

QAM 12002: The Fermilab Quality Assurance Program

Revision History

Author	Description of Change	Revision Date
Jemila Adetunji	Updates throughout the document to reflect alignment with organizational and functional changes. Updates made to hyperlinks throughout the document.	June 2020
Jemila Adetunji	Major update to each section in the document to provide further clarity and direction for enhanced implementation of the QA Program requirements.	February 2019
Dave Baird	Removed reference to Improvements Database and replaced with ESH&Q Section's Quarterly Summaries	August 2018
Kathy Vuletich	<ul style="list-style-type: none"> Removed reference to issues management item type "Finding." The definition is identical to a "Non-conformity." The item type "Finding" has been removed from use in iTrack and applicable documentation. Updated references to Fermilab Policies. 	January 2018
T.J. Sarlina	Removed references to DOE Order 414.1D, <i>Quality Assurance</i> , as per guidance from the Secretary of Energy Advisory Board (SEAB). Also updated Section 5.5.1, Calibration of Equipment.	November 2016
Kathy Zappia/ T.J. Sarlina	Periodic review of program with minor editorial changes, new graphic standards, updated hyperlinks.	March 2016
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T.J. Sarlina / Kathy Zappia	Initial release of the Integrated Quality Assurance Program. Replaces OQBP QA program of 01/20/2012	September 2013

TABLE OF CONTENTS

1		
2		
3	1.0	INTRODUCTION..... 4
4	2.0	DEFINITIONS..... 5
5	3.0	RESPONSIBILITIES 6
6	3.1	Laboratory Director.....6
7	3.2	Chiefs, Deputy Directors, Division/Section Heads, and Project
8		Directors/Managers.....6
9	3.3	Line Management / Supervisors / Group Leaders.....7
10	3.4	Management System Owners (MSOs)7
11	3.5	Quality Management System Owner7
12	3.6	Quality Section Liaisons (QSLs)8
13	3.7	Project Quality Community of Practice (PQCP)8
14	4.0	PROGRAM DESCRIPTION..... 9
15	5.0	PROCEDURES..... 9
16	5.1	Program9
17	5.1.1.	Contractor Assurance System..... 10
18	5.1.2.	Contractor Assurance..... 11
19	5.1.3.	Quality Management System (QMS)..... 11
20	5.1.4.	Graded Approach 11
21	5.2	Personnel Training & Qualifications12
22	5.2.1.	Qualifications..... 12
23	5.2.2.	Personnel Training..... 12
24	5.3	Quality Improvement14
25	5.3.1.	Quality Improvement Program 14
26	5.3.2.	Quality Improvement Support 15
27	5.4	Documents & Records17
28	5.5	Work Processes18
29	5.5.1.	Work Process Control..... 18
30	5.5.2.	Software..... 22
31	5.6	Systems Engineering.....22
32	5.7	Procurement & Procurement Assurance23
33	5.8	Inspection & Acceptance Testing25
34	5.8.1.	Inspection & Testing Process 26
35	5.8.2.	Control of Nonconforming Items 26
36	5.8.3.	Inspection & Test Records 26
37	5.8.4.	Control of Measuring & Test Equipment (M&TE) 27
38	5.9	Management Assessments28
39	5.10	Independent Assessments.....28

40	5.11	Suspect/Counterfeit Items Prevention.....	29
41	5.11.1.	Prevention.....	30
42	5.11.2.	Detection.....	30
43	5.11.3.	Reporting.....	30
44	5.12	Scientific Research.....	30
45	5.12.1.	Responsibilities.....	30
46	5.12.2.	Management of Research Projects.....	31
47	6.0	REFERENCES.....	31
48			
49			
50			
51			
52			
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1.0 INTRODUCTION

The Fermilab Quality Assurance (QA) Program is a vital element of the Quality Management System. The Quality Management System is one of the Management Systems that constitute the Fermilab Contractor Assurance System (CAS) required by the Prime Contract between the Department of Energy (DOE) and the Fermilab Research Association (FRA). The [Fermilab Quality Policy](#) establishes the quality-related goals and expectations for programs and personnel across the laboratory. This document describes the overarching QA Program for the laboratory and addresses how the expectations of the Fermilab Quality Policy shall be met. The primary objective of the Fermilab Quality Assurance Program is to establish a framework for the laboratory to provide reasonable assurance to the DOE, FRA, collaborating institutions/Partners, as well as internal and external customers/suppliers that expectations will be met. This quality framework shall be implemented to guide the laboratory leadership, management system owners, and project/program/process owners in establishing the necessary processes that provide constant, consistent, predictive, and effective assurance. With effective implementation of the requirements established in this QA Program document, the laboratory will be able to:

- consistently meet or exceed customer expectations, applicable regulatory, and Prime Contract requirements;
- implement appropriate quality planning using a graded approach;
- define appropriate measurement systems for critical processes;
- effectively identify and actively address risks and opportunities;
- integrate safety, quality, predictability, and reliability into processes;
- establish effective processes in partnerships and collaborations;
- provide reasonable assurance;
- and continually improve.

The Fermilab Quality Assurance Program applies to all work conducted at Fermilab, other Fermilab-managed facilities and resources, and other sites where work for Fermilab is being performed. It is implemented using a graded approach to the application of controls based on the analysis of risks identified where work is to be performed. It identifies requirements necessary to consistently meet the DOE Prime Contract obligations throughout the laboratory and ensures that essential aspects of quality, safety, health, security/cyber-security, environmental, facilities/infrastructure maintenance, and robust performance of research are integrated into all work conducted under the contract.

Fermilab flows down the QA Program requirements to subcontractors at any tier to the extent necessary to ensure subcontractors' compliance with the requirements and the safe

117 performance of work. Subcontractors performing work for or in conjunction with
118 Fermilab who have an established quality assurance program are also required to meet
119 Fermilab requirements for that particular scope of work. The Fermilab QA Program has
120 aligned with the applicable requirements established in the DOE O 414.1 – *Quality*
121 *Assurance*; as well as both, the national consensus standard ANSI/ASQ Z1.13-1999 to
122 ensure the application of Quality Assurance to scientific research, and ASQ/ANSI/ISO
123 9001:2015 standard to ensure the application of Quality Assurance to business processes
124 that support research activities.

125
126 Fermilab establishes different types of agreements with other DOE laboratories,
127 researchers, institutions or other entities for various types of research, project, and
128 experiment-related activities. Fermilab’s Office of Partnerships and Technology Transfer
129 ([OPTT](#)) defines the processes and parameters for the various agreements. The Fermilab
130 liaison, technical contact, or primary responsible person for the research, project, or
131 experiment-related activity is responsible for ensuring adequate programs, processes,
132 resources, training, and capabilities are in place to meet the requirements established in
133 this document as well other Fermilab policies for deliverables in the scope of the
134 associated agreement.

135
136 The Fermilab QA Program is continually reviewed for improvement opportunities and
137 the QA Program document is reviewed as necessary, or at a minimum of every 3 years.

138 139 **2.0 DEFINITIONS**

140
141 **Corrective Action** – An action to eliminate the cause of a detected nonconformity or other
142 undesirable situation.

143 *Note: There can be more than one cause for a nonconformance. Corrective action is taken to*
144 *prevent recurrence whereas preventive action is taken to prevent occurrence.*

145
146 **Human Performance Improvement (HPI)** – A set of concepts and principles associated
147 with a performance model that illustrates the organizational context of human
148 performance. The model contends that human performance is a system that comprises a
149 network of elements that work together to produce repeatable outcomes. The system
150 encompasses organizational factors, job-site conditions, individual behavior, and results.

151
152 **Lessons Learned (LL)** – A best proactive or innovative approach that is captured and
153 shared to promote repeat application; and may also be an adverse work practice or
154 experience that is captured and shared to avoid recurrence.

156 **Preventive Action** – A proactive action taken to eliminate the cause of a potential
157 nonconformity or other undesirable situation.

158 *Note: There can be more than one cause for a potential nonconformity. Preventive action is*
159 *taken to prevent occurrence whereas corrective action is taken to prevent recurrence.*

161 **Quality Assurance Manual (QAM)** – A living set of procedures established to provide
162 guidance and communicate critical quality program requirements.

164 3.0 RESPONSIBILITIES

166 3.1 Laboratory Director

- 167 • Aligns with, supports, and promotes the Fermilab QA Program; has ultimate
168 accountability for all aspects of Quality for all work done under the FRA/DOE
169 contract.
- 170 • Holds management accountable for the implementation of and compliance with
171 this QA program as well as for its effectiveness.
- 172 • Appoints the Head of Quality Assurance as the Quality Management System
173 Owner and the Fermilab QA Program owner.

175 3.2 Chiefs, Deputy Directors, Division/Section Heads, and Project Directors/Managers

- 176 • Ensure compliance with the requirements in this document for their areas of
177 responsibility including the flow down of requirements and awareness.
- 178 • Ensure integration of the QA Program requirements into Business, Project,
179 Experimental, and Operational programs/processes.
- 180 • Responsible for appropriate quality planning, allocating adequate resources for
181 work, and for implementing quality requirements in their respective
182 organizations.
- 183 • Establish adequate and transparent performance metrics to monitor the
184 performance and health of the organization, business processes, experiment or
185 Project.
- 186 • Ensure line management has the authority, responsibility, and is held
187 accountable for integrating quality into processes and programs.
- 188 • Responsible for assessing the efficacy and robustness of processes within areas of
189 responsibility and resolving gaps to prevent substandard performance or
190 achievement of goals/objectives.
- 191 • Responsible for the effectiveness of this QA Program by establishing adequate
192 assurance processes and practices in their areas of responsibility.

194 3.3 Line Management / Supervisors / Group Leaders

- 195 • Ensure compliance with the requirements in this document for their areas of
- 196 responsibility including the flow down of requirements and awareness.
- 197 • Ensure integration of QA Program requirements in processes and procedures.
- 198 • Ensure processes and procedures in areas of responsibility are assessed to
- 199 evaluate effectiveness and robustness.
- 200 • Ensure the appropriate resources are allocated and assigned to perform tasks
- 201 and quality requirements are met.
- 202 • Complete required Fermilab Quality Program Training modules and ensure
- 203 completion of training by staff.
- 204 • Maintain familiarity with the chapters of the Quality Assurance Manual to
- 205 ensure adequate flow down to staff and areas of responsibility.
- 206

207 3.4 Management System Owners (MSOs)

- 208 • Ensure compliance with this procedure within their respective management
- 209 systems.
- 210 • Ensure integration of the QA Program requirements into Management System
- 211 programs/processes.
- 212 • Establish specific Management System framework upon which D/S Heads, Project
- 213 Managers, and line managers shall implement their processes and allocate/direct
- 214 resources. This framework shall include policies, programs, processes, and
- 215 requirements which must be adhered to and flowed down to all individuals
- 216 executing work.
- 217 • Establish adequate and transparent performance metrics to monitor the
- 218 performance and health of the management system.
- 219 • Responsible for assessing the efficacy and robustness of their respective
- 220 Management Systems and implementation in Divisions, Sections, and Projects and
- 221 resolving any gaps to prevent the laboratory's exposure to loss or failure.
- 222 • Responsible for the effectiveness of this QA Program by establishing adequate
- 223 assurance processes and practices for their respective management systems.
- 224

225 3.5 Quality Management System Owner

- 226 • Possesses the authority to direct and oversee the Fermilab QA Program.
- 227 • Establishes, maintains, communicates, and verifies compliance to the Fermilab
- 228 Quality Policy.
- 229 • Ensures that assessments, using a graded approach to determine necessary rigor,
- 230 are conducted to evaluate compliance with this procedure and the effectiveness
- 231 of implementation.

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- Ensures that appropriate training to identify and handle Suspect/Counterfeit Items (S/CI) is available.
 - Ensures that training is available on the Fermilab Quality Program.
 - Communicates, and escalates when necessary, programmatic gaps, trends, and nonconformances that indicate noncompliance to the QA Program requirements.
 - Assumes responsibility for the content and maintenance of this procedure, the Quality Assurance Manual, and the continuous improvement of the Fermilab QA Program.

3.6 Quality Section Liaisons (QSLs)

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- Members of the Quality Section designated as Fermilab Quality Program points of contact for D/S Leadership and Management System Owners.
 - Proactively support D/S Heads, Project Managers, Line Managers, and Management System Owners with the implementation, maintenance, and continuous improvement of the QA Program requirements in their respective areas.
 - Perform data analysis and use other applicable quality tools to help D/S Heads and Management System Owners identify independent or management assessment opportunities in their areas of responsibility to promote continual improvement. QSLs may also facilitate or participate in these assessment activities.
 - Work closely with other Laboratory leadership, Division Safety Officers (DSOs), and D/S Risk Officers to identify areas of opportunity for improvement and self-assessment over the course of the year or, multi-year, and verify completion.
 - Support the monitoring, tracking, and trending of issues in iTrack for timely and effective resolution and/or escalation.
 - Effectively identify and capture lessons learned by consistently following the Lessons Learned process documented in [QAM Chapter 12010 – Fermilab Lessons Learned Program and Procedures](#).
 - Continuously improve the quality tools to support D/S/P.
 - Monitor the implementation, maintenance, and continual improvement of the Fermilab QA Program.

3.7 Project Quality Community of Practice (PQCP)

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- Consists of Fermilab employees who are Quality Assurance Managers, Quality Coordinators, Quality Engineers, Quality Engineering Specialist or designated quality representatives for Fermilab Projects and Experiments. Other members of the Quality Section are invited per the discretion of the Quality Section Head.

- Works collaboratively to ensure consistent implementation of the Fermilab Quality Assurance Program requirements within and between Projects.
- Identifies new and emerging quality issues in Projects represented in the PQCP; and collaborates on solutions.
- Provides input for the changes/updates/improvements to the Fermilab QA Program that may impact the QA Program implementation in Projects or Experiments.
- Provides input for potential improvements to the processes owned by the Office of the Chief Project Office.
- Shares and discusses lessons learned; monitors implementation of lessons learned across Projects.

4.0 PROGRAM DESCRIPTION

The foundation of Quality management is line responsibility. The line organization must have the authority, responsibility, and be held accountable for integrating quality assurance into all work performed in their areas of responsibility. Line responsibility for QA is woven into the organizational culture at Fermilab for sustainability.

The QA Program ensures that Fermilab's products and services meet or exceed customer expectations; outlines the requirements for implementing and maintaining a QA program throughout the lab; and provides a system capable of monitoring, controlling, and continually improving the laboratory's activities, processes, and systems.

The scope of the QA program applies to Fermi Research Alliance, LLC including all legal entities under its exclusive control (e.g. leased spaces in Sanford Underground Research Lab (SURF)) and all employees, subcontractors, and users when performing work that affects the laboratory's resources.

5.0 PROCEDURES

5.1 Program

Fermilab has established an organizational structure along with responsibilities, authority, and procedures that ensure effective implementation and maintenance of the QA Program.

The Laboratory Director, Chiefs, MSOs, and Heads of each D/S/P ensure that responsibilities and authorities are defined and communicated within the management

308 system or organization. Responsibilities and authorities are recorded as part of employee
309 job descriptions as well as within council and committee charters.

310
311 Fermilab is organized in Offices, Divisions, Sections, and Projects led by Chiefs, Deputy
312 Directors, Project Directors, and Heads. To view the organization at Fermilab at a high-
313 level and for each division, section, and project reference the most recent version of the
314 [Organizational Chart](#).

315
316 The Management System Owners are responsible for defining Management System
317 descriptions as per Contractor Assurance System (CAS) requirements. MSOs are also
318 required to establish foundational programs/processes upon which D/S/P Heads shall
319 establish their programs/processes. MSOs shall monitor and evaluate the implementation
320 and performance of those programs/processes and seek ways to continuously improve.
321 Gaps and issues identified relating to program implementation or performance shall be
322 recorded in iTrack and tracked through resolution. The Quality team shall evaluate the
323 efficacy of the Management Systems and help the MSOs identify opportunities for
324 improvement.

325
326 The Heads of each D/S/P are responsible for adhering to the requirements set forth in this
327 QA Program document and for ensuring adequate and effective processes are in place to
328 implement the requirements in their respective areas of responsibility. D/S/P are
329 responsible for ensuring alignment with the foundational processes established by the
330 Management System Owners, as applicable, within their respective areas. They are
331 responsible for providing adequate quality planning, schedules, and adequate resources
332 for work. As appropriate for their areas of responsibility, they establish additional
333 performance requirements above and beyond those established in the QA Program, while
334 avoiding any unnecessary duplication of effort. They are responsible for the performance
335 and sponsoring of assessment activities to facilitate the achievement of the organizational
336 mission and objectives. They ensure that their D/S/P activities are conducted in accordance
337 with the principles and requirements of this Fermilab QA Program document.

338 339 **5.1.1. Contractor Assurance System**

340 The [Contractor Assurance System \(CAS\)](#) is established to provide reasonable
341 assurance that the objectives of the management systems are accomplished and the
342 systems and controls which have been instituted are effective and efficient. CAS
343 covers all work activities and all personnel performing work at Fermilab including
344 subcontractors and users. The CAS structure encompasses all aspects of the cross-
345 cutting management systems which are essential to the laboratory's success.

347 **5.1.2. Contractor Assurance**

348 The Assurance Council (AC) is charged by the Laboratory Director and chaired by the
349 Chief Operating Officer to serve as a forum to evaluate, monitor, and improve
350 compliance with the Prime Contract Clause H.13 – Contractor Assurance System
351 (CAS) requirements. The AC provides reasonable assurance to the Laboratory
352 Director that the objectives of the CAS are accomplished, risks to achieving
353 compliance to the clause are identified and mitigated, and the systems and controls
354 are effective and efficient. The Assurance Council reviews performance via metrics
355 and key performance indicators that includes, but not limited to:

- 356 ○ PEMP Status updates and other lab initiatives
- 357 ○ Prime Contract deliverable status
- 358 ○ Risk management data
- 359 ○ Management System Assessment results and trends
- 360 ○ Safety and Security data
- 361 ○ Management concerns/emerging issues
- 362 ○ Changes that could impact Fermilab's CAS
- 363 ○ Input/feedback/directives received from DOE

364
365 The Assurance Council serves as the body to continual review the efficacy of the
366 management systems and the CAS as an entirety.

368 **5.1.3. Quality Management System (QMS)**

369 The Quality Management System is one of the laboratory's management
370 systems. It is a set of interrelated or interacting elements that Fermilab uses to
371 plan, direct, control, coordinate, assure and improve how quality policies,
372 objectives, processes, and procedures are established, implemented,
373 monitored, and achieved. The system is intended to establish confidence and
374 assurance that requirements of the Fermilab QA Program and customer
375 expectations for quality are met or exceeded via proactive management of
376 processes, tasks, and activities.

378 **5.1.4. Graded Approach**

379 The Fermilab QA program utilizes a graded approach, defined within [QAM](#)
380 [Chapter 12070](#), to tailor the types and extent of controls applied to implement
381 quality in fulfilling applicable requirements. The graded approach is applied
382 based on prudent management, planning, and cost. Application of the graded
383 approach entails:

- 384 ● Identification of activities which present significant quality risk,
- 385 ● Defining the activity,

- Evaluating risk and control choice, and
- Documenting and reaching concurrence on the application of the graded approach.

This process supports the laboratory's responsibility to prioritize resource usage in areas where the activities have been identified as requiring the most control and oversight. All D/S/P Heads shall ensure that a graded approach to quality requirements is applied in accordance with this section for products, projects, and services under their control, and is used when establishing levels of control.

5.2 Personnel Training & Qualifications

All Fermilab employees and personnel (e.g. users, subcontractors), regardless of their working location, are required to have the necessary experience, knowledge, and skills to perform their jobs. Personnel are qualified to perform their job based on previous experience, education, and training; on-the-job training; and completion of training courses or qualification programs. Line management is required to evaluate and ensure that individuals assigned to perform the work have the appropriate skills, background, education, and training necessary to carry out the work. Line managers are also responsible for ensuring adequate and qualified resources are allocated to fulfill the requirements of the Fermilab Quality Assurance Program.

5.2.1. Qualifications

Initial employee qualification is part of the hiring process administered by the Workforce Development and Resources Section (WDRS). Individuals are hired to meet established position requirements specified by job descriptions and skills as defined by line managers. Line managers ensure that job candidates meet specified requirements.

5.2.2. Personnel Training

Types of personnel training may include:

- Institutional training – conveys general information about the organization's mission, vision, goals, and management system. It may also include general knowledge or skills training.
- Site/facility-specific training – conveys emergency plans and the environmental, safety, security, and operational information necessary for personnel to prepare for and perform their assigned duties in the facility. This includes site-specific access requirements and regulatory based training.

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- Project/task-specific training – imparts the knowledge required for personnel to perform their assigned duties safely and successfully. This training may include project/task goals and schedules, implementing procedures, safety and hazard controls, methods, requirements, process metrics, and skills.
 - On-The-Job (OJT) training – enables personnel to learn their assigned duties while actually performing work. This training may include instruction from a senior-level employee or mentor.

434 Personnel are also provided with continuing training as appropriate to ensure
435 that job competency and compliance are maintained.

436

437 Fermilab line managers are required to ensure personnel possess the
438 experience, knowledge, skills, and abilities necessary to fulfill their
439 responsibilities. This includes:

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- Completing an Individual Training Needs Assessment (ITNA) to develop an Individual Training Plan (ITP) for their employees and revising it as job requirements change. The ITNA covers institutional and site-specific training.
 - Identifying and providing required project/task-specific training.
 - Identifying and providing required On-The-Job (OJT) training. OJT can be mentor based where an expert is assigned by line management to train personnel. It is line management's responsibility to ensure mentors assigned to conduct OJT are qualified.
 - Maintaining appropriate records of training.
 - Utilizing position descriptions, hazard analyses, new employee requisitions, and/or the Work Activities Analysis Form (WAAF) to identify the functional requirements and any physical limitations. This ensures that a continuous match exists between the capabilities of the employee and the physical requirements and/or mental demands of the current assignment.

456 The TRAIN database is the official repository for training provided by the
457 laboratory. Each employee is responsible for participating with their
458 supervisor in defining the necessary training, successfully completing all
459 required training, and applying training on the job. For laboratory training,
460 requirements may be defined by subcommittees and presented by relevant
461 subject matter experts. For training not provided by the laboratory, subsequent
462 records shall be kept in personnel files as appropriate.

463

464 Management and training points of contact are responsible for reviewing the
465 effectiveness of its training programs. Results from these reviews shall be used
466 as inputs for continual improvement.
467

468 **5.3 Quality Improvement**

469 Fermilab maintains continuous quality improvement through a variety of activities,
470 including training, design, assessments, walk-throughs, inspections, tests, monitoring,
471 reviews, data analysis, and communication/feedback.
472

473 **5.3.1. Quality Improvement Program**

474 Issues, improvement opportunities, and corrective actions, generated from the
475 activities listed above are documented and tracked in Fermilab's Issues
476 Management Tracking System, iTrack which resides in the Fermilab Quality
477 Tools Suite (FQTS) Procedures for documenting and tracking these items are
478 documented in the [Quality Assurance Manual Chapters 12030 and 12040](#).
479

480 Management at all levels is responsible for supporting and enabling
481 individuals under their supervision to participate in identifying and analyzing
482 opportunities for improvement; responding to discovery of quality-related and
483 program/process issues; following up on required actions; documenting
484 failures and non-conformances; ensuring that significant problems are
485 reported to the appropriate management levels (program, facility, D/S/P
486 manager, supervisor, or group leader, and Directorate/Chiefs); establishing
487 and measuring performance; and ensure root causes are identified and
488 resolved.
489

490 All line managers are responsible for encouraging the reporting of
491 improvement opportunities and lessons that have been learned from activities
492 across the laboratory. These items shall be documented in iTrack and tracked
493 if there are corresponding actions. All employees planning work activities/task
494 are encouraged to review lessons learned to incorporate relevant aspects to
495 prevent repeating mistakes. Procedures for documenting Lessons Learned are
496 available in the QAM Chapter 12010 - [Fermilab Lessons Learned Program](#).
497

498 Communication is a critical component for ensuring expectations are
499 understood by all levels of stakeholders, suppliers, customers, and staff.
500 Chiefs, Deputy Directors, D/S Heads, Project Directors/Managers, and
501 Management System Owners are responsible for appropriate communication
502 planning and the effective implementation of those plans. Communication

503 methods include verbal, written, listening, and feedback. Effective and timely
504 communication can result in the following:

- 505 • Calibrated understanding of laboratory and organizational strategies,
506 goals, and objectives; and the role all levels of staff have in meeting
507 them.
- 508 • Early insight to risks, issues, and gaps that could preclude the
509 achievement of goals, objectives, and deliverables.
- 510 • Empowered staff that embraces change.

511
512 It is the expectation that all levels of management establish effective
513 communication strategies and plans for their areas of responsibility and
514 continually evaluate these strategies and plans for efficacy, then adjust as
515 necessary. Effective communication strategies and planning with collaborating
516 institutions, partners, and vendors is also critical to the success of research,
517 experiments, Projects, and other collaborative efforts.

518
519 Obtaining feedback is another method of communication and an important
520 mechanism for identifying opportunities for improvement. Feedback can be
521 obtained from internal and external sources. Process owners should clearly
522 understand the customers and suppliers of their processes which can be
523 identified by tools such as process maps and workflow diagrams such as a
524 SIPOC (supplier, input, process, output, and customer) that explicitly
525 highlights the function and flow of each per that particular process.
526 Understanding customers and suppliers (internal and external) allows for the
527 establishment of deliverables/goals as well as the inputs required to achieve
528 the deliverables/goals. Customer feedback can be used to improve the
529 processes relating to a particular deliverable. D/S/P leadership should clearly
530 define methods for obtaining feedback from their staff and use that feedback
531 to address concerns, resolve issues, and improve processes.

532 533 **5.3.2. Quality Improvement Support**

534 It is the responsibility for all levels of management and staff to support,
535 promote, and actively engage in the laboratory's continuous improvement
536 efforts.

- 537 • Fermilab Senior Management members are responsible for supporting the
538 continuous improvement of the Fermilab Quality Management System and
539 QA Program. Senior management shall demonstrate commitment to the
540 Fermilab QA Program and its continuous improvement by promoting this
541 commitment to the individuals in their areas of responsibility as well as to

542 users, collaborators, vendors, and partners. They are responsible for
543 ensuring adequate resources are allocated to implement the requirements
544 established in this program document, monitor implementation, plan and
545 complete self-assessments, address corrective actions, implement
546 preventive actions, and continuously improve by instituting lessons
547 learned.

- 548 • Management System Owners (MSOs) are responsible for the maintenance
549 and improvement of their management system. MSOs identify
550 opportunities for improvement via the issues management process, risk
551 analysis, supplier/customer feedback, annual PEMP results, contract
552 deliverable completion, and other means. There is an expectation for MSOs
553 to continually improve the framework comprised of policies and
554 procedures by actively measuring performance against goals/objectives
555 and seeking input from D/S/P who implement abide by the policies and
556 implement processes as well as the Assurance Council.
- 557 • The Office of Integrated Planning and Performance Management supports
558 quality improvement by leading the Laboratory's strategic planning
559 process, goal setting, and performance planning and oversight processes.
560 Input to the planning process includes feedback from management
561 reviews, issue resolution, root cause analysis, lessons learned, assessments,
562 scientific peer reviews and DOE Office of Science program reviews.
- 563 • Quality issues are analyzed individually and collectively to identify
564 systemic quality issues, trends and opportunities for process improvement.
565 Refer to QAM Chapter 12050 on [Root Cause Analysis](#) and the FESHM
566 Chapter 3020 on [Incident Investigation and Analysis](#) for the procedure
567 relating to incident investigation and analysis.
- 568 • The process of resolving quality issues involves:
 - 569 ○ Identifying a condition adverse to quality and evaluating its
570 significance.
 - 571 ○ Analyzing the problem and determining its causes.
 - 572 ○ Taking prompt containment action and documenting that
573 action.
 - 574 ○ Developing or verifying planned actions with the organization
575 resolving the problem.
 - 576 ○ Assigning responsibility for correcting the problem.
 - 577 ○ Examining training processes, procedures, or management
578 systems.
 - 579 ○ Determining corrective action and documenting that action.
 - 580 ○ Taking steps to prevent recurrence.

- 581 ○ Verifying implementation, and documenting closure.
- 582 ○ Determining effectiveness of the corrective and preventive
- 583 actions.
- 584 • The Incident Analysis Team (IAT) has been established to facilitate
- 585 continual improvement of the HPI Program. Human Performance
- 586 Improvement (HPI) supports resolution of quality issues through
- 587 analyzing problems to determine cause(s), suitable corrective and
- 588 preventive actions, and verifying that the correct actions were taken to
- 589 satisfy the root cause of the original problem(s).
- 590 • Fermilab has an Enterprise Risk Management process to address major,
- 591 cross-cutting risks that potentially jeopardize the overall goals of the lab.
- 592 An Enterprise Risk Management Board has been established to identify,
- 593 categorize, evaluate, monitor, and report significant institutional risks that
- 594 have the potential to affect the achievement of the laboratory mission and
- 595 performance objectives. . Fermilab has an established [Risk Management](#)
- 596 [procedure for Projects](#). Identifying and planning for potential risks is
- 597 imperative for quality, reliability, customer satisfaction, and sustainability.
- 598 Risk management is a key component of continuous improvement.
- 599 • Assessments also support the resolution of quality problems by taking the
- 600 proactive approach to reviewing a program or process to identify
- 601 opportunities for improvement or identify preventive actions through
- 602 discovery. Refer to the [QAM Chapter 12080 – Fermilab Assessment](#)
- 603 [Program](#).
- 604

5.4 Documents & Records

606 Fermilab documents specifying policies, prescribing processes, or establishing design

607 specifications and requirements are controlled per the [Document Management and](#)

608 [Control Policy](#). Additional document control requirements may be required by outside

609 customers/sponsors or be required for certain specific activities.

610

611 Responsibility for lab-wide policies and procedures is shared between the Directorate and

612 the originating D/S/P's. D/S/P's establish methods to control procedural requirements,

613 design, and other quality management documents and records used solely within their

614 organization. Management is responsible for providing the resources necessary to fulfill

615 the document control and records management requirements. Fermilab employees,

616 contractors, users, and collaborators are required to comply with the document control

617 and records management policies and procedures. Project or experiment contacts to

618 collaborating institutions/partners are responsible for ensuring adequate processes are in

619 place to adhere to the requirements set forth in this section.

620
621 Documents are required to safely and effectively manage, perform, and assess work.
622 Management identifies those documents needed to accomplish these objectives and
623 determine the level of control required. Controls include activities such as preparation,
624 review, approval, distribution, usage, availability, revision, and disposal of documents.
625 All policies, program documents, program implementation plans, and procedures are
626 controlled by the issuing organization, which schedules reviews and updates for each
627 document under its control as prescribed by that document.

628
629 Records are necessary to provide evidence of process effectiveness and conformity with
630 requirements. For more information on the policies and procedures for Fermilab's records
631 management program, refer to the [Records Management Policy](#) and the [Records
632 Management Program](#). The program includes provisions for specifying, preparing,
633 reviewing, approving, maintaining, and disposing of records. Disposition of records shall
634 follow the approved DOE records retention schedules.

635 636 **5.5 Work Processes**

637 Line management ensures sufficient resources are available and provided to maintain the
638 site in an operational state and that work controls are in place and effective. Work includes
639 the agreements, procurement, accounting, research, design, fabrication/construction,
640 assembly, storage, transportation, delivery, installation, operation, support, maintenance,
641 modification, and decommissioning of experiments, accelerators, facilities, business
642 systems, and otherwise performed by Fermilab employees, subcontractors, users and
643 partners regardless of location. The set of controls applied to work processes includes
644 written procedures for activities of sufficient complexity or potential hazard; monitoring
645 and assessing performance; personal accountability (roles and responsibilities);
646 incorporating quality and reliability, and specific provisions for activities not otherwise
647 covered in this document. The control of scientific research is described in Section 5.12 –
648 Scientific Research.

649
650 Each person is responsible for the quality of their work, reporting issues, contributing to
651 the incorporation of environment, safety, health, and productivity goals, and for
652 maintaining items to prevent damage, loss or deterioration.

653 654 **5.5.1. Work Process Control**

655 Using a graded approach, line management is responsible for determining the
656 appropriate level of work process controls, including which activities require
657 written procedures and which procedures must be augmented through
658 personnel training and qualifications. Evidence the analysis for work controls

659 shall be provided and maintained. Management defines workmanship
660 standards, equipment to be used, specifications for materials, process
661 measurement points, and measurement standards. ES&H and Quality
662 requirements and controls for work processes are defined in [FESHM](#), [FRCM](#),
663 and [QAM](#).

664
665 Controls are established for the procurement and acceptance of items and
666 services. Controls on Measuring and Test Equipment are designed to meet
667 requirements identified in Section 5.8.4 - Inspection and Acceptance Testing.
668 Controls for preservation of equipment, devices, tools, components, products,
669 and services are implemented by the organization responsible for them.
670 Controls include traveler processes for accompanying components and
671 products through assembly processes; databases for tracking equipment,
672 devices, tools, and services; and response plans for preserving services and
673 equipment when natural phenomenon's or other incidents occur.

674
675 For work performed by vendors and collaborating institutions/partners, work
676 process controls are established by that particular vendor or institution.
677 Fermilab has a responsibility to verify adequate work process controls are
678 established and implemented at the collaborating institution for work
679 performed for Fermilab to ensure requirements can be effectively and
680 consistently met.

681 682 Item Control

683 Items are identified and controlled, with their traceability maintained during
684 receipt, shipping/transportation, storage, handling, installation, use, and
685 disposal. These controls are commensurate with the item's application, usage,
686 cost, and/or associated risk and are managed by D/S/P's. The requirements for
687 controlling and maintaining property, equipment, items, and the site
688 infrastructure follow [DOE Order 430.1, Real Property and Asset Management](#).
689 Personal property is controlled according to [Property/Inventory Policies](#).
690 Fermilab shall have policies and procedures in place for the management and
691 protection of property belonging to other institutions, organizations, or
692 external parties. These policies and procedures shall be maintained by the
693 Management System Owner of the [Property and Infrastructure Management](#)
694 [System](#).

695
696 For items procured, fabricated, assembled, and/or shipped by vendors and
697 collaborating institutions/partners for Fermilab, Fermilab has the

698 responsibility to ensure adequate item control processes are established and
699 implemented.

700
701 Maintenance
702 D/S/P's are responsible for ensuring maintenance is performed on facilities and
703 equipment under their care. Facilities Engineering Services Section (FESS) is
704 the primary maintenance service provider for facilities and the laboratory's
705 infrastructure. These services are agreed upon between FESS and the D/S/P's.
706 Maintenance plans are documented by D/S/P's. The organization coordinating
707 or performing the maintenance is responsible for ensuring that records of
708 maintenance are kept.

709
710 Readiness Reviews
711 Readiness reviews are conducted prior to the start of operations that are new
712 or have been significantly changed. The extent and detail of the reviews are
713 commensurate with the scale, cost, complexity, hazards, and programmatic
714 significance. Reviews which require ES&H approval to operate accelerator
715 facilities are required to follow the [FESHM Chapter 2010 - Planning and](#)
716 [Review of Accelerator Facilities and their Operations](#). D/S/P's are required to
717 document any readiness reviews performed in their respective areas. In
718 addition, certain research projects are required by applicable DOE Orders to
719 perform readiness reviews at specified intervals.

720
721 Calibration of Equipment
722 Calibration is a critical step in any process that utilizes measurement or
723 diagnostic tools to ensure success. Improper calibration can result in injury
724 to workers, damage to equipment and/or a reduction in efficiency,
725 reliability, or quality. It is the responsibility of each D/S/P to identify, monitor
726 and maintain key process equipment that requires calibration or verification.
727 Any equipment used to test or calibrate devices that have safety or scientific
728 significance shall be considered for inclusion in the calibration program.
729 Results shall be documented and retained.

730
731 Process requirements and criticality shall be considered during the
732 evaluation. Where possible, each item requiring calibration shall be clearly
733 labeled identifying the item as requiring calibration, the department or
734 person responsible for the item, the calibration due date, and a unique
735 identification number. (See also: Section 5.8.4 – Control of Measuring & Test
736 Equipment (M&TE). When labeling the item is not possible, another form of

737 identification must be identified to ensure adequate traceability and ability to
738 meeting calibration and verification requirements.

739
740 D/S/P personnel are responsible for ensuring vendors, partners, or
741 collaborating institutions performing work for or in conjunction with
742 Fermilab have processes in place that align with these requirements

743
744 Work Environment
745 All facilities are to be maintained in a state of order, cleanliness, and repair, as
746 appropriate to accomplish their missions. It is everyone's responsibility to
747 maintain the integrity and cleanliness of their work area, assure they
748 understand and meet the requirements at each building location, and follow
749 the general expectation for Fermilab. It is the responsibility of Fermilab
750 building/facilities management to ensure Fermilab facilities are adequate and
751 do not negatively impact the safety, health, environment, or quality of
752 personnel, parts, equipment, or components. D/S/P are responsible for
753 ensuring vendors, partners, or collaborating institutions performing work for
754 or in collaborations with Fermilab have processes in place to assure adequate
755 work environments where work for Fermilab is being performed align with
756 these requirements.

757
758 Change Management
759 The management of change is a critical component of any established process
760 or program. Process owners shall establish appropriate methods for
761 evaluating, initiating, communicating, and implementing changes. This can
762 include changes to procedures, designs, processes, and resources. Common
763 tools used to evaluate changes include Failure Modes and Effects Analysis
764 (FMEA), process maps/flow charts, and Strengths, Weaknesses, Opportunities,
765 and Threats (SWOT) analyses. Management System Owners are responsible
766 for ensuring high-level expectations are set for change management in their
767 management system. Line management is responsible for ensuring the
768 appropriate tools are employed for all aspects of change management in their
769 areas of responsibility. Project/Experiment personnel are responsible for
770 ensuring the appropriate processes are established and followed for changes
771 in design, in-process activities, and delivery.

772
773 Organizational Knowledge
774 Organizational knowledge is information used and shared to achieve
775 Fermilab's mission and objectives. It comprises of work process documentation

necessary to ensure requirements are met. Fermilab has several methods for communicating and managing information and processes for use by individuals performing work. Several platforms such as Document Database (DocDB), Fermipoint, and Teamcenter are employed to share and manage information. These platforms allow for the appropriate maintenance and version control necessary to provide current information when needed. Lessons learned and information gathered from external sources such as collaborating institutions and suppliers also serve as inputs to organizational knowledge.

5.5.2. Software

- **Safety Software**

Fermilab does not employ safety software under the definition of safety software as described within DOE Order 414.1D *Quality Assurance*.

- **Software Quality Assurance**

QA requirements for software used at Fermilab to support the laboratory's program and mission is described in the [Fermilab Software Quality Assurance Program](#).

5.6 Systems Engineering

Fermilab's technical management and engineering processes prescribe the need for adequate control of planning, design inputs, outputs, verification and validation, configuration and design changes, and technical and administrative interfaces. Design work is based on sound engineering and scientific principles and judgment and applicable codes and standards. It applies to research/experimental equipment including accelerator components, detectors, software, hardware, as well as to conventional facilities, structures and equipment. Projects and Experiments designate a system manager or responsible engineer who has the overall responsibility for the efforts of all engineers working on a particular Project or Experiment and ensures effective implementation of engineering processes and procedures. The controls and implementing procedures are established in the [Fermilab Engineering Manual](#).

The [Fermilab Engineering Manual](#) defines a graded approach to engineering controls and configuration management that couples the applicable rigor of management controls to the risk posed by the structures, systems, components, software for engineering design, or construction and manufacturing processes under development.

The Engineering Management System Owner is responsible for ensuring design and engineering processes are established, documented, communicated, and flowed down to

815 the D/S/Ps. Technical management and engineering processes include requirements
816 management, design, interface control, configuration management/change control, value
817 engineering, and technical reviews. Line or systems management or the responsible
818 engineer is responsible for implementing and evaluating the effectiveness of the design
819 and engineering processes. Members of line/system management are responsible for
820 identifying opportunities to improve design and engineering processes appropriately
821 enhancing requirements to the engineering process to ensure the quality and success of
822 experiments and projects executed under their supervision. Other functions having
823 accountability for the successful execution of the technical management and engineering
824 process includes Project and System Directors/Managers, Department Heads, Lead
825 Engineers, and Engineers. Their responsibilities are outlined in the [Fermilab Engineering](#)
826 [Manual](#)

827
828 The [Fermilab Engineering Manual](#) describes, in detail, the design and engineering process
829 steps:

- 830 1) Requirements and Specifications – defines objectives;
- 831 2) Engineering Risk Analysis – determines level of documentation and review
832 required;
- 833 3) Requirements and Specifications and Engineering Risk Reviews;
- 834 4) System Design – steps of design phase;
- 835 5) Engineering Design Review – defines required design reviews;
- 836 6) Procurement & Implementation;
- 837 7) Testing & Validation;
- 838 8) Release to Operations; and
- 839 9) Final Documentation – defines documentation requirements for completion of the
840 project.

841
842 Engineering processes should include the end-to-end management of products,
843 components, and systems. A critical component of the engineering function includes the
844 implementation of effective and efficient change management processes. Refer to Section
845 5.5.1.

846 847 **5.7 Procurement & Procurement Assurance**

848 All materials and services are purchased from acceptable and responsible suppliers
849 including distributors authorized by the manufacturer. Materials and services are
850 acquired by purchase order or use of the procurement credit card (ProCard) and approved
851 per procedures in the [Procurement Manual](#). All requestors and ProCard holders are made
852 aware of the need to purchase from reputable suppliers and distributors. Fermilab
853 suppliers are required to provide goods and services which are in conformance with

854 purchase order requirements or signed subcontracts. Responsibility for the accuracy of
855 purchase requisition data and requirements resides with the requestor. Fermilab may, in
856 accordance with purchase order terms and conditions, perform site audits, require
857 suppliers to perform self-assessments, and provide control plans, manufacturing
858 inspection plans, and data or other reports to ensure compliance. Fermilab provides a
859 necessary and sufficient level of oversight of subcontractors to verify that Fermilab and
860 subcontract requirements are being met.

861
862 The procurement and receipt inspection processes support the identification, and prevents
863 the introduction, of suspect and counterfeit items (S/CI), refer to [QAM Chapter 12020 –](#)
864 [Suspect/Counterfeit Items \(S/CI\) Program](#). Inspection receipt shall occur whether materials
865 were purchased through purchase order or via the ProCard, see section 5.8 in this
866 document. Personnel are informed of the S/CI reporting process and the risks associated
867 with S/CI. The system for S/CI detection, prior to release for use, is detailed in Section 5.11
868 - Suspect and Counterfeit Items. Suspect or counterfeit items must be reported to
869 Procurement for inclusion in vendor files as appropriate.

870
871 The procurement of all goods and services is under the control of the Procurement
872 Department. Procurement coordinates all procurement requests received from laboratory
873 D/S/P's. This includes acquisition planning related to engineering, quality, and other
874 functions as necessary, generating and verifying solicitation and purchase documents,
875 negotiating terms and conditions, performing subcontract administration, and closeout.
876 Procurement processes shall also establish applicable requirements for any necessary
877 post-delivery activities associated with procured items or services.

878
879 All purchase orders, subcontracts, and agreements established per the appropriate
880 Procurement processes shall have a Fermilab contact (person requesting the Procurement
881 action) responsible for ensuring the following elements are established:

- 882 • Ensure all applicable ES&H, quality, and technical requirements are
883 adequately specified.
- 884 • Quality requirements such as Quality Assurance Plans as applicable,
885 and Quality Control Plans which includes elements such as, but not
886 limited to, incoming and in-process inspection criteria, material
887 certification requirements, acceptance criteria, witness/hold points,
888 packaging, storage, transportation/shipping requirements.
- 889 • Ensure subcontractor or supplier can consistently and effectively meet
890 identified requirements.
- 891 • Submit Subcontractor or Supplier's Quality Plans to the Fermilab
892 Quality Assurance Section for review for adequacy.

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- Submit ES&H related documentation to the ES&H Section and/or appropriate FESHCom Subcommittee for review for adequacy where necessary.
 - Personnel responsible for oversight of the subcontractor activities are aware of the subcontract or agreement to ensure adequate resources are allocated to oversee subcontractor activities and verify implementation of requirements throughout the duration of the work.
 - Ensure all obligations to the subcontractor are met.
 - Ensure specified deliverables are completed/received and meet requirements.
 - Notify Procurement and the individuals responsible for the work of any issues with the subcontractor or supplier that would negatively impact, ES&H, quality, reliability, costs, or timely delivery/completion.
 - Provide feedback to Procurement on the performance of the subcontractor or supplier as input to Procurement Supplier Evaluation processes.

910 Prospective suppliers are evaluated based upon their ability to meet quality, technical,
911 and financial performance criteria, and to operate in a safe and environmentally compliant
912 manner as outlined in the [Procurement Manual](#). Evaluation and monitoring of supplier's
913 performance during the life cycle of the purchase order are performed to ensure that
914 technically acceptable items are produced and services continue to meet the quality,
915 technical, delivery, and other performance requirements. Corrective actions in accordance
916 with purchase order terms and conditions are implemented should suppliers not perform
917 as required. The Procurement Management System Owner is responsible for ensuring
918 appropriate processes are established and effectively flowed down to D/S/Ps. The
919 Procurement Management System Owner is responsible for assuring the Procurement
920 processes are effective and continuously improved.

921

922 **5.8 Inspection & Acceptance Testing**

923 Inspections and tests are performed in order to verify that the physical and functional
924 aspects of items, services, and processes meet requirements and are fit for use. The
925 performance expectations, inspections, and tests are considered during the design phase
926 and, where appropriate, are specified in the design output and/or procurement
927 documents. Line management is responsible for specifying when/what type of inspection
928 is required and for ensuring that adequate inspections are performed and documented.

929

930 **5.8.1. Inspection & Testing Process**

931 Inspection and acceptance testing plans identify item characteristics and
932 processes to be inspected/acceptance tested, inspection techniques, acceptance
933 criteria, hold points, and the individuals or organization responsible for
934 performing the inspection. Appropriate corrective actions shall be taken where
935 deficiencies are identified accompanied by the appropriate follow-up to ensure
936 effectiveness.

937
938 When appropriate, inspections and tests are performed by personnel who are
939 independent of the activities being inspected.

940
941 For instances where inspection and testing processes are performed by
942 collaborating institutions/partners performing work under an agreement with
943 Fermilab, the Fermilab responsible person or technical contact is responsible
944 for ensuring adequate processes are established to meet the requirements in
945 this section. The Fermilab responsible person or technical contact is also
946 responsible for verifying consistent implementation of inspection and
947 acceptance testing and obtaining related records, data, and results.
948 Collaborating institutions/partners are required to report inspection and
949 testing that fail to meet requirements/standards. Refer to [QAM Chapter 120100](#)
950 [– Incoming Inspection and Acceptance](#).

951
952 **5.8.2. Control of Nonconforming Items**

953 Items that do not conform to specified requirements are subject to controls to
954 prevent their inadvertent installation or use. D/S/P's are responsible for control
955 of nonconforming items. Projects and experiments working with collaborating
956 institutions/partners are responsible for ensuring adequate controls and
957 processes are established for managing nonconformances that occur within the
958 institution or partnering agreement. Controls include identification,
959 documentation, evaluation, segregation (when practical), item disposition
960 (reject, repair, rework, use-basis), and notification to affected organizations.
961 The FESHM Chapter for [Significant and Reportable Occurrences](#) is consulted
962 to determine if the nonconformance should be considered reportable.

963
964 **5.8.3. Inspection & Test Records**

965 Inspection and test results are documented and preserved. The inspection and
966 test status of items or processes requiring examination are clearly identified to
967 ensure that only those with acceptable results are used. At a minimum,
968 inspection/test records identify the following: item(s) inspected, the

969 inspection/test procedure used, who performed the inspection/test, the
970 identification number(s) of the measuring & test equipment (M&TE) used to
971 perform the inspection or test, the inspection/test data, the inspection/test
972 criteria, and the inspection/test results.
973

974 **5.8.4. Control of Measuring & Test Equipment (M&TE)**

975 The measuring and test equipment used for inspection and acceptance tests are
976 identified, calibrated, maintained, and controlled commensurate with their
977 intended use. Procedures are established by D/S/P's for testing, retesting,
978 adjusting, and recalibrating M&TE. It is the responsibility of line management
979 to ensure established procedures are implemented and followed, and that the
980 appropriate monitoring, measuring, and testing resources are available to
981 employees performing these procedures. It is the responsibility of the Fermilab
982 contact or technical contact to collaborating institutions/partners to ensure
983 adequate processes are in place at the institution or partner for the control of
984 M&TE.

985
986 Equipment is checked to ensure it is the proper type, range, accuracy, and
987 precision and is uniquely identified and traceable to its calibration records.
988 Each D/S/P is responsible for ensuring calibration of equipment per section
989 5.5.1 in this document. Calibration standards are traceable to the National
990 Institute of Standards and Technology or equivalent. M&TE examples include
991 scales, radiation survey instruments, pH monitors, and voltage meters.
992

993 If any M&TE is found to be out of tolerance, then appropriate evaluations shall
994 be performed to assess any adverse impact on previous inspection, testing,
995 collected data, or calibration using that equipment. The evaluation, including
996 conclusions, should be documented and appropriate notifications made. When
997 M&TE equipment or associated computer programs are identified as not
998 operating to specifications, they shall be removed from service or locked out
999 and not returned to service until passing calibration requirements.

1000
1001 Traceability of measuring and test equipment is the responsibility of each
1002 D/S/P. Documentation and tracking of calibration, evaluations, inspection,
1003 testing, and collected data is tracked by methods meeting the unique needs of
1004 each D/S/P including the use of online databases and tracking spreadsheets.
1005 The method selected for traceability shall be reviewed and verified on a
1006 predetermined basis.
1007

1008 **5.9 Management Assessments**

1009 Management assessments are performed, as described in the [Fermilab Quality Policy](#) and
1010 [QAM](#), by an organization to evaluate its own management processes (self-assessment)
1011 and their implementation to identify noteworthy practices, uncover issues, identify
1012 corrective actions, verify meeting of Prime Contract deliverables, PEMP objectives, and
1013 ensure that the work being performed is satisfactory and according to requirements. The
1014 performance of management assessments is a critical assurance activity.

1015
1016 Line managers are required to assess their processes to identify and correct problems that
1017 hinder the organization from achieving its objectives. The Heads of D/S/P's monitor the
1018 progress of objectives and goals in their organizations to ensure work is performed and
1019 resources are allocated to meet those objectives and goals. The D/S/P Heads are
1020 responsible for monitoring the resolution of items identified from assessments, assigning
1021 responsibility for resolution, identifying an appropriate timeframe for resolution,
1022 ensuring the actions are finalized with appropriate objective evidence, and documented
1023 in iTrack. Management System Owners assess the effectiveness of their respective
1024 management systems and identify opportunities to improve or evolve. The QA Section
1025 monitors the adequacy of the assessments, the progress of corrective actions, and sponsors
1026 or conducts periodic assessments of the effectiveness of the implementation of the QA
1027 program throughout the laboratory. Scientific work is assessed by a peer review process.
1028 Scientists determine the extent and adequacy of this process.

1029
1030 Issues and opportunities for improvements identified as the result of an assessment are
1031 presented to the organization that was assessed, provided to the appropriate levels of
1032 management for review, and evaluated to determine the level of follow-up required. Non-
1033 conformances are reported for failure to comply with requirements. Corrective actions are
1034 recorded and tracked to closure through the iTrack database per the [Quality Policy](#) and
1035 the appropriate chapters in the QA Manual. Items having Lab-wide impact are identified
1036 and reported at the Assurance Council and other senior management team meetings for
1037 awareness and action.

1038

1039 **5.10 Independent Assessments**

1040 Independent assessments are conducted on a periodic basis to verify adequate
1041 implementation of the Fermilab QA program and other established programs and
1042 processes across the laboratory. These assessments complement the Management
1043 Assessments described in the section above. Fermilab management in conjunction with
1044 the Quality Section has the responsibility and authority for planning internal independent
1045 assessments, such as QA Assessments, and for providing the necessary resources to
1046 conduct them. The coordination of external independent assessments is performed by the

1047 management of the assessed organization with assistance from the Quality Section if
1048 required. Environmental, health, safety, security, and quality related external independent
1049 assessments shall be coordinated by the ES&H and Quality Sections.

1050
1051 D/S/P Heads are responsible for providing resources for assessments, implementing any
1052 identified corrective actions, tracking/reporting the status of Corrective Action Plans, and
1053 improving processes to prevent recurrence. Personnel planning the assessments are
1054 responsible for ensuring personnel performing the independent assessment do not have
1055 direct responsibilities in the area they are assessing.

1056
1057 Issues and opportunities for improvement identified as the result of an assessment are
1058 presented to the organization that was assessed, provided to the appropriate levels of
1059 management for review, and evaluated to determine the level of follow-up required.
1060 Corrective actions are recorded and tracked to closure through the iTrack database. Items
1061 having Lab-wide impact are identified and reported to the Assurance Council and senior
1062 management team for action.

1063
1064 Nonconformances and corrective actions for DOE assessments are administered in
1065 accordance with the Contractor Requirements Document of DOE O 227.1, *Independent*
1066 *Oversight Program*. Nonconformances and corrective actions for other external assessment
1067 teams are entered into iTrack and tracked to completion per the [Quality Policy](#), and
1068 relevant chapters in the [QAM](#).

1069
1070 **5.11 Suspect/Counterfeit Items Prevention**
1071 Fermilab has established a process for the identification, control, and disposition of
1072 suspect/counterfeit items ([S/CI](#)) detailed in the [QAM Chapter 12020](#). Fermilab provides
1073 training on S/CI processes and controls (including prevention, detection and disposition
1074 of S/CI's). Line managers shall identify individuals requiring S/CI training, ensure they
1075 receive this training, and provide necessary resources for maintaining the S/CI program.

1076
1077 Designers provide appropriate specifications and controls to safeguard the laboratory
1078 against the introduction of S/CI. The Procurement Department is responsible for selecting
1079 acceptable and responsible suppliers including distributors authorized by the
1080 manufacturer. All requestors and ProCard holders are made aware of the need to purchase
1081 from reputable suppliers and distributors. Personnel are informed of the S/CI reporting
1082 procedures and the risks associated with S/CI. Suspect or counterfeit items should be
1083 reported to Procurement for inclusion in vendor files as appropriate.

1084
1085 **5.11.1. Prevention**
1086 Methods to prevent the purchase of S/CI's are based on making all purchases
1087 from reputable suppliers and distributors.
1088

1089 **5.11.2. Detection**
1090 The primary means of detecting S/CI's is through inspection.
1091

1092 **5.11.3. Reporting**
1093 If S/CI's are discovered, the reporting process follows the [S/CI procedure](#) as
1094 outlined in [QAM](#). This includes notifying the area supervisor, the S/CI
1095 coordinator, and may include the Division Safety Officer. The FESHM Chapter
1096 for [Significant and Reportable Occurrences](#) is consulted to determine the
1097 appropriate reportable category.
1098

1099 **5.12 Scientific Research**

1100 Current research at Fermilab involves experiments of varying size and complexity,
1101 theoretical explorations in physics, and development of supporting technologies (e.g.
1102 accelerator elements and systems, cryogenics, material science, detector development, and
1103 computing). Fermilab has adopted the standard, ANSI/ASQ Z1.13-1999 *Quality Guidelines
1104 for Research*, which describes recommended quality assurance activities for research. Each
1105 type of research is unique in its approach and application and requires varying levels of
1106 controls to produce the desired results.
1107

1108 **5.12.1. Responsibilities**

- 1109 • The Fermilab Director, Deputy Directors, Chief Officers, D/S Heads, and
1110 Management System Owners are responsible for setting the strategy for
1111 science at Fermilab and approving expenditures of funds for scientific
1112 proposals and establishment of projects. In performing these actions, they
1113 rely on the advice and recommendation of scientific committees.
1114
- 1115 • Principal Investigators and/or Experiment Spokespersons are responsible
1116 for formally proposing the planned research, including technical approach,
1117 schedule, deliverables, and facility requirements; developing the
1118 contractual documentation between the collaboration and Fermilab for the
1119 implementation of experiments and other projects; overseeing the
1120 execution and documentation of the research by their collaboration;
1121 assisting in the assessment of the research performed by their collaboration;
1122 and ensuring the appropriate publication of research results.

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- Scientific Collaborators are responsible for identification of spokespersons and/or principal investigators, participation in the conduct of research, and securing funding as agreed in applicable contractual agreements.
 - Partnering or Collaborating Institutions are responsible for identifying adequate Technical Coordinators and/or Institutional liaisons for research conducted with Fermilab per partnering agreements.
 - Scientific Peers are responsible for reviewing results of scientific research at various stages of completion. Reviews include examination and testing of data, methods, results, and conclusions to ensure they are properly applied and supported. This can be internal to the collaboration, by Fermilab or external (e.g. DOE) review committees, and by submission of publications to refereed journals.

1139 **5.12.2. Management of Research Projects**

1140 Fermilab's *QA Guidelines for Scientific Research at Fermilab* applies the controls
1141 for scientific research described in ANSI/ASQ Z1.13-1999. Fermilab uses a
1142 graded approach to ensure only the controls appropriate to the activity are
1143 applied and range from Subject Matter Expert reviews to more formal peer
1144 review and other formats appropriate for the conduct of research.

1145

1146 Each Fermilab Project shall appoint a Project QA Manager/Coordinator
1147 responsible to established quality requirements for the Project in alignment
1148 with the requirements established in this Fermilab QA Program document.
1149 This alignment includes quality requirements established for collaborating
1150 institutions or partners performing work for or in collaboration with Fermilab
1151 per established agreements.

1152 **6.0 REFERENCES**

1153 [Fermilab Contractor Assurance System](#)

1154 [Fermilab Quality Policy](#)

1155 [Quality Assurance Manual \(QAM\)](#)

1156 [FESHM](#)

1157 [Engineering Manual](#)

1158 ANSI/ASQ Z1.13-1999, Quality Guidelines for Research

1159 ASQ/ANSI/ISO 9001:2015, Quality Management Systems - Requirements

- 1162 [Fermilab Training Program](#)
- 1163 [Software Quality Assurance Program](#)
- 1164 [Procurement Manual](#)
- 1165 [DOE O 414.1D – Quality Assurance](#)
- 1166 [DOE O 227.1A – Independent Oversight Program](#)
- 1167 [DOE O 430.1C – Real Property Asset Management](#)

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