QAM 12060: Quality Assurance Guidelines for Scientific Research

Revision History

Author	Description of Change	Revision Date
Kathy Zappia	Initial release of QAM 12060. This chapter replaces guideline 4200 rev. 000, written by OQBP, and cancels the OQBP Procedure upon publication.	November 2013

TABLE OF CONTENTS

1.0 INTRODUCTION

This document is the implementation guide for scientific research of Fermilab's Integrated Quality Assurance Program. This guideline does not apply to efforts that have specific quality assurance plans/programs approved separately by the Department of Energy, such as Fermilab projects with specific project QA plans as required by DOE Order 413.3 Program and Project Management for the Acquisition of Capital Assets.

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, host Divisions/Sections, and Management Systems.

This Fermilab implementation follows the American National Standard "Quality Guidelines for Research" ANSI/ASQ Z1.13-1999. This document follows the topics and ordering in the standard.

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. In addition, Fermilab's implementation of the IQA for scientific research follows the "graded approach". The authority level and formality of the implementation of the elements of Fermilab's 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.

2.0 DEFINITIONS & ACRONYMS

ACC- Accelerator Advisory Committee
ES&H – Environment, Safety, & Health
FRA- Fermi Research Alliance
IQA - Integrated Quality Assurance Program
ITNA- Individual Training Needs Assessment
ITP- Individual Training Plan
NSF- National Science Foundation
PAC- Physics Advisory Committee
PI- Principal Investigator
PM- Project Manager
PO- Purchase Order
POC- Point of Contact
UEC- Users Executive Committee

3.0 RESPONSIBILITIES

RESPONSIBILITY FOR THE RESEARCH
Scientific research efforts have a PI, spokesperson or PM (sometimes co-PI's, co-spokespersons, or co-PM's) 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 (theoretical investigations, experiments, tests, and supporting-technology R&D), 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 in venues such as seminars, workshops, and conferences. A proposal is prepared once an idea has generated sufficient interest and adequate starting collaborators. 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.

The criteria for approval 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.

4.0 PROGRAM

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. Specific procedures for the experimental program are documented in the Fermilab "Procedures for Researchers (PFX)."

5.0 PROCEDURES

5.1 Planning The Research

Research efforts are defined initially in a proposal with detailed specifics of the collaborative activities spelled out in project documentation such as a Purchase Order, a Cooperative Research and Development Agreement, a Work for Others, or a User Agreement. These documents 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 collaborative research documents 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 and ACC) or ad hoc committees appointed by and reporting to the Directorate or Division/Section 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 contract may be negotiated, and signed by appropriate representatives of the research collaboration (typically the PI's , PM's or Spokespeople) and the Laboratory. This contract contains the agreed-upon plan for implementing the research.

Proposed and draft project and contractual documents 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 documents 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.

5.2 Performing And Documenting The Research

All research is performed in conformance with the policies and guidelines established by the Director, the host Division/Section, and relevant Management System policies.

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.

Research groups have established various forms of internal review, sometimes multi-stage arrangements given the strong impetus for publishing research results in recognized journals, and interest in them. 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. 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.

5.3 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 its maintenance. Progress during pre-publication parts of the research effort is monitored through various 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.

5.4 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 PM's are contacted directly to fulfill this function.

5.5 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. 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 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.

5.6 Support For The Performance Of The Research

5.6.1. Human and Material Resources

As discussed above, human and material resources are identified as part of the proposal 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 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 changes in duties or hazards, and the requisite training is scheduled and monitored through TRAIN.

User training is also supported. This begins when a user applies for a Laboratory identification card 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 Fermilab 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).

5.6.2. Research Environment

Special attention is paid to the quality and number of seminars, colloquia, workshops, and training sessions available at Fermilab. 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.

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

5.6.3. Assessment

In scientific research where the collection of data occurs, the quality of that data is continuously monitored as it is 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) 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.

5.7 Quality Improvement Goals

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.

5.8 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.

6.0 REFERENCES

ANSI/ASQ Z1.13-1999, Quality Guidelines for Research
DOE Order 413.3B, Program and Project Management for the Acquisition of Capital Assets,
Fermilab Director's Policies: http://www.fnal.gov/directorate/Directors_Policy/
Procedures for Researchers (PFX): http://www.fnal.gov/directorate/PFX/PFX.pdf.