Sandia National Laboratories

QUALITY ASSURANCE PROGRAM DESCRIPTION

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Table 1. Revision History and Descriptions

Revision	Effective Date	Pages Revised	Description	Type of Revision
1.0	07/31/12	N/A	Complete rewrite of the Quality Management System Description	Substantive
2.0	11/30/12	Multiple	Address feedback, editorial, and administrative changes	Administrative
3.0	5/31/13	Multiple	Address feedback, editorial, and administrative changes; modified format; added Table 1; substantive changes to Sections 1.1, 1.2, 2.2, 2.4, 2.5.7, 2.6, 2.7, 3.3.12.	Substantive
4.0	05/30/14	Multiple	Annual review and comment incorporation; update Table in Section 9.0 for NAP-24 applicability; change title to the *Quality Assurance Program Description* (QAPD); and verify currency for all policies, processes, and procedures.	Substantive
4.1	9/11/14	Multiple	FY14 NNSA review comments incorporated; updates made to several broken hyperlinks; correct typographical errors; correct procedure titles in Table 9.0.	Administrative
4.2	5/29/15	Multiple	Updates for 2015 include: changing ILMS references and description to Sandia Management System; Section 9.0 updates for changes to Corporate Policies, Processes, Procedures; updates to the graded approach throughout; updated hyperlinks to key documents; and expanded description of improvements to measures and metrics (Sectior 1.4).	Administrative
4.3	5/27/16	Multiple	Updates for 2016 include: revisions for changes to the Sandia Management System, and to the Sandia Management Model; revisions t figures and verbiage to match the updated *Performing Work at Sandia*; revisions to the list of entities registered to International Standards; added multi-site procurement language; and added reference to Internal Controls as specified in DOE O 413.1B, *Internal Control Program*, and OMB A-123, *Management Accountability and Control Circular*.	Administrative
5.0	8/1/17	Multiple	Updates for 2017 include: funding statement, titles (SLT, Laboratories Director, ALDs, etc.), 9100, Program Management Units (PMUs), programmatic structure, and other formatting and editorial changes.	Substantive
5.1	5/31/18	Multiple	Updates for 2018 include: Safety Software section 7.12 updates to incorporate NNSA/SFO comments and address misalignment between the QAPD and other referenced safety software documentation. Updatec content now reflects current state: Organizational Structure, consensus standard references, and safety software program. Removed redundant content; made other editorial and administrative changes.	Administrative
5.2	11/7/2018	Multiple	Updated system, policy and process references in accordance with new Lab Policy System, updated policy system cross-map in Section 9. Updated consensus standard references in Section 7.12. Updated organizational charts and related references. Updated system names. Restored wording in Section 5 to previous version (QAPD Rev 5.0). Added language to Section 1.0 identifying QA Director as designated authority of interpretation and resolution.	Administrative
5.3	5/1/2019	Multiple	Replaced AIS tool references with Sage. Updated Q-Sig Program with Quality Level Program for procurement. Updated section 1.1.1 programmatic structure terminology definitions. Added PDCA content to section 2.0. Added cross walk tables specific to DOE O 414.1D Attachments 3 & 4 to section 9.0.	Administrative
5.4	5/15/2020	Multiple	Quality Definition updated to align with DOE O 414.1D and regulation 10 CFR 830. LOS incorporated into section 7.0 Crit 3. SMM retired and	Administrative

			replaced with About Sandia. Updated description of Sandia CAS Key Processes and the Sandia Site Governance Model. Realignment of 9100 to 9200. Updated NAP-24 replaced with NAP401.1. Updated description of QL program. PSL developed a new procedure, Standardize Before Use (SBU), for calibration. Added Policy Manager roles and responsibilities. Updated Criterion 9 to reflect Independent QA Assessments. Updated Table 4. LPS Cross-Map to 10 CFR 830 Subpart A, DOE O 414.1d, Attachments 1 & 2, ISO 9001:2015 to reflect additional policy updates and cross-mapping.	

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Introduction

Sandia National Laboratories achieves its national security mission by relying on science, technology, and engineering expertise. Sandia's Strategic Plan directs the Labs to execute innovative technical approaches while operating efficiently, effectively, safely, and securely to provide "exceptional service in the national interest."

To accomplish the mission, Sandia applies this definition of quality to all our programs:

Quality is the condition achieved when an item, service, or process meets or exceeds the user's requirements and expectations.

Sandia operations are rooted in the Laboratories' mission, vision, and values. Work is performed according to quality principles and methodologies, and workflow requirements support quality outcomes. In the Labs' programmatic structure (detailed in Section 1.1.1), designated Associate Laboratories Directors are each accountable for a portfolio of programs. Programs and divisions consistently and predictably execute work and meet unique customer requirements and expectations, which may involve tailored application of additional guidance or standards. Sandia strives for flawless execution to prevent unacceptable consequences. Mindful of safety and security concerns, we plan and perform work, detect and correct errors early to ensure error-free products and services, and tackle problems directly. An empowered workforce, enabled by organizational and management systems, renders the quality products and services customers expect. Each member of the workforce owns the responsibility for consistent and predictable outcomes.

1.0 Sandia National Laboratories Quality Assurance Program

Sandia's Quality Assurance Program (QAP) assigns responsibilities and authorities, defines workflow policies and requirements, and provides for the performance and assessment of work. The QAP integrates with the following elements:

- Laboratories and Programmatic Structure
- Laboratory Policy System (LPS)
- Contractor Assurance System (CAS)
- Mission Assurance Engineering System (MAES) for Programs and Projects

The QAP follows the quality framework defined by the Laboratory policy QA001, *Quality Policy*, which establishes Sandia expectations, authorities, and accountabilities for use of Plan-Do-Check-Act (PDCA) quality principles and defect prevention methodologies to improve performance while fulfilling contractual obligations per DOE O 414.1D, *Quality Assurance* criteria and 10 CFR 830, Subpart A, *Quality Assurance Requirements.* Laboratory policies CA001, *Enterprise Risks, Opportunities, Issues Management Policy,* and CA002, *Performance Monitoring Policy,* establish Sandia expectations, authorities, and accountabilities for assessing, monitoring, and improving the Labs' management and operations.

The Mission Assurance Division (9000) maintains the Sandia QAP using a distributed approach described later in Sections 4.0 and 7.0. In Section 9.0, Table 5 cross-maps the relationship between the LPS policies and processes and each DOE O 414.1D and 10 CFR 830, Subpart A criterion to be met. The Mission Assurance Associate Labs Director (ALD) ensures that necessary quality processes are established, implemented, and maintained; reports on the performance of the QAP and needed improvement; and maintains a quality framework in QA001. The Quality & Performance Assurance Director is the designated interpretative authority for quality assurance and has the authority to resolve interpretation disagreements, if any, among DOE O 414.1D, 10 CFR 830 Subpart A, NQA-1, NAP 401.1 (previously known as NAP-24A), and any other requirements in the suite of quality assurance directives and regulations. The Quality & Performance Assurance Director is responsible for consulting with the appropriate subject matter experts (SMEs) on the requirements of quality standards, directives, and regulations as necessary. The remainder of Section 1, below, addresses the purpose of the QAP, the About Sandia website, including the Labs Assurance portal, the LPS, and the Mission Assurance principles, which all support QAP implementation, assessment, maintenance, and improvement.

1.1. Sandia's QAP Elements

The QAP is an integral element of the framework of interrelated policies, processes, procedures, and resources used to manage Sandia's work, including management functions, structure, and information used to plan, execute, and monitor work. By following the QAP, Sandia delivers on mission commitments, ensures customer confidence, improves management performance and effectiveness, achieves efficiencies to enhance mission work, and satisfies National Nuclear Security Administration (NNSA) and U.S. Department of Energy (DOE) quality and contractor assurance requirements. The QAP includes the LPS and the Laboratory Policy Statement (principles by which Sandia establishes business rules).Figure 1, below, illustrates Sandia's leadership and organizational structure.

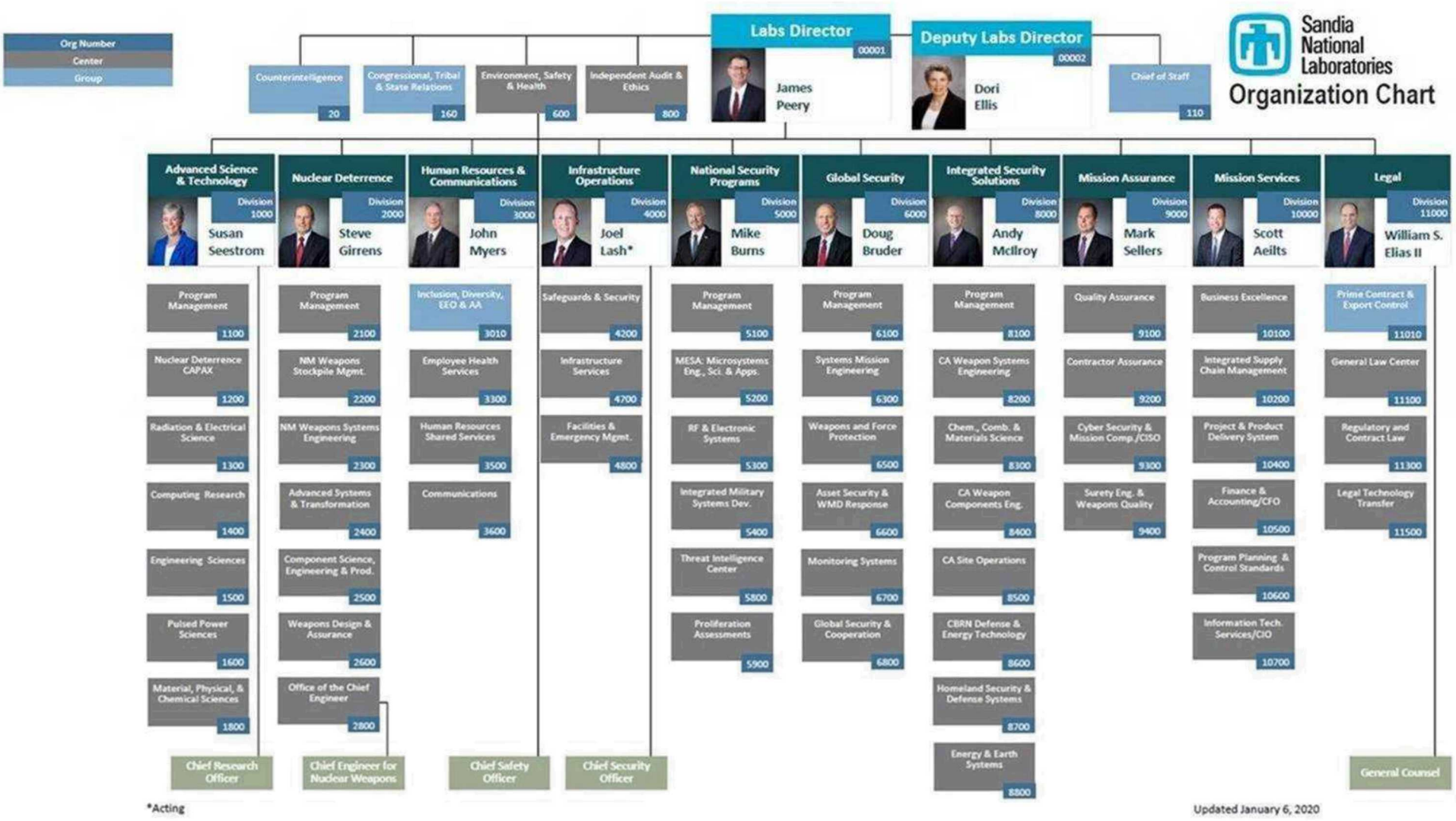

Figure 1. Sandia National Laboratories Organizational Structure

Programmatic Structure

Sandia's programmatic structure (see Table 2 below) distributes accountability for developing and managing Sandia's programs. Together, the organizational and programmatic structures underpin critical governance, financial processes, and decisions:

- Establish responsibilities, accountabilities, and authorities for organizational and programmatic roles
- Guide the flow of performance assurance information throughout the organization and with other stakeholders
- Delineate boundaries for financial projections and workforce planning strategies
- Provide a design framework for a simpler financial model

Table 2. Sandia's programmatic structure terminology

Key terms	
Portfolio	A collection of projects, programs, sub-programs, and operations managed as a group to achieve strategic objectives
Program	A group of related projects, subprograms, and program activities that are managed in a coordinated manner to obtain benefits not available from managing them individually
Sub-program	A group of related projects under a program that support a common objective or related objectives
Project	A temporary endeavor undertaken to create a unique deliverable, service, or result
Division	Organization comprising of centers responsible for performing work in support of the portfolios and to steward their capabilities and workforce in support of current and future needs

ALD Programmatic Alignment

According to the Labs' management structure, each Associate Lab Director (ALD) leads a specific division; however, program execution may span multiple divisions and entities. Similar programs are grouped into a broader portfolio. Figure 2, below, illustrates the programmatic structure in relationship to the roles and responsibilities of ALDs. Specific ALDs are accountable for a portfolio of multiple programs and some or all the programs within that portfolio. Streamlining and consolidating programmatic accountabilities under a single ALD fosters agility needed to meet customer requirements.

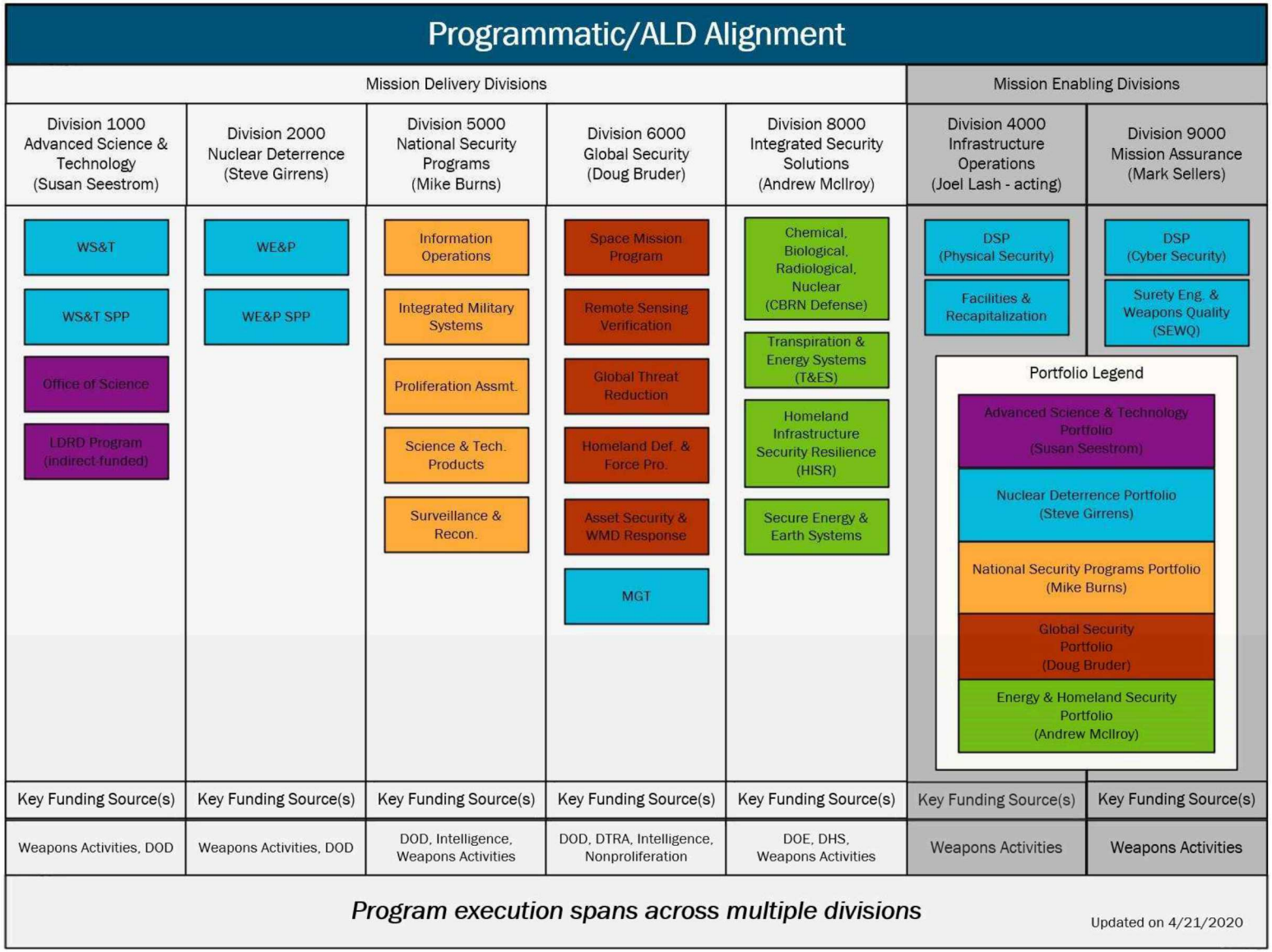

Figure 2. Programmatic/ALD alignment

Non-Weapons Activities-Funded Programs

In Divisions 1000, 5000, 6000, and 8000, a single ALD is accountable for managing an overall non-weapons portfolio and its distinct programs, as follows:

- Division 1000 ALD: entire Advanced Science & Technology Portfolio (including the Laboratories Directed Research and Development Program), and management of select weapons activities programs within the Nuclear Deterrence Portfolio.
- Division 5000 ALD: entire National Security Programs Portfolio
- Division 6000 ALD: entire Global Security Portfolio
- Division 8000 ALD: entire Energy and Homeland Security Portfolio

Weapons Activities-Funded Programs

Due to the Labs' breadth of weapons activities-funded programs that comprise the *Nuclear Deterrence Portfolio*, alignment of programmatic accountability is complex, spanning multiple ALDs. To mitigate inherent risks of nuclear deterrence program distribution, the Division 2000 (Nuclear Deterrence) ALD is accountable for overall program integration and serves as the primary interface with the NNSA Deputy Administrator for Defense Programs (NA-10). Division 1000, 4000, 6000, and 9000 ALDs are accountable not only for the distinct Nuclear Deterrence programs aligned to their divisions, but also for integrating their programs with the broader *Nuclear Deterrence Portfolio*.

Sandia has specified Nuclear Deterrence programmatic accountabilities, including program integration with the broader *Nuclear Deterrence Portfolio*, for each ALD, as set forth below:

- Division 1000: Weapons Science & Technology (WS&T) Program; WS&T SPP Program
- Division 2000: The entire Nuclear Deterrence Portfolio and these Nuclear Deterrence programs:
  - Weapon Engineering & Production (WE&P) Program
  - WE&P Strategic Partnership Program (SPP) Program
- Division 4000: Physical Security component of the Defense Security Programs Program; Facilities and Recapitalization Program
- Division 6000: Secure Transportation Asset (STA) Program
- Division 9000: Cyber Security component of the Defense Security Programs Program, Surety Engineering. & Weapons Quality (SEWQ).

Program Execution Spanning Multiple Divisions

Programs reach across organizational boundaries to leverage appropriate capabilities as needed. Program execution spans multiple divisions in both the organizational and programmatic structures.

ALD Programmatic Accountabilities

A high-level summary of ALD key accountabilities relevant to portfolios, programs, and projects is provided in Table 3, below.

Table 3. ALD Accountabilities by Category

	ALD Accountabilities
Portfolio*	• Set the strategic direction for the portfolio, consistent with Labs strategy; ensure that the impact of decisions made for one portfolio is considered for all portfolios • Serve as the primary customer contact for all stakeholders • Serve as the integrator of all distinct programs; ensure that the impact of decisions made for one program is considered for all programs • Provide funding, cost, and carryover projections to support Sandia's annual operating plan • Monitor, measure, and report on performance, including explanations of significant variances between the annual operating plan and current projections • Ensure operations are being managed (e.g., employee safety; security compliance)
Program*	• Manage customer relationships • Negotiate agreements and commitments for products and services • Manage customer deliverables • Identify resource requirements and the appropriate Sandia capabilities to accomplish work • Monitor, measure, and report on program performance
Project execution	• Execute work within cost, schedule, and performance expectations
Capabilities stewardship	• Ensure proper stewardship and identify gaps to meet program requirements • Attract, develop, and retain members of the workforce • Monitor, measure, and report on the health of organizational capabilities

**Applicable to ALDs with programmatic accountability*

1.1.1. CAS

Sandia's CAS integrates management and assurance systems, processes, analytics, and tools to give Sandia members of the workforce the ability to anticipate, prevent, and solve problems while providing a consistent evaluation of performance to inform Sandia's leaders, parent company, and the NNSA.

Performance assurance is embedded in all aspects of Sandia's operations to verify the Labs performs as intended, ultimately ensuring Sandia can deliver on its national security mission. Figure 3, below, illustrates CAS key processes and activities.

Figure 3. Sandia CAS Key Processes and Activities

Sandia's leaders, the foundation of CAS, actively support and implement CAS elements throughout their areas of responsibility and across divisions. Leaders draw information from the CAS to make decisions driven and backed by both quantitative and qualitative information. Leaders also use CAS to measure and improve performance to ensure that workers, the public, and the environment are safe; operations and information are securely protected; mission objectives and contract requirements are met, including individual Work Authorizations; and that operations, facilities, and business systems are efficiently and effectively operated and maintained.

The Sandia CAS Description (CAS-D) document is owned and maintained by the Mission Assurance ALD and the Quality and Performance Assurance Director, and is approved by the Labs Director or designee. The CAS Description is reviewed annually and updated as appropriate. If significant changes are required, the Labs Director, or designee, and National Technology and Engineering Solutions of Sandia (NTESS) Board of Managers (BoM) will review and approve those changes before sending the updated document to the SFO Contracting Officer for NNSA review and concurrence. The Sandia Site Governance Model is a three-pronged governance system designed to ensure collaboration and transparency between Sandia (contractor), NTESS BoM, and NNSA. Together, these three entities ensure Sandia performs its mission effectively and efficiently though transparency and continual performance assurance reporting. This model is depicted in Figure 4, below.

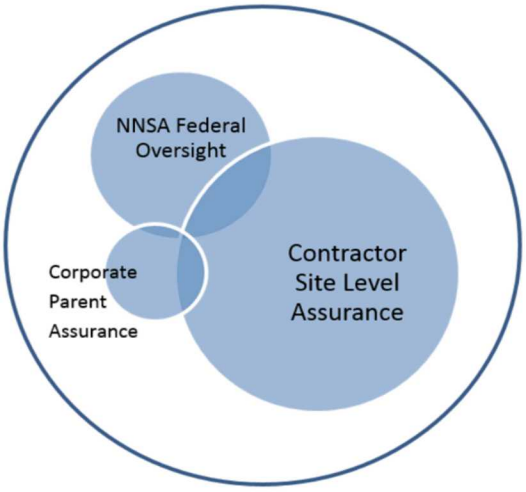

Figure 4: Sandia Site Governance Model

1.1.2. Mission Assurance Engineering System (MAES) for Programs and Projects

Mission Assurance (MA) is defined as the disciplined, integrated application of program/project management (PM), quality management (QM), and systems engineering (SE) for delivering quality products and services to our customers. MA informs management regarding the state of health of both the project and the product to ensure mission success. Sandia is implementing a MAES for science and engineering projects that combines and applies best practices and scalable PM, QM, and SE principles, processes, and compatible tools to meet customer needs.

1.1.3. LPS

Sandia's vision, mission, management system, key activities, management entity accountabilities and commitment to operational and business excellence are documented via LPS. It is Sandia's governance policy to establish and maintain a governance model to ensure

- Establishment of a strategic plan, which includes the Laboratories' purpose and priorities (i.e., vision and mission)
- Exceptional mission performance and customer satisfaction
- Exceptional science, engineering, and operational performance
- Commitment to operational and business excellence
- The Laboratories future through stewardship of human, physical, and financial resources
- Continual performance improvement through measurements, assessments, and reviews of quality measures
- Electronic access by government personnel with performance monitoring responsibilities

Sandia uses a management system and structure of entities (e.g., management entities, councils, and committees), individual roles, and a decision-making framework designed to enable flexible and comprehensive integration of all work required to achieve the mission. Requirements that drive Sandia's management systems, such as Integrated Safety Management, Integrated Safeguards and Security Management, and Environmental Management, are established in Sandia's LPS.

After DOE directives are applied to the Prime Contract per PC001.1, *Modify Prime Contract,* and PC001.2, *Modify Baseline Directives,* the Prime Contract organization assigns each directive to the division that owns the given policy. DOE O 414.1D, *Quality Assurance*, is assigned to the Mission Assurance organization that flows down the requirements through QA001, *Quality Policy*, CA001, *Enterprise Risks, Opportunities, Issues Management Policy,* and CA002, *Performance Monitoring Policy.*

The Sandia Software Quality Program, IT008, *Provide Quality Software Policy*, and Software Quality Assurance Program (SSQAP), SS-R89727, applies to all Sandia software and specifies national or international consensus standards for all Sandia software. The policy and SSQAP establishes and documents grading levels for DOE O 414.1D safety software using a graded approach by determining an acceptable practice level based on consequence and likelihood levels. The SSQAP is submitted for approval to the designated DOE approval authority.

Technical, operational, and quality requirements are passed to subcontractors, vendors, and suppliers through formal procurement documents that implement Sandia's procedures, including ISCM001.1, *Acquire Products or Services*, ISCM1.2, *Supply Chain Risk Management Quality Level Program,* and ISCM001.5, *Purchase Requisition and Purchase Order.* Requestors and buyers identify applicable quality requirements through Sandia SF 6430-SQA, *Quality Assurance Requirements Document*.

1.2. Purpose of the QAPD

The *Sandia National Laboratories Quality Assurance Program Description* (QAPD) serves as the QAP description document required by DOE O 414.1D and 10 CFR 830, Subpart A. The document is divided into several sections.

Section 2.0, *Sandia's Workflow,* describes how expectations are translated into defined work. Implementation of Sandia's quality expectations relies on the PDCA principles and defect prevention methodologies. By consistently implementing PDCA and defect prevention methods, Sandia achieves mission success in a consistent, predictable, and integrated manner.

Section 4.0, *Distributed Approach for Achieving Quality Products and Services,* defines Sandia's approach to delivery of quality products and services by fulfilling the requirements of DOE O 414.1D and 10 CFR 830, Subpart A. This section identifies individual(s) with the responsibility, authority, and accountability to develop, implement, assess, maintain, and improve the QAP. Individual program or project QAPs can also define expectations when more stringent controls are needed for nuclear safety management or quality assurance purposes.

Section 5.0, *Tailoring and the Use of a Graded Approach,* describes how Sandia uses a graded approach to quality assurance, assessing and responding to risk with an appropriate level of rigor.

Section 7.0, *Implementation of Quality Criteria,* details how Sandia meets DOE O 414.1D requirements.

Section 9.0, Laboratory *Policy System Cross-Map to DOE O 414.1D*, cross-maps the requirements of DOE O 414.1D with applicable Sandia procedures. QA001 specifies executive responsibility for ensuring that division-level quality expectations translate into local requirements.

1.3. About Sandia Website and Assurance Portal

Sandia management ensures the quality of products and services; assesses operations, programs, projects, and business systems; identifies deficiencies; and affects continual improvements. Managers apply expertise and ingenuity to accomplish the work in compliance with the approved CAS-D (refer to Section 1.1.3 above).

About Sandia is an interactive website and tool that illustrates how Sandia is structured to manage the work done and assure success. Broadly, About Sandia offers a high-level view of how Sandia operations conform to its QAP.

The Labs Assurance site, a component of Sandia's CAS and Sandia's Site Governance Model, enables navigation of Sandia assurance information useful to Sandia Labs Leadership, the Sandia Field Office, and others with performance monitoring responsibilities.

1.4. Mission Assurance Division

Division 9000, Mission Assurance, partners across Sandia to prevent defects and secure our technological environments. Mission Assurance manages and maintains the processes and procedures that govern elements of Sandia's QAP. The division comprises three centers, each with a distinct mission responsibility, that govern and direct quality assurance activities to achieve operational priorities, as shown in Table 3, below.

Table 3. Division 9000 Centers and Mission Responsibilities

Center	Mission Responsibilities
9200 Quality and Performance Assurance	Provides end-to-end quality assurance systems, technical expertise, and tools that facilitate consistent and successful mission execution that Sandia's leadership evaluates for performance reports to NNSA and our parent company.
9300 Cyber Security & Mission Computing	Defends Sandia from cyber threats and drives mission success through computing.
9400 Surety Engineering and Weapons Quality	Provide technical assurance, analysis, and assessment for Sandia's Nuclear Weapon and technical missions, emphasizing the surety of the Nuclear Weapon stockpile.

2.0 Sandia's Workflow Expectations and Defect Prevention

Sandia and customer expectations are translated into work realized through the Labs' capabilities. To perform work safely and securely while meeting cost, schedule, and performance commitments, Sandia applies PDCA quality principles, defect prevention methodologies, and best practices such as Work Planning and Control (WP&C) criteria.

Work is planned, controlled, authorized, executed, accepted, assessed, and documented using the LPS, applicable local processes that integrate quality-related requirements, and documents such as *Performing Work at Sandia*, Research Quality Standards, the ES&H Manual, and Work Planning and Control Criteria for Safe Design and Operations.

Sandia applies the PDCA cycle (Figure 5, below) to its overall management system:

- Plan: Establish the objectives and capabilities necessary to deliver results in accordance with customer and Sandia expectations.
- Do: Implement the plan; perform the work.
- Check: Monitor and measure performance of the work against requirements, policies, and objectives for the product or service, and report the results.
- Act: Take actions to continually improve performance results to ensure the delivery of quality products and services.

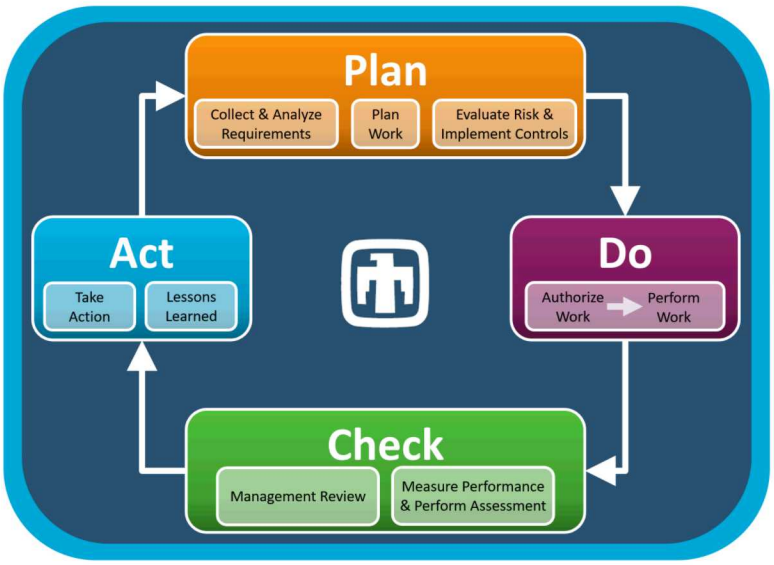

Figure 5. PDCA Approach to Performing Work

By applying PDCA to each step in the product and service realization workflow, Sandia ensures effective, consistent, predictable, and defect-free inputs to the next step.

Sandia's quality requirements begin with LPS requirements. All members of the workforce must recognize, accept, and fulfill their roles and responsibilities to use quality principles (e.g., PDCA) and defect prevention methodologies as defined in LPS.

Policy managers must develop and implement policies, processes, and procedures that enable mission success. They ensure they align with internal and external directives, rules, laws, contractual obligations, and risk-management objectives.

PRM001, *Policy and Requirements Management Policy* identifies several expectations for performing work and preventing defects. Policy and Requirements Management must:

- Assess and address the strategic impact of LPS policy content.
- Ensure that policy-related quality requirements and quality management system criteria (e.g., DOE O 414.1D and ISO 9001:2015) are incorporated into LPS processes associated with assigned policies.
- Develop and implement an approach to regularly monitor and assess the implementation of assigned policies and processes.
- Develop approaches for improving assigned policies and processes, as necessary
- Identify potential critical performance measures for assigned policies and associated processes.
- Perform management-assurance processes, including regular review of trends in performance, and act as necessary to ensure implementation of assigned policies and associated processes.
- Identify and manage risks, ensuring controls are implemented for activities covered by assigned policies and associated processes.

Programs engage the customer and identify the specific customer-based needs that must be met.

Programs and divisions may apply additional guidance and infrastructure, along with government or industry standards, to ensure that deliverables and services meet customer requirements, best work practices, laws, regulations, and contractual obligations.

National or international quality standards implemented at Sandia include

- ISO 9001:2015, *Quality Management System–Requirements*
- AS9100D, *Quality Management Systems–Requirements for Aviation, Space, and Defense Organizations*
- ANSI/ANS 15.8 Quality Assurance Program Requirements for Research Reactors (Department 1300)
- ASME NQA-1-2008/2009a, *Quality Assurance Requirements for Nuclear Facility Applications* Part II, Subpart 2.7 and applicable Part I sections for software quality assurance in Tech Area 5 (TA-V)
- Malcolm Baldrige Criteria for Performance Excellence

Divisions steward Sandia's capabilities and work performance according to applicable requirements and standards (e.g., safety and security) to satisfy customer and Sandia expectations.

Management communicates clearly all program and project requirements and expectations. Management also ensures that process and product nuances are properly understood before, during, and after completing the assigned work. Organizations, working with divisions, use a graded approach when applying the appropriate quality criteria and level of rigor required to meet expectations.

Members of the workforce engage with management to know the requirements associated with their work assignments, recognize that multiple work requirements may apply, use PDCA quality principles implemented through a defect prevention methodology, and provide assurance that Sandia is fulfilling its obligations.

Program and division management conduct routine management reviews that provide transparency and assurance. The Senior Leadership Team (SLT) reviews progress on mission deliverables, safety and security of operations, and customer satisfaction through multiple venues.

3.0 Roles and Responsibilities

QA001, CA001 and CA002 detail the Laboratories' roles and responsibilities for managing quality-related policy and systems to provide adequate oversight and support. QA001 also assigns responsibilities and actions required for development, maintenance, and approval of the QAP.

The LPS defines specific roles, responsibilities, accountabilities, and authorities (R2A2) at all levels of Sandia, from the workforce to the Laboratories Director.

4.0 Distributed Approach for Achieving Quality Products and Services

The Laboratories Director is ultimately responsible for Sandia's delivery of quality products and services, and for mission success. The Mission Assurance ALD ensures that necessary quality processes are established, implemented, and maintained; reports on the performance of the QAP and needed improvement; and maintains a quality framework in QA001.

Programs and divisions apply Sandia and customer expectations to define and assign mission work and to ensure that the capabilities exist to perform that work safely and securely. Divisions with policy implementation responsibilities provide mission support for enabling work through policies, processes, and procedures. Members of the workforce

perform work consistent with assignment-specific expectations. Managers and the workforce not only assure that products and services meet Sandia and customer expectations, but also identify and implement opportunities for improvement. By applying PDCA quality principles and defect prevention methodologies, members of the workforce perform work safely and securely while leveraging sound practices such as WP&C and project management techniques. DOE O 414.1D quality criteria establish the foundational expectations for this framework.

Managers may develop and document a tailored description of their organization's Quality Assurance (QA) program that aligns with Sandia's QAP and includes the Laboratories standard and additional controls responding to customer requirements, risks, or other factors Alternatively, managers may rely on existing documentation—including assurance plans, business plans, project plans, and/or local procedures—to describe their QA program. DOE requires Sandia's nuclear facilities to obtain DOE approval for their QAPs, per 10 CFR 830, Subpart A. Quality Assurance personnel review these QAPs to determine consistency with Sandia's QAP prior to submittal to the appropriate DOE approval authority.

5.0 Tailoring and the Use of a Graded Approach

Because Sandia is a multi-program and multi-customer laboratory, our work requires various implementation approaches for ensuring and achieving the delivery of quality products and services for both internal and external customers. Programs employ multiple means to engage their unique customers and bring work to Sandia. For example, some programs may have one customer with major programs, and smaller projects as a subset of those programs. Other programs are a collection of smaller projects and programs that are aligned by overall strategy and purpose. Because of these variations, each program requires management processes that enable their unique method of conducting business. Program specific QAPs may be needed to meet customer requirements. While Labs requirements apply to all work, programs are expected to tailor the details of their implementation in a way that best suits their business needs.

Sandia employs a graded approach to ensure that the level of analysis, documentation, and actions comply with requirements, meet an appropriate level of rigor, and are commensurate with several concerns:

- the relative importance to safety, safeguards, and security;
- the magnitude of any hazard involved;
- the lifecycle stage of a facility, project, or activity;
- the programmatic mission of a facility, project or activity;
- the characteristics of a facility, project, or activity or item;
- the relative importance of radiological and non-radiological hazards; and
- any other relevant factor, including, but not limited to
    - the relative significance to the mission, the program, or to the customer's needs;
    - the customer's own specified requirements for the product, process, or service;
    - the potential of failure; and
    - legal, regulatory, or contractual requirements,

Sandia follows a defined, graded approach process that includes the following elements:

- Customer specifications, customer-approved QAPs, establish appropriate work-specific requirements (e.g., a separate QAP for a nuclear facility) that build on this QAPD to apply additional required rigor.
- Laboratories requirements in the LPS specify requirements applicable across Sandia for all work and routinely provide a range of controls based on the significance of the work (e.g., more stringent procurement rules for safety significant items than for non-safety significant items).

- Actions specified by division management, based on knowledge, experience, and graded approach factors listed in Section 7.0. Division management is responsible and accountable for specifying the workflow requirements necessary to produce the quality outcomes (e.g., WP&C requirements are based on the entities' determination of the degree of hazard in the work).

The results of the graded approach process are incorporated into the Sandia-generated procedures for performing work. Work procedures can provide a range of controls for a given range of conditions but should not expect the worker to make the graded approach evaluation of what level of rigor is required for a specified task.

The adequacy of Sandia's graded approach process (that is, the adequacy of the rigor with which different types of work are performed) is checked through assessments, metrics, problem reporting, management review, performance data, and customer feedback.

Consistent with determining the appropriate rigor for work performed, Sandia uses a graded approach to evaluate the adequacy of the QAP of a subcontractor, vendor, or supplier, with appropriate methods identified in ISCM001.2, *Supply Chain Risk Management Quality Level Program*. Additional considerations for applying a graded approach to each individual DOE O 414.1D quality criterion are included in Section 7.0.

6.0 Use of Standards

Sandia's work requires QA programs based on several external standards that must also meet the requirements of DOE O 414.1D and 10 CFR 830, Subpart A.

The SLT selected ISO 9001 as the international consensus standard to which Sandia maintains registration of its management system. DOE O 414.1D and ISO 9001:2015 requirements are incorporated into LPS policies and processes or programmatic documents, e.g., manuals, procedures, program description documents, or work instructions that are referenced within LPS. Section 9.0, Table 5 cross-maps the relationship between the LPS policies and processes and requirements from DOE O 414.1D and ISO9001: 2015.

Unless otherwise specified, Sandia Nuclear Facilities use ASME NQA-1, Quality Assurance Requirements for Nuclear Facility Applications Version 2008/9, Part II, Subpart 2.7, and applicable requirements of Part I, with the NQA-1a-2009 addenda (NQA-1-2008/2009a) standard for software quality assurance.

Several Sandia organizations and programs register quality management systems to other directives or international consensus standards through third-party auditors:

- Environmental Management System: registered to ISO 14001:2015, Environmental Management
- Organizations 6780 and 6790 (USNDS space segment) and Organization 6740 (USNDS ground segment): registered to AS9100D, Quality Management Systems—Requirements for Aviation, Space, and Defense Organizations.
- Nuclear Deterrence: executes product realization to the Weapons QAP, Sandia's LPS, and QAPD; complies with NNSA Weapon Quality Policy, NAP 401.1.
- Organization 1380 (Nuclear Facilities and Applied Technologies): aligns with the TA-V consensus standard, ANSI/ANS 15.8 Quality Assurance Program Requirements for Research Reactors. TA-V declares that ASME NQA-1 2008/9a Quality Assurance Requirements for Nuclear Facility Applications Part II, Subpart 2.7 and applicable Part I sections is the consensus standard for software quality assurance. Organization 1380 has developed a

Continuous Improvement Plan, which includes a commitment by TA-V to transition from ANSI/ANS 15.8 requirements to ASME NQA-1 2017 requirements.

- Organization 8880 (Defense Waste Management Programs [DOE Carlsbad Field Office at the Waste Isolation Pilot Plant]): conforms workflow to federal regulations 40 CFR 191 and 40 CFR 194, which both pertain to WIPP. Specifically, 40 CFR 194 requires the application of NQA-1-1989 as the governing quality assurance standard for WIPP.
- Primary Standards Laboratory (PSL): accredited to ISO 17025:2017, General Requirements for the Competence of Testing and Calibration Laboratories
- Employee Health Service (EHS): accredited by Accreditation Association for Ambulatory Health Care

7.0 Implementation of the Quality Criteria

Through its minimum quality criteria established in the LPS, Sandia implements the ten DOE O 414.1D quality assurance criteria, Attachment 3: Suspect/Counterfeit Items Prevention, and Attachment 4: Safety Software Quality Assurance Requirements For Nuclear Facilities.

Sandia uses several avenues to monitor and measure performance across the Labs. At the highest levels Tier 5 Accountability Board, Operational Management Review (OMR), Programmatic Management Review (PMR), and Strategic Management Review (SMR). Tiered accountability at all levels enables teams to communicate regularly, assess performance, identify problems, and respond rapidly to remove barriers. At the weekly Tier 5 meeting, SLT reviews updated metrics related to the Labs' FY20 Priorities and deeper examination of those needing further explanation or attention. These metrics are updated weekly and require the stewardship of multiple members of the leadership team.

Monthly at OMR is a monthly venue where SLT and Sandia Field Office (SFO) are briefed on metrics aligned to operational areas across the Labs. These metrics are linked to Sandia Strategic Objectives, Labs-Level Risks, and Performance Evaluation and Measurement Plan (PEMP) objectives.

PMR is a quarterly venue, chaired by the Laboratories' Director and is the culmination of Sandia's management review process. Management review is an ongoing process of monitoring management programmatic system adequacy and effectiveness, managing issues, risks, performance efficiency and effectiveness, and progress towards delivering projects and programs. The Program Management Review is also a process through which the SFO of NNSA oversees Sandia's programs.

At the quarterly SMR, the SLT aligns, integrates, and matures the Labs' Strategic Plan and division and program area strategies.

Sandia's 10 quality criteria (see Figure 6, below) represent a nonlinear workflow with quality principles and defect prevention layered at every phase of research, operations, service, design, development, and product/service realization.

Quality Criteria DOE O 414.1D	PLAN				DO				CHECK / ACT	
	Criterion 1 Program	Criterion 2 Training/ Competence	Criterion 3 Quality Improvement	Criterion 4 Documents/ Records	Criterion 5 Work Processes	Criterion 6 Design	Criterion 7 Procurement	Criterion 8 Inspection/ Acceptance Testing	Criterion 9 Management Assessment	Criterion 10 Independent Assessment

Figure 6. Sandia's Minimum Quality Criteria

Section 9.0 of this document contains cross-maps of Sandia's policies and processes to these ten criteria and to the requirements in Attachments 3 and 4.

7.1. Criterion 1: Management/Program

Criterion

1. Establish an organizational structure, functional responsibilities, levels of authority, and interfaces for those managing, performing, and assessing work.
2. Establish management processes, including planning, scheduling, and providing resources for work.

Objectives

- To plan workflow that provides all workers with clear expectations and sufficient resources to focus on mission, programmatic, and operational success
- To sustain fundamental management processes (such as planning, scheduling, performing work, feedback and improvement)
- To execute clear policies, processes, and workflow procedures that support performance excellence. Policies define overall expectations while processes provide the minimum and necessary controls to ensure consistent implementation.
- To define roles, responsibilities, and ownership clearly, as are the organizational structure, levels of authority over any activity or facility, and organizational interfaces and expectations for all work.
- To define and clearly communicate commitments, including contractual commitments negotiated with customers and stakeholders.
- Establish objectives and specific, measurable, achievable, relevant, and timely goals for all work, based on customer requirements, requirements derived from line-of-sight to mission objectives, contractual and legal requirements, Laboratories commitments, and improved performance.

Implementation

- Define roles and responsibilities for the work that is assigned including any relevant cost and schedule considerations
- Understand customer requirements or knowing where to access that information, and whom to contact when help is needed
- Establish the cost, schedule, and technical baselines for each effort
- Translate customer requirements using project management techniques to define the necessary planning, work breakdown structure, risk management, and schedule for performing the customer's work
- Understand the necessary project performance monitoring (for example, earned value management) and cost estimating requirements

- Integrate WP&C for safe design and operations considerations, as well as integrated safeguards and security approaches into the plan for doing work
- Identify and preventing deficiencies or defects throughout work processes, and understanding the risks associated with the work
- Bring issues and concerns to management and peers

Graded Approach

Several factors influence the amount of rigor and level of detail for planning work, assigning roles and responsibilities, assessing workflow activities, and communicating expectations: the complexity of the work, customer needs and requirements, the criticality of the tasks, the number of contributing organizations, work-related risks, and consequences of failure. Such factors determine the level of detail needed for the work, the type and frequency of reviews and approvals conducted for the work, and the planning process rigor level required for the work.

For most activities, work-related objectives can be met through a combination of project plans, budget and staffing plans, documentation of local processes (where they add value), organization charts, and individual performance management goals that document or reference workflow documents. In some cases, developing a local quality assurance plan is an option, but is not necessary unless required by the customer, stakeholder, or work complexity. Organizations are responsible for documenting their local quality assurance plans as needed to ensure that all elements described above are understood and communicated to management and employees.

Tools and References

The following tools and references provide information on defining and maintaining the management structure and R2A2:

- The About Sandia website describes Sandia's overall management structure, including a description of the relative R2A2 for the types of management entities and the nature of their interfaces.
- Laboratory Policy PPM001, *Program and Project Management Policy*, was developed to establish a standards-based approach to project management for ensuring appropriate oversight, management and execution of Sandia's programs and projects. Members of the workforce manage and support Sandia programs and projects using consistent and scalable project management methods based on the project category that complies with contractual requirements, internal requirements, and industry standards.
- Project Evaluation (PrE) Science and Engineering Management Framework
- Mission Assurance Plan (MAP)
- PM Framework
- PM Activities Planning Template
- LPS content defines specific roles and responsibilities within each process or procedure.
- Sandia's online Organization Finder, based on the division management structure, identifies the names and managers of all Sandia organizations and links to descriptions of the organizations' roles, responsibilities, and functions.
- Sandia's Strategic Plan provides information on Sandia's mission, vision, and values, as well as the current fiscal year objectives, goals, and milestones.
- Laboratories planning for real property assets occurs at many levels. The Long-Range Development Framework provides a sound strategic framework for decisions pertaining to capital investments in real property assets and site infrastructure. The Long-Range Development Plan (LRDP) describes the integrated site, facility, and

infrastructure plans and investments required for Sandia to fulfill its mission objectives, support the NNSA Program of Record, and effectively execute stewardship of real property assets.

- Succession planning for Sandia's managers and leadership is managed through Management Resource Review process.

7.2. Criterion 2: Management/Personnel Training and Qualification

Criterion

1. Train and qualify personnel to be capable of performing their assigned work.
2. Provide continuing training to personnel to maintain job proficiency.

Objectives

- To ensure that all workers will have the necessary, skills, knowledge, and talent to perform their tasks effectively and safely to meet performance and operational goals and objectives.
- To define the qualifications and competencies necessary for performing work, including a mix of education, experience, and other demonstrated skills, abilities, and competencies.
- To demonstrate that managers have the qualified, competent personnel needed to perform assigned work effectively and safely.
- To enable personnel, through training, to maintain and improve job proficiency and to meet evolving needs. Managers and personnel also identify additional training that is necessary and/or useful in performing current or future work.

Implementation

- Provide appropriate training to safely and securely perform the work, including knowing what to do when the unexpected occurs.
- Provide opportunities for workforce to obtain the necessary education, training, proficiency, or certification required for the job.
- Recruit qualified and diverse personnel through accurate job requisitions, job descriptions, job codes, and capabilities descriptions.

Graded Approach

To determine the content and means of ensuring personnel competency, several factors must be considered. These include complexity of the work, the work's importance, the level of supervision required, and how much discretion personnel have in making work-related decisions.

Additional factors consider the requirements imposed by the nature of the work itself, including the hazards and customer requirements. For example, reactor operators and weapons production personnel have clearly defined training and certification programs. Personnel who operate forklifts must have current certification. Other professional positions, by their very nature, often require evidence of formal training and competency. For other types of work, the needed skills and knowledge may be met through evidence of education and experience, informal mentoring, and/or required reading. Certain work functions may require, or at least benefit by, certification from professional societies.

Tools and References

The following tools and references provide information on personnel training and qualifications:

- TEDS EveryOne contains a catalog of currently available in-house training and offers the tools for registration, tracking course completions, personnel training records, etc.
- The Mentoring website offers tools, guidance, and support for those seeking mentors (as well as those who would like to be mentors).
- The ePerformance application gives managers and employees an additional tool for documenting individual performance and expectations to subsequent job-specific and career development needs.
- TEDS records job function specific training completions to meet job requirements.

7.3. Criterion 3: Management/Quality Improvement

Criterion

1. Establish and implement processes to detect and prevent quality problems.
2. Identify, control, and correct items, services, and processes that do not meet established requirements.
3. Identify the causes of problems and include prevention of recurrence as a part of corrective action planning.
4. Review item characteristics, process implementation, and other quality-related information to identify items, services, and processes needing improvement.

Objectives

- To raise the average level of quality delivery and workflow performance while decreasing variation in quality products and services by using PDCA principles and defect prevention methodologies
- To provide confidence that PDCA is executed as intended
- To identify items, services, and workflow processes that do not meet performance requirements
- To detect and prevent problems before they occur
- To ensure services and products are routinely evaluated and improved
- To use product and service performance data to find, fix, and learn from errors
- To identify root causes of issues and work to prevent recurrence of issues
- To align improvement activities with strategy and structure to achieve breakthrough results
- To deploy lean thinking to increase customer value and to reduce waste
- To apply lessons learned to specific projects or other work efforts

Implementation

- Monitor performance against contractual requirements and customer and Sandia expectations, including the use of measures and metrics where warranted
- Apply a graded approach for scaled implementation of risk and opportunity management
- Establish performance indicators—either leading (predictive) or lagging (results) measures and metrics—based on programmatic/project goals and objectives
- Analyze performance data for trends
- Develop and apply a questioning attitude toward the work, premised on analytical and critical thinking skills, to avoid surprises
- Seek direct customer feedback to verify whether Sandia is meeting contractual obligations, requirements, and needs and to create value for the customer
- Document evidence of PDCA activity and communicate results transparently

- Use data to assign appropriate owners, set milestones, verify activity completion, and validate effectiveness of corrective actions
- Use data to help identify, fix, and solve issues to prevent recurrence or unintended consequences
- Populate risk management records
- Identify and share lessons learned systematically as a means of continual improvement
- Identify and share work requirements *before* starting work
- Adapt industry best-practices for Sandia's Research and Development (R&D) environment

Graded Approach

The criteria for identifying and reporting issues apply variably, depending on the importance of the products and services and the associated risks. Sandia identifies issues, evaluates their significance to determine the assigned level of rigor, and determine the cause and associated corrective actions for resolution and further prevention. The same principle applies to risk management. Sandia identifies a risk, evaluates its relative impact and consequence, and evaluates the treatment activities, and accounts for prevention efforts and cost, benefit, and/or potential savings.

Tools and References

The following tools and references support quality improvement activity:

- The integrated corporate assurance tool, Sage, documents identified issues and associated corrective actions; risks and associated treatments; assessments/audits and associated findings/observations/noteworthy practices; lessons learned; and customer feedback results.
- Sage Lessons Learned, Best Practices Tool provides a means to systematically search, collect, evaluate and communicate lessons learned and best practices. The goal of Sandia Lessons Learned is to support and enable a formal, mature Lessons Learned Program which enables us to capture and apply lessons taken from operating experiences internal and external to the Laboratory to avoid similar events, anticipate and mitigate undesirable consequences, and replicate best practices.
- Sage user guides, available on the Sage Support WordPress site, explain how to use each part of the tool to input data and search for relevant best practices and information, including lessons learned from users' practical experience.
- Measures and Metrics website provides resources and tools with analyses and intuitive visualizations of information to support data-driven decisions.
- The Laboratory Operating System (LOS), maintained by Business Excellence Center 10100, enables Sandia to increase speed and flow in mission delivery. LOS is Sandia's approach to lean for our R&D environment. LOS takes strategy-to-action by (1) standing up intentional management operating systems that help us identify and prioritize problems in alignment with strategic goals and objectives and (2) solves enterprise-level problems with an integrated, customer-focused approach leveraging lean thinking and learning organizational concepts. The LOS website contains many tools and resources for solving problems with the user in mind.
- The Continuous Sandia Improvements (CSI) application is the Laboratories' tool for storing improvement records, communicating reported improvements, recognizing recently completed improvement efforts, and tracking active improvement activities.
- "Help" lines for computer support, facility issues, OOPS (an incident reporting guide), and Security Incident Management Program provide a way to report problems and facilitate performance monitoring.
- The Common Engineering Environment provides resources for quality-related and analysis tools and training, and additional resources to ensure continual workflow improvements in areas such as product realization, defect prevention, and suspect/counterfeit items awareness.

7.4. Criterion 4: Management/Documents and Records

Criterion

1. Prepare, review, approve, issue, use, and revise documents to prescribe processes, specify requirements, or establish design.
2. Specify, prepare, review, approve, and maintain records.

Objectives

- To effectively fulfill job responsibilities with consistency, repeatability and predictability, members of the workforce must be able to access information that is current, complete, and correct.
- To prepare, review, approve, issue, use, control, and revise documents that describe processes, specify requirements, or establish design.
- To ensure that personnel use only the most recently approved version of documents.
- To evaluate operations, tasks, and processes to determine whether they will benefit from documented procedures that may add value (a) when precision is necessary, (b) for activities performed infrequently or after significant personnel turnover, and (c) in situations that may present other types of risk.
- To specify required records for a program or activity, including reports, facility logs, lab notebooks, correspondence, decision papers, results from analyses, drawings, meeting minutes, copies of presentations, assessment results, and corrective action plans. Records provide history, data, and evidence that actions have been completed and/or approved. Programmatic records, identified during project planning, supplement other required records, such as procurement, training, human resources, environment, safety and health, or finance.
- To ensure that expectations, roles, and responsibilities for records preparation, review, approval, and maintenance are clearly communicated.

Implementation

- Prepare, approve, use, and revise well-written documents in all facets of work.
- Document and maintain program and project plans, policies and procedures, and any other prescribed expectations for what to do and how to do it.
- Provide evidence of work results and of activities performed by maintaining accurate and accessible records.
- Use consistent processes, practices and tools applied in consideration of graded approach for project size and consequence to improve performance through systemic quality approaches.

Graded Approach

Several factors are considered to determine whether a process or task should be documented:

- Consequences of performing the tasks incorrectly (Is it a key or critical process or task?)
- Likelihood of performing tasks incorrectly (Is it a complicated or new process?)
- Level of personnel skill and experience
- Amount of personnel turnover
- Number of personnel performing the task, and consistency requirements
- Contractual or legal requirements for documenting procedures

The same factors may also determine the appropriate level of detail necessary in the documentation, and the resources needed for adequate document development, review, and approval.

Several factors determine what records should be kept and how they will be controlled. Records may be required by the customer, by the business need, or by Sandia policy and procedures. Managers consider what data should be retained so that future program participants can understand project decisions and identify trends.

Specific local controls for programmatic records—such as numbers of reviews, levels of approval, instructions for use, and retention schedules—are applied using a graded approach, depending on the importance of the work involved.

Other procedures in the LPS may identify, as necessary, specific records to demonstrate that the procedures in question have been correctly implemented.

Tools and References

The following tools and references provide information on managing documents and records:

- The Recorded Information Management home page contains information and links to policies, procedures, systems, tools, templates, and assistance for appropriate, effective information management.
- The Records Management Manual emphasizes individual responsibility for the management of recorded information in accordance with Laboratories and programmatic policies, procedures, and standards.
- Where to Store Your Information provides guidance on where to store documents, records, drawings, etc.
- The Sandia Records Retention and Disposition Schedule provides direction on records retention, storage, disposition, and archival.
- The Records Decision Tree guidance tool helps users to determine whether the information being considered is indeed a record.
- The Common Engineering Environment (CEE) provides systemic quality approaches for consistency in processes, practices and tools in critical areas such as engineering standards, configuration management, risk management, and project management consistent with a graded approach for project size and consequence. Sandia engineers and scientists can access training on the CEE portal.

7.5. Criterion 5: Performance/Work Processes

Criterion

1. Perform work consistent with technical standards, administrative controls, and hazard controls adopted to meet regulatory or contract requirements using approved instructions, procedures, etc.
2. Identify and control items to ensure their proper use.
3. Maintain items to prevent their damage, loss, or deterioration.
4. Calibrate and maintain equipment used for process monitoring or data collection.

Objectives

- To establish appropriate work process controls for managing items and equipment to mitigate any operational or programmatic risks associated with the performance of work.
- To perform work to established technical standards and controls using approved instructions, procedures, or other appropriate means.
- To ensure that employees supervision have the appropriate knowledge, skills, competencies, equipment, resources, and documentation (including procedures) necessary to accomplish their tasks.
- To ensure that personnel use only the most recently approved version.

- To hold personnel accountable for following workflow procedures.
- To ensure that if equipment for process monitoring or data collection could impact quality, then it is calibrated and maintained through the PSL and maintained by the user.
- To ensure that items are identified and controlled for proper use and are maintained to prevent damage, loss, or deterioration.

Implementation

- Integrate WP&C for safe design and all operational considerations
- Integrate safeguards and security approaches into work planning
- Invoke customer requirements, technical standards, management expectations, risk understandings, and other appropriate requirements (e.g., regulatory) when planning work
- Establish document control measures for program and project plans, policies and procedures, and any document that prescribes expectations for what to do and how to do it.
- Apply a questioning attitude to the work, premised on analytical and critical thinking skills, to avoid surprises.
- Take full responsibility for the work and commit to "do the right thing" in every situation
- Advocate safety by challenging assumptions
- Identify and eliminate, or mitigate, all hazards

Graded Approach

When working to a procedure, the level of control can vary from referencing the procedure only occasionally to using a line-by-line checklist that shows the completion of each step. Factors to consider when executing procedures include the complexity of the process, the criticality of the outcome, the hazards involved, and the experience of the worker.

In controlling items, several factors should be considered: How critical is the item to the activity? Is it replaceable? How fragile is it? Is it easily lost or stolen? Is misuse likely? If an item is nonconforming, what is the impact? Will misuse have profound consequences? These factors should determine how carefully the item is labeled and controlled. The Sandia *Research Quality Standards* provides considerations applicable to research and development work activities.

The frequency and rigor of calibration of measurement devices are tailored to the potential programmatic and/or safety impact, the required accuracy of the data, and equipment calibration tolerance.

Tools and References

- The Sandia PSL aids in obtaining calibration and maintenance of metrology instruments throughout Sandia. The PSL website provides links to pertinent LPS procedures, purchasing guidelines, calibration requests, and documentation of their capabilities and services.
- The PSL provides advice and feedback for purchasing new Measuring and Test Equipment (M&TE), to help ensure that the asset can be properly calibrated and can adequately perform the measurements of interest.
- PSL has developed a new procedure for calibration, the Standardize Before Use (SBU), which allows more flexibility in ensuring that measurement equipment is correctly certified. PSL has procedures to authorize a specific organization to calibrate their measurement equipment with PSL oversight.
- The Environment, Safety &Health (ES&H) LiveSafe site provides a shared environment to help all members of the workforce adopt a safe work environment, both at home and at work.

- EIMS FileNet offers centralized document- and records-management storage to all Sandia users on both the Sandia Restricted Network (SRN) and Sandia Classified Network (SCN). Content is organized in folders per organizational file plans (by org number, policy area, or functional area); searchable by metadata and/or file content; secure with access determined by users; and version controlled.
- The Recorded Information Management home page contains information and links to policies, procedures, systems, tools, templates, and assistance for appropriate, effective information management.
- The Primary Hazard Screening (PHS) Module (with integrated hazard analysis) provides a high-level hazard identification and analysis for specific activities, tasks, or facilities. It also serves as the starting point for activity-level work in accordance with Sandia's work planning and control processes.
- ES&H Manual

7.6. Criterion 6: Performance/Design

Criterion

1. Design items and processes using sound engineering/scientific principles and appropriate standards.
2. Incorporate applicable requirements and design bases in design work and design changes.
3. Identify and control design interfaces.
4. Verify/validate the adequacy of design products using individuals or groups other than those who performed the work.
5. Verify/validate work before approval and implementation of the design.

Objectives

- To institute and follow controls to ensure that designed services, products, processes, firmware, or software, perform as intended
- To define design requirements that incorporate all appropriate customer and relevant stakeholder expectations; needs related to the intended use in the operational environment, if known; statutory and regulatory requirements; and any applicable technical and/or industrial standards.
- To review design requirements, thereby ensuring that design requirements are correct, unambiguous, complete, feasible, necessary, ranked, and verifiable. After the review has been completed, the requirements are approved by the customer and relevant stakeholders, and that the prerequisite resources are available to meet the addressed expectations.
- To plan and control the design process. This includes defining the roles, responsibilities, and interfaces for the design work; identifying the appropriate design stages, or phases; and determining the review, verification, and validation activities that are appropriate to each design stage.
- To verify and validate design. Verification ensures that the design requirements have been met; validation ensures that the resulting product or service can fulfill its expected use.
- To approve the design. The final design is approved at an appropriate level before release and will contain (or reference) appropriate acceptance criteria.
- To identify and document all design changes. Changes are reviewed, verified, and validated, as appropriate, and approved before implementation. The review shall evaluate how the changes may affect other parts of the design.

Implementation

- Design with defect prevention in mind

- Apply safe-by-design considerations in WP&C activities
- Conduct research and design using engineering/scientific principles and standards
- Consider how the product will be used across the product lifecycle (e.g., prototype only used in lab, a fielded item to be used in real environments, or item that could make its way to production)
- Ensure designs incorporate applicable requirements and design bases into the work and subsequent changes, and engineering/technical interfaces are identified and controlled
- Pursue independent peer reviews to verify and validate the adequacy of design through all phases of product realization and service/support realization

Graded Approach

Following the Laboratories' graded approach, Sandia uses its project evaluation tool, PrE, to examine technical and programmatic risks that must be considered in any design management process. For example:

- How complex is the design?
- How new is the technology?
- How many different organizations or functions are participating?
- How critical is the process or item that is being designed?

Answers to such questions should influence the number and frequency of design reviews and approvals, the needed level of rigor in communicating roles and responsibilities, the control of designs and design changes, and the documentation required for verification and validation.

Customers may specify the types and levels of control over design activities they require. Nationally recognized technical and design standards, whether developed by governmental or non-governmental agencies, should be incorporated where applicable. Sandia's Technical Library maintains links to Standards and Specifications from a wide variety of sources. The Technical Library staff can aid in locating specific standards.

Tools and References

- PrE Science and Engineering Management Framework
- MAP
- PM Framework
- PM Activities Planning Template
- Management entities deploy division-specific training, tools, and resources to eliminate defects in performance and design, Research Quality Standards
- Defect Prevention Microsystems Science, Technology and Components website
- Nuclear Security Quality Training (NQT) SharePoint site
- Nuclear Weapons (NW) Knowledge Development Program (KDP)
- Common Engineering Environment

7.7. Criterion 7: Performance/Procurement

Criterion

1. Procure items and services that meet established requirements and perform as specified.
2. Evaluate and select prospective suppliers based on specified criteria.

3. Establish and implement processes to ensure that approved suppliers continue to provide acceptable items and services.

Objectives

To meet commitments, Sandia requires a reasonable level of confidence that suppliers will meet requirements for cost, schedule, and performance, and that procured items and materials will perform as specified.

- Procured items and services meet established requirements and perform as specified. Expectations and specifications for items and services must be correct, specific, clear, and unambiguous.
- Prospective suppliers are evaluated and selected based on specified criteria.
- Processes to ensure that approved suppliers continue to provide acceptable items and services must be established and implemented.

Implementation

- Specify exactly what is required when procuring items and services required for the work, and verifying that what is received meets specifications
- Work closely with the buyer to ensure that the technical requirements for the items and services needed, including distinct performance requirements, are specified on the purchase order
- Evaluate and select prospective suppliers using the Supply Chain Risk Management Quality Level Program which provides an objective framework for applying a graded approach to procurement to ensure that the supplier can meet quality and performance requirements.
- Evaluate and monitor supplier performance to ensure that approved suppliers provide acceptable items and services and enable Sandia to detect and prevent supplier performance problems.

Graded Approach

These requirements govern all aspects of product and service procurement.

Supply Chain Management Procurement Policy ISCM001.2, Supply Chain Risk Management Quality Level Program, provides a graded approach framework for procurement using four risk-based quality levels, each of which corresponds to a degree of rigor for control and assurance activities. Sandia requires that all purchases have an assigned quality level (QL), from QL1 to QL4, highest to lowest risk, and are subject to purchasing process controls. For items and services identified as other than QL-4, lowest risk), more stringent requirements and controls afford greater confidence that the item or service will perform as specified. Approval levels based on cost are also an example of graded approach.

Potential suppliers of critical, complex, or costly items and services undergo more rigorous evaluations prior to contract award to determine whether they can meet requirements consistently. Evaluations may include a review of the supplier's performance history for providing comparable items or services, a review of shared supplier quality information, an evaluation of third-party certifications or registrations, or a supplier quality and security assessment.

During and after contract performance, the Supply Chain Management Procurement Process ISCM001.9, Administer a Subcontract, provides for ongoing evaluations of approved suppliers. Sandia collects timely performance data through the **S**ub**CO**ntractor **R**eview and **E**valuation (SCORE) program using supplier performance evaluation questions deployed through the Invoice Action Process.

Tools and References

Most Supply Chain Management (SCM) procedures are found in LPS, and list requirements and processes for procurement when the products or services are external to Sandia. With internal suppliers, expectations and

requirements should be just as clear, although communication methods may vary. Most Sandia service organizations have developed specific methods for customers to communicate requirements. Currently, Sandia's programs may each develop their own means of defining and controlling the work that divisions will perform on their behalf.

The Quality Level Program home page provides supplemental information and tools to support the Quality Level (QL) process. SC-OP-WI-026, *Submitting SCORE evaluations: A How-To Guide*, instructs personnel to evaluate supplier performance through the Invoice Action process.

Multi-Site Procurements

The Supply Chain Management Center (SCMC) builds upon existing capabilities, activities, and organizations within the NNSA's eight M&O Prime Contractors, known as the Nuclear Security Enterprise (NSE). The SCMC ensures improved efficiencies and economies in NSE acquisitions by implementing strategically driven integrated functions that maximize value for every acquisition dollar spent. The SCMC oversees creation and execution of commodity agreements and infrastructure. The SCMC is staffed primarily by employees of the Kansas City National Security Campus (KCNSC), managed and operated by Honeywell Federal Manufacturing and Technologies with support from NSE procurement staff. The Sandia Contracting Representative (SCR) may use various SCMC agreements that are available for obtaining discounted pricing.

Sandia participates in biweekly meetings with enterprise-wide representatives, receives SCMC specific data monthly, informs the SCMC performance scorecard, and manages the Procurement Policy PP-631, *Ordering/Corporate Agreements*.

- NNSA Supply Chain Management Center (SCMC) website
- DOE Integrated Contractor Purchasing Team (ICPT) website

The Cross-Complex Supplier Qualification Data Sharing team redesigned the NNSA funded Master Approved Supplier List (MASL) database for use by all eight NSE weapons sites.

7.8. Criterion 8: Performance/Inspection and Acceptance Testing

Criterion

1. Inspect and test specified items, services, and processes using established acceptance and performance criteria.
2. Calibrate and maintain equipment used for inspections and tests.

Objectives

To meet our customers' needs and maintain safe operations, Sandia verifies that items, services, and processes perform as intended.

- The requestor determines acceptance and performance criteria. These criteria can address form, fit, and/or function (e.g., product identification, physical and performance characteristics, or personnel qualification).
- Specific items, services, and processes are inspected and tested using established acceptance and performance criteria**.**
- Inspection and test equipment are calibrated and maintained.

Implementation

- Use a graded approach to manage supply chain risks such as poor manufacturing and/ or development practices, counterfeit products, tampering, theft, malicious insertions, and fraudulent services

- Assess critical Subcontractors' quality prior to commencement of work
- Ensure that measuring equipment required for the work (e.g., inspections and tests) is calibrated and maintained

Graded Approach

In ascending order of rigor, the inspection/testing methods are (a) acceptable subcontractor/item performance record, (b) standard receipt inspection, (c) subcontractor assessment/source verification/surveillance, and (d) special tests and inspections. The frequency or amount of testing may also vary, from statistical sampling to full testing of all incoming items. The requester may use these methods individually or in combination to provide an appropriate level of assurance that the items or services meet the critical requirements.

Tools and References

- ISCM001.2 Supply Chain Risk Management (SCRM) *Quality Level Program* (corporate requirement regarding inspections as well as the overall SCRM policy)
- *ISCM001.9* Administer a Subcontract, "Evaluate Subcontractor Performance" (SCORE system is the corporate requirement for performance evaluations of subcontractors)
- SubContractor Approval Navigation (SCAN) system (records repository for interactive pre-award assessments of subcontractors; access controlled)
- Quality Level Program Inspection Home site (tools and instructions for inspecting deliverables; resources available for projects or programs that do not already have local processes and tools for inspection activities)
- The Sandia PSL provides technical guidance, support, and consultation across the Laboratories to aid in the calibration of metrology instruments. The PSL website provides links to pertinent LPS procedures, purchasing guidelines, calibration requests, and documentation of their capabilities and services.

7.9. Criterion 9: Assessment/Management Assessment

Criterion

Ensure that managers assess their management processes and identify and correct problems that hinder the organization from achieving its objectives**.**

Objectives

Management assessment includes all activities that determine and improve the effectiveness of management-related processes, systems and programs, regardless of the type of work being conducted. Effectiveness is measured by progress toward established performance-related goals and objectives, which, at a minimum, include compliance with contractual and legal requirements as well as meeting customer cost, schedule, and performance expectations.

Managers perform assessments to find and fix issues before they impede progress toward established goals and expectations. Issues are identified and corrected, and learning opportunities acknowledged.

An effective management assessment program provides:

- a regular, systematic evaluation process for assessing management-related processes and operations against established performance objectives
- graded approaches for performance monitoring through formal assessment, monitoring and measurement, and management review
- the information managers use to make decisions that will continually improve performance

Implementation

- Initiate value-added assessments to discover conditions that could prevent Sandia from achieving objectives
- Seek opportunities to continually improve performance
- Act promptly to correct and prevent recurrence of issues identified by assessments

Graded Approach

The depth, rigor, and frequency of management assessments depend on several factors including contractual and regulatory obligations, the risks associated with the work, the results from past assessments (favorable or unfavorable) the needs of the customer, the determination of extent of conditions, and the information needed by management to aid in understanding the conditions.

Managers at all levels of the organization must determine the assessments necessary to identify actual or potential issues in their operations.

Tools and References

The corporate assurance system, Sage, houses documented assessments, corrective actions taken in response to assessment results or other issues, identified risks and associated treatment activities, and lessons learned. Some programs may use other tools such as Active Risk Management (ARM) or Risk Engineering Management Solution (REMS) to track risks and treatment activities per customer requirements.

7.10. Criterion 10: Assessment/Independent Assessment

Criterion

1. Plan and conduct independent assessments to measure item and service quality and the adequacy of work performance, and to promote improvement.
2. Establish sufficient authority and freedom from line management for independent assessment teams.
3. Ensure that persons conducting independent assessments are technically qualified and knowledgeable in the areas to be assessed.

Objectives

- To assure management Sandia is meeting programmatic, contractual, and legal commitments and requirements.
- To provide management meaningful data and information to determine which conditions or causes need to be addressed to improve performance.
- To ensure that assessors have sufficient authority and freedom from the assessed organization to carry out their responsibilities and are selected on the basis of their technical qualifications and knowledge in the areas to be assessed.

Implementation

- Plan and conduct independent assessments at regular intervals
- Enlist the help of independent reviewers to identify improvement opportunities
- Measure, among other things, product/service quality and adequacy of work performance
- Provide sufficient authority and freedom to independent review teams to ensure objective and unbiased results
- Provide management with reliable assessment results that document acceptable performance and identify opportunities for improvement
- Take appropriate and timely action in response to assessment results

Graded Approach
Sandia determines independent assessments to be performed by considering concerns or risks, timing, required assessment activities, already scheduled review activities (both internal and external), and other factors.

Functional areas assess implementation of their policies, including those policies which implement elements of the QAP; for example, the Quality Assurance Functional Area assesses flow-down and implementation of DOE O 414.1D and ISO 9001:2015. Center 800 (Independent Audit, Ethics, and Business Conduct), which is accountable to the NTESS BoM, additionally performs audits on QAP elements using a risk-based approach. Other independent assessments, including assessments of item quality, are performed as needed using a graded approach to provide assurance and drive improvement.

Third-party reviews and assessments, including management system registration and surveillance audits (e.g., ISO 9001, ISO 14001), external advisory board reviews, and external peer reviews, complement, but do not replace, internal, independent assessments of the QAP.

Independent assessments and audits must be conducted by qualified, independent evaluators. These evaluators may be internal assessors from relevant Functional Areas, independent auditors from Center 800, or internal or external peer reviewers, consultants, or counterparts from other organizations or laboratories, with the requisite expertise and sufficient independence from the program being assessed.

Tools and References
Independent assessments, their results, and actions taken in response to the results are documented in the Sage tool.

7.11. Suspect/Counterfeit Items (S/CI) Prevention

Requirements
See DOE O 414.1D, Attachment 3, Suspect/Counterfeit Items Prevention.

Objectives
Prevent and detect suspect and counterfeit items from affecting the supply chain, causing unreliable products and creating unsafe working conditions.

- To create awareness among employees and management about S/CI concerns, prevention, detection, and reporting requirements
- To prevent S/CI from entering the supply chain
- To identify S/CI to prevent their use
- To report S/CI to share information with other potential users and notify authorities of potential criminal activity

Implementation

- Provide relevant training to all members of the workforce and subcontractors
- Use standard processes to detect, control, report, disposition, and dispose of suspect/counterfeit items
- Use quality suppliers competent to perform the work
- Purchase directly from original equipment manufacturers (OEMs) and/or authorized distributors that have rigorous counterfeit prevention programs
- Independently verify critical components or devices with unsure pedigrees

Graded Approach
Procurement requesters should analyze the potential consequences of product or service failure during procurement planning and procurement execution using the Supply Chain Risk Management Quality Level Program. This risk-based approach will inform the level of controls over the purchase and the inspection requirements.

Tools and References
The Suspect/Counterfeit Items website provides a way to report suspect or counterfeit items and provides points of contact, links to guidance and procedures, training, examples, announcements, safety and counterfeit recall information, and the Supply Chain Risk Management & S/CI Newsletter.

Laboratory Policy ISCM001.7, Manage Suspect or Counterfeit Items specifies actions necessary to ensure the quality and integrity of purchased products or services. Suspect/Counterfeit items (S/CI) are identified and controlled to prevent the procurement or introduction or introduction of, and installation or use of, such items at Sandia. S/CI are a threat to safety and mission success at Sandia and the DOE Laboratories complex.

The Quality Level Program website identifies contacts for the Supply Chain Risk Management Program and provides links to resources, inspection tools, examples, training, Frequently Asked Questions, and announcements for the Quality Level Program.

7.12. Safety Software Quality Assurance Requirements for Nuclear Facilities

Requirements
See DOE O 414.1D, Attachment 4, Safety Software Quality Assurance Requirements for Nuclear Facilities.

Objective
To ensure that the software Sandia relies on for the safety of our nuclear facilities is managed (designed, developed, tested, and maintained) with sufficient rigor.

Implementation
- Acquire, develop, and implement software that meets requirements

Graded Approach
DOE O 414.1D Attachment 4 requires the establishment and documentation of grading levels, subject to the approval of DOE. These grades are built into the procedures and guidance found in the QA cross-mapping table in Section 9.

Tools and References
The Software Quality Implementation Group (SQUIG) website is maintained by the SQUIG. This group represents software engineering professionals from across the Laboratories and is chartered and managed by the Chief Information Officer to provide software quality consulting and support upon request. SQUIG identifies and shares training, lessons learned, and best practices throughout the Sandia software development community. Additionally, the Sandia Safety Software Inventory Tool, which is the formal inventory of DOE O 414.1D safety software at Sandia, is updated annually, and is reported to NNSA/SFO upon completion.

All software developed and used at Sandia must incorporate IT008, *Provide Quality Software*, and Sandia National Laboratories Specific Use Specification, SSQAP, SS-R89727, as part of their SQA activities. These documents elaborate on general software requirements and specific requirements for DOE O 414.1D nuclear facility safety software. The SSQAP

specifies ASME NQA-1, Quality Assurance Requirements for Nuclear Facility Applications Version 2008/9, Part II, Subpart 2.7, and applicable requirements of Part I, with the NQA-1a-2009 addenda (and subsequent versions) as the consensus standard used to address safety software quality assurance requirements and defines the grading methodology and grading levels for software. IT008, *Provide Quality Software* and the SSQAP are both reviewed at least every two years and any major updates are submitted for approval by the designated NNSA/SFO approval authority.

Organization 1380 (Nuclear Facilities and Applied Technologies) is the primary producer and user of DOE O 414.1D nuclear facility safety software and specifies in the Technical Area V (TA-V) Management System document that ASME NQA-1, Quality Assurance Requirements for Nuclear Facility Applications Version 2008/9 (or later version) Part II, Subpart 2.7 and applicable requirements of Part I, with NQA-1a-2009 addenda (and subsequent versions) as the TA-V official SQA) consensus standard. TA-V declared standards and grading levels are reviewed and approved annually as part of the TA-V Management System approval process.

NNSA/SFO-approved QAPs applicable to safety software based on requirements from DOE O 414.1D are acceptable (per Attachment 4, 2.a).

Critical (non-DOE O 414.1D nuclear facility) Safety Software
Sandia defines an additional class of software that fulfills a safety function but is not nuclear facility safety software (e.g., analysis software, or software used to monitor and provide status of hazardous equipment and/or materials). This software is controlled in a similar manner as DOE O 414.1D safety software and is also defined in the SSQAP.

8.0 List of Acronyms

ALD	Associate Laboratories Director
ARM	Active Risk Manager
BoM	Board of Managers
CAS	Contractor Assurance System
CAS-D	Contractor Assurance System Description (Link)
CSI	Continuous Sandia Improvements
DOE	Department of Energy
ESH	Employee Health Service
ES&H	Environment, Safety & Health
ICPT	Integrated Contractor Purchasing Team
ISMS	Integrated Safety Management System
KCNSC	Kansas City National Security Plant
KDP	Knowledge Development Program
LOS	Laboratory Operating System
LPS	Laboratory Policy System
LRDP	Long-Range Development Plan
M&TE	Measuring and Test Equipment
MA	Mission Assurance
MAES	Mission Assurance Engineering System
MAP	Mission Assurance Plan
MASL	Master Approved Supplier List
NNSA	National Nuclear Security Administration

NQT	Nuclear Security Quality Training
NSE	Nuclear Security Enterprise
NTESS	National Technology and Engineering Solutions of Sandia, Inc.
NW	Nuclear Weapons
OEM	Original Equipment Manufacturer
OMB	Office of Management and Budget
OMR	Operational Management Review
PDCA	Plan Do Check Act
PEMP	Performance Evaluation and Measurement Plan
PHS	Primary Hazard Screening
PM	Program/Project Management
PMR	Programmatic Management Review
PMU	Program Management Unit
PrE	Project-Evaluation
PSL	Primary Standards Laboratory
PMR	Programmatic Management Review
PMU	Program Management Unit
QA	Quality Assurance
QL	Quality Level
QAP	Quality Assurance Program
QAPD	Quality Assurance Program Description
QM	Quality Management
QMS	Quality Management System
R&D	Research and Development
R2A2	Roles, Responsibilities, Accountabilities, and Authorities
REMS	Risk Engineering Management Solution
S/CI	Suspect/Counterfeit Items
Sandia	National Technology and Engineering Solutions of Sandia, Inc.
SBU	Standardize Before Use
SCAN	SubContractor Approval Navigation
SCM	Supply Chain Management
SCMC	Supply Chain Management Center
SCN	Sandia Classified Network
SCORE	SubCOntractor Review and Evaluation
SCRM	Supply Chain Risk Management
SCR	Sandia Contracting Representative
SE	Systems Engineering
SEWQ	Surety Engineering. & Weapons Quality
SFO	Sandia Field Office (NNSA)
SLT	Senior Leadership Team
SME	Subject Matter Expert
SMR	Strategic Management Review
SPP	Strategic Partnership Projects

SQA	Software Quality Assurance
SQUIG	Software Quality Implementation Group
SSQAP	Sandia Software Quality Assurance Program
SRN	Sandia Restricted Network
STA	Secure Transportation Asset
TA-V	Technical Area V
WIPP	Waste Isolation Pilot Plant
WP&C	Work Planning and Control
WE&P	Weapon Engineering & Production
WS&T	Weapons Science and Technology

Laboratory Policy Prefixes

CA	Contractor Assurance
COM	Communications
EM	Emergency Management
EHS	Employee Health Services
ESH	Environment, Safety & Health
FAC	Facilities & Building Management
FIN	Financial Management
GGR	Governance and Government Relations
HR	Human Resources/Workforce Management
IAEB	Independent Audit, Ethics & Business Conduct
IT	Information Technology
LG	Legal Management
PC	Prime Contract
PPM	Program & Project Management
PRM	Policy and Requirements Management
QA	Quality Assurance
SS	Safeguards & Security
ISCM	Integrated Supply Chain Management

9.0 Laboratory Policy System Cross-Map to DOE O 414.1D

The cross-mapped tables on the following pages illustrates the relationship between the individual LPS policy or process, and each DOE O 414.1D and 10 CFR 830, Subpart A criterion it is intended to meet. Table 4 also cross-references the sections and titles of NAP 401.1, ISO 9001:2015, and AS9100D. Table 5and Table 6 provide detailed cross-references of DOE O 414.1D Attachments 3 and 4.

Table Notes

[1] DOE O 414.1D specifies in the Contractor Requirements Document additional requirements in Attachment 2, 3, and 4.

[2] DOE O 414.1D provides direction for determining appropriate consensus standards for developing a QAP. Distinction is made for Hazardous Category 1, 2, and 3 nuclear facilities.

General Notes

- Mapping was developed with DOE O 414.1D and 10 CFR 830, Subpart A as the baseline showing associations to NAP 401.1, ISO 9001:2015, and AS9100D. Because ISO 9001 and AS9100 are more detailed, there may be multiple associations of a given criteria from these standards to NAP 401.1.
- Mapping was intended to show the most direct association and best fit. The user should not assume that associations shown represent perfect one-to-one mapping. The actual criteria should be read, as the requirements may vary in detail from left to right, with DOE O 414/10 CFR 830 being the most general and AS9100D providing the most detail.
- When the highest-level section is noted (e.g., NAP 401.1, 5.5), all subsequent subsections apply.
- 10 CFR Subpart B - Safety Basis Requirements is not included in this mapping. Subpart B establishes safety basis requirements for hazard category 1, 2, and 3 DOE nuclear facilities.
- Pink highlighted items identify additional requirements.
- Italicized wording implies paraphrasing of requirements.
- The most current versions of the Laboratories' policies, processes, and procedures can be found in the Laboratory Policy System.

Table 4: LPS Cross-Map to 10 CFR 830 Subpart A, DOE O 414.1d, Attachments 1 & 2, ISO 9001:2015

Laboratory-Required				NW-Required		Laboratory Required		Elected	
DOE O 414.1D [1] / 10 CFR 830 Subpart A		Laboratory Policy System Procedure		NAP 401.1A		ISO 9001:2015		AS9100D	
Section Number	**Section Title**	**QAPD Section Number**	**Section Title**	**Section Number**	**Section Title**	**Section Number**	**Section Title**	**Section Number**	**Section Title**
1.	Purpose	1.1	Introduction (Quality Assurance Program Description)	1.0	Purpose	0.1	General - Introduction	0.1	General - Introduction
3./830.120	Applicability	1.3	Laboratory Policy System and Requirements Flow Down (Quality Assurance Program Description) ISCM001.1 Acquire Products or Services ISCM001.2 Supply Chain Risk Management Quality Level Program ISCM001.5 Purchase Requisition and Purchase Order PC001 Manager Prime Contract and Baseline Directives Policy PC001.1 Modify Prime Contract PC001.2 Modify Baseline Directives	1.1	Scope	1	Scope	1	Scope
				1.2	Supplemental Policy and Clarifications				
6./830.3	Definitions				Definitions are documented and maintained in the NNSA Definition Lexicon	3	Terms and Definitions	3	Terms and Definitions
7.	References					2	Normative References	2	Normative References
Attachment 1	**Contractor Requirements Document**								
1./830.121[2]	**Quality Assurance Program Development and Implementation**			2.2	Weapon Quality Management System	0.3	Process Approach	0.3	Process Approach
2./830.121b	**Quality Assurance Program Approvals and Changes**	1.0	Sandia's Quality Assurance Program (Quality Assurance Program Description) CA001 Enterprise Risks, Opportunities, Issues Management Policy CA001.2 Identify and Manage Issues CA002 Performance Monitoring Policy FAC002 Space Management Policy FIN004 Budget Policy HR002 Talent Acquisition Policy IT010 Manage Records Policy PPM001 Program and Project Management Policy PRM001 Policy and Requirements Management Policy QA001 Quality Policy	2.2.1	WQAP	4.4	Quality management system and its processes	4.4	Quality management system and its processes
			CA001 Enterprise Risks, Opportunities, Issues Management Policy CA001.1 Identify and Manage Risks and Opportunities CA002 Performance Monitoring Policy CA002.2 Develop, Modify, and Monitor Performance Measures and Metrics CA002.3 Management Review Process HR002 Talent Acquisition Policy HR005 Employee Performance Policy PPM001 Program and Project Management Policy PRM001 Policy and Requirements Management Policy QA001 Quality Policy	2.2.2	Submittal, Approval, Implementation, and Reporting	6	Planning	6	Planning
Attach.2/830.122	**Quality Assurance Criteria**								
1.	**Criterion 1 - Management/Program**	**QAPD Section Number**	**Section Title**	**Section Number**	**Section Title**	**Section Number**	**Section Title**	**Section Number**	**Section Title**
1.a	Establish an organizational structure, functional responsibilities, levels of authority, and interfaces for those managing, performing, and assessing the work.	7.1	CA001 Enterprise Risks, Opportunities, Issues Management Policy CA001.1 Identify and Manage Risks and Opportunities CA001.2 Identify and Manage Issues CA002 Performance Monitoring Policy	2.1	Risk Management	6.1 6.3	Actions to Address Risk and Opportunities Planning of Changes	6.1 6.3	Actions to Address Risk and Opportunities Planning of Changes
				2.2	Weapon Quality Management System	5.1 4 5.3	Leadership and Commitment Context of the Organization Organization Roles, Responsibility and Authorities	5.1 4 5.3	Leadership and Commitment Context of the Organization Organization Roles, Responsibilities and Authorities

			CA002.2 Develop, Modify, and Monitor Performance Measures and Metrics CA002.3 Management Review Process COM001 External Communications Policy COM002 Internal Communication Policy EM004 Continuity of Operations Policy ES&H Manual ESH001 Environment, Safety, and Health Policy ESH001.1 Integrate ES&H into Work Planning and Execution	2.3	Organization	5.3	Organizational Roles, Responsibility and Authorities	5.3	Organizational Roles, Responsibility and Authorities
				4.0	Responsibilities	5.1 5.1.2 5.2	Leadership and Commitment Customer Focus Policy	5.1 5.1.2 5.2	Leadership and Commitment Customer Focus Policy
				4.7	Contractors				
				2.6	Planning	6	Planning	6	Planning
1.b	Establish management processes, including planning, scheduling, and providing resources for the work.		FAC001 Construction Policy FAC002 Space Management Policy FAC005 Maintain Buildings and Equipment Policy FAC006 Government Vehicles and Motorized Equipment Policy FIN004 Budget Policy FIN010 Strategic Partnership Projects (SPP) and Cooperative Research and Development Agreements (CRADA) Policy" GGR001 Governance Policy GGR002 Government Relations Policy HR002 Talent Acquisition Policy HR003 Employee Development Policy HR005 Employee Performance Policy HR008 Non-Discrimination and Harassment Free Policy ISCM001 Procurement Policy ISCM001.1 Acquire Products or Services ISCM001.3 Request Goods through Fabrication ISCM001.5 Purchase Requisition and Purchase Order ISCM001.8 Acquire Services of Nonemployees ISCM001.9 Administer a Subcontract ISCM004 Manage Property, Materials, and Services IT008 Provide Quality Software Policy IT009 Manage Controlled Documents Policy IT010 Manage Records Policy IT012 Unclassified Controlled Information Policy IT013 Sandia Proprietary Information Policy IT017 Official Use Only Information Policy IT024 Third-Party Proprietary Information Policy PC003.1 Respond to an Opportunity or Request for Information (RFI) PPM001 Program and Project Management Policy PRM001 Policy and Requirements Management Policy QA001 Quality Policy QA001.1 Control Nonconforming Products and Services QA002 Calibration Policy QA004 Survey Policy	2.6	Planning	7.1 7.1.6	Resources Organizational Knowledge	7.1 7.1.6	Resources Organizational Knowledge
						7.1.3	Infrastructure	7.1.3	Infrastructure
						8.2	Requirements for Products and Services	8.2	Requirements for Products and Services
						7	Support	7	Support

DOE O 414.1D [1] / 10 CFR 830 Subpart A		Laboratory Policy System Procedure		NAP 401.1A		ISO 9001:2015		AS9100D	
2.	**Criterion 2 - Management/Personnel Training and Qualification**	**QAPD Section Number**	**Section Title**	**Section Number**	**Section Title**	**Section Number**	**Section Title**	**Section Number**	**Section Title**
2.a **2.b**	Train and qualify personnel to be capable of performing their assigned work. Provide continuing training to personnel to maintain their job proficiency.	7.2	CA001 Enterprise Risks, Opportunities, Issues Management Policy CA002 Performance Monitoring Policy COM001 External Communications Policy COM002 Internal Communication Policy ES&H Manual GGR001 Governance Policy GGR002 Government Relations PolicyHR002 Talent Acquisition Policy HR003 Employee Development Policy HR003.3 Maintain Training Compliance HR005 Employee Performance Policy ISCM001.3 Request Goods Through Fabrication ISCM001.5 Purchase Requisition and Purchase Order ISCM001.8 Acquire Services of Non-employees ISCM001.9 Administer a Subcontract IT010 Manage Records Policy PPM001 Program and Project Management Policy QA001 Quality Policy QA004 Survey Policy SS008.6 Human Reliability Program (HRP)	3.2	Training	7.1.2 7.2 7.3 7.4	People Competence Awareness Communication	7.1.2 7.2 7.3 7.4	People Competence Awareness Communication
3.	**Criterion 3 - Management/Quality Improvement**	**QAPD Section Number**	**Section Title**	**Section Number**	**Section Title**	**Section Number**	**Section Title**	**Section Number**	**Section Title**
3.a **3.b** **3.c** **3.d**	Establish and implement processes to detect and prevent quality problems. Identify, control, and correct items, services, and processes that do not meet established requirements. Identify the causes of problems and include prevention of recurrence as a part of corrective action planning. Review item characteristics, processes implementation, and other quality related information to identify items, services, and processes needing improvement.	7.3	CA001 Enterprise Risks, Opportunities, Issues Management Policy CA001.1 Identify and Manage Risks and Opportunities CA001.2 Identify and Manage Issues CA002 Performance Monitoring Policy CA002.1 Conduct Internal Assessments CA002.2 Develop, Modify, and Monitor Performance Measures and Metrics CA002.3 Management Review Process ES&H Manual GGR001 Governance Policy HR002 Talent Acquisition Policy HR005 Employee Performance Policy IAEB001 Refer Matters to Ethics, EEO, and Security Incident Management Program Policy ISCM001.2 Supply Chain Risk Management Quality Level Program ISCM001.7 Manage Suspect or Counterfeit Items PPM001 Program and Project Management Policy PRM001 Policy and Requirements Management Policy QA001 Quality Policy QA001.1 Control Nonconforming Products and Services QA002 Calibration Policy SS001 Derivative Classifiers Policy SS002 Identifying Classified Information Policy SS003 Classified Matter Protection and Control (CMPC) Policy SS012 Report Personnel Security Information and Security Incidents Policy	3.1.3	Metrics (See 4.7d for specific reporting)	9.1 9.1.3	Monitoring, measurement, analysis and evaluation Analysis and Evaluation	9.1 9.1.3	Monitoring, measurement, analysis and evaluation Analysis and Evaluation
				3.1 3.1.1 3.1.2	Quality Improvement Continuous Improvement Process Prevention versus Detection	6.2 10.1 10.3	Quality Objectives and planning to achieve them General Continual Improvement	6.2 10.1 10.3	Quality Objectives and planning to achieve them General Continual Improvement
				3.1.3	Metrics				
				3.12 3.12.1 3.12.2	Nonconformance Nonconforming Item Control Nonconforming Item Disposition	8.7 10.1 10.2	Control of Nonconforming Outputs General Nonconformity and Corrective Action	8.7 10.1 10.2	Control of Nonconforming Outputs General Nonconformity and Corrective Action
				3.13	Corrective Action (See 4.7c for associated management responsibilities)	10.2	Nonconformity and Corrective Action	10.2	Nonconformity and Corrective Action
						9.1.2	Customer Satisfaction	9.1.2	Customer Satisfaction

DOE O 414.1D [1] / 10 CFR 830 Subpart A		Laboratory Policy System Procedure		NAP 401.1A		ISO 9001:2015		AS9100D	
4.	**Criterion 4 - Management/ Documents and Records**	**QAPD Section Number**	**Section Title**	**Section Number**	**Section Title**	**Section Number**	**Section Title**	**Section Number**	**Section Title**
4.a **4.b**	Prepare, review, approve, issue, use, and revise documents to prescribe processes, specify requirements, or establish design. Specify, prepare, review, approve, and maintain records.	7.4	COM001 External Communications Policy COM002 Internal Communication Policy ES&H Manual FAC001 Construction Policy HR003 Employee Development Policy IT006 Acquire or Develop and Implement Information Technology Resources Policy IT009 Manage Controlled Documents Policy IT010 Manage Records Policy IT011 Prepare and Release Information Policy IT012 Unclassified Controlled Information Policy IT013 Sandia Proprietary Information Policy IT014 Attorney-Client and Attorney Work Product Privileged Information Policy IT015 Patent Caution Information Policy IT016 Protected Cooperative Research and Development Agreement (PCI) Information Policy IT017 Official Use Only Information (OUO) Policy IT018 Unclassified Controlled Nuclear Information (UCNI) Policy IT019 Safeguards Information (SGI) Policy IT020 Unclassified Naval Nuclear Propulsion Information (U-NNPI) Policy IT021 Privacy Act Information Policy IT022 Export Controlled Information (ECI) Policy IT024 Third-Party Proprietary Information Policy IT023 Personally Identifiable Information (PII) Policy PPM001 Program and Project Management Policy PRM001 Policy and Requirements Management Policy QA003 Configuration Management Policy SS003 Classified Matter Protection and Control (CMPC) Policy SS011 Managing Foreign Government Information (FGI) Policy	3.3.9 3.4 3.5 3.14	Design Records Instructions, Procedures, and Drawings Document Control Records	7.5 7.5.1 7.5.3 7.5.2 8.5.6	Documented Information General Control of Documented Information Creating and Updating Control of Changes	7.5 7.5.1 7.5.3 7.5.2 8.5.6	Documented Information General Control of Documented Information Creating and Updating Control of Changes

DOE O 414.1D [1] / 10 CFR 830 Subpart A		Laboratory Policy System Procedure		NAP 401.1A		ISO 9001:2015		AS9100D	
5.	**Criterion 5 - Performance/ Work Process**	**QAPD Section Number**	**Section Title**	**Section Number**	**Section Title**	**Section Number**	**Section Title**	**Section Number**	**Section Title**
5.a	Perform work consistent with technical standards, administrative controls, and other hazard controls adopted to meet regulatory or contract requirements using approved instructions, procedures, or other appropriate means.	7.5	CA001 Enterprise Risks, Opportunities, Issues Management Policy CA001.2 Identify and Manage Issues EM001 Emergency Planning and Response for Members of the Workforce Policy EM001.1 Actions to Take in an Emergency ESH001 Environment, Safety, and Health Policy ESH001.1 Integrate ES&H into Work Planning and Execution ES&H Manual FAC002 Space Management Policy FAC005 Maintain Buildings and Equipment Policy FAC006 Government Vehicles and Motorized Equipment Policy HR003.3 Maintain Training Compliance HR008 Non-Discrimination and Harassment Free Policy ISCM001.1 Acquire Products or Services ISCM1.5 Purchase Requisition and Purchase OrderISCM001.7 Manage Suspect or Counterfeit Items ISCM004 Manage Property, Materials, and Services Policy ISCM004.1 Manage Property or Materials ISCM004.2 Relocate Property and Materials and Store Items in Corporate Storage ISCM004.3 Manage Precious Metals ISCM004.4 Manage High Risk Personal PropertyIT003 Protect Sandia's Information Technology Resources Policy IT004 Manage Controlled Electronic Devices and Media Policy IT008 Provide Quality Software Policy IT010 Manage Records Policy IT011 Prepare and Release Information Policy PPM001 Program and Project Management Policy QA001 Quality Policy QA001.1 Control Nonconforming Products and Services QA002 Calibration Policy QA003 Configuration Management Policy SS003 Classified Matter Protection and Control (CMPC) Policy SS006 Safeguard Accountable Nuclear Material (ANM) Policy SS007 Controlled and Prohibited Articles Policy SS008.4 Security Badges SS008.5 Security Locks and Keys Process	3.8 3.8.1 3.8.2 3.4	Control of processes Process Control Methods Special Processes Instructions, Procedures, and Drawings	7.1.4 8.5 8.5.1	Environment for the operation of processes Production and Service Control of Production and Service Provision	7.1.4 8.5 8.5.1	Environment for the operation of processes Production and Service Control of Production and Service Provision
								8.5.1.1	Control of Equipment, Tools, and Software
								8.5.1.3	Production Process Verification
5.b **5.c**	Identify and control items to ensure proper use. Maintain items to prevent damage, loss, or deterioration.			3.7 3.7.1 3.7.2 3.7.3 3.7.4 3.7.5 3.7.6 3.7.7 3.11 3.11.1 3.11.2	Identification, Control and Status of Items Identification of Items Control of Items Status of Items Tooling and Fixtures Limited Life Materials and Components Materials or Items Designated for Destructive Testing Special Instructions and Environments Handling, Storage, Packaging and Delivery Government - Furnished Material NNSA - Accepted Material	8.2.2 8.5.5 8.5.2 8.5.3 8.5.4	Determination of Requirements Related to the product and Services Post-delivery activities Identification and Traceability Property Belonging to Customers or External Providers Preservation	8.2.2 8.5.5 8.5.2 8.5.3 8.5.4	Determination of Requirements Related to the product and Services Post-delivery activities Identification and Traceability Property Belonging to Customers or External Providers Preservation
5.d	Calibrate and maintain equipment used for process monitoring or data collection.			3.10	Control of Measuring and Test Equipment	7.1.5	Monitoring and Measuring Resources	7.1.5	Monitoring and Measuring Resources

DOE O 414.1D [1] / 10 CFR 830 Subpart A		Laboratory Policy System Procedure		NAP 401.1A		ISO 9001:2015		AS9100D	
6.	**Criterion 6 - Performance/Design**	**QAPD Section Number**	**Section Title**	**Section Number**	**Section Title**	**Section Number**	**Section Title**	**Section Number**	**Section Title**
6.a	Design items and processes using sound engineering/ scientific principles and appropriate standards.	7.6	CA001 Enterprise Risks, Opportunities, Issues Management Policy CA001.1 Identify and Manage Risks and Opportunities CA001.2 Identify and Manage Issues CA002 Performance Monitoring Policy EM004 Continuity of Operations Policy ESH001.1 Integrate ES&H into Work Planning and Execution FAC001 Construction Policy FAC002 Space Management Policy FAC005 Maintain Buildings and Equipment Policy FAC007 Building Code and Fire Safety Policy HR002 Talent Acquisition Policy ISCM001.2 Supply Chain Risk Management Quality Level Program ISCM1.5 Purchase Requisition and Purchase Order ISCM001.9 Administer a Subcontract ISCM004 Manage Property, Materials, and Services PolicyIT006 Acquire or Develop and Implement Information Technology Resources Policy IT008 Provide Quality Software Policy IT010 Manage Records Policy PC003.1 Respond to an Opportunity or Request for Information (RFI) PPM001 Program and Project Management Policy QA001 Quality Policy QA001.1 Control Nonconforming Products and Services QA003 Configuration Management Policy RD001 Research & Development Integrity Policy	2.4 2.4.1 3.3 3.3.9 3.3.2	Early and Continuous Application of Quality Principles Producibility Design Design Records Design Process	8.1 8.3 8.3.2	Operational Planning and Control Design and Development of Products and Services Design and Development Planning	8.1 8.1.1 8.3 8.3.2 8.1.3	Operational Planning and Control Operational Risk Management Design and Development of Products and Services Design and Development Planning Product Safety
						8.2.1	Customer Communication	8.2.1	Customer Communication
6.b	Incorporate applicable requirements and design bases in design work and design changes.			2.5 3.3.1	Establishing and Validating Requirements (See 4.7d for management responsibilities) Design Input	8.2 8.2.2 8.3.3 8.3.4 8.2.3	Requirements for Products and Services Determination of Requirements Related to the Product and Services Design and Development Inputs Design and Development Controls Review of the Requirements for Products and Services	8.1.2 8.2 8.2.2 8.3.3 8.3.4 8.2.3	Configuration Management Requirements for Products and Services Determination of Requirements Related to the Product and Services Design and Development Inputs Design and Development Controls Review of the Requirements for Products and Services
								8.5.5	Post-Delivery Activities
6.c	Identify and control design interfaces.			3.3.8	Interface Control	8.3.4	Design and Development Controls	8.3.4	Design and Development Controls
6.d **6.e**	Verify or validate the adequacy of design products using individuals or groups other than those who performed the work. Verify or validate work before approval and implementation of the design.			3.3.3 3.3.4 3.3.5 3.3.6 3.3.7	Design Verification Design Reviews Design Qualification Design Documents Design Change Control and Configuration Management	8.3.5 8.3.4 8.3.6 8.2.4	Design and Development Outputs Design and Development Controls Design and Development Changes Changes to Requirements for Products and Services	8.1.2 8.3.5 8.3.4 8.3.6 8.2.4	Configuration Management Design and Development Outputs Design and Development Controls Design and Development Changes Changes to Requirements for Products and Services
7.	**Criterion 7 - Performance/Procurement**	**QAPD Section Number**	**Section Title**	**Section Number**	**Section Title**	**Section Number**	**Section Title**	**Section Number**	**Section Title**
7.a **7.b** **7.c**	Procure items and services that meet established requirements and perform as specified. Evaluate and select prospective suppliers on the basis of specified criteria. Establish and implement processes to ensure that approved suppliers continue to provide acceptance items and services.	7.7	FAC006 Government Vehicles and Motorized Equipment Policy ISCM001.1 Acquire Products or Services ISCM001.2 Supply Chain Risk Management Quality Level Program ISCM001.3 Request Goods Through Fabrication ISCM001.4 Order through Self-Service Procurement (JIT) ISCM001.5 Purchase Requisition and Purchase Order ISCM001.7 Manage Suspect or Counterfeit Items ISCM001.8 Acquire Services of Non-Employees ISCM001.9 Administer a Subcontract PPM001 Program and Project Management Policy	3.6 3.6.1 3.6.2 3.6.3 3.6.4 3.6.5	Procurement (Refer to 4.7c for specific responsibilities) Supplier Evaluation, Selection and Monitoring Procurement Documentation Acceptance of Procured Items, and Materials Acceptance of Procured Services Certificate of Conformance	8.4 8.4.1 8.4.2	Control of Externally Provided Products and Services General Type and extent of control	8.4 8.4.1 8.4.2	Control of Externally Provided Products and Services General Type and extent of control
								8.4.2.c.3	Take into consideration the results of the periodic review of external provider performance (See 8.4.1.1.c)

DOE O 414.1D [1] / 10 CFR 830 Subpart A		Laboratory Policy System Procedure		NAP 401.1A		ISO 9001:2015		AS9100D	
8.	**Criterion 8 - Performance/Inspection and Acceptance Testing**	**QAPD Section Number**	**Section Title**	**Section Number**	**Section Title**	**Section Number**	**Section Title**	**Section Number**	**Section Title**
8.a **8.b**	Inspect and test specified items, services, and processes using established acceptance and performance criteria. Calibrate and maintain equipment used for inspections and tests.	7.8	ISCM001.1 Acquire Products or Services ISCM001.2 Supply Chain Risk Management Quality Level Program ISCM001.9 Administer a Subcontract IT008 Provide Quality Software Policy IT010 Manage Records Policy PPM001 Program and Project Management Policy QA001 Quality Policy QA001.1 Control Nonconforming Products and Services QA002 Calibration Policy SS-R89727, Specific Use Specification, Sandia Software Quality Assurance Program	3.9 3.9.1 3.9.2	Inspection, Test, and Acceptance Inspection and Test Acceptance	7.1.5 8.6	Monitoring and Measuring Resources Release of Products and Services	7.1.5 8.6	Monitoring and Measuring Resources Release of Products and Services
9.	**Criterion 9 - Assessment/Management Assessment**	**QAPD Section Number**	**Section Title**	**Section Number**	**Section Title**	**Section Number**	**Section Title**	**Section Number**	**Section Title**
9.	Ensure that managers assess their management processes, identify, and correct problems that hinder the organization from achieving its objectives.	7.9	CA001 Enterprise Risks, Opportunities, Issues Management Policy CA002 Performance Monitoring Policy CA001.2 Identify and Manage Issues CA002.1 Conduct Internal Assessments CA002.2 Develop, Modify, and Monitor Performance Measures and Metrics CA002.3 Management Review Process ES&H Manual PPM001 Program and Project Management Policy QA001 Quality Policy	3.15 3.15.1 3.15.2 3.15.3 3.15.4 3.15.5 3.15.6 3.15.7	Assessments (See 4.7d for management responsibilities) Management Assessments Independent Assessments Assessor Qualification Scheduling Planning Performance Reporting	9.3 9.3.1 9.3.2 9.3.3 9.1.3	Management Review General Review Input Review Output Analysis and Evaluation	9.3 9.3.1 9.3.2 9.3.3 9.1.3 9.3.2c.8	Management Review General Review Input Review Output Analysis and Evaluation On-time Delivery Performance
10.	**Criterion 10 □ Assessment/Independent Assessment**	**QAPD Section Number**	**Section Title**	**Section Number**	**Section Title**	**Section Number**	**Section Title**	**Section Number**	**Section Title**
10.a 10.b 10.c	Plan and conduct independent assessments to measure item and service quality, to measure the adequacy of work performance, and to promote improvement. Establish sufficient authority and freedom from line management for independent assessment teams. Ensure persons who perform independent assessments are technically qualified and knowledgeable in the areas to be assessed.	7.10	CA001.2 Identify and Manage Issues CA002 Performance Monitoring Policy CA002.1 Conduct Internal Assessments ES&H Manual IAEB001 Refer Matters to Ethics, EEO, and Security Incident Management Program Policy PRM001 Policy and Requirements Management Policy	3.15 3.15.2 3.15.3 3.15.4 3.15.5 3.15.6 3.15.7	Assessments (See 4.7d for management responsibilities) Independent Assessments Assessor Qualification Scheduling Planning Performance Reporting	9.2	Internal Audit	9.2	Internal Audit

[1] DOE O 414.1D calls out in the CRD additional requirements in attachment 2, 3, and 4.
[2] In DOE O 414.1D, direction is provided for determining appropriate consensus standards for developing QAP. Distinction is made for Hazardous Category 1, 2, and 3 nuclear facilities.
GENERAL NOTES:
• This mapping was developed with NAP-24A as the baseline showing associations to 414.1D, 10 CFR 830 Subpart A, ISO 9001:2015, and AS9100D. Because ISO 9001 and AS9100D are more detailed, there may be multiple associations of a given criteria from these standards to the NAP-24A baseline.
• Mapping was intended to show the most direct association; best fit. The user should not assume that associations shown represents perfect 1-to-1 mapping. The actual criteria should be read as the requirements vary in detail from left to right, with DOE O 414/10 CFR 830 being the most general and AS9100D providing the most detail.
• When the highest-level section is noted (e.g. NAP-24A, 5.5), all subsequent subsections apply.
• 10 CFR 830 Subpart B - Safety Basis Requirements is not included in this mapping. Subpart B establishes safety basis requirements for hazard category 1, 2, and 3 DOE nuclear facilities.
• The pink highlighted items identify additional requirements.
• Italicized wording implies paraphrasing of requirements.

Table 5. LPS Cross-Map to DOE O 414.1D Attachment 3, Suspect/Counterfeit Items Prevention

DOE O 414.1D Attachment 3 Requirements	Sandia Procedure/Process
2.a. Include a S/CI oversight and prevention process commensurate with the facility/activity hazards and mission impact.	ISCM001.7, Manage Suspect or Counterfeit Items This is the procedure that is applicable to the entire laboratory. It includes information about reporting, marking, segregating, controlling, investigating, and disposing of suspect or counterfeit items. Additional information included in the process includes training requirements, contacts, resources, and measures and metrics.
2.b. Identify the position responsible for S/CI activities and for serving as a point of contact with the Office of Health, Safety, and Security.	SC-OP-SP-022, Suspect/Counterfeit Items (S/CI) Program Plan (document maintained on SCQMS site which is limited access) This document establishes the Suspect/Counterfeit Items Program Coordinator (SCIPC) as the main point-of-contact for the Laboratories and manages the process that the SCIPC follows.
2.c. Provide for training and informing managers, supervisors, and workers on S/CI processes and controls (including prevention, detection, and disposition of S/CIs).	ISCM001.7, Manage Suspect or Counterfeit Items, discusses requirements for members of the workforce to take S/CI training SC-OP-SP-021, Suspect/Counterfeit Items (S/CI) Training and Communication Plan (document maintained on SCQMS site which is limited access) This document discusses current training available and current methods used for communications.
2.d. Prevent introduction of S/CIs into DOE work by— (1) engineering involvement: a. in the development of procurement specifications; b. during inspection and testing; and c. when maintaining, replacing, or modifying equipment;	This next question can be broken down into a couple of different ways: a. Procurement specifications and terms and conditions go through the process: SC-OP-WI-004, Create, Modify, and Publish Terms & Conditions. b. Inspection and testing requirements for the laboratory are per policy ISCM001.2, Supply Chain Risk Management Quality Level Program c. Maintenance, replacement, and modification operations through procurement would also be per laboratory policy ISCM001.2, Supply Chain Risk Management Quality Level Program for assigning a quality level which would aid in deciding what inspection/test or oversight would be needed for the operations.
Prevent introduction of S/CIs into DOE work by— (2) identifying and placing technical and QA requirements in procurement specifications;	Currently, there is a Suspect/Counterfeit Items clause that is included in the Section II boilerplates of most Sandia procurement contracts. The only contracts that are currently excluded from this clause are the following: • International contracts • Consulting • Services from Sandia Retirees
Prevent introduction of S/CIs into DOE work by— (3) accepting only those items that comply with procurement specifications, consensus standards, and commonly accepted industry practices; and	Laboratory policy ISCM001.2, Supply Chain Risk Management Quality Level Program has created a standardized approach to identifying items that require inspection Labs-wide, which aids in meeting this requirement.
Prevent introduction of S/CIs into DOE work by— (4) inspecting inventory and storage areas to identify, control, and disposition for S/CIs.	Reference RPP-711, Control Material in Production Stores for Nuclear Deterrence groups where this process is very formal; for other groups throughout Sandia processes for inventory control and inspection are much less formal and include more rigorous inspections prior to inventory placement and a quick visual or undocumented inspection when removed from inventory just to verify that the item is still okay for use.
2.e. Include processes for inspection, identification, evaluation, and disposition of S/CIs that have been installed in safety applications and other applications that create potential hazards. Also address the use of supporting engineering evaluations for acceptance of installed S/CI as well as marking to prevent future reuse.	SC-OP-WI-015, Suspect/Counterfeit Items (S/CI) Program Coordinator Handbook and Work Instruction This process details how the Suspect/Counterfeit Items Program Coordinator will process items that are safety critical or have a potential hazard associated. The process runs through the Occurrence Reporting process, Inspector General, all the way through the disposition of the item.
2.f. Conduct engineering evaluations to be used in the disposition of identified S/Cis installed in safety applications/systems or in applications that create potential hazards. Evaluations must consider potential risks to the environment, the public and workers along with a cost/benefit impact, and a schedule for replacement (if required).	ISCM001.7, Manage Suspect and Counterfeit Items and SC-OP-SP-022, Suspect/Counterfeit Items (S/CI) Program Plan (document maintained on SCQMS site which is limited access) Also works with ES&H Coordinators and Subject Matter Experts to perform any evaluations or dispositions of equipment that is or may be installed.
2.g. Perform the evaluation to determine whether S/CIs installed in non-safety applications pose potential safety hazards or may remain in place. Disposition S/CIs identified during routine maintenance and/or inspections to prevent future use in these applications.	ISCM001.7, Manage Suspect and Counterfeit Items and SC-OP-SP-022, Suspect/Counterfeit Items (S/CI) Program Plan (document maintained on SCQMS site which is limited access) Also works with ES&H Coordinators, Subject Matter Experts, Engineering, etc. as applicable to perform any evaluations or dispositions of equipment or items that is or may be installed or continued to be used.
2.h. Report to the DOE Inspector General per paragraph 3. below, and DOE O 221.1A, Reporting Fraud, Waste, and Abuse to the Office of Inspector General, dated 04-19-08 (or latest version).	ISCM001.7, Manage Suspect and Counterfeit Items and SC-OP-SP-022, Suspect/Counterfeit Items (S/CI) Program Plan (document maintained on SCQMS site which is limited access). Items that are found to be S/CI are reported to the OIG. There is proof of this and a log is kept by the Sandia SCIPC for communications with the OIG.
2.i. Collect, maintain, disseminate, and use the most accurate, up to date information on S/CIs and suppliers. Sources are identified on the DOE S/CI website (http://www.hss.energy.gov/sesa/corporatesafety/sci/).	SC-OP-SP-022, Suspect/Counterfeit Items (S/CI) Program Plan and SC-OP-SP-021, Suspect/Counterfeit Items (S/CI) Training and Communication Plan The SCIPC reviews and collects data from various sources to verify that any alerts on suspect or counterfeit materials or suppliers with sales of fraudulent material sales are reviewed against any materials and procurement of materials here at the laboratory. Data sources include GIDEP, ERAI, Consumer Product Safety Commission (CPSC), etc. On average, over 100 alerts for different products or suppliers are reviewed monthly.
2.j. Conduct trend analyses for use in improving the S/CI prevention process.	Trend analysis are conducted quarterly for the S/CI and SCRM Quarterly Meeting and then reviewed with the group. Trends are also reviewed with the S/CI Working Group to see if there are any potential gaps or areas of concern.
3. INSPECTOR GENERAL. Contact the DOE Inspector General (IG), before destroying or disposing of S/CIs and corresponding documentation, to allow the IG to determine whether the items and documentation need to be retained for criminal investigation or litigation.	ISCM001.7, Manage Suspect and Counterfeit Items and SC-OP-SP-022, Suspect/Counterfeit Items (S/CI) Program Plan (document maintained on SCQMS site which is limited access). Items that are found to be S/CI are reported to the OIG. There is proof of this and a log is kept by the Sandia SCIPC for communications with the OIG.
4. OCCURRENCE REPORTING. S/CIs must be reported in accordance with DOE O 232.2, Occurrence Reporting and Processing of Operations Information, dated 08-30-11 (or latest version).	SC-OP-SP-022, Suspect/Counterfeit Items (S/CI) Program Plan and SC-OP-WI-015, Suspect/Counterfeit Items (S/CI) Program Coordinator Handbook and Work Instruction

Table 6. LPS Cross-Map to DOE O 414.1d, Attachment 4, Safety Software Quality Assurance Requirements for Nuclear Facilities

DOE O 414.1D	LPS IT008 and Laboratory Policies and Processes	SSQAP Mapping
Implement QA Criteria as defined in Attachment 2 and the requirements in Attachment 4 for nuclear facilities. This requires that all software meet applicable QA requirements in Attachment 2 using a graded approach.		
MANAGEMENT		
1. Program		
a. Establish an organizational structure, functional responsibilities, levels of authority, and interfaces for those managing, performing, and assessing the work.	LPS IT008, Applicability, Exceptions & Consequences - paragraph 1 LPS IT008, Requirement Tables - All Activities, Responsible Individuals, and Required Actions	Sections 1.2.2, 1.2.3, and 1.3
b. Establish management processes, including planning, scheduling, and providing resources for the work.	LPS IT008, Applicability, Exceptions & Consequences - paragraph 1 LPS IT008, Requirement Tables - All Activities, Responsible Individuals, and Required Actions	Sections 1.2 and 1.2.1
2. Personnel Training and Qualification	LPS IT008 is supported by LPS HR003.1, Design, Develop, and Administer Training	Sections 1.2.1 and 1.2.2 Objective 1
a. Train and qualify personnel to be capable of performing their assigned work.	LPS IT008, Requirements Table - Sponsor Quality Software Activities; Provide Safety Software Training	Section 1.2.2 Objective 1
b. Provide continuing training to personnel to maintain their job proficiency.	LPS IT008, Requirements Table - Document Required Information; Provide Safety Software Training	
3. Quality Improvement		
a. Establish and implement processes to detect and prevent quality problems.	LPS IT008, Requirements Table -Implement Software Quality Processes; Document Required Information	Section 1.2.1
b. Identify, control, and correct items, services, and processes that do not meet established requirements.	LPS QA001.1, Control Nonconforming Products and Services LPS ISCM001.7, Manage Suspect or Counterfeit Items LPS IT008, Implement Software Quality Processes and Document Required Information	
c. Identify the causes of problems and include prevention of recurrence as a part of corrective action planning.	LPS CA002.3, Management Review Process LPS CA001.2, Identify and Manage Issues	
d. Review item characteristics, process implementation, and other quality related information to identify items, services, and processes needing improvement.	LPS IT008, Document Required Information	Section 1.2.2, Process Areas: Verification [VE], Problem Reporting and Corrective Actions [PR], and Collection of Improvement Information [CI]
4. Documents and Records		Section 1.2.2 covers required program documentation as well as requirements for review of documentation from a program-level perspective
a. Prepare, review, approve, issue, use, and revise documents to prescribe processes, specify requirements, or establish design.	LPS IT008, Use a Documented Software Process; Implement Software Quality Processes	Section 1.2.1 covers the process areas as well as the requirement to document the processes for those areas
b. Specify, prepare, review, approve, and maintain records.	LPS IT008, Implement Software Quality Processes - covers documenting the process, ensuring that quality records provide evidence, and the Configuration Management process area, which supports managing information including project records	Section 1.2.1 covers the requirement that quality records must provide evidence that documented practices are being performed
PERFORMANCE		
5. Work Processes		
a. Perform work consistent with technical standards, administrative controls, and other hazard controls adopted to meet regulatory or contract requirements using approved instructions, procedures, or other appropriate means.	LPS IT008, Use the Specific Use Specification, Sandia Software Quality Assurance Program (SSQAP) for Implementation; Ensure Safety Software Satisfies Requirements of a Consensus Standard	Section 1.2 covers policy requirements, process areas, and required program documentation, including consensus standard. It also covers approval by Sandia Field Office and review by NSA. The Policy Requirements at the beginning of section 1.2 states that LPS IT008 requires this
b. Identify and control items to ensure proper use.	LPS IT008, Configuration Management	Configuration Management
c. Maintain items to prevent damage, loss, or deterioration.	This is implicitly covered under Configuration Management, Verification, and Validation in LPS IT008	Configuration Management; see also definition for "Maintained"
d. Calibrate and maintain equipment used for process monitoring or data collection.	When necessary, LPS QA001, Quality Assurance Policy is invoked LPS IT008, Implement Software Quality Processes --> Measurement and Analysis; Document Required Information --> Collection of Improvement Information	Equipment used for process monitoring or data collection rarely requires calibration. Maintenance of processes and tools for data collection would be covered under Measurement and Analysis [MA], Collection of Improvement Information [CI], and Quantitative Measurement [QM] process areas.
6. Design		

DOE O 414.1D	LPS IT008 and Laboratory Policies and Processes	SSQAP Mapping
a. Design items and processes using sound engineering/scientific principles and appropriate standards.	LPS IT008, Implement Software Quality Processes-->Technical Solution; Ensure Safety Software Satisfies Requirements of a Consensus Standard covers standards	For nuclear weapon software, this is covered under DG10235; for nuclear facility safety software, this is covered under NQA-1; for all other software, the SSQAP references the CMMI® as a potential "best practice" engineering methodology for appropriate software development processes
b. Incorporate applicable requirements and design bases in design work and design changes.	LPS IT008, Implement Software Quality Processes-->Technical Solution; the Requirement Table constitutes the applicable requirements	The safety basis for a facility must include its safety requirements and design and analysis results. Design features is listed as one of the Technical Safety Requirements (TSRs). Section B.4.3 discusses the system analysis portion of System/Software Safety Integration. This includes phases involving design activities. Figure B-3 contains a hazard/risk reduction system design process flow diagram. Sections B.5.5, B.5.6, and B.5.7 and the Technical Solution [TS] Process Area also cover this.
c. Identify and control design interfaces.	LPS IT008, Configuration Management	Configuration Management
d. Verify and validate the adequacy of design products using individuals or groups other than those who performed the work.	LPS IT008, Verification and Validation are parts of the section entitled "Implement Software Quality Processes"	Verification [VE] and Validation [VA] Process Areas; Section B.5.8 covers Software Verification and Validation for Safety Software
e. Verify or validate work before approval and implementation of the design.	LPS IT008, Verification and Validation	Verification [VE] and Validation [VA] Process Areas
7. Procurement		
a. Procure items and services that meet established requirements and perform as specified.	LPS IT008 Overview: "This procedure describes the requirements to provide quality software regardless of its source" and one of the sources is procured. The LPS ISCM004 Overview states: "Sandia manages property, materials, and services in a timely and streamlined manner. LPS ISCM001.1 is the same, except it covers the "acquire" part of SCM, whereas LPS ISCM004 covers the "manage" part.	Table 2-2 containing the NQA-1 mapping to LPS IT008 contains a requirement pertaining to procured software and software services that states to apply the same/similar guidance as software produced internally (301) and another requirement to establish standards and convention for developed and procured product (500).
b. Evaluate and select prospective suppliers on the basis of specified criteria.	The LPS ISCM004 Overview states: "Sandia manages property, materials, and services in a timely and streamlined manner.	Supplier Management [SM] in table 2-1; Validation [VA] in Table 3-3 includes Evaluation of selected supplier work products; Stakeholder Involvement [SI] contains supplier/selection/evaluation criteria as work products
c. Establish and implement processes to ensure that approved suppliers continue to provide acceptable items and services.	LPS ISCM004 states in the Overview "Develop and maintain procurement systems and processes that monitor and complete contracts for goods and services".	Section B.3.1.2 states that the supplier is responsible for following all DOE 414.1D safety software requirements in their QAP and meet the requirements of LPS IT008.
8. Inspection and Acceptance Testing		
a. Inspect and test specified items, services, and processes using established acceptance and performance criteria.	LPS IT008, Verification and Validation	Table 2-3 includes Requirement 10 - Inspection and Requirement 14 - Inspection, Test, and Operating Status from NQA-1-2008 Part I, both of which map to Verification and Validation in LPS IT008. NQA-1 also specifically mentions Acceptance Testing (404), which is mapped to Validation in LPS IT008. At the beginning of Table 2-2, Difference 2 states that NQA-1 has a strong focus on acceptance testing to ensure that the product meets its intended use. LPS IT008 uses a defect detection, removal, and prevention approach based on peer reviews as an additional feature to help ensure that a product meets its intended use. Section B.5.8 covers Software Verification and Validation, including Component-Level Testing, Integration Testing, System Testing, and Reliability Testing. Section B.5.9 then covers Installation Testing and Acceptance Testing.
b. Calibrate and maintain equipment used for inspections and tests.	LPS IT008, Implement Software Quality Processes --> Measurement and Analysis; Document Required Information --> Collection of Improvement Information	
ASSESSMENT		
9. Management Assessment		
Ensure that managers assess their management processes and identify and correct problems that hinder the organization from achieving its objectives.	LPS CA002.3, Management Review Process LPS IT008 Section: Conduct a Periodic "Quality Software" Policy Adequacy Review	Section 1.2.2 covers this under Maintenance, stating that a review of the processes is required to be done at least every two years.
10. Independent Assessment	LPS IT008 + LPS CA002.1, Conduct Internal Assessments	
a. Plan and conduct independent assessments to measure item and service quality, to measure the adequacy of work performance, and to promote improvement.	LPS IT008, Report Quality Assurance Issues and Perform Self-Assessments; Assess Safety Software	
b. Establish sufficient authority and freedom from line management for independent assessment teams.	LPS IT008, Report Quality Assurance Issues and Perform Self-Assessments LPS CA002.1, Conduct Internal Assessments	
c. Ensure persons who perform independent assessments are technically qualified and knowledgeable in the areas to be assessed.	LPS CA002.1, Conduct Internal Assessments	

DOE O 414.1D	LPS IT008 and Laboratory Policies and Processes	SSQAP Mapping
DOE ORDER 414.1D ATTACHMENT 4: SAFETY SOFTWARE REQUIREMENTS		
Safety software must be acquired, developed and implemented using ASME NQA-1-2008 with the NQA-1a-2009 addenda (or a later edition), Quality Assurance Requirements for Nuclear Facility Applications, Part I and Subpart 2.7, or other national or international consensus standards that provide an equivalent level of quality assurance requirements as NQA-1-2008. DOE-approved QAPs applicable to safety software based on requirements from DOE O 414.1C are acceptable. The standards used must be specified by the user and approved by the designated DOE approval authority. Management of safety software must include the following elements.	LPS IT008, Ensure Safety Software Satisfies Requirements of a Consensus Standard	Section 1.2.2 and 1.2.3
1. Involve facility design authority in the following for safety software:	LPS IT008, Ensure Safety Software Satisfies Requirements of a Consensus Standard	Section 1.3.4
a. identification of	LPS IT008, Implement Software Quality Processes	Section 1.3.4
b. requirements specification	LPS IT008, Implement Software Quality Processes	Section 1.3.4
c. acquisition	LPS IT008, Use a Documented Software Process; It also states at the beginning: "This corporate procedure applies to all Members of the Workforce who use, acquire or develop and implement software, who acquire and maintain Sandia's information technology infrastructure or who manage those who do."	Section 1.3.4
d. design	LPS IT008, Implement Software Quality Processes	Section 1.3.4
e. development	LPS IT008, Use a Documented Software Process; also see all required actions with Software Developer as a Responsible Individual	Section 1.3.4
f. verification and validation (including inspection and testing)	LPS IT008, Implement Software Quality Processes	Section 1.3.4
g. configuration management	LPS IT008, Implement Software Quality Processes	Section 1.3.4
h. maintenance	LPS IT008, Maintain Safety Software	Section 1.3.4
i. retirement	LPS IT008, Lifecycle Support definition	Section 1.3.4
2. Safety Software Inventory	LPS IT008, Inventory Safety Software	Section 1.2.2 Performance Objective 1, Appendix F.2
a. Identify		Appendix F.1
b. Document		
c. Control		
d. Maintain		
3. Establish and document grading levels for safety software using the graded approach		Section 1.2.2 Performance Objective 1, Appendix D
4. Implement Applicable SSQA work activities from list below	LPS IT008, Implement Software Quality Processes	Section 1.2.2 Performance Objective 2, Appendix B
a. Software project management and quality planning	LPS IT008, Implement Software Quality Processes	
b. Software risk management	LPS IT008, Implement Software Quality Processes	
c. Software configuration management	LPS IT008, Implement Software Quality Processes	
d. Procurement and supplier management	LPS ISCM001, Procurement Policy + LPS ISCM004, Manage Property, Materials, and Services	
e. Software requirements identification and management	LPS IT008, Implement Software Quality Processes	
f. Software design and implementation	LPS IT008, Implement Software Quality Processes	
g. Software safety analysis and safety design methods	LPS IT008, Implement Software Quality Processes	
h. Software verification and validation	LPS IT008, Implement Software Quality Processes	
i. Problem reporting and corrective action	LPS IT008, Document Required Information	
j. Training of personnel in the design, development, use, and evaluation of safety software	LPS IT008, Provide Safety Software Training	Section 1.2.2 Performance Objective 1