



Department of Energy

Washington, DC 20585

June 14, 2010

MEMORANDUM FOR ROXANNE E. PURUCKER
MANAGER, CHICAGO OFFICE
OFFICE OF SCIENCE

FROM: GEORGE J. MALOSH 
DEPUTY DIRECTOR FOR FIELD OPERATIONS
OFFICE OF SCIENCE

SUBJECT: Approval of Revision 2 of the Chicago Office Quality
Assurance Program

Revision 2 of the Chicago Office Quality Assurance Program, dated May 11, 2010, is approved.

If you have any questions or need further information, please contact Matt Cole of my staff at 301-903-8388 or via email at matt.cole@science.doe.gov.

Attachment





U.S. DEPARTMENT OF
ENERGY

Office of
Science

Integrated Support Center
Chicago Office

Quality Assurance Program

May 2010

Roxanne E. Purucker

May 11, 2010

Roxanne E. Purucker, Manager
Office of Science – Chicago Office

Date

George J. Malosh

June 14, 2010

George J. Malosh, Deputy Director for Field Operations
Office of Science

Date

SC-CH Document Revision History

TITLE: Quality Assurance Program

DOCUMENT OWNER: John Adachi, STI-STS

SCMS MANAGEMENT SYSTEM: Quality Assurance & Oversight

EXPIRATION DATE: May 2011

REVISION	DATE	REASON/DRIVER	DESCRIPTION
0	January 2009	Update to align SC-CH QAP with SCMS, and update organization names and position titles.	Include references to appropriate SCMS components. SC-CH QAP was previously maintained in the CH Directives System as an attachment to directive CH O 414.1C; the SC-CH QAP will now be maintained on CH website.
1	January 2010	Update to address ISO 9001-2008.	Include references to SCMS components developed since the previous version of the SC-CH QAP.
2	May 2010	Update to address findings from ISC ISO baseline assessment.	Expand on use of ISO 9001-2008 as selected consensus standard, customer satisfaction feedback, internal independent assessments, responsibilities of the MR, quality management document system.

Table of Contents

Purpose and Scope	1
Overview	1
Local Requirements	2
Quality Management System Documentation	2
SC-CH Quality Policy	3
Quality Objectives	3
Management Commitment	3
Customer Focus	4
QA Criteria	
Management/Criterion 1 – Program	5
Management/Criterion 2 – Personnel training and Qualification	8
Management/Criterion 3 – Quality Improvement	9
Management/Criterion 4 – Documents and Records	10
Performance/Criterion 5 – Work Processes	12
Performance/Criterion 6 – Design	13
Performance/Criterion 7 – Procurement	14
Performance/Criterion 8 – Inspection and Acceptance Testing	14
Assessment/Criterion 9 – Management Assessment	15
Assessment/Criterion 10 – Independent Assessment	16
References	17
SC-CH Quality Management System Document Hierarchy	Attachment

Office of Science - Chicago Office

Quality Assurance Program

PURPOSE AND SCOPE

The Department of Energy's (DOE's) directive on quality assurance (QA), DOE O 414.1C, *Quality Assurance*, requires every Secretarial Officer and Field Element Manager to develop and implement a Quality Assurance Program (QAP) governing the work under their purview. The DOE QA Directive presents upper-level QA criteria, and requires organizations to select and use a national/international consensus QA standard where practicable. The Office of Science (SC) Chicago Office (CH) has selected ANSI/ISO/ASQ Q 9001-2008, *Quality Management System Requirements* (ISO 9001-2008), as its QA standard. The SC-CH Quality Assurance Program (QAP) is a quality management system (MS) description which, when implemented, enables SC-CH to achieve its quality objectives while accomplishing its mission. The goal of the QAP is to achieve continuous improvement while satisfying customer requirements in a cost-effective manner. SC-CH management has ultimate responsibility for implementing the QAP.

The SC-CH QAP applies to all work of SC-CH. SC-CH and SC Oak Ridge Office (ORO) together comprise the SC Integrated Support Center (ISC). The SC ISC provides a broad range of technical, environment, safety and health (ES&H), business, legal and administrative support to SC Site Offices and to SC-Headquarters. In addition to its ISC role, SC-CH is responsible for line management oversight of New Brunswick Laboratory (NBL); that oversight falls under the purview of this SC-CH QAP. This QAP is not applicable to the operations of NBL. NBL is a government-owned government-operated nuclear chemistry analytical laboratory and maintains its own QA Program specifically tailored to its work.

OVERVIEW

SC presents the SC-wide processes by which SC accomplishes work in the Office of Science Management System (SCMS), which is comprised of nineteen MSs, each of which may contain Program Descriptions, Subject Areas, Procedures, and Exhibits. SCMS describes how SC offices perform their work, the authorities it operates within and the management approach to achieve its mission. SC-CH uses SCMS as the fundamental and primary basis for providing customer support and executing its mission and functions.

One of the SCMS MSs is the SCMS QA & Oversight Management System. One of the components of the QA & Oversight MS is the SC-Wide QA Program Description, which provides an overview of how QA is implemented throughout all elements of SC. To satisfy the requirements of DOE O 414.1C, each of the elements of SC (e.g., Site Offices, Support Offices, etc.) maintains and implements a QAP for its work that is consistent with the requirements of DOE O 414.1C as well as the appropriate components of SCMS.

The SC-ISC is pursuing accreditation to ISO 9001-2008. As part of that effort, the ISC Quality Management System Description (QMSD) has been developed to describe how ISO 9001-2008 is implemented by SC-CH and SC-OR for their support role. The ISC QMSD is formatted using the ISO 9001-2008 requirements.

This SC-CH QAP describes how SC-CH implements the Department's ten QA criteria delineated in DOE Order 414.1C while maintaining consistency with the SC-Wide QA Program Description contained in the SCMS QA & Oversight Management System, and the ISC QMSD. It is formatted using the QA criteria of DOE O 414.1C.

Appendix C of the ISC-QMSD provides a detailed crosswalk between DOE Order 414.1C, ISO 9001-2008 and SCMS.

LOCAL REQUIREMENTS

The majority of the processes and procedures necessary for accomplishing the work of SC-CH are contained within SCMS. Select DOE Directives also require site-level documents, and in these situations, SC-CH maintains SC-CH-wide key management documents to satisfy those requirements. These are documents, usually programmatically cross-cutting in scope, which are either required by DOE Directives, Headquarters mandate or the SC-CH Manager to be promulgated and implemented at the SC-CH-wide level.

At the discretion of the responsible Assistant Manager or Division Director, an organization within SC-CH may create organization-specific desk references, standard operating procedures, etc. This level of document specifies requirements solely for that particular organization as a further supplement to higher level protocols; it does not establish requirements for any activity outside that particular organization.

QUALITY MANAGEMENT SYSTEM DOCUMENTATION

The upper level requirements for the quality MS are delineated in DOE O 414.1C. The DOE QA Directive requires the selection and use of a national/international consensus standard to obtain implementation-level requirements. SC-CH uses ISO 9001-2008 as its consensus standard. Therefore DOE O 414.1C and ISO 9001-2008 comprise the primary source of requirements for the SC-CH quality MS.

This SC-CH QAP describes the SC-CH quality MS, and is formatted using the criteria of DOE O 414.1C. The quality MS of SC-CH is comprised of several documents at various levels. The quality MS includes those documented systems and processes identified by SC-CH as needed to assure successful operation in a safe and quality manner.

Numerous SCMS documents serve as components of the SC-CH quality MS. Examples include:

- SC Management System MS
- Quality Assurance and Oversight MS, and its Subject Areas and Procedures
- SC-wide QA Program Description
- SC Line Management Oversight Program Description
- Requirements Management MS, and various Subject Areas and Procedures
- Records Management MS, and various Subject Areas and Procedures
- Human Resources MS, and various Subject Areas and Procedures
- ES&H MS, and various Subject Areas and Procedures
- SC ES&H Functions, Responsibilities and Authorities Manual

The ISC QMSD is a component of the SC-CH quality MS. It is formatted against the structure of ISO 9001-2008.

Documents developed and maintained at the SC-CH-specific level also are components of the SC-CH quality MS. Such documents include:

- SC-CH QA Program
- SC-CH Missions and Functions
- SC-CH Roles & Responsibilities Directory
- SC-CH Performance Planning and Evaluation Procedure
- SC-CH Oversight Program Description
- SC-CH Conducting Assessments Procedure
- SC-CH Preventive and Corrective Action Tracking Procedure
- SC-CH Document Control Procedure
- SC-CH Records Management Procedure
- SC-CH ES&H Functions, Responsibilities and Authorities Manual
- SC-CH Integrated Safety Management System Description
- SC-CH Technical Qualification Program

The attachment presents a graphical representation of the hierarchy of the MS documentation that comprises the overall quality system of SC-CH.

SC-CH QUALITY POLICY

It is the policy of SC-CH to excel at meeting customer expectations and providing high quality products and services. SC-CH will, with the aid of customer feedback, continually improve how we deliver on commitments, meet requirements, and operate in a safe, environmentally-conscious, and cost-effective manner. SC-CH respects and rewards individuals for their contributions to the success of our mission. Methods are employed to confirm customer satisfaction with the services and documents delivered by SC-CH, and implementation of DOE-SC quality requirements.

SC-CH expects this policy to be used in all activities. Management ensures that the quality policy is communicated to each SC-CH organization. The Policy is reviewed at least annually for suitability during Management Reviews.

QUALITY OBJECTIVES

SC-CH has adopted the following Quality Objectives to achieve the goals set forth in the SC Quality Policy:

- Use a customer-focused, process-based approach to managing work,
- Use a factual approach to decision-making,
- Recognize the commonalities and synergy between Integrated Safety Management (ISM), Integrated Safeguards and Security Management (ISSM), Quality Assurance (QA), and Environmental Management System (EMS) by using SCMS;
- Continually improve its products, processes and services; and
- Achieve positive customer satisfaction responses on at least 90% of the feedback received.

SC-CH management periodically reviews organizational performance against these quality objectives and may supplement these objectives as deemed necessary.

MANAGEMENT COMMITMENT

SC-CH management is committed to the belief that by embracing the quality policy, striving to reach the quality objectives, and implementing the QAP, SC-CH will be able to continually improve the services that SC-CH provides its customers. Management ensures that the quality policy and quality objectives are understood and implemented. Management also communicates to its staff the importance of meeting customer as well as statutory and

regulatory requirements. This communication is provided through a variety of methods including office-wide meetings, Manager's announcements, organizational meetings, electronic messages, subject-specific training, employee performance reviews, etc.

CUSTOMER FOCUS

SC-CH focuses on meeting customer requirements through the process of determining what customer needs are, monitoring customer satisfaction, and regular communication. SC-CH's principle customers are SC Site Offices and SC-Headquarters. SC-CH's primary service mission is functional support. Frequent contact helps to ensure customer interfaces are maintained and issues are properly and mutually addressed.

SC-CH customer service efforts include:

- Accurately and specifically identifying our customers;
- Periodically surveying our customers to determine the kind and quality of service they need and their levels of satisfaction with existing services;
- Developing and communicating customer service standards and measure results against them;
- Benchmarking our customer service efforts and results against the best comparable organizations;
- Surveying our employees for ideas on how we can eliminate barriers to better customer service and make improvements;
- Providing our customers, wherever possible, with choices and options regarding the services we provide and how we provide them;
- Working with our customers to elicit information from them in order to improve and provide superior services;
- Making our services and information about them easily accessible; and
- Providing mechanisms for responding effectively to customer feedback and complaints.

Prior to the beginning of every fiscal year, SC-CH develops its Annual Performance Plan (APP), in which goals and commitments for the coming year are established. At the end of the fiscal year, SC-CH assesses itself regarding how well it met the goals and commitments of the APP; this assessment is documented in the Annual Assessment Report (AAR). Annual planning, and the subsequent annual assessment, cannot be adequately performed if our customers' expectations and our customers' satisfaction with the support services we provide are not determined and measured. Therefore obtaining information on our customers' expectations is a key part of the APP process, and obtaining customer satisfaction feedback is a key part of the AAR process. (Reference SCMS Subject Area: Performance Planning and Evaluation)

The following sections describe how the criteria of DOE O 414.1C are implemented by SC-CH. The criterion from DOE O 414.1C is quoted at the beginning of each section. The criterion is followed by a description of the systems SC-CH uses to implement the QA criterion. To avoid repetition, existing processes are referenced rather than repeated in this document.

Management/Criterion 1 – Program

- (a) Establish an organizational structure, functional responsibilities, levels of authority, and interfaces for those managing, performing, and assessing work.
- (b) Establish management processes, including planning, scheduling, and providing resources for work.

The SC-CH QAP applies to all aspects of the work of SC-CH; and applies to every SC-CH organization and employee. It is approved by the SC-CH Manager, and provided to the SC-Deputy Director for Field Operations (DDFO) for review and approval.

DOE establishes requirements in Federal regulations and Department-wide directives. Other requirements relevant to SC-CH work are found in statutes, the regulations of other Federal agencies, and direction from the SC and DOE Staff Offices conveyed through memoranda. SC delineates how it identifies and implements applicable requirements in the nineteen (19) MSs of the SCMS, each of which contain Program Descriptions, Subject Areas, Procedures, and Exhibits. The SCMS program descriptions, procedures and exhibits describe the common processes implemented throughout SC to perform work. The SC QA & Oversight Management System delineates the SC-wide processes by which SC implements the Department's QA and oversight directives. QA applies to all aspects of the work of SC, therefore the SC-CH QAP incorporates by reference many of the SCMS MSs. This SC-CH QAP addresses the applicability of QA-related requirements to the work of SC-CH. SC-CH management may determine it necessary to develop and issue SC-CH specific program descriptions, manuals, procedures, instructions, or responsibility matrices to further detail how certain aspects of work are performed. Such documents are maintained and controlled by the Office of the Manager-Performance Analysis and Evaluation Group (OM-PAE).

Not all items, services, and processes have the same effect on products, deliverables, safety and reliability. The rigor with which the SC-CH QAP is applied is determined using a graded approach. The graded approach focuses on plans, schedules, and processes, and considers cost impacts by considering the following:

- customer needs, requirements, and expectations;
- complexity of products/processes/services;
- the relative importance to safety, safeguards, security and cyber-security;
- the magnitude of any risk or hazard involved;
- potential impact/consequences on the programmatic mission;
- adequacy of existing documentation;
- performance history;
- regulatory drivers; and
- any other relevant factors.

SC-CH documents its objectives, goals, and commitments for the coming fiscal year in its APP. SC-CH APP is supportive of the annual SC-wide objectives and goals that relate to our work. The SC-CH-wide objectives, goals, and commitments are flowed down to the divisions of SC-CH, and ultimately into the performance plans of every Senior Staff member, Division Director, supervisor, team leader, and staff member of SC-CH.

The current organizational chart of SC-CH is maintained on the SC-CH website. Responsibilities, authorities, and interfaces for the management, performance, and assessment of work are delineated in the MSs, program descriptions, subject areas, and procedures of the SCMS. Functions, responsibilities and authorities within SC-CH that are related to Integrated Safety Management (ISM) and the protection of the environment, safety and health (ES&H) are delineated in the SC-CH Functions, Responsibilities and Authorities Manual (CH FRAM). SC-CH maintains a SC-CH Roles and Responsibilities Directory that extends the FRAM concept beyond ISM/ES&H to all aspects of SC-CH work.

SC-CH is an element of SC, therefore our primary organizational interface in DOE-Headquarters is with the SC DDFO/SC-3. SC-CH, together with SC-OR, comprise the SC ISC to provide the SC Site Offices with technical and business management services that aid the Site Offices in achieving their mission objectives. SC-CH management and staff interface and coordinate with their counterparts at SC-OR to ensure delivery of the support services requested by the Site Offices.

The SC-CH Manager is ultimately responsible for the quality of work performed by the staff of SC-CH. While authority may be delegated, the associated responsibility cannot. With responsibility and authority comes accountability. The SC-CH Manager holds each Senior Staff member accountable for the quality of work performed by his/her organization. The SC-CH Senior Staff holds their direct reports accountable for the quality of work performed by his/her division. When delegating an authority, the cognizant SC-CH management official must consider whether the position and expertise of the delegate is suitable for carrying out the delegated authority. Delegations of authority must be codified in appropriate documents such as position descriptions, SCMS MSs, subject areas, procedures, and/or program descriptions, the SC-CH FRAM, division-specific procedures, etc.

The role of the Management Representative (MR) as defined by ISO 9001-2008 resides in OM-PAE; therefore the MR has access to top SC-CH management.

Senior Staff members appoint members of their staff to serve as their organization's Quality Assurance Representative (QAR). QARs may be appointed to represent an entire Assistant Manager's organization, or may be appointed to represent a division; this determination is based upon factors such as the size, variety and complexity of the work of the organization. QARs support their Assistant Manager / Director / Officer in their implementation of the SC-CH quality MS, and support the SC-CH MR in the SC-CH wide QA activities.

Key responsibilities of SC-CH personnel regarding the implementation of this SC-CH QAP are described below.

a. SC-CH Manager

- (1) Approves the SC-CH QAP.
- (2) Submits the SC-CH-approved SC-CH QAP to the SC DDFO for review and approval.

b. SC-CH ISO 9001-2008 Management Representative (MR)

- (1) Ensures that processes needed for the quality MS are established, implemented and maintained.
- (2) Reports to the SC-CH Manager on the performance of the SC-CH quality MS and any need for improvement
- (3) Ensures the promotion of customer requirements throughout SC-CH.
- (4) Ensures that the SC-CH QAP is maintained current.

- c. SC-CH Senior Staff¹
 - (1) Implements the SC-CH QAP to ensure that the work of his/her office meets or exceeds their customers' quality-related requirements and expectations.
 - (2) Establishes and implements documented mechanisms for obtaining, analyzing, and acting on customer feedback.
 - (3) Determines whether group-specific QA-related plans, manuals, procedures and/or instructions for the work of his/her office would be beneficial. If so, develops, approves, and implements the office-specific documents and ensures they are consistent with this SC-CH QAP and relevant regulations, statutes, directives, and SCMS.
 - (4) Appoints QARs for their organization.
- d. SC-CH Quality Assurance Representatives (QARs)
 - (1) Support their organization's efforts to implement the SC-CH quality MS.
 - (2) Supports the SC-CH MR's efforts for SC-CH wide QA activities.
- e. SC-CH QA Engineers/Specialists
 - (1) Provide expertise and assistance to the SC-CH ISO 9001-2008 MR on the development and maintenance of quality MS documentation.
 - (2) Provide expertise and assistance to SC-CH Senior Staff members on implementation of the quality MS.
- f. SCMS Management System Owners (MSOs) and Secondary MSOs that Reside at SC-CH, and appropriate Subject Matter Experts (SMEs)
 - (1) Determines whether staff training on their components of SCMS is necessary; and if so develop and deliver the training.
 - (2) Determines whether changes to their portion of SCMS impacts the SC-CH quality MS.
 - (3) Communicates the impact(s) to the cognizant SC-CH document owner and works with them on the necessary document revisions.
- g. All SC-CH Employees
 - (1) Implements the SC-CH QAP as it applies to their work.
 - (2) Communicates to their supervisor and team leader any problems that hinder them from successfully accomplishing their work.

¹ The SC-CH Senior Staff is comprised of the Deputy Manager, Assistant Manager for the Office of Safety, Technical and Infrastructure Services, the Assistant Manager of the Office of Acquisition and Assistance, the Chief Counsel, the Chief Financial Officer, the Chief Information Officer, the Human Capital Officer, and the Performance Analysis and Effectiveness Officer.

Management/Criterion 2 – Personnel Training and Qualification

- (a) Train and qualify personnel to be capable of performing assigned work.
- (b) Provide continuing training to personnel to maintain job proficiency.

All supervisors within SC-CH are expected to assure that their employees are qualified to perform their assigned duties. Initial training and qualification requirements are established for each job position. The Federal hiring process ensures that new employees have the knowledge, abilities, and experience necessary for the duties described in their position description.

Supervisors work with their employees to determine any training, continuing education, and/or developmental assignments needed to maintain competencies, or to obtain new competencies that become necessary as processes and/or technology for current duties evolve, and/or new job responsibilities are added. Supervisors work with their employees and Human Resources Services (HRS) to ensure that personnel receive the appropriate continuing training. The mechanism known as an Individual Development Plan (IDP) is used by the employee and his/her supervisor to plan, document, and track these training activities. The IDP process is governed by SC-CH HRS.

SC-CH employees are subjected to periodic mandatory training on a wide variety of topics, such as ethics, cyber-security, security and counter-intelligence.

SCMS MSOs and SMSOs that reside within SC-CH, and appropriate SCMS SMEs and Points-of-Contact (POCs), determine whether SC-CH employees need training on the portions of SCMS for which they are responsible. If so, they develop the training and coordinate with SC-CH management to deliver the training to the appropriate audience of SC-CH employees.

Many job positions are required to participate in the various DOE qualification certification programs established for their area of expertise, such as the Technical Qualification Program (TQP) for ES&H, QA, and engineering disciplines; the Project Management Certification System (PMCS) for project managers; the Realty Officer/Specialist certification program; and the Contracting Officer certification program. DOE-wide qualification standards are established for these areas of expertise. SC-CH employees participate in these qualification/certification programs.

Attainment of oversight skills by SC employees is addressed in the Oversight Skills Subject Area of the SC QA & Oversight MS. The training and certification of personnel is further described in DOE directives and in the SC Human Resources Services Management System.

SC-CH employees are required to read this SC-CH QAP upon issuance and revision. In addition, all SC-CH employees are required annually to take QA training/refresher training.

Management/Criterion 3 – Quality Improvement

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

The SC-CH management approach to promoting continuous improvement is to instill a culture in which every employee believes that he or she can make a difference in the quality of products and services. To ensure success, a “no fault” attitude is fostered that encourages employees to participate in identifying and solving problems, and suggesting improvements. The processes used to implement this approach are described in SCMS and in the SC-CH Oversight Program Description.

Processes for detecting quality problems and opportunities for improvement are presented in the SCMS Assessments Subject Area, Operational Awareness Subject Area, Approval of Federal and Contractor Assurance Systems and Evaluation of Implementation Effectiveness Subject Area, Review and Approval of DOE and Contractor QA Program Descriptions Subject Area, Performance Trending Subject Area, Corporate Operating Experience / Lessons Learned Subject Area, SC Performance Planning and Evaluation Subject Area, and the Line Management Oversight Program Description of the SC QA & Oversight MS. Quality problems and opportunities for improvement of work output or work processes of SC-CH organizational units, identified by SC-CH employees, are brought to the attention of the cognizant Senior Staff member through the established chain of command.

SCMS provides a mechanism for any user to submit comments and suggestions for improvements on the various components of SCMS. SCMS is a web-based system. The webpage of each SCMS document (MS descriptions, subject areas, procedures, and program descriptions) contains a “comment button” that provides a direct path for electronically submitting comments to the document “owner”. The process requires the document owner to provide resolution to each submitted comment. In addition, SCMS requires MSOs and Subject Area POCs to review, and revise as necessary, their SCMS documents on an annual basis. These features of SCMS drive continuous improvement of the SCMS documents.

The conditions or circumstances associated with quality problems and opportunities for improvement of SC-CH work processes and/or services are evaluated by the cognizant Senior Staff member with the assistance of their organization’s QAR, and appropriate corrective and preventive actions are devised and implemented. Corrective actions address the identified problem as well as preventing recurrence of the problem. Preventive action is action taken to prevent a problem from occurring. The Issues Management Subject Area of the SCMS QA & Oversight MS delineates the processes for causal analysis, corrective and preventative action development, and tracking actions through completion and verification. Formally identified actions to improve quality are tracked to closure using various action tracking systems, depending on various considerations such as the entity that initiated the finding that necessitated the action, and the discipline or function that the action addresses. Action tracking systems include the DOE CATS for actions responding to findings cited through assessments performed by the DOE Office of Independent Oversight within the Office of Health, Safety, and Security (HSS-OIO) or the DOE Office of Aviation

Management, and Type A accident investigations; SSIMS for security-related actions; CAIRS for reportable injuries; ORPS for occurrences; and/or the SC-CH SMART tool for corrective actions for SC-CH internally identified issues. SC-CH implementing procedures provide further details and guidance on the use of these systems within SC-CH.

Implementation of the ISO 9001-2008 Management review requirements, as described in the SC-CH Oversight Program Description, contributes to quality improvement efforts. Data on performance indicators and the status of on-going improvement activities are reviewed during Quarterly Management Review meetings. This can aid in identifying potential improvement activities and assessment focus areas, which in turn can drive further quality improvement.

The SC-CH Operating Experience Program objective is to share information from Federal and contractor work activities and industry experience that may be useful in preventing adverse events or in improving performance. The distribution of operational experience/lessons learned generated with the SC-CH workplace and outside SC-CH are necessary to satisfy the DOE requirements for feedback and improvement. Lessons learned are shared as widely as possible to promote positive recurrence or to avoid negative recurrence. Lessons learned are collected from all available sources, including DOE, its contractors and subcontractors, other government agencies, and private industry. The requirements for feedback and continuous improvement are found in 48 CFR 970.5223-1, *Integration of Environment, Safety, and Health into Work Planning and Execution*, and DOE P 450.4 *Safety Management System Policy*. Additional guidance can be found in Chapters II and III of DOE G 450.4-1B, *Integrated Safety Management System Guide*. The SC-CH Operating Experience and Lessons Learned Program is based on the DOE Order 210.2 *DOE Operating Experience Program* and DOE Standard (STD) 7501-99, *The DOE Corporate Lessons Learned Program*.

DOE O 414.1C contains specific requirements for the control of software that performs a safety function at nuclear facilities, and for the prevention of the introduction of suspect/counterfeit items (S/CI) to DOE facilities. As an element of the SC-ISC, SC-CH does not procure critical equipment or hardware that necessitates S/CI prevention measures, nor does it operate, develop, or control nuclear safety software.

Management/Criterion 4 – Documents and Records

- (a) Prepare, review, approve, issue, use, and revise documents to prescribe processes, specify requirements, or establish design.
- (b) Specify, prepare, review, approve, and maintain records.

Requirements that govern SC-CH's work are delineated in Federal regulations and statutes, DOE directives, and direction conveyed through memoranda from DOE-Headquarters. SC makes use of the various systems maintained by entities outside of SC to control documents, such as the DOE-wide RevCom system used to control DOE directives. The SCMS Requirements Management MS delineates the processes by which requirements are managed within SC, and establishes requirements for the control of SCMS documents as well as for control of non-SCMS documents. The MSs, subject areas, procedures, and program descriptions of SCMS delineate the processes by which work is performed throughout SC. SCMS exists on a web-based platform. Only the most current approved versions of SCMS documents are posted on the SCMS website. This is the mechanism by which SC management controls the document configuration of SCMS and provides its staff with the current approved revision of SCMS documents used in the performance of work.

SC elements, including SC-CH, may find it useful to develop and maintain documents that further describe the methods and responsibilities for executing the processes delineated in SCMS. The Subject Area Document Control Management within the Requirements Management MS delineates the processes by which non-SCMS documents are controlled. Examples of such SC-CH specific documents include the SC-CH ES&H Functions, Responsibilities and Authorities Manual (FRAM), the SC-CH Integrated Safety Management System Description, and this SC-CH QAP. The mechanism used by SC-CH management to control the configuration of SC-CH-wide documents, and ensure that SC-CH staff are provided the current approved version of the documents, is maintenance of the document on the internet-based SC-CH Information Portal (CHIP), which is also accessible through the SC-CH Gateway.

SC-CH organizational units may determine that very important and/or very complex and unique processes merit documentation through office-specific procedures or instructions. Such office-specific Standard Operating Procedures (SOPs) are maintained by the particular office. Such organization-specific documents must be afforded the control measures specified in SCMS Document Control Subject Area of the Requirements Management MS. Configuration control for the SC-CH organization-specific documents is provided by maintaining the documents on an organization-specific segment of CHIP.

SC-CH has appointed a Document Manager, who resides within OM-PAE, to ensure implementation of document control requirements throughout SC-CH.

DOE has identified record retention requirements in the CFR and in DOE directives. The MSs, subject areas, procedures, and program descriptions of SCMS specify the records that must be prepared, reviewed, approved, and maintained when executing the processes delineated in SCMS. The SCMS records system ensures records are specified, prepared, reviewed, approved, and maintained to accurately reflect completed work and include the following features:

- Provisions for the retention and disposition of records to satisfy the requirements of DOE O 200.1A, *Information Management Program*, and the National Archives and Records Administration's methods to preclude unauthorized access to SC-CH records;
- Provisions for record storage areas that minimize the risk of damage from natural disasters and environmental conditions;
- Methods for maintaining record accountability;
- Provisions for the retrieval of records; and
- Provisions that ensure records are legible, accurate, complete, and traceable to the activities to which they apply.

Quality records are those records and documents that demonstrate implementation of the quality MS. Quality records, along with all other records generated by SC-CH, are controlled and maintained in accordance with the SC Records Management MS.

The SC Records Management MS provides the SC-wide records management processes of SC. The SC-CH DocLog System, which is a module of the SC-CH SMART database, is used by SC-CH to distribute, track and retain records such as correspondences and other media received or generated. Each division within SC-CH maintains the records they generate, in accordance with the requirements of SCMS.

SC-CH has appointed a Records Manager, who resides within OM-PAE, to ensure implementation of records management requirements throughout SC-CH.

Performance/Criterion 5 – Work Processes

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

SC-CH's work is planned, authorized, and performed by technically competent individuals who provide leadership, direction, and oversight. Work processes are performed using SCMS documents and SC-CH specific documents that translate regulatory requirements, DOE Directives, and consensus technical standards, into implementation-level processes, procedures, and instructions commensurate with the complexity and importance of the work being performed (i.e., graded approach).

Work output is reviewed to ensure the expected level of quality is achieved and to identify areas needing improvement.

As an element of the SC-ISC, SC-CH performs a broad range of administrative, business, legal, security, safety, and technical services for the SC Site Offices and SC-Headquarters. The work processes implemented by the various SC-CH divisions to deliver such services are set forth in the subject areas, procedures, and program descriptions of the MSs of SCMS. The purpose, scope, and design of SCMS are presented in the Office of Science Management System (SCMS) Management System Description. SCMS delineates work processes in the areas of:

- management of SCMS
- requirements management
- QA and oversight
- human resources
- legal services
- records management
- communications and public affairs
- budget and finance
- financial assistance
- M&O contracting
- non-M&O contracting
- information technology
- personal property
- real property
- project management
- program management

- ES&H
- safeguards and security
- facilities and infrastructure

SCMS delineates work processes that are common across all elements of SC, and address all of the major Federal functions of SC (SCMS does not apply to the work of SC's contractors). Management of particular SC-CH divisions may determine that their implementation of particular processes would benefit from more detailed instructions or guidance than what is provided in SCMS. Such additional instruction/guidance is documented in division-specific procedures, manuals, or desk instructions. Such documents are applicable solely to the promulgating organization and cannot specify requirements for entities outside the issuing organization.

As a support services provider for the SC Site Offices and SC-Headquarters, and line management oversight of NBL, SC-CH does not produce a physical product. Therefore SC-CH does not maintain/control items that are used in the production of physical products, nor does SC-CH employ process monitoring and data collection equipment that contribute to the production of a physical product. SC-CH does not have line management responsibilities/authorities related to suspect/counterfeit items prevention (refer to DOE O 414.1C Attachment 3), or for ensuring that safety software in nuclear facilities performs its intended safety functions (refer to DOE O 414.1C Attachment 5).

Performance/Criterion 6 – Design

- (a) Design items and processes using sound engineering/scientific principles and appropriate standards.
- (b) Incorporate applicable requirements and design bases in design work and design changes.
- (c) Identify and control design interfaces.
- (d) Verify/validate the adequacy of design products using individuals or groups other than those who performed the work.
- (e) Verify/validate work before approval and implementation of the design.

SC-CH does not directly perform the design of structures, facilities, equipment, assemblies, subassemblies, components, parts, material, systems, subsystems, software or hardware. SC-CH involvement in the design of physical items is through the project management process; such involvement is typically focused on the oversight of design activities performed by contractors or a GOGO entity. Refer to the SC Project Management MS. Design of computer software and information technology (IT) systems is typically performed by contractors, and SC-CH involvement is limited to oversight of the contractor's work. Refer to the SC Information Technology MS.

Performance/Criterion 7 – Procurement

- (a) Procure items and services that meet established requirements and perform as specified.
- (b) Evaluate and select prospective suppliers on the basis of specified criteria.
- (c) Establish and implement processes to ensure that approved suppliers continue to provide acceptable items and services.

The SC-CH Office of Acquisition and Assistance (ACQ) is the SC Center of Excellence for Financial Assistance Instruments used to fund research at hundreds of universities across the country. Procurement actions carried out by SC-CH are conducted in accordance with requirements delineated in the Federal Acquisition Regulation (FAR), the DOE Acquisition Regulation (DEAR), DOE Acquisition Guide, DOE Directives, SCMS (i.e., Financial Assistance MS, Real Property Management MS, Non-M&O Contracting MS, M&O Contracting MS) and procedures/instructions maintained by the SC-CH ACQ.

SC-CH's procurement processes provide for the evaluation of quotations, bids, and proposals; and methods for accepting procured services (e.g., review of technical data provided, review of objective evidence for conformance to procurement documents, and evaluation of the services provided). SC-CH's procurement documents identify the performance requirements that must be fulfilled by the supplier/contractor. These requirements are specified in a results driven manner. SC-CH's procurement documents are reviewed to ensure the following provisions are included, as applicable to the service or product being procured:

- Technical Requirements – Applicable technical requirements (e.g., specifications, codes, and standards) are specified in or referenced by specific DOE Directives, regulations, or procedures.
- QA, ES&H, and Security Requirements – Applicable QA, ES&H, and security requirements are developed using a graded approach considering the hazards and risks characteristic of the work while also considering contract type.
- Right of Access – The procurement documents specify allowances for access to the supplier/contractor facilities and records for the purpose of evaluation.
- Documentation Requirements – Applicable document requirements are identified.

Performance/Criterion 8 – Inspection and Acceptance Testing

- (a) Inspect and test specified items, services, and processes using established acceptance and performance criteria.
- (b) Calibrate and maintain equipment used for inspections and tests.

SC-CH does not produce hardware items, therefore there are no items to be inspected or tested, nor are there measuring and testing equipment that must be calibrated and maintained. The IT support contractor monitors and tests the IT equipment and systems used by SC-CH staff; the IT contractor's work is subjected to oversight by SC-CH Federal staff (refer to the SC Information Technology MS). SC-CH provides support services to SC Site Offices and SC-Headquarters, and performs line management oversight of NBL. The support services for SC Site Offices may include oversight of contractors performing inspection and acceptance testing, and the SC-CH line management oversight of NBL includes oversight of NBL's performance of acceptance testing and inspection activities; however SC-CH is not responsible for accomplishment of inspection and/or acceptance

testing. Some support tasks include the production of documentation and/or records, such as plans, procedures, and reports. SC-CH management, in consultation with SC-CH's customers and in concert with the requirements set forth in SCMS, establishes expectations for these services, conveys the expectations to the staff, and checks the staff's work prior to delivering services to the customer.

Assessment/Criterion 9 – Management Assessment

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

Components of the SC QA & Oversight Management System, in particular the Line Management Oversight Program Description, the Assessments Subject Area, and the SC Performance Planning and Evaluation Subject Area, delineate the processes by which management/self-assessments are planned, performed, and reported throughout SC. The Issues Management Subject Area delineates the processes by which the output (i.e., findings) of management/self-assessments of SC Offices is addressed. The SC-CH Oversight Program Description provides SC-CH specific information on the implementation of the SCMS Assessment Subject Area and the ISO 9001-2008 requirements for management review.

The SC-CH management team reviews its implementation of the quality MS and the commitments made in the APP through the Quarterly Management Reviews, which culminate each year in the Management Review documented in the SC-CH Annual Assessment Report (AAR).

Inputs to the management review include:

- Results of audits;
- Customer feedback;
- Process performance and product conformity;
- Status of preventative and corrective actions;
- Follow-up actions from previous management reviews;
- Changes that could impact the quality MS;
- Recommendations for improvement.

Outputs from the management review include decisions and actions related to:

- Improvement of the effectiveness of the quality MS;
- Improvement of products related to customer requirements;
- Status of meeting the commitments contained in the APP;
- Resource needs.

Other mechanisms, such as the Federal Management Financial Integrity Act (FMFIA) process, Contingent Liabilities reporting, and Freedom of Information Act/Privacy Act and Ethics reporting also serve as forms of management/self-assessment.

Each Senior Staff member conducts an annual management/self-assessment of processes used to perform work, and the quality/adequacy of the resulting work products, of his/her office. The *SC-CH Oversight Program Description* guides the establishment of assessment criteria and methods (observations, document/records reviews, interviews) used in the performance of the management/self-assessment. Results of the management assessments are documented and a copy of the report is provided to the SC-CH Manager. Problems or issues identified in the management/self-assessment must be resolved.

Actions to correct the problem, as well as prevent recurrence, are instituted as necessary. Corrective actions are tracked to completion in the SMART database, and a follow-up review is performed to assess the effectiveness of the corrective actions. Corrective action development, causal analysis, action tracking, and effectiveness verification are accomplished in accordance with the Issues Management Subject Area. Each Senior Staff member keeps the SC-CH Manager informed of corrective action status and effectiveness.

Assessment/Criterion 10 – Independent Assessment

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

SC-CH management recognizes the value of an occasional review by an independent set of eyes. Therefore SC-CH fully supports and cooperates with the efforts of external oversight groups, and their input regarding opportunities to improve SC-CH's processes and work output is given due consideration. SC-CH ensures that external oversight personnel are afforded access to facilities, staff, documents, and records necessary for accomplishment of the oversight.

SC-CH plans and conducts internal independent assessments as described in the SC-CH Oversight Program Description. The SC-CH Manager scopes, schedules and commissions internal independent assessments or audits to evaluate the effectiveness and efficiency of SC-CH work processes, the quality of work output/products, and to identify problems that are hindering SC-CH from meeting its goals, objectives, and commitments. The scope of internal independent assessments is determined by the SC-CH Manager using risk-based considerations. The SC-CH internal independent assessments/audits are performed by persons that are knowledgeable of the work being assessed but are not directly responsible for the accomplishment of that work.

SC-CH internal independent assessments/audits are accomplished in accordance with the SCMS components addressed in the previous section of this QAP. Problems and issues identified through such independent assessments are resolved and corrective or improvement actions are developed and implemented. The results of such independent assessments are documented and a copy of the report is provided to the SC-CH Manager.

As stated on Page 1 of this QAP, in addition to our primary role as a component of the SC ISC of providing technical and business/administrative services to SC Site Offices, SC-CH has also been assigned responsibility for performing line management oversight of NBL on behalf of the SC-DDFO. In that capacity, SC-CH plans and performs independent oversight of all aspects of NBL's operations. This oversight of NBL is accomplished through formal (Facility Representative operational awareness activities, and structured assessments of applicable functional areas/disciplines) and informal (periodic meetings and routine interactions) means; this is further described in the SC-CH Oversight Program for New Brunswick Laboratory (dated September 24, 2008).

REFERENCES: The following documents provide guidance related to QA. The revision status indicated below for these reference documents was current at the time this SC-CH QAP was developed. The latest revision of the reference document should be used.

- a. DOE O 414.1C, *Quality Assurance*, dated 06-17-05.
- b. DOE G 414.1-2A, *Quality Assurance Management System Guide for Use with 10 CFR 830 Subpart A, Quality Assurance Requirements, and DOE O 414.1C, Quality Assurance*, dated 06-17-05.
- c. DOE G 414.1-1B, *Management Assessment and Independent Assessment Guide for use with 10 CFR Part 830 Subpart A, and DOE O 414.1C, Quality Assurance; DOE M 450.4-1, Integrated Safety Management System Manual; and DOE O 226.1A Implementation of DOE Line Oversight Policy*, dated 09-27-07.
- d. DOE M 411.1-1C, *Safety Management Functions, Responsibilities, and Authorities Manual*, dated 12-31-03.
- e. DOE O 226.1A, *Implementation of Department of Energy Oversight Policy*, dated 7-31-07.
- f. DOE P 450.4, *Safety Management System Policy*, dated 10-15-96.
- g. Office of Science Management System (SCMS)
- h. SC-ISC Quality Management System Description
- i. ISO 9001-2008 *Quality Management Systems – Requirements*

SC-CH Quality Management System document hierarchy integrates quality and safety management systems.

DOE Quality Assurance (QA) Directive objective: "To achieve quality assurance for all work." Safety Management System Policy is to "systematically integrate safety into management and work practices at all levels."

ISO 9001 was chosen by SC to meet DOE Order 414.1C requirement for QA Programs to use an international consensus standard.

SCMS QA and Oversight MS and Environment Safety and Health MS outline the roles, responsibilities and key functions for SC Federal employees to implement SC QA, Oversight and ES&H requirements.

SC's Program Descriptions are high-level documents that cross Management Systems, consolidate responsibilities and accountabilities, and are required to meet DOE Directive requirements.

ISC's Quality Management System Description describes policy, objectives and quality-based work processes, common to the SC-CH and SC-OR Offices of the ISC, to meet requirements and customer expectations.

SC-CH QA Program Description governing the work under SC-CH purview.

SCMS Subject Areas and Procedures deliver SC-wide work procedures that implement requirements.

SC-CH local implementing documents provide details of SC-CH processes, functions, responsibilities and authorities.

