

Quarks, Leptons, and **Quality Assurance**

Fermilab is working to define a QA doctrine for governmentfunded research.

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OR ALL ITS QUANTIFIABLE CERTAINTY and mathematical rigor, the sociology of pure research remains somewhat of an enigma to most people outside the scientific community. Because the community is a tightly knit culture of peers (the origins of which are traceable to 17th- and 18th-century natural philosophers, such as Robert Boyle and 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 elusiveness has important ramifications when a funding agency attempts to impose an institutionwide quality philosophy that might be at odds with the scientific community's established culture.1

In the days when table-top experiments were financed by a single university, this wasn't an issue because the experiments' scope and complexity were more modest and no outside funding agency was involved. But in a time when basic scientific research costs more than \$2 billion, questions about QA professionals' role in government-funded basic research have surfaced. 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 involved.2

A doctrine has two distinct components: orthodoxy, the right belief, and orthopraxy, the right practice. While government funding agencies have interfered little with the orthodoxy of basic research (the scientific knowledge produced), they have increasingly interfered with its orthopraxy (the mechanics of how the research is obtained). Many misconceptions exist about the primary mechanism used to ensure quality in basic research for the last 300 years: peer review. Three major issues surround the relationship between peer review and QA in basic research en-

vironments. These issues will be explored using examples from the development of an institutionwide QA program at the Fermi National Accelerator Laboratory (Fermilab), which is operated by Universities Research Association, Inc. under contract with the United States Department of Energy.

Basic research and Fermilab's mission

It is important to define exactly how basic research differs from other research. The goal of applied research (R&D) is to investigate important aspects of the physical world that can be used for practical or technologically definable purposes. (The role of QA in applied research has been skillfully described by George Roberts in Quality Assurance in Research and Development.3) In contrast, the goal of basic research is to more clearly define or create new laws of physics that consequently constitute the starting point for new knowledge about the physical world and future applied research. As such, it is a natural extension of the training provided by universities. The distinction between applied and basic research is vital to understanding the role QA and peer review play in such environments because the nature of the science dictates who can assure the quality of the data.

Fermilab's mission is to perform basic research in high-energy physics by exploring and defining the fundamental parameters of the universe. This includes studies of the constituents of 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 highenergy physics parameters measured at the laboratory. The tools at this basic research are one-of-a-kind particle accelerators and detectors designed and built by international high-energy physics collaborations. How does one apply the standard methods of the QA profession in this environment? One approach is to understand the peer review process, i.e., the process by which basic researchers assure the quality of the data that are eventually formulated into new physical laws

The nature and function of peer review

To understand the nature and function of peer review, one must understand what it means to have authority in the highenergy physics community and what it means to be a peer.

The question of authority is vital because the entire notion of peer review rests on the credibility of the individuals involved. One of the most celebrated philosophers of science, Thomas Kuhn, states the ultimate authority in a scientific community is contained in its network of commitments to conceptual, theoretical, instrumental, and methodological ways to carry out the goal of the discipline. He calls this network of commitments a "paradigm."

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 paradigm's theoretical and experimental aspects are articulated in the textbooks and journals used to train new physicists. According to Kuhn, physicists have no intrinsic authority independent of the authority contained in the paradigm. A physicist's authority is directly proportional to his understanding of the paradigm and the theoretical and experimental puzzles he devises to test it. The more tests and experimental challenges the paradigm stands up to, the more authority it gains within the scientific community. Kuhn calls this "normal science."

Vicarious authority presides in other fields. An engineer's authority in the engineering community is based on his ability to solve puzzles and problems within the paradigm of standard engineering, which is based on methods embodied in engineering texts and subject to the laws of nature and the rigors of mathematical calculation. Similarly, the quality professional has authority only to the degree that he is able to solve quality problems using the standard tools of the quality paradigm (SPC, Taguchi loss function curves, etc.).

The second key to understanding the nature and function of peer review is the definition of "peer." To be a peer simply means to be equal or rank equally. A peer is a professional who is actively engaged in the same profession as his colleagues.

It is important to note 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 be a peer only to someone 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 loses his status as a peer. He can regain that status only by resuming research in that field and catching up on the data and experimental work done during his absence. As mentioned previously, this is true in other fields.

When basic research activities are reviewed for quality, the rules of peer review and scientific orthopraxy demand that one first define the nature of the work being reviewed (what discipline it falls under) and 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 question in basic research: How does one define the boundaries of a particular discipline? More specifically, when people from many different disciplines (hardware engineers, technicians, physicists, software engineers, etc.) work as a team to design and construct a sophisticated high-energy physics detector, where should the boundaries between these disciplines be drawn and how should peers be assigned to review those areas defined? In other words, where does basic research stop and standard engineering begin?

The basic research-engineering boundaries

Clearly defining the boundaries between basic research and standard engineering is one of the most difficult tasks in preparing a workable doctrine for basic research QA. Fermilab defined those boundaries by analyzing its process for developing experimental detectors. Here is a description of that eight-level process and the respective peers:

Level 1. Theory-effect. Groups of physicists often come together at physics workshops to define what topics are critical to advancing the field and what detectors are required to develop the predicted effect into something measurable. The peers at this level are physicists. Any independent quality verification performed at this level is also carried out by these peers.

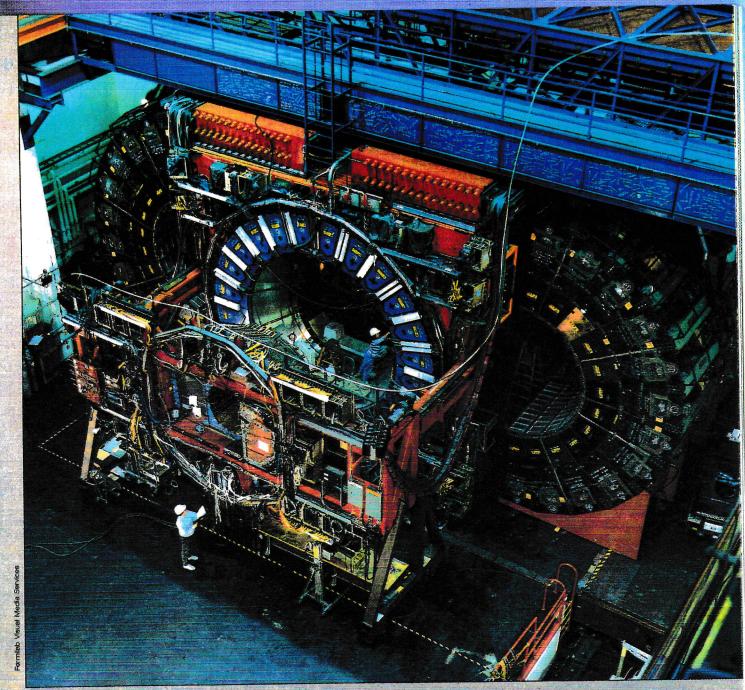
Level 2. Early conceptual detector design. An initial core group of physicists designs the broad parameters of a detector so that it will yield the highest data accumulation rate. The group must devise a way to identify the predicted events amid uninteresting background events and to record only the salient ones for later analysis. The peers at this level are the same as those in Level 1.

Level 3. Proposal. Physicists interested in working on the project assemble into a formal collaboration (a group of as many as 200 peers from various universities). The conceptual design of the detector becomes more defined as the collaborating institutions give their input and their commitment in dollars and manpower. The physicists make sure the production rates of the predicted effects are matched to the capabilities of the detector and data acquisition system. The Fermilab engineers who specialize in high-energy physics detector design are then brought in to help design the detector. All this work leads to a formal proposal. Most of the peers at this level are physicists. However, specialized engineering peers review the engineers' contributions to the project.

Level 4. Physics Advisory Committee (PAC). The PAC consists of prominent physicist peers from other laboratories and universities throughout the United States. Based on the PAC's review of the project, Fermilab management either approves or rejects the experiment. If approved, the experiment becomes a formal Fermilab project. The peers at this level, once again, are physicists.

Level 5. Conceptual to final design. A large number of engineers are brought in to develop the final design. Consequently, basic research practices mesh with standard engineering practices. The project physicist makes sure the detector will yield the data rate needed to measure the predicted effect identified at Levels 1 and 2. The general rules for peer review are that all contributions made by a particular discipline are reviewed by peers from that discipline and that all work is subject to the specifications established at Levels 1 and 2.

Level 6. Fabrication and installation. The detector is fabri-



Fermilab's 2,000-ton collider detector gathers high-energy physics data. The experimental collaboration involves more than 200 physicists, post-doctorate students, and graduate students from the United States, Japan, and Italy.

cated and installed. The general rules for peer review are followed.

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Level 7. Operation. The detector is operated. The general rules for peer review are followed.

Level 8. Data analysis. The collaboration completely dominates the project in an attempt to discover whether the proposed effect has been manifested convincingly in the detector. After the data have been analyzed, peer referees and other physicist peers review the results of the experiment, trying to replicate, improve, or discredit a particular measurement. This is done before any results are published.

The stage is now set for discussing the most important part of defining a workable doctrine for basic research QA: determining the role of the QA professional.

The QA professional's role

The reliance on peer review as the primary QA mechanism in basic research produces a certain type of isolation 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 the quality level is. Although the QA professional might have some technical training in physics or engineering, for example, that training does not make him a peer. The distinction between performing QA activities (peer line function) and being a QA professional (independent audit function) is important.

The QA professional can be described as a consultant who advises clients on how to run their businesses or invest their money. Although the consultant gets paid for his time and ad-

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vice, the client makes all the decisions, because it is the client's money not the consultant's.

Although this analogy is simple, it can help QA professionals working in a basic research environment understand their roles: mediating, documenting, training, and auditing.

Mediating

The QA professional's first and most important role is to mediate between basic researchers and the government funding agency regarding the imposed quality requirements. Many of the problems that arise are matters of semantics. For example, what the basic researcher calls a magnet development and test facility, the funding agency calls an independent audit function. What the basic researcher calls peer review, the funding agency calls control of special processes.

Semantic problems can be avoided by facilitating communication among all parties involved, including the quality assurance staff. Fermilab has a translation process by which conceptual equivalents for the topic being discussed are found and then translated into the language spoken by the respective professionals. QA professionals at basic research facilities like Fermilab, therefore, must be able to speak all languages fluently and serve as an interpreter.

Documenting

The QA professional's second role is to help those in line functions (scientists, department managers, etc.) document their QA processes in a manner that is acceptable to them and the funding agency. QA professionals will have to use their interpreting skills in this role as well.

Because Fermilab had some quality processes already in place before the Department of Energy required a QA program traceable to NQA-1, it had to determine which requirements were already met and which were not. To do this, the QA staff turned the 18 basic requirements of ANSI/ASME NQA-1 into a questionnaire. Each requirement was clearly stated. Above it was the heading "Scope"; below it were questions such as: How do you practice design control? Who is responsible for design control? What requirements does that person have to meet? The questionnaires were given to all laboratory managers. The answers were reviewed by the QA staff and became the data base for developing Fermilab's institutionwide QA program.

Fermilab's bottom-up approach to developing its QA program produced several advantages over the more orthodox approach of imposing NQA-1 requirements:

- 1. The QA program does not attempt to replace scientific orthopraxy with the NQA-1 standard, which was written for radically different purposes and (by its own applicability statement) does not apply to basic research. Fermilab's program uses NQA-1 as it ought to be used: as a check or calibration point against which to measure the adequacy of the scientific practice. It is not used as a substitute for peer review and scientific practice.
- 2. The program places primary responsibility for QA where it belongs, on the line functions.
- 3. All aspects of the QA program are traceable to NQA-l because all activities are measured against it.
- 4. Because the scientists and support staff designed the QA program to meet their day-to-day needs, they own the program and comply with it.
 - 5. The program lets scientists maintain the freedom and crea-

tive latitude they need to do scientific work and, at the same time, defines the boundaries within which that freedom can be exercised.

6. The program provides assurance to the government funding agency that Fermilab is accountable for its actions and is fiscally responsible.

Training

The QA professional must educate laboratory personnel about the NQA-1 requirements. This might also involve training on the general principles of quality.

Auditing

Finally, the QA professional must regularly audit the QA program to ensure it truly reflects the laboratory's day-to-day operation. In basic research environments, it is important to maintain a division of labor between peers (those who perform and ensure the quality of the work) and QA professionals (those who audit to ensure the traceability of the paperwork that describes that work).

Place responsibility where it belongs

It is important to remember the QA professional is not a peer to anyone except other QA professionals; consequently, he has no place in the actual process of peer review as carried out by a separate community of peers. Using this approach, responsibility for quality assurance is placed where it belongs, with the people doing the work, not with the QA professional.

References

- 1. ANSI/ASME NQA-1 is required of all Department of Energy contractors, including non-nuclear basic research laboratories, even though the applicability statement of NQA-1 excludes such facilities by virtue of their being non-nuclear. For further information, see Mark Bodnarczuk, "QA At Fermilab; The Hermeneutics of NQA-1," Proceedings of the 29th Annual Meeting of the Institute of Nuclear Materials Management, June 1988, pp. 413-416, (Fermilab-Conf-88/55)
- 2. Some of the first attempts at defining a workable doctrine were developed at Los Alamos National Laboratory. See Peter L. Bussolini, Alvin H. Davis, and R. Ronald Geoffrion, "A New Approach to Quality for National Research Labs," *Quality Progress*, January 1988, pp. 24-27, and *Institutional Quality Assurance at DOE-CH Laboratories; A Partnership*, U.S. Department of Energy Chicago Operations Office, June 1988.
- 3. George W. Roberts, Quality Assurance in Research and Development (New York: Marcel Dekker Inc., 1983).
- 4. Thomas Kuhn, *The Structure of Scientific Revolutions*, second edition (Chicago: The University of Chicago Press, 1970).
 - 5. Kuhn, The Structure of Scientific Revolutions, p. 36.
- 6. For example, the theory of quantum electrodynamics has been tested against experimental results to an accuracy of one part per billion. See Richard P. Feynman, *QED The Strange Theory of Light and Matter* (Princeton, NJ: Princeton University Press, 1985), p. 7.
- 7. Oxford Compact Edition of the Oxford English Dictionary, Vol. 2 (Oxford: The Clarendon Press, 1972), p. 2113.

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