

Plan for Conducting the
Scientific Research QA As-Is Assessment
at Fermilab

January 2010 through April 2010

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Plan for Conducting the Scientific Research QA As-Is Assessment

EXECUTIVE SUMMARY

This plan describes the assessment that will be performed to document the current status of Quality Assurance implementation in scientific research at Fermilab, referred to as the “Scientific Research QA As-Is” assessment or simply the “As-Is”. This assessment is scheduled to be conducted from January 7, 2010 to February 18, 2010. The assessment will be sponsored by the Directorate (Associate Director for Research, the Associate Director for Accelerators, and the Assistant Laboratory Director) and conducted under the direction of the Fermilab Office of Quality and Best Practices (OQBP). The assessment will be performed by selected Quality Assurance Representatives (QARs) and scientific process owners from Fermilab Divisions, Sections and Centers (D/S/Cs) with the assistance of on-site OQBP quality assurance staff. A selected number of scientific staff will be invited to be independent observers of the process. The team will work with process owners and apply a graded approach when determining the level of rigor the application of requirements must meet prior to assessing implementation in each area. The assessment effort is planned to evaluate a number Fermilab scientific processes sufficient to give Fermilab management a baseline understanding of the extent of current implementation of its contractual commitments to the U.S. Department of Energy (DOE) as specified in DOE Order 226.1 *Implementation of DOE Oversight Policy* and DOE Order 414.1C *Quality Assurance*. The scope of the assessment is the implementation status of quality assurance in scientific research to the requirements contained in the Integrated Quality Assurance (IQA), its subordinate documents, and Fermilab Integrated Contractor Assurance Program (FICAP). Per DOE Order 414.1C, Fermilab is assessing and implementing ANSI/ASQ Z1.13-1999, *Quality Assurance Guidelines for Research*, to ensure the application of quality assurance to scientific research. The results of this assessment activity will be used to evaluate conformity of Fermilab’s scientific processes to the Quality Assurance Guidelines for Scientific Research at Fermilab issued on September 9, 2009. This document was developed to establish DOE’s objectives for scientific research at Fermilab. The scientific processes (see Appendix) to be reviewed will be selected by the Directorate sponsors based on risk to the laboratory. The As-Is assessment will document the steps in each process and compare existing controls for the activity with a range of available controls identified within the Quality Assurance Guidelines for Scientific Research or from subordinate policy or program documents associated with the collaborations/projects, with a focus on the value impact to science. If gaps are identified between quality controls applied in the current state and controls identified for the desired state, these gaps will be reviewed by a QA Scientific Review Committee to be appointed by the Associate Director for Research. If the gaps are determined to require changes, Corrective Action Plans (CAPs) will be prepared, approved and implemented by Fermilab management to

bridge those gaps. The OQBP will assist the scientific groups in closing the CAPs, if requested, and provide independent verification of their closure as part of the QA implementation process. A status of Fermilab's progress in closure of the CAPs will be produced in April 2010 to meet the Quality requirements specified in Fermilab's Performance Evaluation Management Plan (PEMP).

The following sections of this plan provide more details on the As-Is assessment process including resources that will be used to accomplish the Fermilab objectives for this activity.

AS-IS ASSESSMENT PURPOSE & SCOPE

As stated in the Executive Summary, this plan describes the processes and resources that will be used to conduct the Fermilab "Scientific Research As-Is" assessment. The scope of this effort will be to conduct and document a quality assurance assessment of a selection of Fermilab scientific processes detailed in the As-Is schedule. The results of this activity will give Fermilab senior management and department heads a good understanding where the Laboratory stands relative to implementation of the quality assurance in scientific research and the commitments in the prime contract with DOE pertaining to DOE O 226.1 and DOE O 414.1C. The FICAP and IQA are Fermilab documents that provide a link between these DOE orders for all work conducted at Fermilab and the Quality Assurance Guidelines for Scientific Research at Fermilab and its subordinate documents specify the quality assurance requirements for scientific research at Fermilab.

BACKGROUND

QARs from Fermilab's Particle Physics Division (PPD) and Computing Division (CD), and a Quality Assurance Engineers (QAE) from the Fermilab OQBP staff, participated in the planning of the implementation of the scientific research quality assurance program at Fermilab. The following are the objectives and deliverables used to prepare for the As-Is assessment.

As-Is Assessment Objectives

1. Identify QARs from PPD and CD and a QAE for the assessment team
2. AD for Research to identify members of the scientific community to be on the QA Scientific Review Committee
3. AD for Research to identify member(s) of the scientific community to be independent observer(s) during the assessment
 - a. Proposed selection criteria
 - i. From Theoretical or Experimental area
 - ii. Recognized
 - iii. Fermilab employee
 - iv. Fermilab collaboration
 - v. Previously participated in external independent reviews

4. Create & deploy a QA awareness strategy throughout Fermilab scientific community
5. Identify Fermilab's scientific processes
6. Prioritize scientific processes for the assessment
7. Identify existing quality controls
8. Identify Fermilab Best Practices
9. Evaluate compliance of scientific research to ANSI/ASQ Z1.13
10. Evaluate compliance of scientific research to Quality Assurance Guidelines for Scientific Research and the FICAP at Fermilab
11. Identify gaps between existing quality controls "As-Is" and required controls
12. Provide Fermilab management with a clear understanding of the current state of compliance
13. Work with QA Scientific Review Committee appointed by the Directorate management from Fermilab
14. Obtain concurrence from the QA Scientific Review Committee regarding gaps to create, approve and implement corrective action plans (CAPs) whose purpose is to bridge any gaps between As-Is and As-Required conditions.

As Is Assessment Deliverables

1. Plan for conduct of As-Is Assessment
2. Communication of assessment of QA in scientific processes awareness
 - a. Fermilab Today "Director's Corner" publications on QA at Fermilab
 - b. Associate Director for Research create and publish a charge for science As-Is
 - c. Assistant and Associate Directors' direct promotion to scientific community
 - d. Director publish support for QA in science in the Fermilab Today Director's Corner
 - e. D/S/C write a letter of support for QA in science
 - f. D/S/C QA communications
 - g. Other QA awareness media such as posters and presentations within management staff meetings
3. Identification and hierarchical list of Fermilab's scientific process and the documentation of why these processes are to be assessed
4. Publish detailed schedule of As-Is Assessment activities
5. Comparison of scientific processes assessed to Quality Assurance Guidelines for Scientific Research at Fermilab based on ANSI/ASQ Z1.13 requirements
6. Once gaps are identified and concurred to exist by the QA Scientific Review Committee, CAPs will be generated to bridge quality control gaps identified during the aforementioned comparisons
7. Quality Assurance Report on the status of QA implementation in scientific research, including items generated in 6, above.

ASSESSMENT PROCESS DESCRIPTION

The scientific process assessment will be conducted by a team composed of two QARs and a QAE working with process owners and one or more independent observer to determine if their

processes are currently implementing the expectations of the FICAP, IQA, ANSI/ASQ Z1.13 and Quality Assurance Guidelines for Scientific Research at Fermilab using the following assessment tools:

- Process flow descriptions, diagrams, mappings, or narratives to determine inputs, outputs, and controls
- Other guidance tools such as
 - Include elements from the Quality Assurance Guidelines for Scientific Research at Fermilab
 - ANSI/ASQ Z1.13 and Quality Assurance Guidelines for Scientific Research checklists containing questions to assist in determining compliance

Planning & Preparation

- Identification of scientific processes in Fermilab for As-Is assessment
- Briefings for senior management and Fermilab staff describing As-Is activities
- Identification of processes owners in Fermilab
- Prioritization of processes in Fermilab for As-Is assessment
- Create detailed schedule of processes areas to be evaluated
- Create QA awareness strategy throughout Fermilab
- Create tools and guides for conducting the As-Is

NOTE: The above underlined items, while complete, are living entities. It is expected that the team will be required to modify the prioritized list of processes and subsequent evaluation schedule based upon conditions found and resources required to acquire and review information acquired during the As-Is activity.

Lifecycle Phases of As-Is Assessment Activities

Initiation Phase

- Schedule initial informational / planning meeting(s) with process owners, subject matter experts and/or appropriate departmental management

Development Phase

- Use preliminary meeting information to understand process and plan

Collection Phase

- Document processes and their quality controls
- Return and complete evaluation of process quality controls
- Identify potential gaps in quality controls

Verification Phase

- Verify the accuracy of data identified with process owner
- Review the evaluation of controls and gaps identified with process owner with a focus on consensus
 - Record when consensus was not achieved
- Prepare preliminary reports on observations to be provided or presented to the Scientific Review Committee

Corrective Action Phase

- Review potential gaps in quality with the QA Scientific Review Committee

- Develop and document CAPs to bridge agreed upon gaps (Process Owner)
- Approve CAPs and forward to the Head of OQBP (D/S/C Head)
- Track & report status of CAPs locally (QAR & Process Owner)
- Review the approved CAPs, reconcile differences, and obtain concurrence (OQBP Head)
- Verify closure of CAPs as they are completed (QAEs & Quality Manager)
- Track and report status of CAPs globally (Quality Manager & OQBP Head)

DETAILED SCHEDULE

- December 21, 2009 – Complete As-Is Plan
 - Assignment of QAR/QAE team, identification of relevant scientific process owners/SME designees
 - As-Is Schedule (to include review, evaluation, report, and parallel corrective action review & assistance, as needed)
 - Identification and prioritization of processes by D/S/C for As-Is
- December 30, 2009 – Receive approved Scientific Process Assessment List
- January 7, 2010 – February 18, 2010 – Conduct As-Is Assessment: desktop and field activities.
- March 5 to April 15, 2010 – Corrective Action Plans Approved, OQBP concurrence & Implementation underway
- April 2010 – Quality Assurance Report on the status of QA implementation in scientific research at Fermilab and progress in closure of the CAPs

ROLES & RESPONSIBILITIES

The QA program implementation required conscription and alignment of many resources to develop the QA science assessment program. Individuals throughout Fermilab are involved in the development and implementation of the plan.

Laboratory Director – Responsible for implementation of QA. Senior manager providing direction, funding, and support for QA implementation and awareness.

Directorate & The Assurance Council – Management support & oversight

Head of OQBP – Designee by the Laboratory Director responsible for QA system implementation at Fermilab. Provides periodic status reports to the Laboratory Director, Senior Management & the Assurance Council. Reconciles issues raised during the As-Is. Single point of contact between Fermilab and DOE

Associate Director for Research, the Associate Director for Accelerators, and the Assistant Laboratory Director – Responsible for implementation of QA in science; provide direction, funding, and support for QA in science implementation and awareness.

Scientific Review Committee – Designees by the Associate Director for Research responsible for reviews, advising, corroborations, mediations, and approvals for all observations, documents and activities for the Scientific Research QA As-Is program

Independent Scientific Observer(s) – Accompanies the QA Sub-Team for Science as an unbiased observer to help conveyance and interpretation of QA questions and answers exchanged between scientific community and QA Sub-Team for Science during the Scientific Research QA As-Is program. Corroborates the assessment process and the results/observations from the As-Is process

D/S/C heads – Designees by the laboratory Director for establishment and compliance with QA requirements in their respective organizations. Provide resources for the As-Is assessment. Reconcile issues raised. Provide implementation support and feedback to the QARs & QAE.

Quality Assurance Manager – Manage the project. Provide periodic status briefs and reports to the OQBP Head and the QA Program Manager. Ensure that plans and documents are aligned with DOE Orders, the IQA, FICAP and Quality Assurance Guidelines for Scientific Research at Fermilab. Provide guidance & direction to D/S/Cs and QA Sub-Team for Science.

QA Sub-Team for Science – QARs & QAE assigned to engage management in scientific community in the Scientific Research QA As-Is assessment & subsequent IQA implementation

D/S/C Quality Assurance Representatives (QARs) – Serve as invited observers and advisors within their D/S/C during the conduction of the Scientific Research QA As-Is process. Elevate concerns or issues to QA Manager and D/S/C Head as appropriate

Quality Assurance Engineer (QAE) – Provide subject matter expertise to QARs and D/S/C staff on the application of quality controls to Fermilab scientific research processes. Assist the OQBP and Quality Assurance Manager with implementation of QA system.

REFERENCE DOCUMENTS

- Fermilab Director's QA communications
- As-Is Assessment Plan (this document)
- As-Is Assessment Schedule
- DOE Order 226.1 *Implementation of DOE Oversight Policy*
- Fermilab Integrated Contractor Assurance Program (FICAP)
- DOE Order 414 *Quality Assurance*
- Integrated Quality Assurance (IQA)
- ANSI/ASQ Z1.13-1999 *Quality Guidelines for Research*
- Quality Assurance Guidelines for Scientific Research at Fermilab
- Scientific process As-Is lines-of-inquiry, guides & checklists

D/S/C	Name	Full Name	Approved for "As-is" Assessment? Yes/No	Priority	Website
multiple D/S/C	21cm	21cm		L	Some info: http://cd-docdb.fnal.gov/0032/003289/003/FY10-strategic-CosmicFrontier.pdf
AD	A0 Photo-injector lab	A0 Photo-injector lab		M	http://nicadd.niu.edu/fnpl/
PPD	ArgoNeut	ArgoNeut		L	http://t962.fnal.gov/index.html
multiple D/S/C	CDF	Collider Detector at Fermilab		M	http://www-cdf.fnal.gov/
multiple D/S/C	CDMS/CDMSII/SuperCDMS	Cryogenic Dark Matter Search		L	http://ppd.fnal.gov/experiments/cdms/
multiple D/S/C	CMS	Compact Muon Solenoid Detector		L	http://uscms.fnal.gov/
multiple D/S/C	COUPP	Chicagoland Observatory for Underground Particle Physics,		H	http://www-coupp.fnal.gov/
multiple D/S/C	D0 Experiments			H	http://www-d0.fnal.gov/
CD	DES	Dark Energy Survey		H	https://www.darkenergysurvey.org/
multiple D/S/C	Detector R&D - engineering	Detector R&D - engineering		L	No single web page - see http://www.uslarp.org/
CD	Geant - simulation science	Geometry and Tracking		L	http://www.geant4.org/geant4/index.shtml
CD	High Space Charge Beam Dynamics - accelerator simulation science	High Space Charge Beam Dynamics - accelerator simulation science		L	https://compass.fnal.gov/
TD	High-field magnet development and associated material/conductor research - LARP engineering	Very High Field Superconducting Magnet Collaboration		M	http://www.uslarp.org/
multiple D/S/C	JDEM	Joint Dark Energy Mission		L	No single web page yet - see http://www.fnal.gov/pub/science/experiments/works-in-progress/

D/S/C	Name	Full Name	Approved for "As-is" Assessment? Yes/No	Priority	Website
multiple D/S/C	LARP	LHC Accelerator Research Program		H	http://www.uslarp.org/
multiple D/S/C	Lattice QCD	Lattice Quantum Chromodynamics		M	http://www.usqcd.org/
multiple D/S/C	LBNE	Long Baseline Neutrino Experiments		L	No single web page yet. See http://www.fnal.gov/pub/science/experiments/works-in-progress/
multiple D/S/C	Microboone			L	http://www-microboone.fnal.gov/Test/index.html
multiple D/S/C	Minerva			H	http://minerva.fnal.gov/
multiple D/S/C	MiniBoone			H	http://www-boone.fnal.gov/
PPD	MINOS			M	http://www-numi.fnal.gov/
multiple D/S/C	Mu2E	Muon-to-Electron-Conversion		M	http://mu2e.fnal.gov/
multiple D/S/C	NOvA	NuMI Off-Axis Electron Neutrino Appearance experiment		H	http://www-nova.fnal.gov/
AD	NuMI (up until the point of the detector where it becomes PPD) - engineering improvement	Neutrinos at the Main Injector		L	http://www-numi.fnal.gov/
PPD	Peanut			M	No single web page. See http://www-numi.fnal.gov/MinosAreas/projects.html
multiple D/S/C	Pierre Auger Observatory related experiment - MIPP			M	http://www.auger.org/
multiple D/S/C	Project X R&D			L	http://projectx.fnal.gov/
TD	SCRF Cavity Program - engineering	Superconducting Radio-Frequency Cavity Program - engineering		L	http://ilc.fnal.gov/accelerators/cavity_program.html
multiple D/S/C	SDSS	Sloan Digital Sky Survey		M	http://www.sdss.org/

			Activity or Tasks Description	START	FINISH	STATUS
Phase	Phase	SCIENTIFIC RESEARCH QA PROGRAM DEVELOPMENT & IMPLEMENTATION		1-Oct	7/19/2010	
		2.8.1 Scientific Research QA Program Development		1-Oct		done
		2.8.1.1 Procedures		1-Oct		done
			Start Scientific Research QA Program Procedures	1-Oct		done
			PROCEDURES Define Procedure & Forms Needed	2-Oct		done
			PROCEDURES Determine Teams/Resources to Create Procedures	2-Oct		done
			PROCEDURES Document Procedure & Forms Needed	30-Oct		done
		2.8.1.2 GAP Analysis		1-Oct	14-Dec	
			GAP ANALYSIS Identify Team & Lead	1-Oct	7-Oct	done
			GAP ANALYSIS Review Program Document against standard	30-Nov	14-Dec	done
		2.8.1.3 As Is Assessment		15-Dec	2/18/2010	
INITIATION			Identify Existing Process for Analysis	15-Dec	21-Dec	current
DEVELOPMENT			Develop Check Lists	15-Dec	30-Dec	
	COLLECTION	iterative process	Schedule and Conduct Preliminary Meetings	22-Dec	1/7/2010	
		iterative process	Define Process & Conduct Preliminary Meetings	1/22/2010	1/14/2010	
		iterative process	Update Checklist w Process/Activity Specific Elements	1/15/2010	1/21/2010	
VERIFY		iterative process	Conduct Assessment Mapping	1/22/2010	2/18/2010	
CORRECTIVE ACTION		2.8.1.4 Corrective Action		2/19/2010	4/15/2010	
			CORRECTIVE ACTION - Define Corrective Action Plan	2/19/2010	3/4/2010	
			CORRECTIVE ACTION - Review and Approve CAPS	3/5/2010	3/11/2010	
			CORRECTIVE ACTION - Develop Implementation Plan	3/12/2010	3/25/2010	
			CORRECTIVE ACTION - Review & Approval of Implementation Plan	3/26/2010	4/8/2010	
			CORRECTIVE ACTION - CAP Closure Verification	4/9/2010	4/15/2010	
			Work Tasks Completed		4/15/2010	
		2.8.2 Scientific Research QA Program Implementation		4/16/2010	7/19/2010	
			IMPLEMENTATION - Orientation (Communications - Training & Meetings)	4/16/2010	5/6/2010	
			IMPLEMENTATION - Perform Graded Approach	5/7/2010	7/19/2010	

*FICAP - Contractor Assurance: Lessons Learned, Worker Feedback, Issues Mgmt, Event Reporting, Performance Measurement