SUBJECT:	Quality Assurance Guidelines for Scientific Research at Fermilab	**NUMBER:**	**4200**
RESPONSIBILITY:	Head, Office of Quality and Best Practices	**REVISION:**	001
APPROVED BY:	FNAL Laboratory Director	**EFFECTIVE:**	**SEPT. 9, 2009**

Quality Assurance Guidelines for Scientific Research at Fermilab

Office of Quality and Best Practices

Fermi National Accelerator Laboratory

Batavia, IL

August 29, 2009

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Overview

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INTRODUCTION

Science, by its very nature, is an enterprise with built in mechanisms of self-checking, which in turn assure quality in scientific research. Peer review is an essential element at many stages in our research, and is central to quality assurance. The output of research is knowledge, information, data, or proof-of-concept. The research effort itself involves the use of such methods as laboratory experimentation, computer modeling, theory formulation, and field-testing.

The output of scientific research is necessarily reproducible in its form, and is made available for checking. Recognition in the community of results and of the individuals involved in their generation is based on these features. This leads to very high goals for the quality of research generally, and at Fermilab in particular.

This document is the implementation for scientific research of Fermilab's Integrated Quality Assurance (IQA) Program, as identified in Chapter 11, Section 11.4 on Policy and Program Documents. This guideline does not apply to efforts that have specific quality assurance (QA) plans/programs approved separately by the Department of Energy (DOE), such as Fermilab projects with specific project QA plans as required by DOE Order 413.3A.

It is recognized that there are research efforts that are at the edges of what is described herein, and are handled on a case-by-case basis, typically by those responsible for managing the resources needed for the research. All research at Fermilab complies with the policies and guidelines established by the Director (http://www.fnal.gov/directorate/Policy_Manual.html) and relevant Divisions/Sections/Centers.

This Fermilab implementation follows the American National Standard "Quality Guidelines for Research" ANSI/ASQ Z1.13-1999. The document adopts the definitions in the ANSI standard, and follows the topics and ordering in that standard. The focus of Fermilab's implementation, as stated in the ANSI standard, is "on the application of quality systems on the main output of research institutions – the research results."

As with other integrated management systems at Fermilab, the IQA program for scientific research depends on the active commitment of all participants in the research. Quality assurance relies on the individual participants and their professional judgment. This is not simply an upper-management program. In this context, personal accountability is relevant for all the individual researchers. In addition, Fermilab's implementation of the IQA for scientific research follows the "graded approach" as detailed in this document. The authority level and formality of the implementation of the elements of Fermilab IQA for scientific research are tied directly to the scale and needs of each research effort, and as determined by the line management for that effort. See Table I.

Table I. Scientific Research Process and Control Levels

Process Step\Research Type	Theory	Experiments	Tests	Technology R&D
Goals Set, Methodology Selected, & Proposal Made	G	F	G	F
Research Start	G	A	D	B,C
Progress Review(s)	D	A	E	B,C
Completion of Data Taking	N/A	A	E	C
Analysis	G	F	G	G
Draft Publication/Presentation	G	F	G	F
Publication Submission	G	F	G	C
Publication	H	H	H	H

Control/Approval Level Key:

A	Fermilab Director/Deputy Director
B	Fermilab Associate Director
C	Fermilab Division/Section/Center Head
D	Fermilab Department Head
E	Fermilab Group Leader
F	Spokesperson, Principal Investigator, or Experiment-Based Review Body
G	Individual Researcher or Research Team
H	Publication Editor/Peer Review

Where two levels are indicated, the control depends on established cost thresholds.

Specific procedures for much of the experimental program are documented in the Fermilab "Procedures for Researchers (PFX)," available on the web at http://www.fnal.gov/directorate/PFX/PFX.pdf

Scientific research at Fermilab contains four elements: theoretical investigations, experiments, tests, and supporting-technology R&D. These four elements generally follow the same steps as they develop, and move toward publication of results. However, the scales of cost and human effort involved tend to be quite different, with different risks, and therefore different levels of control to assure quality. In general, theoretical investigations depend on the efforts of researchers without the use of specialized equipment. The effort in this research tends to be done by individuals or by a small group of individuals. Experiments are those research efforts that require larger groups and/or the use of extensive or specialized equipment. Lattice gauge theoretical research and computational cosmology fall into the experiment category for this reason. Experiments typically extend over years and aim at taking measurements, learning new physical principles and laws of nature through direct observation, testing theories, or searching for physical effects. Tests are shorter duration efforts, requiring fewer resources, and are typically aimed at demonstrating apparatus capability or making short time-duration measurements. Finally, research and development of supporting technology is typically done in the form of research programs that develop capabilities to be used in other research efforts. These programs typically extend over longer periods than the efforts of shorter tests.

Chapter 1. MANAGEMENT OF RESEARCH PROGRAM

1.1. RESPONSIBILITY FOR THE RESEARCH

Scientific research efforts have a principal investigator (PI) or spokesperson (sometimes co-PI's or co-spokespersons) to share the work and to help ensure availability for operational issues. These leaders are identified when the research is proposed, and there are orderly processes for changes to these leaders when the research will continue for extended periods of time. Normally, the Fermilab Directorate is informed of such changes at the time they occur.

These leaders are the primary contact between the Laboratory and the research, and these leaders have responsibility for the quality of the research, the safety of people and equipment in the research, as well as for reporting on the progress, status, and any relevant issues involving the research. This latter function is essential for determining, assuring, and improving the quality of the research.

Aspects of these responsibilities may be delegated as appropriate to facilitate effectiveness and communication. The Fermilab Directorate is notified at the time of any such delegation of responsibility.

Independent of which of the four research processes being considered, the steps in the research process are nearly the same, although the inputs and controls vary with the research type and the scale of the effort.

The germination of ideas for scientific research has inputs from individual discussions, reading of scientific and technical papers, and presentations and discussions at in venues such as seminars, workshops, and conferences. Once an idea has generated sufficient interest and adequate starting collaborators, a proposal is prepared. Sometimes,

collaborations send an Expression of Interest (EOI) and/or Letter of Intent (LOI) to the Laboratory to apprise the Laboratory of things that might impact its planning. Typically, an LOI has a more developed plan for the research and a more complete list of proponents. Once there is a proposal, the Fermilab Quality Assurance program plays a role for research in which Fermilab is involved. The decision to proceed with the research gets input from further discussions and reviews, and the approval authority level varies with the research category and the scale of the effort. Proceeding through the research includes various steps or milestones. See Figures 1 through 4 for a representation of the process flows in the four types of scientific research at Fermilab, and Table I for the typical approval levels at each step of the research. While the Figures show a linear progression, it is possible that there will be iteration (a loop) at one or more points in the research; e.g., when reviews or outside inputs influence the plans.

In the Figures, where Outside Input is indicated, this includes:

- External review and priority-setting committee recommendations to funding agencies and other arms of governments, both domestic and foreign
- Peer review of individual projects by committees, referees, peer reactions to seminars and conference talks.

The criteria for approval at a given stage are that

1. the research is and remains relevant to the Fermilab mission,

2. there has been adequate progress during the previous phase and there is a plan for proceeding with the research (including resources and ES&H concerns),

3. there is a reasonable prospect for the required support to be available to complete the research effort,

4. the needs for the next stage of the research are identified in adequate detail (including personnel and funding), and
5. there is a plan for satisfying the identified needs for the next stage of the research.

The control and approval levels associated with the steps in the process of doing scientific research are delineated in Table I.

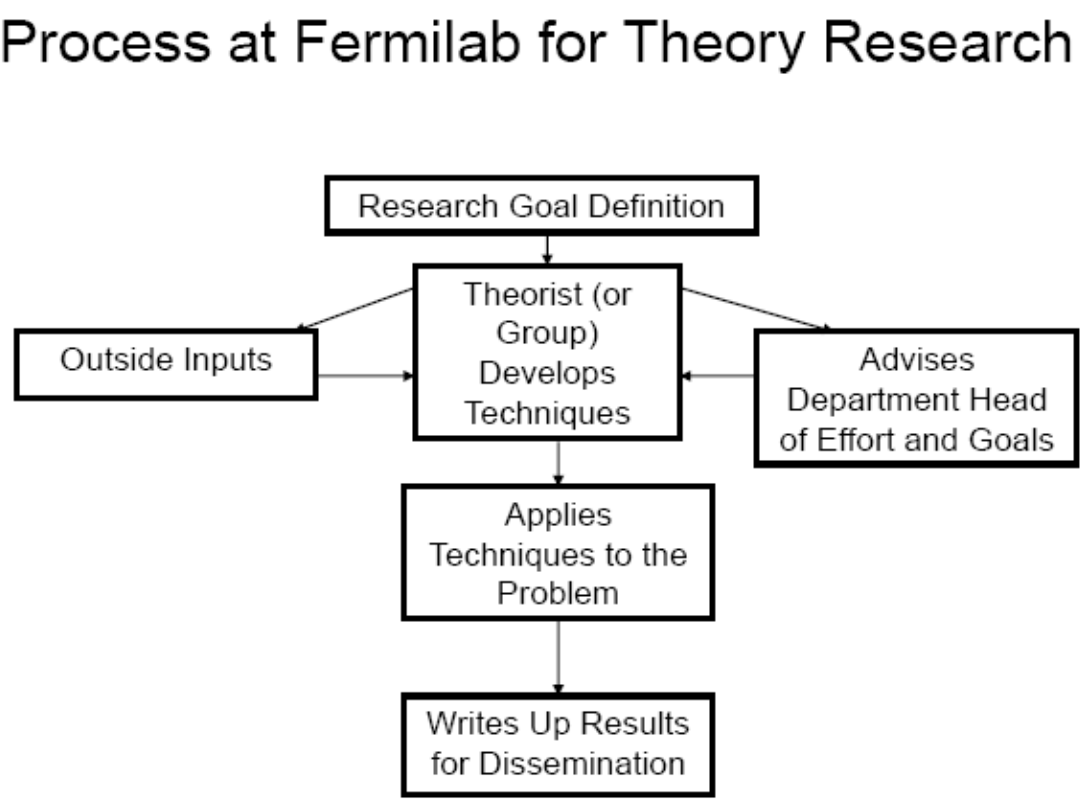

Figure 1 Process at Fermilab for Theory Research

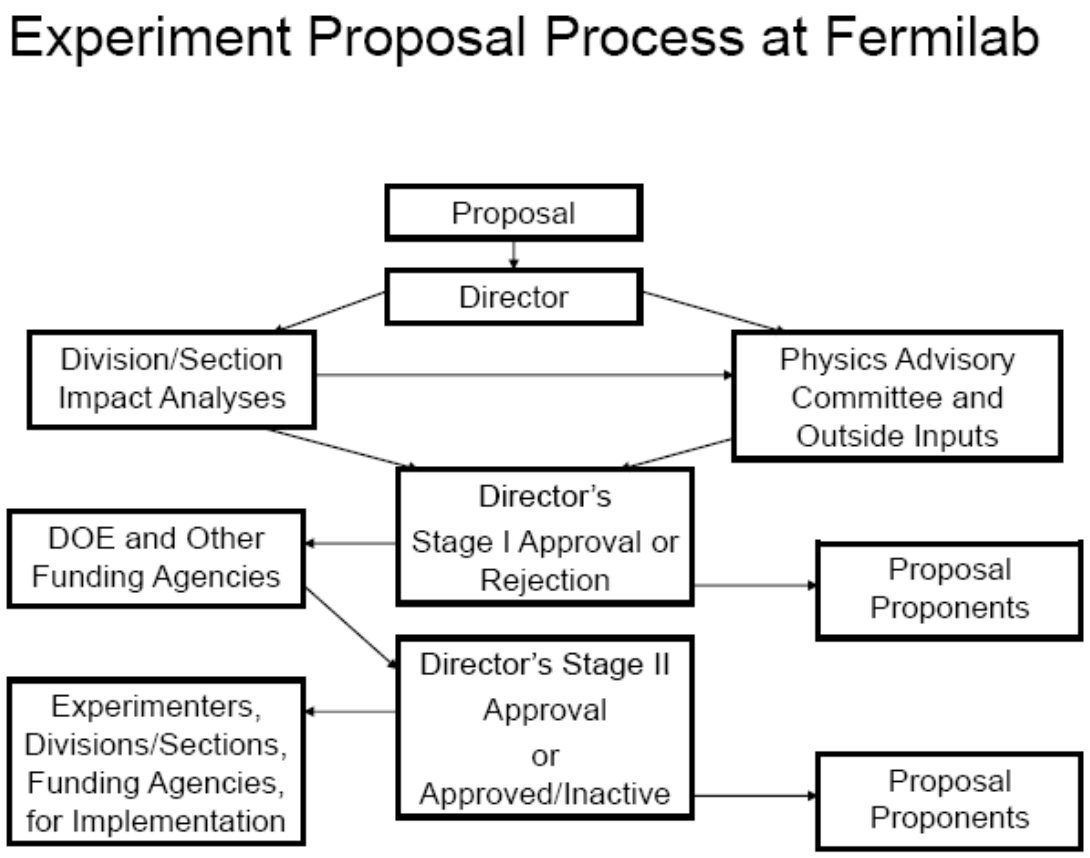

Figure 2 Experimental Proposal Approval Process at Fermilab. See text for QA process at later stages of research. Experiments that are approved, but inactive, are typically those which have been deemed worthwhile, but for which resources have not been found.

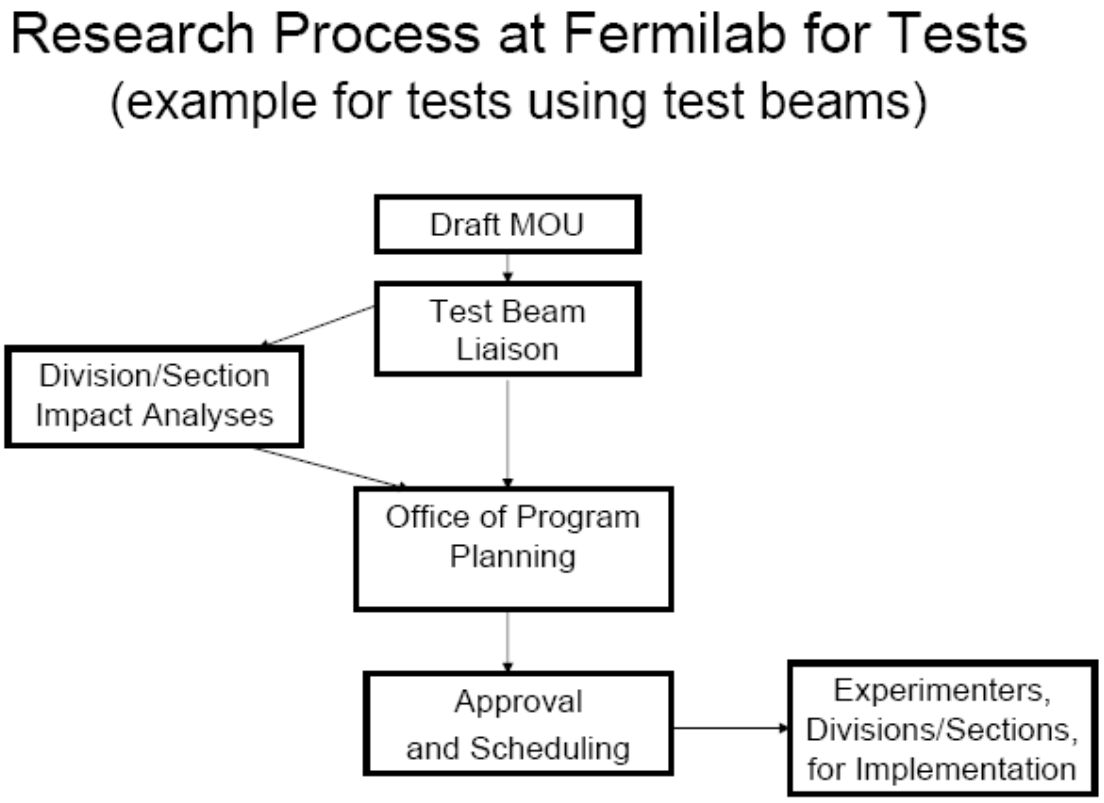

Figure 3 Research Approval Process at Fermilab for Tests. Tests that do not require use of beams may have the draft MOU go directly to the Office of Program Planning for circulation to Divisions and Sections for review. See text for QA process at later stages of tests.

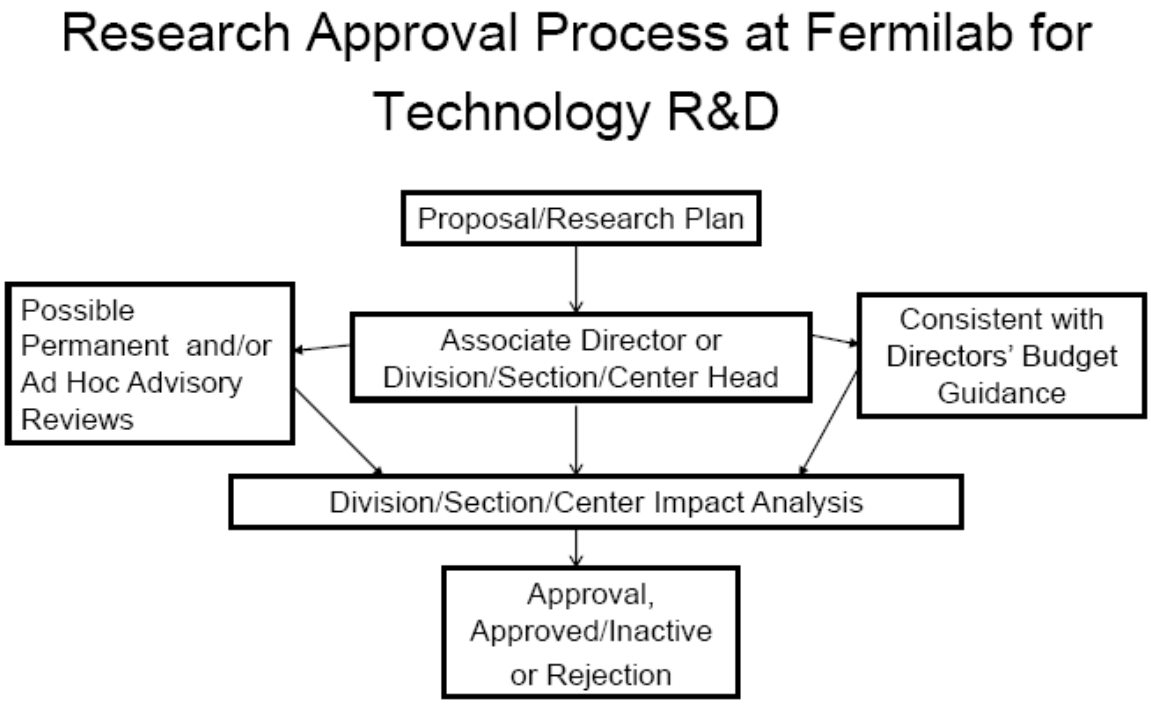

Figure 4 Research Approval Process at Fermilab for Technology R&D. See text for QA process at later stages of research. Efforts that are approved but inactive are typically those which have been deemed worthwhile, but for which resources have not been found.

1.2. PLANNING THE RESEARCH

Research efforts are defined initially in a proposal or draft Memorandum of Understanding (MOU). These documents (whether a simple e-mail for the smallest efforts, full-blown proposals to the Director, or anything in between) include the goals of the research; information on roles and responsibilities anticipated for the research; the technical approach proposed to achieve the goals of the research; resources (both funding and human resources) needed for implementation of the research and anticipated sources of those resources; any special environmental, safety, or health issues associated with the research; and the anticipated schedule.

Proposals and draft MOU's are reviewed by the relevant management at the Laboratory for appropriateness for the Laboratory mission, feasibility, and how the research fits into the broader research program at the Laboratory and around the world. For major research, such reviews are often performed with the advice of internal or external review committees (e.g., standing committees such as the Director's Physics Advisory Committee (PAC) and Accelerator Advisory Committee (AAC)) or ad hoc committees appointed by and reporting to the Directorate or Division/Section/Center Heads. The level of such review depends on the nature of the research and the scale of resources needed. Laboratory approvals both influence national and international advisory and review committees, and take cognizance of recommendations from them. For large efforts, a Stage I approval may be granted once the goals of the research and techniques intended for use are accepted, with full (Stage II) approval awaiting more definitive plans and understanding of the availability of resources.

If the research is approved, depending again on the nature of the research and scale of resources needed, a formal MOU may be negotiated, and signed by appropriate representatives of the research collaboration (typically the PI's or Spokespeople) and the Laboratory. This MOU contains the agreed-upon plan for implementing the research. Examples of MOU's for smaller projects (Tests) are available on the web at http://www-ppd.fnal.gov/mtbf-w/MOU/mtbf_mou.htm

MOU's may also be used between experiments or programs and subsets of collaborators as an aid to planning, and to delineate the same elements as the MOU's above.

Quality assurance for construction projects associated with research is covered in the broader Fermilab Quality Assurance program, and is not addressed in this document.

1.3. PERFORMING AND DOCUMENTING THE RESEARCH

All research is performed in conformance with the policies and guidelines established by the Director (http://www.fnal.gov/directorate/Policy_Manual.html) and relevant Divisions/Sections/Centers; e.g., ES&H and computing policy.

In addition, research is performed with the highest regard for the scientific method, with the anticipation that results may be checked by independent researchers, and implications of the research results may lead to additional research efforts in the future whose utility and viability depend on the more current results.

Given the strong impetus for publishing research results in recognized journals, and interest in them, research groups have established various forms of internal review, sometimes multi-stage arrangements. These reviews may include working early-on in analysis groups, assignment of "godparents" (individuals or groups to mentor and monitor the research) when the work reaches a certain level of maturity, formal review of first and second drafts of papers by assigned reviewers and open to the full research collaboration – all this before the work is submitted for publication. Less formal release of preliminary results for conference and other presentation may occur before formal submission of results for publication. This level of scrutiny already goes a long way in assuring high quality in the results. In addition, submission to journals is accompanied by submission to the Fermilab Publications Office, which reviews for intellectual property rights and adds an additional level of quality assurance. Finally, there is the peer review of the most important results by the editors and referees before acceptance for publication in refereed journals – and scrutiny by the broader research community, often in parallel through the mechanism of public preprint archives.

1.4. ASSESSING THE PERFORMANCE OF THE SCIENTIFIC RESEARCH

Indications of the quality of scientific research include:

- Peer review of individual projects by committees, referees, peer reactions to seminars and conference talks
- Assessment of impact by citation counts; e.g., using the SPIRES database, counts and prestige of awards and recognition, etc.
- Overall assessment of group quality by agency reviews; e.g., Triennial DOE reviews
- Performance in job market and recruitment.

At the most general level, there are regular Laboratory and agency reviews of the research output of the Fermilab program. As part of preparations for these reviews, statistics are accumulated about the numbers of publications and the numbers of citations for each publication using the facilities of public archival services, some of which the Laboratory contributes directly to maintaining. Progress during pre-publication parts of the research effort is monitored, for example at weekly All Experimenters' Meetings. These meetings provide a forum for monitoring progress as data is accumulated and analyzed in the ongoing scientific research.

The external advisory committees (PAC and AAC) are regularly apprised of the progress of the research at the Laboratory and the results of research performed at Fermilab. For major research efforts, these committees may have recommended approval of the research in the first place, and they monitor the results in the context of the original goals for which the research was approved. These reviews try to identify and anticipate problems, and make recommendations for corrective action.

In some cases, there are ad hoc internal and/or external reviews of potential and identified research problems organized within the research effort itself, and reporting directly to that

research effort organization – again with the goal of defining methods of preventing or correcting problems.

1.5. TRANSFERRING THE RESULTS OF THE RESEARCH

While archival publication of research results remains the primary record of research, additional transfer of the results occurs in multiple forums. Relevant regular and one-time conferences and workshops are keen on hearing the results of Fermilab research. Some of these meetings are sponsored by Fermilab, but all such relevant meetings include major presentations of Fermilab-based research results in their programs, both as invited presentations and by accepting submitted papers, etc. Assurance of this broad dissemination of the results of research is aided by the participation of Fermilab staff members and users as conveners and on the organizing and/or international advisory committees of nearly all major conferences.

Major collaborations have dedicated, standing speaker committees to facilitate the inclusion of research results from their collaboration in conferences and workshops. When no such mechanism exists, PI's and spokespeople are contacted directly to fulfill this function.

Chapter 2. INSTITUTIONAL QUALITY MANAGEMENT PROGRAM

2.1. PLANNING

In planning the Laboratory program, in addition to the various Laboratory advisory committees that review the research, the Laboratory obtains input from the funding agencies and the user community. From the agencies, this input comes directly from frequent and regular communication, and as an output of agency reviews. From the users of the facilities, the Laboratory obtains input from individual contacts with colleagues, and more formally through the Users Organization and its Users Executive Committee (UEC). [See links to the Users Organization constitution and other relevant information at http://www.fnal.gov/orgs/fermilab_users_org/index.html]

The UEC is supported by the Fermi Research Alliance, the contractor-operator of Fermilab. The UEC meets monthly, and meetings include direct discussions with Laboratory management. The UEC also organizes an annual users meeting, which further enhances the input from these stakeholders.

2.2. LEADERSHIP

The tradition of Fermilab's scientific managers is to remain active in the research endeavor as part of their employment. Promotion opportunities are enhanced at the Laboratory for those who do so with success. As such, managers are sensitive to the needs of younger staff members to participate actively in research, and mentor their doing so with success. The continuing participation in research also enhances the managerial focus on the research goals of the scientific programs.

2.3. SUPPORT FOR THE PERFORMANCE OF THE RESEARCH

2.3.1. Human and Material Resources

As discussed above, human and material resources are identified as part of the proposal/MOU processes, and included directly in budget and staff planning processes. In the case of major programs, human and material resources are also included in additional program planning documents.

Individual scientists receive informal training as a part of doing research at the Laboratory and collaborating with other scientists and engineers. Informal training also occurs as part of the research environment at the Laboratory. The typical degree of earlier training of the laboratory scientists who have responsibility for directing or participating in research is generally a Ph.D., 6 years of postdoctoral experience, and a graded sequence of assignments at the lab. A similar profile exists for university researchers as they advance through a series of experiments.

In addition, the Laboratory maintains formal training databases for staff and users. These take the form of interconnected Individual Training Needs Assessment (ITNA) and the Laboratory's ES&H Training Database known as TRAIN. The ITNA asks a series of questions regarding the hazards one might be exposed to while working at Fermilab. Each question is tied to one or more required ES&H training classes. Staff-member supervisors and longer-term visitor's Points of Contact (POC's) answer each of the questions and a computer automatically generates an Individual Training Plan (ITP). The ITNA and ITP are integrated into TRAIN. TRAIN serves to keep up to date the ES&H training needs of each individual. The ITNA is reviewed by supervisors or POC's annually for appropriateness, and the requisite training is scheduled and monitored through TRAIN. This system has been found effective enough that some non-ES&H training is also logged by that system.

User training is also supported. This begins when a user applies for a Laboratory identification card (ID) and user number. Initial training is required before an ID is issued. In addition to the initial training, specialized training is common for users and staff members; e.g., radioactive source training and controlled access training. Access to controlled areas, for example, can only occur when a person's relevant training is up-to-date.

In addition to training, mentoring is necessary to assure the longer-term quality of the research effort at the Laboratory and beyond. For Laboratory employees, such mentoring is a part of the annual goal setting and performance review processes. For users, mentoring is performed by the home institution, assisted by efforts internal to individual research efforts where they exist (e.g., in large experiments).

The methods of ensuring that sound engineering/scientific principles are applied to the design and construction of research facilities and to the design of supporting computing and networking are covered in the main IQA document.

2.3.2. Research Environment

The research environment is maintained as part of the Director's Policy. Specific policies on human rights, nondiscrimination, and anti-harassment (http://www.fnal.gov/pub/news03/humanrightspolicy.html) exists, in addition to policies on quality assurance, community outreach, training, assessments, code of conduct, and other matters that affect the research environment.

In addition, special attention is paid to the quality and number of seminars, colloquia, workshops, and training sessions available at the Laboratory. Public calendars and daily e-mailed reminders of such events are available to all. An atmosphere that encourages exchanges between speakers and audience at such events is a recognized goal.

As noted above, the Laboratory staff engages directly in the research effort at the Laboratory. In this way, awareness of the research environment is known directly by the Laboratory, and discussion and efforts are continuous on maintaining the strengths of the research environment and increasing its effectiveness. Efforts on diversity enhancement are a recent example of this ongoing level of attention and commitment.

One of the subcommittees of the Users Executive Committee is concerned with the research and more general environment at the Laboratory. The Laboratory management meets as requested with this group, and responds to suggestions and concerns expressed.

The Laboratory maintains document repository services through its Publications Office, Archives, and Documents Control Policy.

2.3.3. Assessment

In scientific research where the collection of data occurs, the quality of that data is continuously monitored as it taken. This quality assurance is typically built into the data acquisition process itself, with follow-up monitoring in near-real time and later off-line analysis, separate from the research-goal analysis itself.

Reviews of research quality are held regularly and ad hoc, both by internal reviews (e.g., via Director's Reviews and those organized within Divisions/Sections/Centers) and by external reviews (e.g., by the FRA, DOE, NSF, PAC, and AAC).

Assessments have also been accomplished via surveys by the Users Organization, American Physical Society, and individual Divisions and Sections.

Annual assessments of the performance of Fermilab staff members are part of the standard procedure at the Laboratory. This process includes annual goal setting, self-assessment of achievements, and review by supervisors. These assessments directly affect the salary of staff members.

Chapter 3. **QUALITY IMPROVEMENT**

3.1. QUALITY IMPROVEMENT GOALS

Quality improvement goals for individual performance are established pro-actively as part of the goal setting and annual performance assessment processes. Where possible, these goals are meant to be measurable. The line supervision responsible for the Annual Performance Review is responsible for assuring that there is appropriate mentoring of researchers and support staff.

Given the competitiveness of the research environment, no additional mechanisms are needed for the goal of making the most of the data in terms of scientific results and impact. Nevertheless, quality improvement is enhanced by the processes of providing local forums for presentations of results (e.g., seminars and weekly All Experimenters' Meetings), publicity for major achievements through the Office of Communication, and the active involvement in the nomination and selection processes for national and international awards, and presenters at conferences and workshops.

3.2. TRAINING

Training for quality assurance in research is a built-in part of the scientific process, with students learning from mentors and researchers regularly needing to present and defend their work internally to their collaborators and externally to the larger community. In addition, scientists are constantly participating in workshops, seminars, and physics studies and going to various schools and technology training to keep current.

REFERENCES

References

ANSI/ASQ Z1.13-1999, *Quality Guidelines for Research*

DOE G 414.1-1A, *Management Assessment and Independent Assessment Guide for Use with* 10 CFR 830, Subpart A, *and* DOE O 414.1A, *Attachment 2* DOE O 414.1C, *Quality Assurance,* dated 6-17-05*; DOE P 450.4, Safety Management System Policy; and* DOE P 450.5*, Line ES&H Oversight Policy,* dated 5-31-01.

DOE G 414.1-2A, *Quality Assurance Management System Guide* for Use with 10 CFR 830 *Subpart A Quality Assurance Requirements*

DOE Order 226.1A *Implementation of Department of Energy Oversight Policy*

DOE Order 413.3A, *Program and Project Management for the Acquisition of Capital Assets,* dated 7-28-06.

DOE O 414.1C, *Quality Assurance,* dated 6-17-05.

DOE O 470.2B, *Independent Oversight and Performance Assurance Program, Attachment 2,* dated 10-31-02

Fermilab Integrated Quality Management Program

Fermilab Director's Policy Manual, Policy 10, *Quality Assurance*

Fermilab Director's Policy Manual, Policy 42, *Scientific Research*

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Table of Revisions

Author(s)	Description	Revision	Date
Jeff Appel	Approved by Fermilab Director as Rev000. Initial release, includes reconciled peer review feedback from Fermilab scientists and OQBP. Promoted to Rev 001 for release.	001	09/09/2009