to have authority in the high-energy physics community. This is vital to the discussion because the entire notion of peer review rests upon the credibility of the individuals involved in the process. One of the most celebrated philosophers of science, Thomas Kuhn, claims that the ultimate authority in a scientific community is contained in the shared network of commitments to conceptual, theoretical, instrumental, and methodological ways of carrying out the goal of the discipline. He calls this

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[4] George W. Roberts, *Quality Assurance in Research and Development*, (New York: Marcel Dekker Inc., 1983).

network of commitments a "paradigm."[5] In high-energy physics where the goal is to isolate the fundamental constituents of the universe and the forces that interact between them, the paradigm consists of the "Standard Model" along with current accelerator, detector, and computing technologies. The theoretical and experimental aspects of the paradigm for high-energy physics are articulated in the textbooks and journal publications used to train new physicists. According to Kuhn, physicists have no intrinsic authority *independent* of the authority contained in the paradigm. A physicist achieves *vicarious* authority only to the degree that he can articulate the parameters of the paradigm and design theoretical and experimental puzzles which probe and test them in every conceivable way. The more tests and experimental challenges the paradigm stands up to, the more "authority" it gains within the scientific community. Kuhn called this "Normal Science."[6] A *physicist's* authority is directly proportional to his understanding of the paradigm and the puzzles he devises to test it.[7] In a very real sense, the notion of *vicarious* authority is no different in any other field. The engineer's authority in the engineering community is based upon his ability to solve puzzles and problems within the paradigm of standard engineering which is based upon methods embodied in engineering texts and subject to the laws of nature and the rigors of mathematical calculations. In a similar way, the quality professional only has authority to the degree that he can solve "quality" problems using the standard tools of the quality paradigm (SPC, Taguchi's loss function curves etc.).

The second aspect of understanding the nature and function of peer review involves defining what a peer is. To be a peer simply means "to be equal, to rank equally."[8] A peer is a colleague who is actively engaged in the same profession, more particularly he is a colleague who is actively working on the same types of physics. It is important to note here, that although being trained in the same field (having a degree) is a prerequisite to being a peer, the crucial factor is being an *active* practicing *competitor* who pursues the *same* type of research. The word "peer" is a relational or comparative term. Someone can only be a peer in relation to someone else with whom he competes in the same type of research. If an individual has received a PhD in high-energy physics and leaves the field for an extended period of time, he looses his status as a peer. He can regain that status only by once again joining an experimental collaboration which is doing research in that field and coming up to speed on the data and experimental work done during his absence from the field. If he once again leaves the field, he once again looses his status as a peer. As mentioned above, this is no different than any other field of expertise like engineering or QA.

When basic research activities are reviewed for quality, scientific orthopraxy and the rules of peer review demand that we first define the nature of the work being reviewed (what discipline it falls under), then pick individuals to review work only within their area of competency, i.e., the area in which they are peers. This raises an important issue in basic research, namely how does one

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[5] Thomas Kuhn, *The Structure of Scientific Revolutions*, 2nd ed., enlarged, (Chicago: The University of Chicago Press, 1970), pp 35 ff.

[6] For example, the theory of quantum electrodynamics has been tested against experimental results to an accuracy of 1 part in a billion, see Richard P. Feynman, *QED The Strange Theory of Light and Matter*, (Princeton, NJ: Princeton University Press, 1985), p 7.

[7] Kuhn, p 36.

[8] *Oxford Compact Edition of the Oxford English Dictionary*, 2 vols., (Oxford: The Clarendon Press, 1972), vol. 2, p 2113.

define the boundaries of a particular discipline. More particularly, in the design and construction of today's sophisticated high-energy physics detectors which use people from many different disciplines as part of a team (hardware engineers, technicians, physicists, software engineers etc.), where are the boundaries between these disciplines to be drawn and how should peers be assigned to review those areas once defined? In other words, where does the basic research stop and the standard engineering begin?

The Basic Research/Engineering Interface

Clearly defining the boundaries between basic research and standard engineering activities is one of the most difficult issues faced in defining a workable doctrine for basic research QA. We can illustrate this point, and define the interface between basic research and standard engineering, by analyzing the process of developing an experimental detector at Fermilab at its various levels.

Level 1 Theory-Effect
Level 2 Early Conceptual Detector Design
Level 3 Proposal Stage
Level 4 PAC Stage (Overviews Above Levels)
Level 5 Conceptual to Final Design
Level 6 Fabrication and Installation
Level 7 Operation
Level 8 Data Analysis

At Level 1 (theory-effect), groups of physicists often come together at physics workshops with the goal of defining what physics topics are critical to advancing the field and what detectors are required to "cash out" the predicted effect into something that is measurable in an unambiguous way. At Level 2, an initial core group of physicists design the broad parameters of a detector in a way that will yield the highest data accumulation rate with the detector. Of importance here, is devising a way of clearly identifying the predicted events amidst uninteresting background events, then recording only the salient ones to be used for later analysis. The peers at these two levels quite obviously must be physicist peers. Any independent quality verification done at these levels must also be carried out by physicist peers.

Level 3 involves the assembling of a formal collaboration of physicists from many universities who are interested in working on the same type of physics problems. At this level, the conceptual design of the detector becomes more defined as the collaborating institutions give their input to the design along with commitments in dollars and manpower to carry out those tasks. One of the most important points at this level is to be sure that the production rates of the predicted effects are matched to the capabilities of the detector and data acquisition system. Increasingly, engineers at Fermilab who specialize in high-energy physics detector design are brought in to the design process at this point. This work leads to the formal proposal stage. The peers at level 4 are mostly physicist peers with specialized engineering peers reviewing their contributions to the project.

The Fermilab Physics Advisory Committee (PAC) is composed of prominent physicist peers from other laboratories and universities throughout the United States. Based upon the review of the PAC, Fermilab management approves experiments to take data. It is at Level 4 that an experiment becomes a formal Fermilab project. The peers at this level, once again, must be physicist peers.

If approved, the experiment moves to Level 5. It is at this level that a large number of engineers are brought in to "cash out" the design into what will become a final design. It is also at this point that basic research first interacts strongly with a wide variety of engineering disciplines. Consequently, it is at

Level 5 that the basic research interfaces with standard engineering practice. Throughout Level 5, those aspects of the detector designed by the engineering staff are reviewed by engineering peers, along with the project physicist who assure that the final engineering decisions will produce a detector that will yield a data rate that will enable him to measure the predicted effect identified at Levels 1 and 2. Wherever a particular engineering discipline makes a contribution to the project, those contributions must be reviewed by peers from that discipline. The general rule is that all work must be reviewed by competent peers as defined above.

The next two levels (Level 6 [Fabrication and Installation] and Level 7 [Operation]) are rather straight forward and follow the same rule as Level 5, namely that all work should be reviewed by peers from that discipline subject to the specifications established at Levels 1 and 2. At Level 8 [Data analysis], the domain of review once again becomes exclusively determined by the expertise of physics peers. It is at this level that the collaboration (which is itself a group of up to 200 competitive peers) totally dominates the project in an attempt to discover whether or not the proposed effect has been manifested convincingly in the detector. Upon completion of the data analysis, the results of the experiment are reviewed by peer referees prior to publication in journals and by other physicist peers who upon reading the journal data may try to replicate, improve, or discredit a particular measurement.

The stage has now been set for discussing the most important aspect of defining a workable doctrine for basic research QA because none of the above process involves the QA professional. What then is the role of the QA professional in basic research environments?

A Role for QA Professionals in Basic Research

The reliance on peer review as the primary QA mechanism in basic research produces a certain type of *voyeurism* for the QA professional. The QA professional is (so to speak) "on the outside looking in" because only those who are peers within a specific community are qualified to judge what quality *is*. This does not of course mean that the QA professional may not have some technical training in physics or engineering for example. But as we said above, training alone does not necessarily make an individual a peer. The intuition about *QA voyeurism* is an important one because it makes the distinction between doing QA (peer line function) and being a QA professional (independent audit function) crystal clear. Let's use a number of analogies to try to concretize what the role of a QA professional might be in basic research.

We can describe the QA professional as a consultant who gives advise to other people on how to run their business or invest their money. However, in the end it is the *client's* money not the consultant's. He gets paid for his time and advice, but must voyeuristically leave the actual decisions to the client. We can also describe the QA Professional as a therapist, who while seeking to help and guide a patient to a more productive healthy life must in the end allow the person to make their own decisions. It is also enlightening to describe the QA Professional as an evangelist who is brought into a church for a series of "revival" meetings then is on to the next church (sounds a lot like some QA gurus). The evangelist is like a "hit'n run type" that assumes no continuing responsibility for the lives of the people he preaches to. This is unlike the model of the pastor who comes and "lives among" his parishioners. But as close as the pastor is to his people, he still plays a *voyeuristic* role in regard to making their decisions for them. In the end, it is up to the parishioners. The pastor's role is to preach the "truth" and hope some of it sinks in. Although these are fairly impressionistic descriptions, they can be very instructive to the QA professional who finds himself working in a basic research environment. From these impressionistic analogies, we can begin to define some practical roles for the QA professional working in a basic research environment.

The first, and most important, component is to mediate between the culture of science and the structure of the government funding agency which imposes quality requirements that may or may not fit the basic research environment. Many of the problems that have been caused between the funding agency, basic researchers, and QA professionals are matters of semantics which can be avoided by developing models that communicate between the three parties. In this case, the QA professional plays the role of mediator and "go-between." At Fermilab, we have addressed this problem by moving below the level of the sometimes paradoxical conflicts caused by the unique languages spoken by QA professionals and basic researchers and addressed the issues at the conceptual level. In other words, what the basic researcher calls a Magnet Development and Test Facility, the QA professional may call an "independent audit function." What the basic researcher calls peer review (the intense technical review of proposed experimental projects by physics peers from other competing laboratories) the QA professional might call Control of Special Processes (because it is the certification of the participants and procedures of the process that are at stake). The goal of this translation process should be to find the conceptual equivalents and translate them into the language spoken in the respective professions. The QA Manager at a basic research facility like Fermilab must be able to speak both languages fluently. In fact, this is one of his major tasks.

The second component involves helping the line QA people (department heads, scientists etc.) to document the process of doing QA in a way that is acceptable both to them and the funding agency. Because Fermilab had been successfully operating for 20 years prior to the issuance of the requirement to establish a QA program that was traceable to NQA-1, we began by attempting to determine what types of quality traditions already existed using a bottoms-up approach. The QA staff turned the 18 basic requirements of ANSI/ASME NQA-1 into a series of questions and circulated these questionnaires to all Laboratory management. After clearly stating the requirement under the heading of "scope," management were asked things like, "How is it that you practice design control? Who is responsible for design control? What requirements does that person have to meet? The answers to these questionnaires were reviewed by the QA staff, and subsequently became the database for developing the institution-wide QA program.

While the finished QA program looks identical to programs that are forced over the existing culture of an organization, and while it is traceable to NQA-1, the bottoms-up approach has distinct advantages over more orthodox approaches that "impose" the standard on laboratory activities. First, it does not attempt to *replace* scientific "orthopraxy" with another standard (NQA-1) that was written for radically different purposes and (by its own applicability statement) does not apply to basic research. Fermilab's approach uses NQA-1 as standards *ought* to be used, as a check or calibration point against which to measure the adequacy of scientific practice. It is not used as a *substitute* for peer review and scientific practice. Second, it places primary responsibility for QA where it belongs, on the line functions. Third, all aspects of the QA program are traceable to NQA-1 because it is the basis against which the activities are measured. Fourth, because the scientists and support staff design the program to meet the needs of their day-to-day activities, they will more readily "own" the program and comply with it. Fifth, it allows the scientist to maintain the freedom and creative latitude necessary to do scientific work, and at the same time defines the boundaries within which that freedom can be exercised. Finally, it provides assurance to the government funding agency that the public trust afforded Fermilab is being carried out with accountability and fiscal responsibility. The QA professional's role in these activities is interpreter. This is vitally related to the previously mentioned role of mediator.

Third, the QA professional must provide the type of training necessary to inform laboratory personnel about the ANSI/ASME NQA-1 requirements. This may also involve training about the general principles of quality as presented by some of the presently accepted QA gurus. Here the QA professional's role is as trainer. Finally, the fourth component is to regularly audit the QA programs to insure that what's written truly reflects the day-to-day operation of the laboratory. This area demands that QA professional assume the role of auditor. In basic research environments, it is important to maintain a division of labor between peers who perform and assure the quality of the *work* and QA professionals who audit to assure the traceability of the *paperwork* that describes that work.

Depending on the circumstances, the QA professional in basic research must be ready to assume one or more of the roles described above. But it is important to remember that the QA professional is not a peer to anyone except *other QA professionals* and consequently has no place in the actual process of peer review as carried out by the respective community of peers. Using this type of approach, responsibility for quality assurance is placed where it belongs, with the people doing the work, not the QA professional.