Sanford Underground Research Facility

QUALITY ASSURANCE PROGRAM

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1.0 INTRODUCTION

This document describes Sanford Lab's Quality Assurance (QA) Program which is required by contract with Fermi Research Alliance (FRA). The contract requires Sanford Lab to flow down its Quality Assurance (QA) requirements to subcontractors at any tier to the extent necessary to ensure contractors' compliance with the requirements and the safe performance of work. Sanford Lab will align with both the national consensus standard ANSI/ASQ Z1.13-1999 to ensure the application of Quality Assurance to scientific research, and ANSI/ISO/ASQ Q9001-2015 standard to ensure the application of Quality Assurance to non-research activities and management systems.

Quality Assurance applies to all work conducted at Sanford Lab. This QA document describes the overarching QA program for the SDSTA. 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 quality requirements necessary to consistently meet the FRA contract obligations throughout the facility to ensure that quality, safety, health, security, cyber-security, environmental, facilities/infrastructure maintenance and performance of research are integrated into all work conducted under the contract with FRA.

The QA program is reviewed at least annually. Revisions to the QA program that change commitments to the program will be submitted to the FRA for review and approval. If no revisions are necessary, or if only minor editorial changes are made the FRA will be notified that a review has occurred and resulted in no changes.

2.0 DEFINITIONS

Lessons Learned (LL) – A "good work practice" or innovative approach that is captured and shared to promote repeat application; A lesson learned may also be an adverse work practice or experience that is captured and shared to avoid recurrence.

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

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

Preventive Action – An action to eliminate the cause of a potential nonconformity or other undesirable potential situation.

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

3.0 RESPONSIBILITIES

3.1 Executive Director/Laboratory Director

- Approves the QA Program and has ultimate responsibility for all aspects of QA for all work done under the FRA contract.
- Holds management accountable for implementation of and compliance with this program.
- Appoints the Quality Assurance Manager as the Sanford Lab site QA Program Manager.

3.2 Directors, Supervisors and Project Managers

- Ensure compliance with this procedure for their areas of responsibility including flow down of requirements and awareness.
- Responsible for providing plans, schedules, and resources for work, and for implementing quality in their respective organizations.
- Ensure that line management has the authority, responsibility and be held accountable for integrating Quality Assurance into processes and programs.

3.3 Quality Assurance Manager

- Ensures that assessments are conducted to evaluate compliance with this program and the effectiveness of implementation.
- Ensures that appropriate training to identify and handle Suspect/Counterfeit Items (S/CI) is available.
- Assumes responsibility for the content and maintenance of this program.

4.0 PROGRAM DESCRIPTION

The foundation of QA management is a line responsibility; i.e. the line organization must have the authority, responsibility, and be held accountable for integrating QA into all of the work they perform. Line responsibility for QA is woven into the organizational culture at Sanford Lab.

The Quality Assurance Program ensures that Sanford Lab'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 SDSTA and all employees, contractors, subcontractors, and Sanford Lab users when performing work that affects the laboratory.

5.0 PROCEDURES

5.1 Program

Sanford Lab has established an organizational structure along with responsibilities, authority, and written procedures that ensure successful implementation and maintenance of the QA program.

The Executive Director/Laboratory Director and the Directors and Supervisors ensure that responsibilities and authorities are defined and communicated within the organization. Responsibilities and authorities are recorded as part of employee position descriptions.

To see the organization at Sanford Lab at a high-level reference the most recent version of the SDSTA Organizational Chart.

Directors and Supervisors are responsible for providing plans, schedules, and resources for work, and for implementing quality in their respective organizations. As appropriate for their areas of responsibility, they establish additional performance requirements above and beyond those established in the QA program, while avoiding any unnecessary duplication of effort. They are responsible for the performance and sponsoring of assessments to facilitate the achievement of the organizational mission, objectives, and performance requirements. They ensure that their activities are conducted in accordance with the principles and requirements of the QA program.

5.1.1. Construction Quality Management Program

The CQMP is established to provide reasonable assurance that the objectives of the management program are being accomplished and that the systems and controls which have been put into place are effective and efficient. CQMP covers all work activities and all personnel performing work at Sanford Lab including subcontractors and guests. The CQMP process encompasses all aspects of the quality program which are essential to the laboratory's success.

5.1.2. Quality Monitoring System

The Quality Monitoring System is one of several oversight systems and is a set of interrelated or interacting elements that Sanford Lab uses to plan, direct, control, coordinate, assure and improve how quality policies, objectives, processes, and procedures are established, implemented, monitored, and achieved. The system is intended to establish confidence and assurance that requirements of QA, FRA, and customer expectations for quality are met or exceeded via proactive management of processes, tasks, and activities.

5.1.3. Graded Approach

The QA program utilizes a graded approach, defined within this program to tailor the kinds and extent of controls applied to implement quality in fulfilling applicable requirements. The graded approach is applied based on prudent management, planning, and cost. Application of the graded approach entails:

- identification of activities which present significant quality risk,
- defining the activity,

- evaluating risk and control choice, and
- documenting and approving 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. Directors and Supervisors 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 Sanford Lab employees and personnel, 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 people performing work have the appropriate skills, background, education, and training necessary to carry out the work.

5.2.1. Qualifications

Initial employee qualification is part of the hiring process administered by the SURF Human Resources Department. Individuals are hired to meet established position requirements specified by position 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.
- 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.

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

Sanford Lab line managers are required to ensure personnel possess the experience, knowledge, skills, and abilities necessary to fulfill their responsibilities.

This includes:

- 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 work planning process 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.

The Training Manager database is the official repository for training provided by the laboratory. Each employee is responsible for participating with their supervisor in defining the necessary training, successfully completing all required training, and applying training on the job. For laboratory training, requirements may be defined by subcommittees and presented by relevant subject matter experts. For training not provided by the laboratory, records should be kept in personnel files if appropriate.

A program for equivalency of specific training topics between SURF and FRA has been established to integrate and augment the training offered by and accepted by each organization. This will allow for a review and evaluation of those training topics that will allow training to be provided at either SURF or FRA and allow the training to be acceptable to each organization.

Management is responsible for reviewing the effectiveness of its training programs. Results from these reviews shall be used as inputs for continual improvement.

5.3 Quality Improvement

Sanford Lab maintains continuous quality improvement through a variety of activities, including training, design, assessments, observation by walk-through, inspections, tests, monitoring, reviews, and analysis.

5.3.1. Quality Improvement Program

Issues, improvement opportunities, and corrective actions, generated from the activities listed above are documented and tracked in the laboratory's Action Item Tracking Database.

Management at all levels is responsible for encouraging and enabling individuals under their supervision to participate in identifying and analyzing opportunities for improvement; responding to discovery of quality-related issues; following up on required actions; documenting failures and non-conformances; ensuring that significant problems are reported to the appropriate management area and ensure root causes are identified and issues corrected.

All line managers are responsible for encouraging the reporting of improvement opportunities and lessons that have been learned from activities across the laboratory. These items are tracked in the ESH Incident Database and the Action Item tracking database.

The SDSTA Management Delegation supports quality improvement by leading the Laboratory's strategic planning process, goal setting, project and program oversight, and performance planning and oversight processes. Input to the planning process includes feedback from management reviews, issue resolution, root cause analysis, lessons learned, assessments, scientific peer reviews and specific QA reviews.

5.4 Documents & Records

Sanford Lab documents specifying policies, prescribing processes, or establishing design specifications and requirements are controlled through the document management system (DocuShare) and the CCB process. Additional document control requirements may be required by outside customers/sponsors, or be required for certain specific activities.

Responsibility for lab-wide policies and procedures is shared between ESH and the Directors and Supervisors, who establish methods to control procedural requirements, design, and other quality management documents and records used solely within their operational area. Management is responsible for providing the resources necessary to fulfill the document control and records management requirements. Sanford Lab employees, contractors, users, and collaborators are required to comply with the document control and records management policies and procedures.

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

Records are necessary to provide evidence of process effectiveness and conformity with requirements. Sanford Lab's policies and procedures for a centralized records management program are described in more detail in the Records Management Policy. The program includes provisions for specifying, preparing, reviewing, approving, maintaining, and disposing of records.

5.5 Work Processes

Line management ensures sufficient resources are available and provided to maintain the site in an operational state and that work controls are in place and effective. Work includes the design, construction, operation, support, maintenance, modification, and decommissioning of experiments, performed by Sanford Lab employees. In addition to Sanford Lab employees, this applies to users, contractors, and collaborators. The set of controls applied to work processes includes written

procedures for activities of sufficient complexity or potential hazard; periodically monitoring and assessing performance; personal accountability; and specific provisions for activities not otherwise covered in this document.

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

5.5.1. Work Process Control

Line management determines the appropriate level of work process controls, including which activities require written procedures and which procedures must be augmented through personnel training and qualifications. Management defines workmanship standards, equipment to be used, specifications for materials, process measurement points, and measurement standards. ESH requirements and controls for work processes are defined in the WPC Program.

Controls are established for the procurement and acceptance of items and services. Controls on Measuring and Test Equipment are designed to meet requirements identified in Section 5.8 - Inspection and Acceptance Testing.

Item Control

Items are identified and controlled, with their traceability maintained during receipt, shipping, storage, handling, installation, use, and disposal. These controls are commensurate with the item's application, usage, cost, and/or associated risk and are managed by Directors and Supervisors.

Maintenance

Directors and Supervisors are responsible for ensuring maintenance is performed on facilities and equipment under their care. Facilities Infrastructure is the primary maintenance service provider for facilities and the laboratory's infrastructure. These services are agreed upon between facilities and the Directors and Supervisors. Maintenance plans are documented. The organization coordinating or performing the maintenance is responsible for ensuring that records of maintenance are kept.

Readiness Reviews

Readiness reviews are conducted prior to the start of operations that are new or have been significantly changed. The extent and detail of the reviews are commensurate with the scale, cost, complexity, hazards, and programmatic significance.

Calibration of Process Equipment

It is the responsibility of each Collaboration or Operational Area to identify, monitor and maintain key process equipment that requires calibration or verification. Results are documented and retained. (See also: Section 5.8 - Inspection and Acceptance Testing.) Process equipment examples include buildings, pumps, water supply systems, building air supply systems, experimental apparatuses, etc. which are then calibrated by using measuring & test equipment.

Work Environment
All facilities are to be maintained in a state of order, cleanliness, and repair, as appropriate to accomplish their missions. It is everyone's responsibility to maintain the integrity and cleanliness of their work area, assure they understand and meet the requirements at each building location, and follow the general expectation for Sanford Lab.

5.6 Design

Sanford Lab's design process provides appropriate 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 judgment, scientific principles, and applicable codes and standards. It applies to research/experimental equipment including accelerator components, and detectors as well as to conventional facilities, structures and equipment. The Engineering Director has overall responsibility for the efforts of all engineers working on a single project.

The Sanford Lab Engineering Department 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 (hereafter referred to as design elements).

Responsibility and effectiveness of the design and engineering process lies primarily with line management. Members of line management are responsible for adding additional requirements to the engineering process as they see fit to ensure the quality and success of projects executed under their supervision. Other functions having responsibilities for the successful execution of the design and engineering process includes Project Managers, Department Heads, and Engineers.

5.7 Procurement

All materials and services are purchased from technically acceptable and responsible suppliers including distributors authorized by the manufacturer. Materials and services are acquired by purchase order or use of the procurement credit card and approved per procedures in the Policy and Procedure Manual. All requestors are made aware of the need to purchase from reputable suppliers and distributors. Sanford Lab suppliers are required to provide goods and services which are in conformity with purchase order requirements. Responsibility for the accuracy of purchase requisition data and requirements resides with the requestor. Sanford Lab may, in accordance with purchase order terms and conditions, perform site audits, require suppliers to perform self-assessments, and provide control plans and data or other reports to ensure compliance.

The procurement and receipt inspection processes supports the identification and prevents the introduction of suspect and counterfeit items. Inspection receipt shall occur whether materials were purchased through purchase order. Personnel are informed of the reporting process and the risks associated with suspect items.

The procurement of all goods and services is under the control of the Procurement Department. Procurement coordinates all procurement requests received from all Operational Areas. This includes acquisition planning related to engineering, quality and other functions as necessary,

generating and verifying solicitation and purchase documents, negotiating terms and conditions, performing subcontract administration, and closeout.

Prospective suppliers are evaluated based upon their ability to meet quality, technical, and financial performance criteria, and to operate in a safe and environmentally compliant manner as outlined in the Policy and Procedure Manual. Evaluation and monitoring of supplier's performance during the life cycle of the purchase order are performed to ensure that technically acceptable items are produced and services continue to meet the quality, technical, delivery, and other performance requirements. Corrective actions in accordance with purchase order terms and conditions are implemented should suppliers not perform as required.

5.8 Inspection & Acceptance Testing (See section 2.11 of the CQMP)

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

5.8.1. Inspection & Testing Process

Inspection and acceptance testing plans identify item characteristics and processes to be inspected/acceptance tested, inspection techniques, acceptance criteria, hold points, and the organization responsible for performing the inspection. Appropriate corrective actions shall be taken where deficiencies are identified.

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

5.8.2. Control of Nonconforming Items

Items that do not conform to specified requirements are subject to controls to prevent their inadvertent installation or use. Project Managers are responsible for control of nonconforming items. Controls include identification, documentation, evaluation, segregation (when practical), item disposition (reject, repair, rework, use-basis), and notification to affected organizations.

5.8.3. Inspection & Test Records

Inspection and test results are documented and preserved. The inspection and test status of items or processes requiring examination are clearly identified to ensure that only those with acceptable results are used. At a minimum, inspection/test records identify the following: item(s) inspected, the inspection/test procedure used, who performed the inspection/test, the identification number(s) of the measuring & test equipment (M&TE) used to perform the inspection or test, the inspection/test data, the inspection/test criteria, and the inspection/test results.

5.8.4. Control of Measuring & Test Equipment

The measuring and test equipment (M&TE) used for inspection and acceptance tests are identified, calibrated, maintained, and controlled commensurate with their intended

use. Procedures are established by Operational Areas for testing, retesting, adjusting, and recalibrating M&TE. Equipment is checked to ensure it is the proper type, range, accuracy, and precision and is uniquely identified and traceable to its calibration records. M&TE examples include scales, radiation survey instruments, pH monitors, voltage meters and NDT equipment.

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

5.9 Management Assessments

Management assessments performed as described in the QA Program. They are performed by an organization to evaluate its own management processes and their implementation to identify noteworthy practices, uncover issues, identify corrective actions, and ensure that the work being performed is satisfactory and according to requirements. Scientific work is assessed by a peer review process. Scientists determine the extent and adequacy of this process.

The QA program requires that managers assess their processes to identify and correct problems that hinder the organization from achieving its objectives. The Directors and Supervisors monitor the progress of actions in their organizations on a periodic basis and ensure that the actions are finalized with appropriate objective evidence. The ESH Section monitors the adequacy of the assessments, the progress of corrective actions, and conducts periodic assessments of the effectiveness of the implementation of the QA program throughout the laboratory.

Issues and opportunities for improvements identified as the result of an assessment are presented to the area that was assessed, provided to the appropriate levels of management for review, and evaluated to determine the level of follow-up required. Findings are reported for failure to comply with requirements. Corrective actions are recorded and tracked in the Action Item tracking database.

5.10 Independent Assessments

Independent assessments are conducted on a periodic basis to ensure adequate implementation of the QA program. These assessments compliment the Management Assessments described in the Management Assessments section. Sanford Lab management and ESH have the responsibility and authority for planning internal independent assessments and for providing the necessary resources to conduct them. The coordination of external independent assessments is performed by the management of the assessed organization, and environmental, health, safety, and quality related external independent assessments are coordinated by ESH.

Department heads are responsible for providing resources for assessments, implementing any identified corrective actions, and tracking/reporting the status of Corrective Action Plans. Personnel planning the assessments are responsible for ensuring personnel performing the independent

assessment do not have direct responsibilities in the area they are assessing.

Issues and opportunities for improvement identified as the result of an assessment are presented to the organization that was assessed, provided to the appropriate levels of management for review, and evaluated to determine the level of follow-up required. Corrective actions are recorded and tracked to closure through the Action Item Tracking database. Items having Lab-wide impact are identified and reported to the senior management team for action.

5.11 Suspect/Counterfeit Items Prevention

Sanford Lab has established a process for the identification, control, and disposition of suspect/counterfeit items. Line managers shall identify individuals requiring training, ensure they receive this training, and provide necessary resources for maintaining the program.

Designers provide appropriate specifications and controls to safeguard the laboratory against the introduction of suspect or counterfeit items. Procurement is responsible for selecting technically acceptable and responsible suppliers including distributors authorized by the manufacturer. All requestors are made aware of the need to purchase from reputable suppliers and distributors.

5.11.1. Prevention

Methods to prevent the purchase of S/CI's are based on making all purchases from reputable suppliers and distributors.

5.11.2. Detection

The primary means of detecting S/CI's is through inspections and audits.

5.11.3. Reporting

If S/CI's are discovered procurement is notified., reporting also includes notifying the area supervisor, may include the ESH and the QA Manager.

5.12 Scientific Research

Current research at Sanford Lab involves experiments of varying size and complexity, Theoretical Explorations in Physics, and development of supporting technologies (e.g. accelerator elements and systems, cryogenics, material science, detector development, etc). Each type of research is unique in its approach and application and requires varying levels of controls to produce the desired results.

5.12.1. Responsibilities

These elements are described in more detail in the Experiment Planning Statement

1. The Sanford Executive Director/Lab Director, Science Director are responsible for setting the strategy for science at Sanford Lab, and approving expenditures of funds for scientific proposals and establishment of projects. In performing these actions, they rely on the advice and recommendation of scientific committees.

2. Principal Investigators and/or Experiment Spokespersons are responsible for formally proposing the planned research, including technical approach, schedule, deliverables, and facility requirements; developing the contractual documentation between the collaboration and Sanford Lab for the implementation of experiments

and other projects; overseeing the execution and documentation of the research by their collaboration; assisting in the assessment of the research performed by their collaboration; and ensuring the appropriate publication of research results.

3. 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 documents.

4. 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 Sanford Lab or external (e.g. DOE) review committees, and by submission of publications to refereed journals.

5.12.2. Management of Research Projects

Sanford Lab's QA Guidelines for Scientific Research at Sanford Lab is integrated with this program. Sanford Lab uses a graded approach to ensure only the controls appropriate to the activity are applied and range from Subject Matter Expert reviews to more formal peer review and other formats appropriate for the conduct of research.

Each large project appoints a Project QA responsible person that supports and assesses the implementation of QA for the project.

6.0 REFERENCES

ANSI/ASQ Z1.13-1999, Quality Guidelines for Research
Experiment Planning Statement
Sanford Lab Training Program
Construction Quality Management Program
ESH Manual