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DOE HANDBOOK

WORK SMART STANDARDS (WSS) USERS HANDBOOK

U.S. Department of Energy
Washington, D.C. 20585

MGMT-0002

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Appendix H - Request for approval of the WSS set and the final approval document used during the N&S Process conducted at the Fermi Laboratory.

Appendix I - The procedure for managing change control of laboratory operating standards and requirements (including the WSS set) at the Los Alamos National Laboratory.

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FOREWORD

A set of Work Smart Standards (WSS) is the product of the Necessary and Sufficient Closure Process. This Handbook provides amplification, practical examples, and cross references to assist users in the application of the Necessary and Sufficient (N&S) Closure Process within the context of the Integrated Safety Management System (ISMS)[1]. This Handbook is based on practical experience and lessons learned in applying the Process across the DOE complex over the course of four years. It reflects not only the collective principles of the ISMS and the N&S Process, but the applied knowledge of many people who have successfully used the Process in a variety of applications.

The N&S Process is based on the same safety philosophy as prescribed for DOE's Integrated Safety Management System which begins with a thorough understanding of the work and associated hazards. Within the contractual framework of ISMS, DEAR 970.5204-78, *Laws, regulations, and DOE directives*, requires contractors to use a DOE approved process to identify environment, safety and health (ES&H) requirements appropriate for work and the associated hazards. The N&S Process provides a DOE approved means of identifying sets of standards that, when properly implemented, will provide reasonable assurance of adequate protection of workers, the public, and the environment.

The N&S Closure Process can be used for the identification of standards in situations where there exists significant uncertainty: about the definition of the work; the nature of the hazards associated with a piece of specific work definition; or in regard to what work plan(s) can provide the assurance of adequate protection from those hazards. Significant uncertainty may exist simultaneously in all these aspects of standards identification and approval. Accordingly, the N&S Closure Process incorporates features that are intended to systematically build confidence in the resulting WSS set. Confidence is created during the course of recognizing, eliminating or mitigating the potential effects of the various uncertainties that arise from the need to do the specific work.

[1]In this Handbook, consistent with Department practice, "The Integrated Safety Management System" or "Integrated Safety Management" is spelled out or designated as either ISMS or ISM. "The Necessary and Sufficient Closure Process" is referred to as the N&S process or simply the process.

The N&S Process depends on the cooperative agreement and engagement of all affected parties. The commitment of senior managers, participation by workers, and input from Stakeholders and Interested Parties are all essential elements in successful N&S Process applications. The means of successfully achieving these goals and the techniques used in doing so will vary substantially among different applications. DOE P 450.3, *Authorizing Use of the Necessary and Sufficient Process for Standards-Based Environment, Safety, and Health Management*, permits flexibility in developing and implementing standards. DOE M 450.3-1, *The Department of Energy Closure Process for Necessary and Sufficient Sets of Standards (*the N&S Manual), states basic requirements for the Process and is the primary source document. The contents of this Handbook are not additional requirements. This Handbook is not written to stand alone, but relies on its users to be knowledgeable of the N&S Manual and committed to its requirements.

Both the N&S Manual and this Handbook are components of the overall knowledge base concerning the N&S Process. The Department Standards Committee (DSC) provides authoritative information about the N&S Process on the Work Smart Standards web site, located at:

http://tis.eh.doe.gov/dsc/worksmart.html

This Handbook identifies and discusses a selection of significant information on this web site and identifies where to locate specific items of interest. Users about to assume responsibilities in the N&S Process, or contemplate using the Process, are encouraged to carefully review the web site in its entirety. Process participants should confer with appropriate line management for any additional assistance. Further support to line management is available from the collective experience of the DSC.

The initiation and implementation of the N&S Process has occurred widely across the complex since its inception in 1995. Through early pilots and follow on N&S Process applications, a considerable number of lessons were learned. A discussion of these lessons learned can be found on the Work Smart Standards home page (http://tis.eh.doe.gov/dsc/worksmart.html). General information about Integrated Safety Management implementation is available at the ISM home page. In addition, the Department's Lesson Learned home page (http://tis-

hq.eh.doe.gov:80/LL/) has specific information useful to managers and participants who intend to use the N&S Process in the future.

This is Revision 0 of this Handbook. This Department of Energy Handbook is approved for use by all DOE components and their contractors. Beneficial comments (recommendations, additions, deletions) and any pertinent data that may improve this document should be sent to: Executive Secretary, Department Standards Committee, U. S. Department of Energy, 1000 Independence Avenue, SW, Washington, DC 20585 by letter or by using the Document Improvement Proposal (DOE F 1300.3) appearing at the end of this document.

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1.0 Purpose

The purpose of this Handbook is to provide users of the N&S Process with amplification, practical examples, and references to available resource material to assist in developing, implementing, and maintaining the WSS set as a vital component of Integrated Safety Management (see Section 3.0, Applicable Documents.) This Handbook is intended to improve the understanding of the application of the N&S Process so that substantial benefit can be realized in terms of worker and public safety, environmental protection, mission accomplishment, and cost. The information in this Handbook is based on lessons learned from applications of the Necessary and Sufficient Closure Process for Work Smart Standards and was prepared by an experienced team of DOE and contractor practioners of the N&S process and the ISMS.

1.1 Organization of the Work Smart Standards User's Handbook

This Handbook provides amplifying explanations on the methods and processes that should be considered by users in conducting a formal process to develop, implement, and maintain the WSS set. The Handbook discusses topics based on the N&S Process actions. Figure 1 is a graphic illustration of the actions as listed in the N&S Manual.

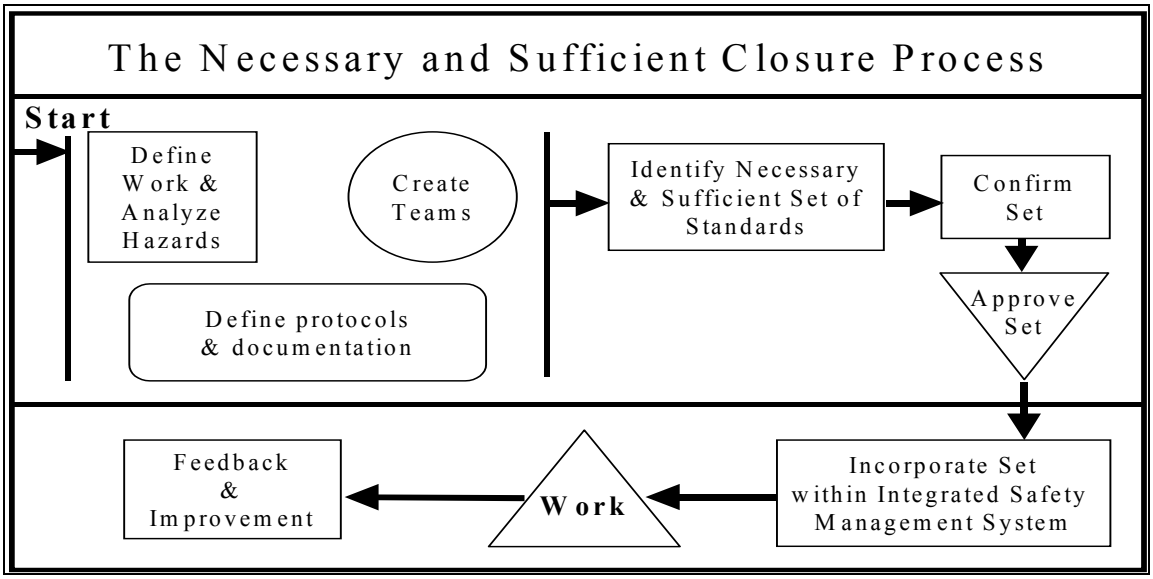


Figure 1. Necessary and Sufficient Closure Process

Scope: Section 2.0 discusses the relationship of this Handbook to Department policy and guidance as established in the Necessary and Sufficient Closure Process, the Integrated Safety Management System (ISMS) Policy, and the Department of Energy Acquisition Regulations (DEAR).

Applicable Documents: Section 3.0 lists references directly applicable to the methods and processes described in the Handbook.

Glossary: Section 4.0 reiterates the definitions listed in the N&S Manual and introduces a new term “Interested Parties.”

Understanding the Necessary and Sufficient (N&S) Closure Process: Section 5.0 describes the interface between the Process and ISMS, emphasizes the need for cooperation among parties, the importance of establishing good communications, and the need to provide for flexibility.

N&S Process Participants: Section 6.0 provides an overview of the roles and responsibilities of key participants in the Process, describes the need for involvement of senior DOE and contractor managers and discusses the value of workers in the Process.

Conduct of the Process: Sections 7.0 through 13.0 describe the actions and techniques found useful in successfully conducting the Process. These topics amplify requirements found in the N&S Manual, M 450.3-1, *The Department of Energy Closure Process for Necessary and Sufficient Sets of Standards*, and provide practical examples and lessons learned from experience in the field. Each section is introduced with a chart that depicts the key features of the N&S Process element as described in that section. References to other applicable materials and web sites are provided.

Implementation: Section 14.0 describes field experience in successful implementation of the standards sets developed by the N&S Process.

Maintaining the Set of Standards: Section 15.0 discusses establishing effective change control mechanisms from experience and practical application.

Providing Feedback and Lessons Learned: Section 16.0 discusses the use of feedback and lessons learned.

Appendices: The appendices contain detailed information and example documentation useful to those responsible for implementing an application of the N&S Process and maintaining the resulting set of Work Smart Standards. These appendices are provided as examples of methods, processes and work products which have been found to be successful in field applications. They make up only a small part of the available information included in the authoritative data base which is available on the Work Smart Standards web site at – http://tis.eh.doe.gov/dsc/worksmart.html.

- Appendix A contains frequently asked questions with corresponding answers concerning the N&S Process.

- Appendix B contains a sample outline of actions and assigned responsibilities pertinent to Stakeholder involvement in the N&S Process at the Savannah River Site.

- Appendix C contains a sample of a protocol defining the qualification requirements used for Identification Team Members who participated in the N&S Process at the Los Alamos National Laboratory (LANL).

- Appendix D contains examples of N&S Process organizational structures used at Fermi Laboratory.

- Appendix E contains a charter and confirmation protocols used during the N&S Process conducted at the Fermi Laboratory.

- Appendix F contains a crosswalk “Orders and Rules of interest to the DNFSB and Appendix G of the LANL Contract” developed for the Work Smart Standards Set at Los Alamos National Laboratory.

- Appendix G contains "Criteria for Evaluating the Performance of the N&S Process and Confirmation of Readiness."

- Appendix H contains a request for approval of a WSS set and the final approval document used during the N&S Process conducted at the Fermi Laboratory.

- Appendix I contains a procedure for managing change control of laboratory operating standards (including the WSS set) at LANL.

2.0 Scope of the Handbook

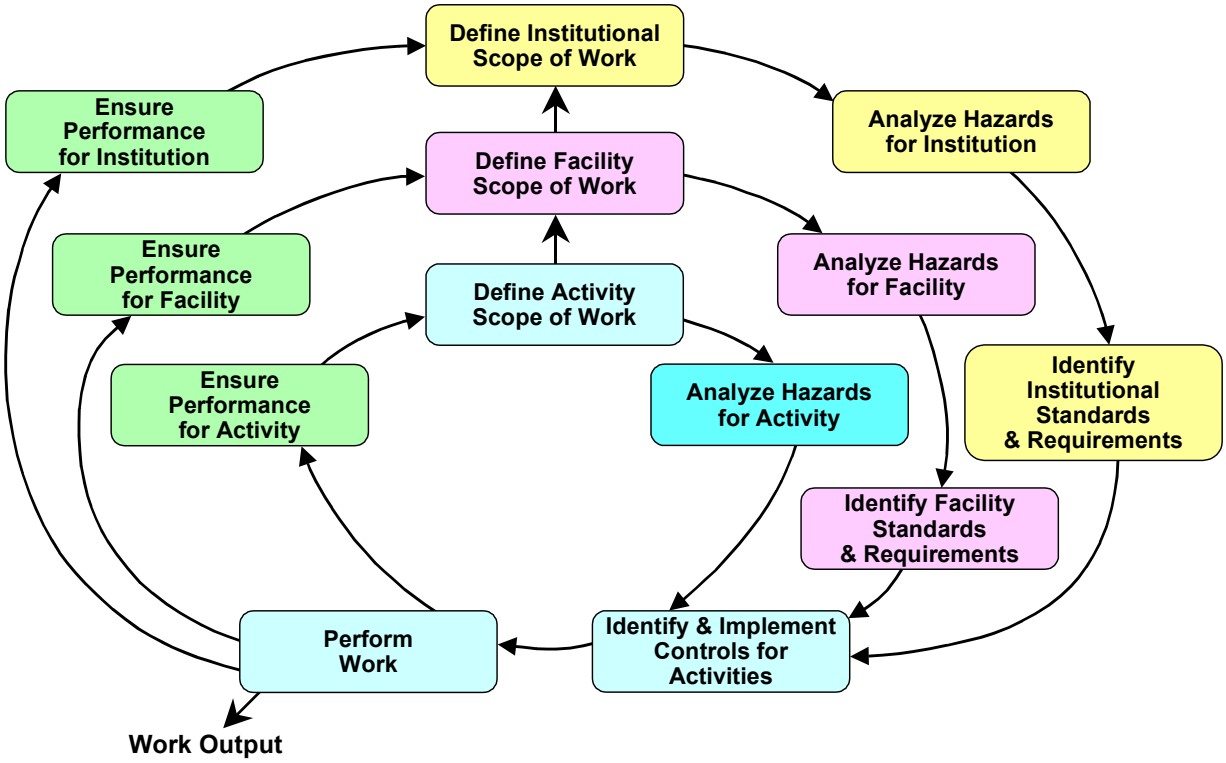


Figure 2. Integrated Safety Management System

2.1 Scope

The DOE Guiding Principles of Integrated Safety Management permit different approaches to tailoring a set of implementing mechanisms. Figure 2 portrays the ISMS concept. The objective of ISMS is to perform work safely. As the figure illustrates, ISMS is a comprehensive management system approach that integrates safety into all levels of DOE work: sitewide, facility and activity. The DOE mission comprises exceptional diversity in its scope and complexity. In some cases, the uncertainties associated with the characterization of the work, the work environment, and the hazards require tailored management approaches. DEAR 970.5204-78. *Laws, Regulations, and DOE Directives*, states in paragraph (c):

> "Environmental, safety, and health (ES&H) requirements appropriate for work may be determined by a DOE approved process to evaluate the work and the associated hazards and identify an appropriately tailored set of standards, practices, and controls, such as a tailoring process included in a DOE approved Safety Management System implemented under 48 CFR (DEAR) 970.5204-2. When such a process is used, the set of tailored ES&H requirements, as approved by DOE pursuant to the process, shall be incorporated into List B as contract requirements with full force and effect."

DOE P 450.3, *Authorizing Use of the Necessary and Sufficient Process for Standards-Based Environment, Safety, and Health Management*, establishes the N&S Process as a means of addressing work, hazards, and related controls. For many routine activities, experience has been codified in formally promulgated standards and procedures. For other non-routine activities, guidance documents identify best practices that, while not prescriptive requirements, communicate what is known at the edge of formalized consensus standards. The result of the N&S Process is a set of tailored environment, safety and health (ES&H) standards. This set is termed the Work Smart Standards set to emphasize the importance that the actual work definition plays in resolving safety uncertainty. This policy further states that carrying out this Process with fidelity and implementing the results will provide reasonable assurance of adequate protection of the workers, the public and the environment and will increase Stakeholder trust and confidence.

When the N&S Process is selected as the means to arrive at a tailored set of standards, then compliance with the N&S Manual is mandatory as stated in the Policy. The Manual provides the framework for conducting the N&S Process. Manual requirements and the individual steps of the Process are designed to ensure that the Work Smart Standards set can result in reasonable assurance of adequate protection, is feasible for implementation where intended, and can be applied with confidence. Lack of fidelity to the requirements of the Manual may void the results of the Process application. Since 1995, as the Process has been applied, the Manual has been validated. This Handbook is intended to be used in conjunction with the Manual to provide users of the N&S Process with useful guidance based on lessons learned.

3.0 Applicable Documents

a. 48 CFR (DEAR) 970.5204-2, Integration of Environment, Safety, and Health into Work Planning and Execution

b. 48 CFR (DEAR) 970.5204-78, Laws, Regulations, and DOE Directives

c. DOE Policy 450.3, Authorizing Use of the Necessary and Sufficient Process for Standards-based Environment, Safety, and Health Management

d. DOE Policy 450.4, Safety Management Policy

e. DOE Policy 450.5, Line Management, Safety, and Health Oversight

f. DOE Policy 450.6, Secretarial Policy Statement, Environment, Safety, and Health

g. DOE Policy 1210.1, Public Participation

h. DOE Manual 450.3-1, the Department of Energy Closure Process for Necessary and Sufficient Sets of Standards

I. DOE Guide 450.3-1, Documentation for Work Smart Standards Applications: Characteristics and Considerations

j. DOE Guide, 450.3-2, Attributes of Effective Implementation

k. DOE Guide, 450.3-3, Tailoring for Integrated Safety Management Applications

l. DOE Guide 450.4-1, Integrated Safety Management System Guide

m. DOE-STD-1083-95, Requesting and Granting Exemption to Nuclear Safety Rules

n. Criteria for the Department Standards Program (DOE/EH/-0416)

4.0 Glossary

This section reiterates and supplements the definitions as listed in the N&S Manual for the purpose of standardizing terms used in this Handbook and introduces the term "Interested Parties."

Agreement Party: Any party, including at a minimum the Responsible Organization and the Customer Organization, that must agree to the necessary and sufficient set of standards for the work (e.g., parties to a contract) as in the case of DOE and an M&O/M&I contractor.

Approval Authority: One or more Department and contractor employees designated by the Convened Group to determine the adequacy of the Work Smart set of standards and to approve or disapprove a set of standards.

Confirmation Team: A group of individuals who meet the membership criteria and qualifications defined by the Convened Group with responsibility for confirming the adequacy and feasibility of the necessary and sufficient set of standards based on documentation provided by the Identification Team.

Convened Group: A steering committee for the conduct of the Process, which represents the Agreement Parties, the Resource Authority, and other appropriate Federal organizations. The Convened Group establishes the criteria for approval of the set of standards identified by the Identification Team and must, therefore, consist of organizational representatives empowered to make the necessary commitments.

Customer Organization: The organization with direct responsibility, accountability, and authority for having the work performed subject to the agreed-upon set of standards.

Identification Team: A group of individuals who meet the membership criteria and qualifications defined by the Convened Group and are responsible for identifying and justifying the necessary and sufficient set of standards based on the work, the performance expectations, and the associated hazards and uncertainties defined in Process Element 1.

Interested Party: DOE contractors or subcontractors, Federal organizations or State organizations not directly participating in the Process but having significant interest or responsibility in the outcome. An example is the Defense Nuclear Facilities Safety Board (DNFSB) which has statutory responsibilities relating to defense nuclear facility standards.

Operational Experts: Individuals with knowledge and expertise relevant to the work and the site, facility, and activities addressed by the necessary and sufficient set of standards.

Resource Authorities: Organizations or individuals with control over and authority to commit the equipment, facilities, personnel, and budget necessary to accomplish the work. For example, line managers are typical resource authorities in classical organizations. Program and project managers are also line managers who are typical resource authorities in matrix organizations. Some organizations may have resource managers who are independent of programs and projects.

Responsible Organization: The organization with direct responsibility, accountability, and authority for performing the work subject to the agreed-upon set of standards.

Stakeholder: Any party other than Federal employees or DOE contractor or subcontractor employees that will be materially affected by, or can materially affect, the outcome of the work, either favorably or unfavorably (for example, representatives of state and local governments, labor unions, and citizens' groups).

Technical Experts: Individuals with knowledge and expertise relevant to the work or to one of the environment, safety and health disciplines (for example, industrial hygiene, criticality control, or industrial safety).

5.0 Understanding the Necessary and Sufficient (N&S) Closure Process

The authority for Process use is established in the contracting mechanisms specified in the Department of Energy Acquisition Regulation (DEAR). When adopted, it is envisioned that the Process will form a key tailoring mechanism for the standards set established within a formally structured Integrated Safety Management System (ISMS). The Process always builds on the cooperative engagement of the parties involved and will not function properly if this precept is not fully understood and honored. The Process promotes good communication among all participants and a recognition that the application of the Process is tailored based on the work, hazards and work place. Poor communication and preemptive rigidity in Process implementation are signs that an "agreement to agree," that is the basis for cooperative engagement, is lacking. Frequently asked questions with corresponding answers concerning the N&S Process are provided in Appendix 1.

5.1 Incorporation of the Process within the Integrated Safety Management System (ISMS)

DOE P 450.4, *Safety Management Policy*, commits the Department to conducting work efficiently and in a way that provides reasonable assurance of adequate protection of workers, the public and the environment. Demonstrating ISMS effectiveness is more than just an internal affair between the Department and its contractors. While protecting the environment and the safety and health of the public and workers, DOE is also committed to demonstrating good stewardship of resources, and to building public trust and confidence in its programs and plans. The Department has deliberately adopted a standards-based approach to safety management that is intended to allow for good judgment in work design and resource allocation. This approach creates consistency and stability of expectations and accountability, permits judgment to be exercised at the level appropriate to effective management, and helps people do their jobs through teamwork. These features are the outward sign of an effective ISMS at work. Central to understanding ISM are the five core functions and seven guiding principles that undergird the contract requirements that mandate an ISMS. Key references for the establishment of ISMS include DOE P 450.4, *Safety Management Policy*; DOE G 450.4-1, *Integrated Safety Management System Guide*; DEAR 970.5204-2, *Integration of Environment,*

Safety, and Health into Work Planning and Execution; and DEAR 970.5204-78; *Laws, Regulations, and DOE Directives*. DEAR 970.5204-78(a) requires that the contractor assist DOE to comply with any applicable federal, state, and local laws (List A), and conform to the agreed upon requirements of those Department of Energy directives, or parts thereof, identified in the List of Applicable Directives (List B). As noted in the ISMS Guide, ES&H requirements appropriate for work conducted by a contractor may be determined using a DOE-approved process to:

- evaluate the work and the associated hazards, and
- identify an appropriately tailored set of standards, practices, and controls. The resulting approved set shall be incorporated into the contract as required by DEAR 970.5204-78.

Approved processes for establishing ES&H requirements include the following:

- incorporation of a Standards/Requirements Identification Document (S/RID) into the contract,
- use of the Necessary and Sufficient Closure Process, and
- compliance with the DOE directives and other applicable laws and regulations.

Within the overall context of ISM, the Process can be used to demonstrate that an agreed upon, tailored, and standards-based definition of work, hazards, and expected controls exists. The relationship between the specific ISMS and the WSS set is inseparable when the Process is used. This is not to say that an ISMS cannot be established with a previously established S/RID or order compliance base first, but the subsequent initiation of the Process may necessitate conducting a follow on verification of the ISMS after the WSS set has been selected and implemented. Process leadership and the Convened Group are charged with ensuring that implementation of the WSS set is feasible and that the basis for this assurance is examined as part of confirmation.

5.2 Cooperative Engagement, Communications, and Flexibility

The N&S Process is based upon the principle of cooperative engagement, which involves two elements:

- The right parties are involved in the Process. As stated in the N&S Manual: "To establish a basis for agreement, all parties who must agree on the set of standards shall participate in the Process planning." Additional Stakeholders and Interested Parties are always invited to contribute to the Process.

- The identified Agreement Parties "agree to agree" at the outset. They recognize that they are engaged in a common task and focus their efforts on finding ways to reach agreement.

Cooperative engagement is sustained through a sense of partnership among those involved and affected by the work to be performed. The relationship requires communication and a shared vision of the work outcome that includes commitment to reasonable assurance of adequate protection of the workers, the public, and the environment. Process effectiveness improves in direct measure to the degree of communication and shared vision among the participants. Cooperative engagement by senior management, designated representatives on the Convened Group, and the various team members is the backbone of successful application of the Process.

The N&S Process is not intended to be a task or "project" that DOE assigns to a contractor and reviews after completion. The N&S Process is intended to engage DOE, its contractors, Stakeholders, and Interested Parties (as determined by the likely effects of the actual work and hazards) in a cooperative and constructive dialogue that leads to greater mutual trust in the pursuit of a common goal. There is no single recipe or step-by-step procedure for application of this principle.

The N&S Process is designed to be rigorous yet flexible and to require thoughtful application. The N&S Process is also designed to achieve final agreement through iteration. Results from

one process element may indicate a need to revise or expand information from a previous element. This is true of the earlier process elements, where identification of the work and hazards, creation of the teams, and establishment of protocols are closely related and interdependent. Hence in Figure 1, these elements are shown as being accomplished together rather than in a stepwise linear fashion. Similarly, in later stages of the N&S Process (for example, standards identification or confirmation), a number of factors such as the need for different/additional team members, or the need to better define the work and hazards may arise that will require revisiting one or more of the earlier process elements. In addition, considerations of feasibility can lead to iteration. Such iterations should be expected as part of a robust, properly operating N&S Process application.

6.0 N&S Process Participants

An essential element for success in performing the N&S Process is assigning clear roles and responsibilities to persons in key positions for administering the Process and in assigning to these positions knowledgeable and competent individuals. Management support is demonstrated most critically in selection of key Process leadership and Convened Group personnel.

6.1 Overview of Key Participants

A principle of the N&S Closure Process is that teams must be comprised of the people with requisite knowledge and expertise; people who have direct experience with the work, hazards and specific work place. The concept of “workers” as used in WSS is intentionally broad. It is intended to include people experienced in the large number of skill and knowledge categories required to perform the work of DOE. Scientists, engineers, mechanics, electricians, financial specialists, contracts specialists and many others all bring important knowledge to the identification and approval of a set of standards. Within the context of the Closure Process application, the term “workers” is particularly intended to underscore the need to involve those who perform the physical work such as operating equipment, conducting experiments, construction, testing and other similar activities. They are the individuals most directly exposed to hazards and most directly knowledgeable of work conditions and practices.

The N&S Manual uses a number of unique terms to describe roles and responsibilities in conducting the N&S Process. Since N&S Process roles and responsibilities are not defined in terms of specific contractor or DOE organizational levels, flexibility is afforded for each Process application to determine the appropriate parties for participation. Tables I and II describe the N&S roles and give examples of the organizational levels at which they were performed for representative applications. These examples and illustrations are intended only to aid in understanding some of the most common Process applications, and do not limit the ability of the N&S Process to be applied at other levels.

Table I. Key Participants in the N&S Process

Group or Person	Who They Are (typical contract-level application)	What They Do
Agreement Party	DOE and Contractor organizations	Designate members of Convened Group and Process Leader. Identify Resource Authorities, Stakeholders, and Interested Parties.
Customer Organization	DOE	One of the Agreement Parties
Responsible Organization	Contractor	One of the Agreement Parties.
Convened Group	Personnel from DOE and Contractor organizations	Oversees the Process and provides direction to Process Leader. Designates the Approval Authorities.
Process Leader	From Contractor organization	Leads the N&S Process. Works with Convened Group to assemble Identification and Confirmation Teams.
Resource Authorities	DOE and Contractor officials who control funding, resources, equipment, and personnel	Identify available resources and resource constraints.
Stakeholders	Representatives of organizations outside of DOE and Contractor and other Federal agencies	As desired, provide input via channels established by the Convened Group.
Interested Parties	Representatives of DOE contractors, subcontractors, or federal organizations who are not directly participating in the Process but have a significant interest in the outcome.	As desired, provide input via channels established by the Convened Group.
Technical Experts Operational Experts	Subject matter experts from DOE, Contractor, and outside organizations	Assist the Convened Group, Process Leader, and Identification and Confirmation Teams as requested.
Identification Team	Usually DOE and Contractor personnel	Identify N&S set.
Confirmation Team	Usually DOE and Contractor personnel	Confirm adequacy of the N&S set.
Approval Authorities	DOE and/or Contractor senior managers, (usually from same organizations as Agreement Parties), including the Contracting Officer	Approves the Work Smart Standards set.

Table II. Examples of Participants in Typical Contract-Level N&S Applications[1]

Group or Person	Examples		
	Fermi	**LBNL**	**LANL**
Agreement Parties	• DOE-BAO • Universities Research Association (URA) • Office of Science-DOE HQ	• DOE • University of California • LBNL	• DOE • University of California
Customer Organization	DOE-BAO	• DOE • University of California	DOE
Responsible Organization	URA	LBNL	University of California
Convened Group	5 individuals from: • Fermi • DOE-BAO • SC (HQ) • DOE-CH The Extended Convened Group included the above plus support of 4 other senior managers from: • Fermi (Deputy Dir.) • DOE-CH (Manager) • SC (HQ) (Assoc. Div. Dir.) • URA (Vice President)	11 individuals from: • LBNL • Univ. of California • DOE-OAK • DOE-BSO • Fermi • LLNL • SC (HQ)	8 individuals from: • DOE-AL • DOE-LAAO • Univ. of California • LANL • DP (HQ) • EH (HQ)
Process Leader	Line manager at Fermi	Line manager at LBNL	Senior Technical Manager at LANL
Resource Authorities	Director, SC HQ High Energy Physics Division	Line management from LBNL, Univ. of California, DOE, and other organizations supporting research at LBNL.	Senior line and program management at LANL and DOE
Stakeholders	• Union representatives • General public • Research user community	• Neighbors	• General public • State, county, city, and tribal government representatives • Labor unions • Citizen's groups
Interested Parties[2]	• Employees • State and local regulators • Site subcontractors	• Regulatory agencies	

Group or Person	Examples		
	Fermi	**LBNL**	**LANL**
Identification Team	15 individuals from: • ANL • BNL • Cornell Univ. • LLNL • TJNAF • SLAC and the Extended Convened Group	40 individuals from: • LBNL • LLNL • DOE-OAK • DOE-BSO	approx 200 individuals from • LANL • DOE-AL • DOE-LAAO • LANL subcontractors
Confirmation Team	6 individuals from: • ANL • BNL • Cornell Univ. • LBNL • TJNAF • SLAC Extended Convened Group	17 individuals from: • BNL • Carroll Ramsey Assoc. • Bechtel International • Fermi • LLNL • LANL • Univ. of California • DOE-OAK • Lichtenstein Assoc. • SC (HQ) • E.I. DuPont de Nemours	13 individuals from: • LBNL • DOE-NV • LANL • DOE-AL • Nat'l.Safety Council • indep. consultants • LANL subcontractors
Approval Authorities	• URA President • SC HQ Div. Director • DOE-BAO Manager (Contracting Officer)	• LBNL Director • DOE-OAK Manager (Contracting Officer)	• LANL Director • LAAO Manager • DOE-AL Manager (Contracting Officer)

[1]Conventions for defining Process roles and participants have varied, particularly among some of the early Process applications. For a complete understanding of Process participants and their roles in the above examples or other applications, the complete report of the individual Process application should be consulted. These records are available from the organization which performed the Process application. Reference information is available through the DSC Home Page.

[2]The DNFSB did act as an Interested Party for LANL. However, at the time of the LANL N&S Process application, the term "Interested Parties" had not been established to denote a particular category of participants.

6.2 Involvement of Senior DOE and Contractor Managers

As specified in the *Criteria for the Department's Standards Program* (DOE/EH/-0416), DOE line management and contractor management are to implement necessary and sufficient sets of standards to provide protection during the accomplishment of work, including all requirements imposed by law. Central to management involvement in the N&S Process is the awareness and acceptance by managers of the fundamental role of the proper standards on the managers' success in meeting the ISMS objective: Doing Work Safely. Senior managers are expected to demonstrate their safety ownership by:

- being knowledgeable and involved in their commitment to the safety culture;
- aligning resources (fiscal, personnel, and time) to meet agreed-upon standards;
- assigning recognized leaders of the organization to safety culture strengthening activities;
- ensuring the presence or assistance of experts and knowledgeable participants;
- interacting personally with Stakeholders and Interested Parties; and
- insisting on accountability for improved safety performance.

Experience has shown that proper discharge of the management responsibility and accountability for this Process may necessitate significant organizational and work practice restructuring to clearly identify the ownership of safety by line management and to make explicit where accountability resides. For this reason, Process leadership and the Convened Group are expected to attend, throughout the Process application, to actions needed to make implementation of the WSS set feasible. Where necessary, managers should take the initiative and direct these reorganizations. Reorganization can be essential in clarifying roles, responsibility, and accountability among the organization components. Such clarification is essential for an organization to conduct work safely.

The emphasis of DOE on standards-based work represents a change in DOE culture. DOE relies on senior management to confront and resolve the disharmony inherent in achieving this significant cultural change. DOE's ISMS clearly establishes line managers as responsible for safe mission performance. To achieve this, the line manager is expected to rely on staff functional expertise for department policy, guidance, and support.

In the context of the N&S Process, senior management commitment and involvement are crucial. For a Process application to be successful, DOE and contractor management must provide the necessary resources (people, time, and funding). Since the N&S Process is often resource-intensive, providing the right people may require reassignment or deferral of other high-priority activities. This cannot be done without the strong and continued commitment of senior management. Furthermore, the members of the Agreement Parties and the Convened Group must be empowered to make decisions and commitments for their respective organizations. Senior management participation with these groups is therefore essential. Finally, a successful N&S Process application may need to draw on resources and expertise throughout the DOE and contractor organizations, as well as possibly from outside organizations. For example, Fermi Lab engaged the DOE and academic accelerator community. (Reference Appendix 4) Such cross-organizational participation is not readily obtained without strong support from senior management.

6.3 Role of Workers

Effective use of the N&S Process depends upon the demonstrated skills, knowledge, and abilities of the DOE work force. Those resources are derived from many collective years of experience with the types of hazards that characterize the Department's diverse missions. For many routine activities this experience has been codified in formally promulgated standards and procedures. For other non-routine activities, guidance documents identify best practices that while not prescriptive requirements communicate what is known at the edge of formalized consensus standards. When the N&S Process is applied, the contemporary knowledge present in the work force is integrated with historical knowledge found in recognized standards. For those engaged in exploratory work design, the N&S Process encourages the integration of both practical knowledge and all forms of received wisdom. In the standards-based approach to ISMS, the expectations for involving workers are addressed with standards identification processes that are tailored to the specific characteristics of the work.

In the N&S Process, workers can provide invaluable contributions either as members of the Identification or Confirmation Teams, or as Operational Experts who assist these teams with their "knowledge and expertise relevant to the work and the site, facility, and activities." The definition of who is a "worker" will of course depend on the nature of the work. For purposes of the N&S Process, "workers" may include crafts personnel, engineers, designers, researchers, ES&H professionals, and others.

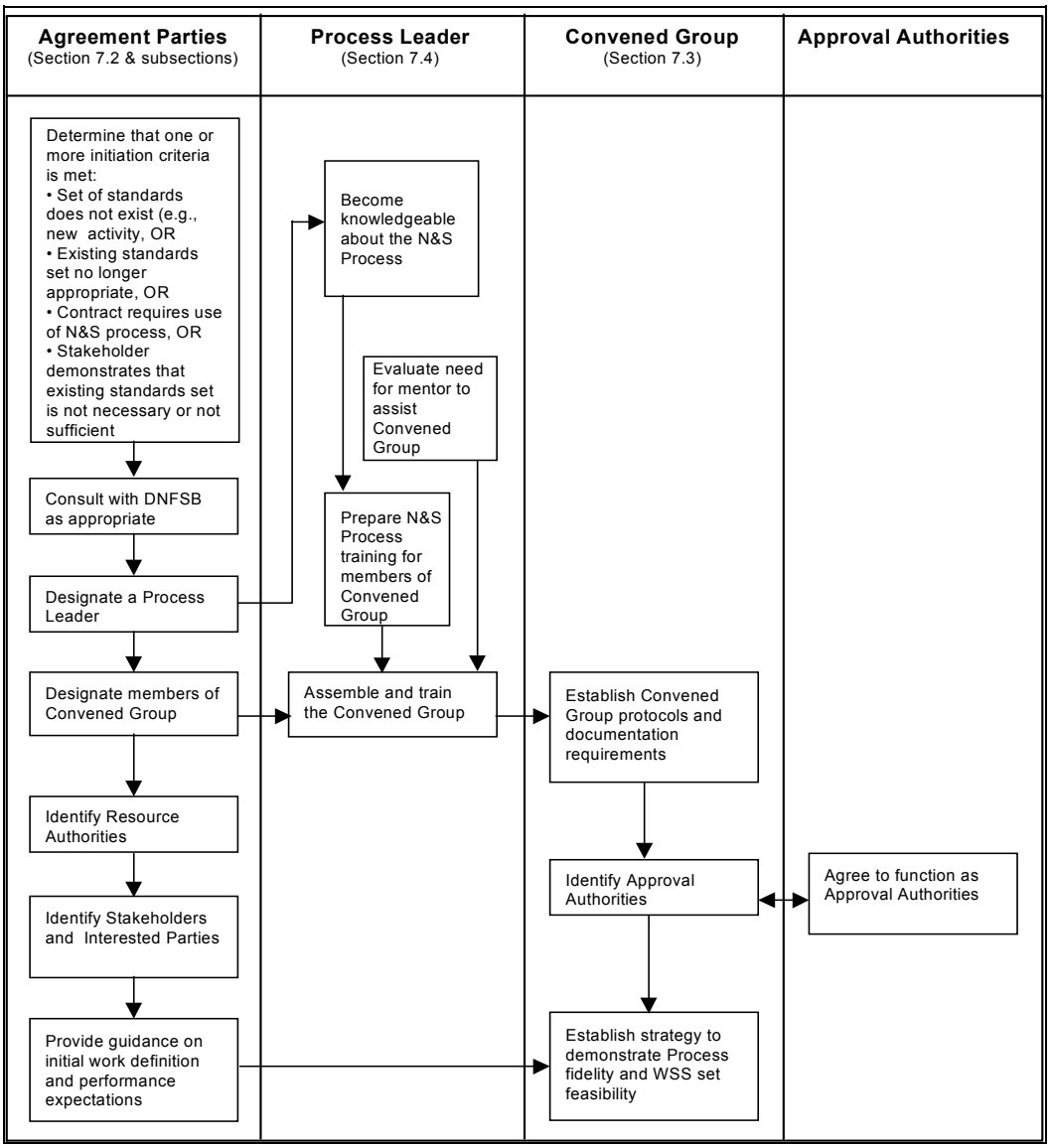
Workers can be particularly valuable in the N&S Process by:

- Identifying the work, associated hazards and standards. Those who regularly perform the work in question will have detailed knowledge of how that work is done, and may often be able to identify specific hazards, standards utilized or inefficiencies associated with the work that would not be apparent to an outside analyst.

- Evaluating the feasibility of the WSS set for implementation. Because workers are the ones who directly implement the standards, they can provide insight into whether those standards are reasonable and practical in the context of the actual work environment.

Unions representing workers are Stakeholders in any N&S Process application and should be informed about the N&S Process and its expected effects on the workplace. Both the communication of information about the N&S Process and the involvement of union workers as Operational Experts should be coordinated through appropriate channels such as union representatives.

7.0 Initiating the Necessary and Sufficient Closure Process



7.1 Initiating the Process

There must first be appropriate conditions for initiating the N&S Process. As stated in the N&S Manual, one of the following criteria must be met:

- A set of standards does not exist, as in the case of a new activity. This may include a newly constructed facility, or new activities at an existing facility.

- An existing set of standards (for example, the current set of all applicable Department directives) is no longer appropriate due to changes in mission, regulatory environment, degree of hazards, performance expectation, or knowledge. For example, facilities that are undergoing transitions from operations to decommissioning and deactivation will require a transition to a different set of standards.

- The applicable contract requires that the Process be used. The N&S Process may be specifically called out in a new or modified contract.

- A Stakeholder (or Interested Party) demonstrates to the satisfaction of the Agreement Parties that the existing set of standards is either not necessary or not sufficient to provide reasonable assurance of adequate protection. Evidence provided should be based on the set of standards, not on the way the standards are implemented. To meet this criteria, two conditions are necessary:

  (1) input from a Stakeholder (or Interested Party), and

  (2) Agreement Parties agree that the Stakeholder (or Interested Party) has a valid concern.

  A Stakeholder complaint, regardless of validity, does not in itself satisfy this condition to initiate the Process. However, all input from Stakeholders and Interested Parties should be carefully evaluated to determine if the adequacy of current standards is at issue.

7.2 Role of the Agreement Parties

The Agreement Parties must be fully supportive of and interactive within the Process and be capable of reaching full agreement in the outcome. They should fully understand and agree on the form of the contract or contract modification as specified in the DEAR which will result from implementing the Process. Agreement Parties provide the initial description of the scope of the work and hazards to the Convened Group and provide related performance expectations. Throughout the Process, they should maintain close communication with the Convened Group as the work and hazards identifications are refined and a set of standards is identified within the context of the specified expectations. They must be able to agree on the defined scope of work. Any boundaries for the Process must be established and agreed to at the outset. Early identification of all the Agreement Parties is essential to ensure that the N&S Process can proceed to closure.

The Agreement Parties, having concluded that at least one of the criteria for initiating the N&S Process has been met, must:

- jointly designate a Process Leader;
- designate individuals from their respective organizations to serve as members of the Convened Group, and identify members needed from other organizations;
- identify the Resource Authorities and include them as members of the Convened Group; and
- identify Stakeholders and Interested Parties.

The Agreement Parties should also consider and provide guidance in the form of their performance expectations for the Process application. Key performance expectations may include:

- the schedule and cost for conducting the Process,
- cost savings to be achieved by the new set of standards,

- degree of continuous improvement to be called for in the standards set developed,
- the extent of institutional change the new standards set may bring about when implemented, and
- feasibility of the standards set including considerations of the implementation of the set within the ISM system, changes that may be required to existing equipment, infrastructure or work processes and cost.

7.2.1 Assigning the Process Leader

When the Agreement Parties have reached a decision that it is appropriate to initiate the Process, they should jointly designate, preferably from within the Responsible Organization, a Process Leader who will be responsible for conducting the Process and will represent the interests of all the Agreement Parties. They should select a Process Leader who has their confidence and will be able to effectively interface with all levels of appropriate management, the Convened Group, the Identification and Confirmation Teams, and Stakeholders and Interested Parties. The Process Leader should serve as a trusted agent for the communication of issues among these groups and should be the conduit for formal liaison. In this role, the Process Leader will be expected to bring important issues for resolution to the attention of the appropriate people.

A technical background in the standards to be considered, a proven record of organizing and coordinating diverse groups of technical personnel, and knowledge of the work should be considered as prerequisites for assignment as Process Leader. The designation as Process Leader is a significant assignment. As this individual will be required to dedicate extensive amounts of time to ensuring the success of the Process, this assignment should be a principal duty. Other assignments made to this individual during the time of conducting the Process should be made only on a collateral basis. The Process Leader must provide leadership and guidance to the Identification and Confirmation Teams and is responsible for supervising the preparation of reports which will serve as the basis for approving the agreed-upon standards set. The Responsible Organization should make available to the Process Leader the necessary resources to ensure the success of the effort.

A successful N&S Process application requires commitment and a large amount of effort by well qualified and motivated people. Before standards identification begins, the Process Leader should fully understand the Process. This understanding can be obtained by previous experience in the Process or can be gained by a review of information found on the Work Smart Standards home page (http://tis.eh.doe.gov/dsc/worksmart.html). Involvement of mentors and personnel experienced in the Process can be invaluable.

Effective training and coaching/mentoring programs have been proven to be valuable in successful applications of the N&S Process. The existence of an effective training program is important to reinforce the understanding of the Process, explain roles and responsibilities, and help establish expectations for the outcomes. Training should be customized for the groups receiving the training. This customization should focus on the roles and responsibilities of management in initiating the Process, roles and responsibilities of management representatives on the Convened Group in setting the course of the application and steering its progress, roles and responsibilities of the Identification and Confirmation Team members, and the involvement of Stakeholders and Interested Parties in the Process. This training should be provided as early as practical in the Process. As with ISM, faithful application of the N&S Process depends more on a conceptual understanding of the principles involved rather than a rote following of procedural steps. Training for both ISM and the N&S Process should emphasize understanding of key concepts and principles.

Teams should be fully trained prior to conducting N&S Process responsibilities. Plans for training should take into account that new members may need to be added as the Process develops. These personnel may need to be trained before participating. A complete discussion of available training materials is included on the Department Standards Committee home page (http://tis.eh.doe.gov/dsc/) under the report of Standards Process Action Teams (SPAT) 8, *Training for the Necessary and Sufficient Process*.

7.2.2 Assigning the Convened Group

The Agreement Parties will establish the Convened Group to provide leadership and to serve as the focal point for decision making authority for the Process. To properly support the Process

Leader, the Convened Group members should be knowledgeable and effective personnel who can provide advice and guidance on a timely basis. The Convened Group is fully responsible and accountable for the entire Process and the resulting set of WSS, and its members should understand and accept this role. In general, members of the Convened Group should be selected from the managers responsible for allocating resources and managing the affected work. The personnel selected must be capable and designated to make commitments on behalf of the management of their parent organizations. Members to be assigned to the Convened Group should be individuals who fully support and will become fully engaged in the N&S Process. Should it be necessary to provide an alternate for these personnel during the Process, this substitution should only be considered if the replacement is adequately trained, experienced, and empowered. All Convened Group members should have sufficient knowledge and the appropriate authority if they are to make a significant contribution.

Typical members of the Convened Group include representatives from the Agreement Parties, Resource Authorities, and other appropriate Federal organizations. In support of the requirement that the proposed WSS set be feasible, a range of key function managers in the affected contractor organizations should be included in the Convened Group. The Convened Group may be chaired by the Process Leader who is the catalyst for ensuring that the Process is formally developed and approved.

7.2.3 Identifying the Resource Authorities

Resource Authorities are organizations or individuals who control the equipment, facilities, personnel, and budget necessary to accomplish work. Line managers, including program and project managers, are typical Resource Authorities. Some organizations may have multiple resource managers and some of these may be independent of programs and projects. Without the proper recognition and active participation of the Resource Authorities, the Process will fail. This does not mean, however, that each Resource Authority must be a member of the Convened Group.

7.2.4 Informing and Involving Stakeholders and Other Interested Parties

Key Stakeholders and Interested Parties should be informed early of the intent to conduct the Process and be invited to contribute. Experience has proven the value of inviting these parties'

participation, even when it merely provides them with an opportunity to decline. Informing and inviting Interested Parties' participation and input is particularly crucial since these organizations often play important decision making roles (outside of the N&S Process) regarding the acceptability of the WSS set in relation to the work being performed. A Process application can fail if it is not well understood and supported by the relevant Interested Parties.

The Defense Nuclear Facilities Safety Board (DNFSB) should be considered as an Interested Party in all N&S Process activities associated with defense nuclear facilities since the DNFSB has statutory responsibilities regarding standards for such facilities. Once a decision has been made to undertake the Process, Agreement Parties should consult with the DNFSB on the nature and opportunities of DNFSB involvement in a Process application.

Including representation from the applicable DOE Headquarters staff organization as an Interested Party has been useful to ensure that issues and lessons learned from other DOE N&S Process activities can be quickly identified and assimilated. Considering key citizens groups as Stakeholders is particularly important. State and federal regulators should be considered as Interested Parties because they often define the scope and requirements of activities. Examples of these organizations include the Environmental Protection Agency (EPA) and State Departments of Health.

To properly include the public in these matters requires good judgment and often dictates that public relations experts be involved. Scheduling of public meetings may be needed to ensure that the public is apprised of the key aspects of the Process application. News releases, newspaper advertisements, and announcement to employees in electronic and printed forms have been useful. The involvement of local unions and members of professional societies should be considered. DOE Policy P 1210.1, Public Participation, provides a framework for the operation of public participation programs at all DOE sites. Stakeholder involvement in N&S Closure Process applications should be conducted though those existing programs and specialists in those programs should be involved early in the initiation of the Process. A sample discussion pertinent to Stakeholder involvement in a Process application at the Savannah River Site is included as Appendix 2.

7.3 Role of the Convened Group

A fully engaged Convened Group will significantly reduce the time needed to define the work and identify the hazards. Throughout the Process the Convened Group acts in a leadership role and closely interacts with assigned task teams to:

- Define the work;
- Identify the hazards;
- Identify performance objectives and expectations to be satisfied by the WSS set;
- Identify resource constraints; and
- Ensure that the implementation of the resulting WSS set is feasible.

Should the Convened Group fail to come to a consensus on any one of these tasks or fails to communicate its consensus clearly, the Process will not proceed efficiently and there will be a continuous need to provide revised guidance. When the Convened Group "begins with an end in mind," one that is focused first on the work performance objectives, the Convened Group helps the Identification and Confirmation Teams to converge on a tailored set of standards. A tailored WSS set contributes directly to accomplishment of doing work safely.

To provide a framework for the formal structure to the Process, the Convened Group will establish protocols and documentation requirements. These are developed and presented for approval by the Process Leader. While the Convened Group is responsible for deciding on subjects to be addressed by protocols (based on complexity and uncertainty), the following is a typical list of items for which a protocol should be developed or a specific decision should be reserved to the Convened Group:

- identification of the Approval Authorities,
- identification of the process to be followed to gain approval (schedules, time limitations, and approval defaults),

- identification of methods for identifying significant issues and for resolving differing opinions,

- identification of qualification requirements for team members, and

- identification of the basis for the establishment of a necessary and sufficient set of standards

While the primary documentation for adequacy of the Process product will be developed by the teams, the Convened Group should develop a formal method to document their decisions as the Process develops. Many of the attributes that support a feasibility determination for the proposed WSS set will be captured in this record. It will be necessary to describe in detail some of the key steps and responses to the uncertainties which are inevitable. Experience has shown that it is far better to document these events when they occur, rather than attempting to build the record later.

Effective Convened Groups obtain Stakeholders and Interested Parties' views often as input to the decision making process and provide clear, consistent information to the Process Leader concerning performance expectations and objectives that must ultimately be satisfied by the implemented WSS set.

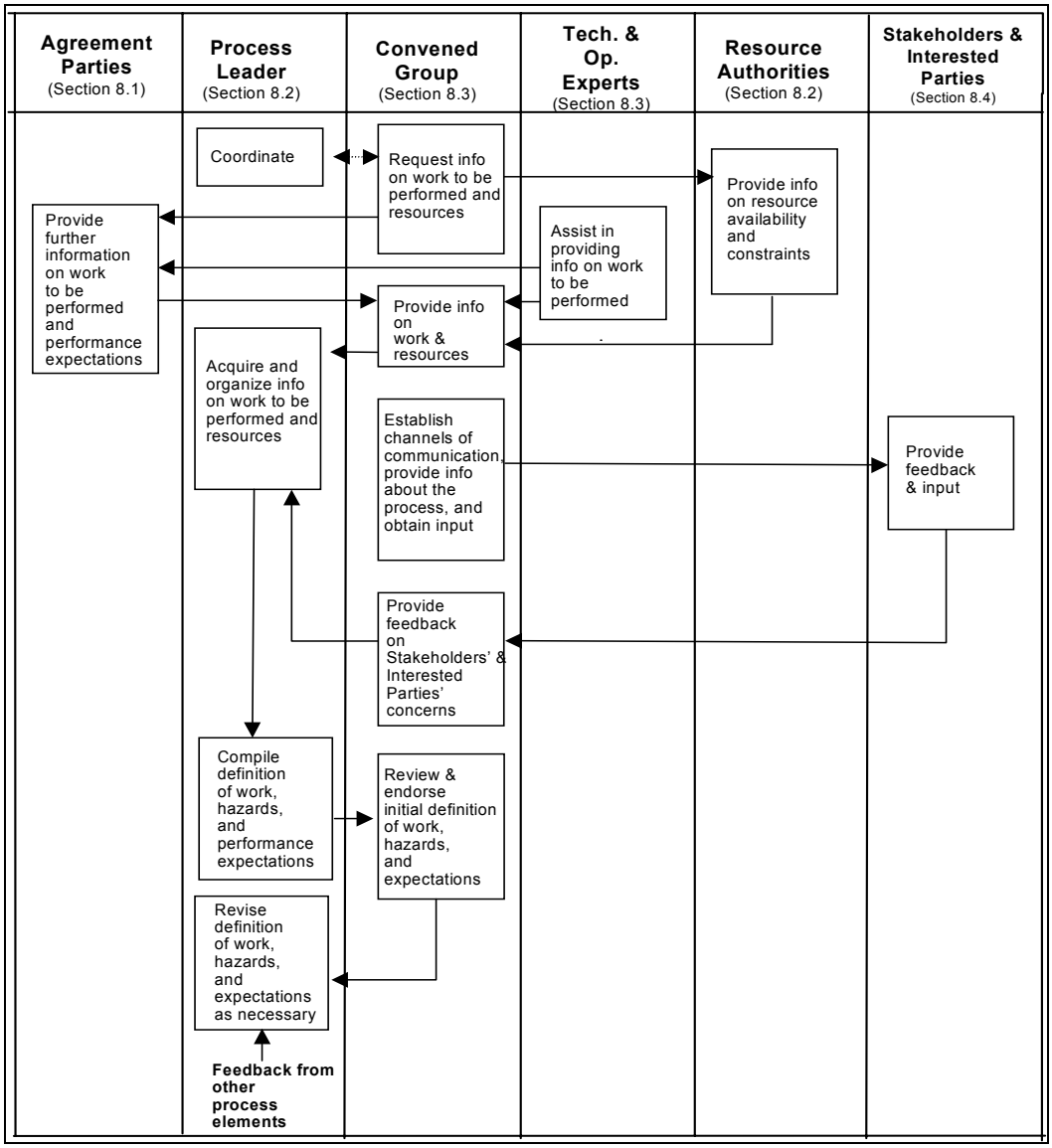
7.4 Role of the Process Leader

The Process Leader should be proactive in identifying appropriate individuals to serve on the Convened Group. Typical candidates are representatives from the Agreement Parties and the Resource Authorities.

The Process Leader convenes the first meetings of the Convened Group. There are two items of business which should be addressed during the early meetings. First, the Process Leader should conduct an appropriate level of training and indoctrination for members of the Convened Group. This training can be tailored based on the experience and background of the Convened Group. Second, the Process Leader should present to the Convened Group a recommended approach for the development of Convened Group protocols and documentation requirements. These are the top level or initiating decision making processes, which are discussed as

Convened Group responsibilities in Section 7.3 above. The objective of these tasks is to establish a credible structure that will provide assurance that the final set of standards will be adequate and meet the Process work requirements of the Approval Authorities. The efforts of and documentation created by the Process Leader typically provide the foremost evidence of fidelity to the Process Manual requirements.

8.0 Defining the Work and Associated Hazards



8.1 Defining the Work and Hazards

The identification of work and associated hazards is one of the most critical elements in the N&S Process. Proper identification requires application of the collective knowledge of DOE and contractor personnel who have direct experience with the work, the hazards and the workplace. Without a clear definition of the work and its associated hazards and uncertainties, a set of standards may be insufficient to provide the desired level of protection or may contain inappropriate standards that will waste resources. For established and on going activities, this may only require assembling existing documentation. For new activities, this effort may involve the development of a rigorous hazards identification process conducted in conjunction with the formal engineering design process.

The identification of the work and the hazards actually begins with the determination that the N&S Closure Process should be applied. DOE and contractor management identify the scope(s) of work for Process application. As work progresses from Agreement Parties to Convened Group to Identification Team, the definition of the work and hazards becomes progressively more refined. The N&S Closure Process is by intent iterative in nature and this iteration among the teams has been most evident in reaching agreement on clear definition of the work and hazards. Teams have gone though many cycles of work design, hazards elimination and hazards control in order to first eliminate hazards from the work place and then agree on the residual hazards which must be controlled. Good communication among teams is essential and the Agreement Parties must be well engaged to assure themselves that factors of engineered design, process design, work design and other hazard controls are addressed.

8.2 Role of the Process Leader

Ensuring the accurate identification of the standards set for the scope of work and associated hazards is one of the most important duties performed by the Process Leader. After conducting any research and study of the subject, the Process Leader should schedule a session with the members of the Convened Group to ensure that a good understanding of the scope of work and the definition of the hazards has been established. The Process Leader should have resolved any questions on this subject with key personnel such as line managers, the contracting officer, and the Resource Authorities, and should be prepared to present the findings to the Convened Group.

Accurate definition of the work and hazards is the heart of the N&S Process, and reaching closure on this definition is an iterative process that will require the Process Leader, with assistance from the Convened Group, to acquire and organize information from other sources such as Agreement Parties, Technical and Operational Experts, and Resource Authorities. The end result should be a clear definition of the work, hazards, and performance expectations that is agreed upon by both the Process Leader and the Convened Group. Typical questions and concerns that the Process Leader should discuss and resolve with the Convened Group include:

- What are the goals for safety, quality, and performance expectations for the work?
- What is the scope of the work and what are the associated hazards?
- What are the physical conditions within which the work is performed?
- What materials and conditions could cause adverse consequences?
- What are the areas of uncertainty associated with the work?
- What are the resource availabilities and constraints?
- What are the organization and management relationships that must be considered?
- Who are the Stakeholders and Interested Parties?
- What is the previous extent of Stakeholders' and Interested Parties' involvement?
- What are Stakeholders' and Interested Parties' concerns and channels of communication?
- Are there unions involved who need to be contacted?
- Will the work to be done have an impact on the public as well as workers?

- Are there citizen's groups that need to be notified?

- How will Stakeholders and Interested Parties be notified?

8.3 Role of the Convened Group

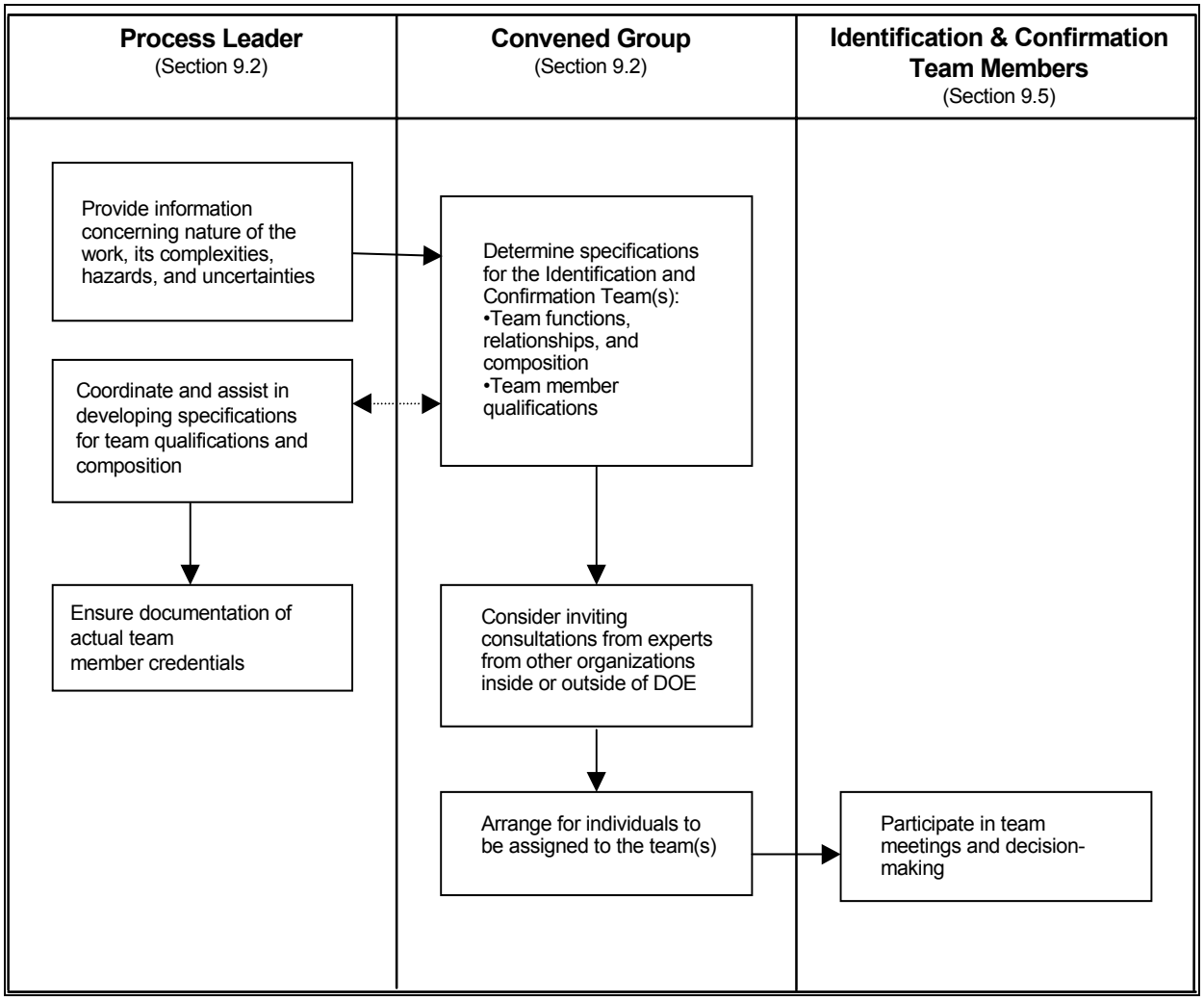
As discussed above, the Convened Group should provide any necessary direction to the Process Leader to ensure that the scope of work and the identification of hazards are well understood. This scope may be broader than originally conceived. Just as ISM encompasses all aspects of safety management, the N&S Process should include all ES&H aspects of the performance and management of work. The Convened Group should carefully review any data and information assembled by the Process Leader to ensure that it is complete. To do a credible job may require additional Technical Experts to assist the Convened Group. This review also provides an opportunity for the Convened Group to determine if any of the identified hazards can be reduced or eliminated by the use of alternative material or methods. At the end of this assignment, the Convened Group should be able to endorse the initial definition of the work, hazards, and performance expectations as compiled by the Process Leader.

The Convened Group must decide what interfaces will be established with Stakeholders and Interested Parties. After establishing the need for the interface, there will be a need to establish how the information can best be provided to them. The goal of this step should be to achieve Stakeholders' and Interested Parties' support for the Process and to solicit their input. Input received should be provided to the Process Leader for consideration in developing the definition of work, hazards, and performance expectations.

8.4 Stakeholder and Interested Parties Involvement

Stakeholders and Interested Parties who have indicated that they want to participate should be provided ample opportunity to do so. The effective involvement of Stakeholders and Interested Parties will help to ensure that the resulting tailored set of standards will be received with support and understanding. The procedures for involving the Stakeholders and Interested Parties should follow the normal site practices or site plan for conducting these interactions.

9.0 Creating Teams



9.1 Creating Teams

Teams are formed to identify the Work Smart Standards set and to confirm that the set is adequate for protection and feasible for implementation. These teams are: the Identification Team, the Confirmation Team, and additional teams, as required (for example, Work/Hazard Identification Team).

It is important that the criteria for selecting all team members reflect the full breadth of issues to be addressed, and that well qualified personnel are made available for these critical assignments.

9.2 Roles of the Convened Group and Process Leader

The Process Leader and the Convened Group should carefully deliberate and agree on the composition and prerequisite qualifications and experience required for membership in the Identification Team(s) and the Confirmation Team. The breadth and specialties of technical and management systems should be specifically identified. Typical candidates to be considered include personnel who are knowledgeable of the work design and performance as well as experts in occupational safety and health, radiation safety, waste management, environmental protection, and quality assurance. Each application of the N&S Process will be unique, so the selection of technical expertise should be appropriate for the work; including personnel with operational expertise and practical work experience is essential. Typical candidates include representatives from facility management and operations. Consideration should also be given to inviting participation by experts from other organizations, either inside or outside the DOE complex. Such broadened participation will enhance the Process and the resulting set of Work Smart Standards.

The Convened Group, in coordination with the Process Leader, should establish the specific criteria for assignment to membership on the Identification and Confirmation teams. These requirements may include a prerequisite number of years experience in a technical field, educational degrees, and specified operational expertise. It may be appropriate to require demonstrated performance in fields requiring knowledge of both commercial standards, DOE Orders and standards applicable to the discipline. Establishing the correct prerequisites for assignment to the Identification Team is an essential first step to ensure that qualified personnel are assembled to develop a comprehensive set of standards. Appendix 3 provides an example of such qualification requirements.

9.3 Criteria for the Identification Team

The identification of a Work Smart Standards Set for a defined scope of work relies on the collective judgment of a team of people who are knowledgeable of the work. The team must establish that implementation of the set is feasible and that the set provides a basis for reasonable assurance of adequate protection. The nature of the work, its complexity, hazards, and uncertainties will determine the breadth of knowledge needed within the Identification Team. Stakeholder input should be managed by the Convened Group since the Federal Advisory Committee Act (FACA) precludes direct involvement by Stakeholders.

The Identification Team collective qualifications should include:

- relevant knowledge, experience, and competence in the work to be performed under the WSS set;
- relevant knowledge, experience, and competence in identifying and evaluating the hazards associated with the work;
- relevant knowledge and competence in the broad array of existing requirements, standards, and proven techniques for control of hazards (for example, DOE Directives, industry codes and standards, applicable laws and regulations); and
- the contribution of subject matter experts, as needed, when qualifications and skills are required.

A sample of a protocol defining the qualification requirements for membership in an Identification Team is included in Appendix 3.

9.4 Criteria for the Confirmation Team

There is considerable latitude available in selecting the Confirmation Team. The Confirmation Team should be separate from the Identification Team but need not be completely independent, for example, the same organization may provide individuals to serve on both teams. The level of formality and degree of independence should be determined by the Convened Group based on individual circumstances of the particular Process application. For complex or controversial issues, Confirmation is expected to involve rigorous methods including, as appropriate, fully independent review teams. The decision of the Convened Group on the Confirmation approach should be based on an evaluation of the complexity, risk, and significance of the work. Past Confirmation Teams have consisted of a separate peer review group within the Identification Team in lower hazard applications; Confirmation Teams in applications dealing with nuclear category II hazards have included an independent group of technical experts, many from external organizations.

Including technical experts from outside the DOE complex can provide useful perspectives to the Confirmation Team. The requirements of the Federal Advisory Committee Act may apply to Confirmation Team activities. Appropriate legal counsel should be consulted if it is desired to include personnel other than DOE and other Federal employees, and DOE contractor and subcontractor personnel.

The collective qualifications of the Confirmation Team should be sufficient to demonstrate and justify the team's conclusion that the proposed WSS set can provide reasonable assurance of adequate protection and is feasible for implementation. The collective skill inventory of the Confirmation Team should be sufficient to examine the application of skills by the Identification Team. The collective skills inventory of the Confirmation Team should overlay the collective skill inventory of the Identification Team; however, it is not expected to be identical. The Confirmation Team should have maturity of view, broadness of perspective and application of skills. The Confirmation Team collective qualifications should include:

- relevant knowledge, experience, and competence in the work to be performed under the WSS set;

- relevant knowledge, experience, and competence in identifying and evaluating the hazards associated with the work;

- relevant knowledge and competence concerning existing requirements, standards and proven techniques (both technical and management) for controlling hazards; and

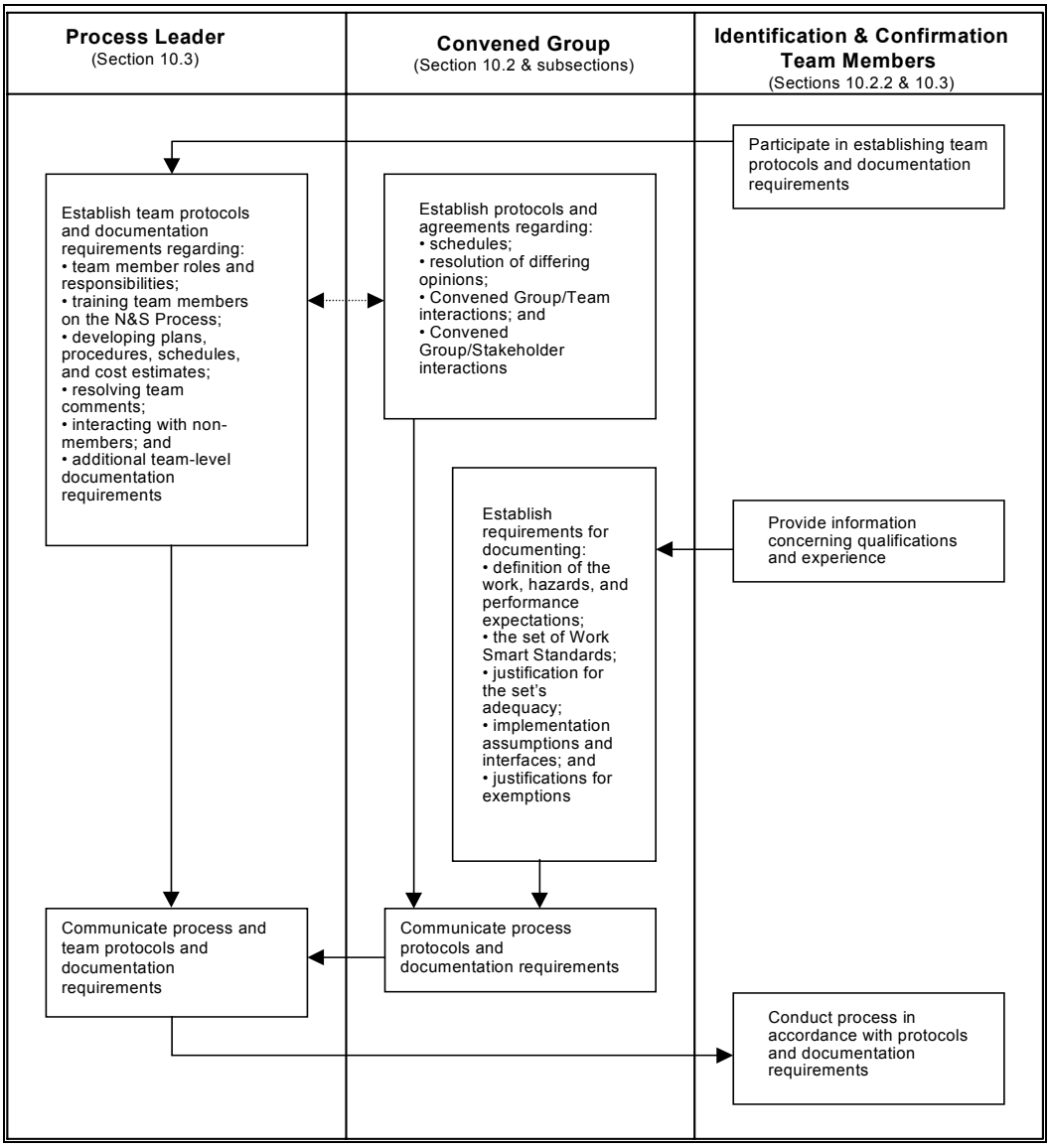
- "intellectual expertise" as would be required in the application to hazards control of scientific, engineering, analytical, and legal matters and "experience expertise" as would be required to conduct skilled hands-on work, applied engineering, work planning and procedure development, and management/supervision.

With respect to feasibility of the proposed WSS set, the Confirmation Team is expected to assess the credibility of the Convened Group's demonstration on this point. The Confirmation Team is not expected to develop a completely independent verification of feasibility. Subject matter experts should be provided to the Confirmation Team to augment the team with detailed knowledge if required. The individuals selected for membership on the Confirmation Team should be capable of rationally developing and articulating their judgments and should have the ability to judge the feasibility of the WSS set.

9.5 Selecting the Identification and Confirmation Teams

Once the criteria for team selection have been established, the process of selecting and notifying the team members should proceed. Members selected should be able to dedicate themselves for the period of time allotted to develop/confirm the comprehensive list of standards. For this process to work effectively, managers should support the assignment of qualified individuals to these teams. The Process Leader may consider the assignment of personnel within subteams to efficiently address selection of standards within specific disciplines. Selection of effective subteam leaders is an important step to ensuring that the identification efforts are closely coordinated, well managed, and that good communications among the subteams and the Process Leader are established. Examples of organizational structures established to conduct the N&S Process are included in Appendix 4.

10.0 Defining and Agreeing to Protocols and Documentation Requirements



10.1 Protocols and Documentation

Effective protocols and documentation requirements provide an important foundation for smooth functioning of the Process and understanding of its results by others who were not directly involved. As discussed in Section 7.3, the Convened Group, with the support of the Process Leader, should identify and develop protocols and documentation requirements

beginning shortly after the Convened Group is assembled. This is particularly important so that necessary records can be constructed early in the application. Then records can continue to be maintained as the Process proceeds, rather than having to reconstruct the history of decisions later. Before beginning the work of identifying, confirming, and approving the set of WSS, all participants must understand and agree to the "ground rules" governing how the various groups and teams will interact with each other and with outside parties. Clear and concise protocols will aid in efficient team functioning, while overly prescriptive protocols that are not thoroughly thought out can cause confusion and lead to inadequate results. It is equally important to define documentation requirements. Careful documentation of the N&S Process will aid in communication between the Identification and Confirmation Teams and assist others in understanding the standards set developed. Records of Process decisions help to demonstrate both the feasibility and fidelity of the Process results. The relationship between protocols and documentation requirements is an important one. A protocol should address each item of documentation (expected output) from the Process.

10.2 Role of the Convened Group

The Convened Group establishes the framework for how their particular application of the N&S Process will be conducted. Decisions are needed in two areas: (1) protocols and agreements for interactions among the various groups and teams involved in the N&S Process, and (2) documentation requirements for the Process and its results. These decisions should be made in close coordination with the Process Leader, and should be documented in a record of decisions. Doing so will establish a common basis for implementing the Process, aid in orienting new team members, and provide a record that will be helpful in demonstrating Process fidelity.

10.2.1 Establishing Protocols and Agreements

The Convened Group establishes protocols and agreements concerning the following:

- *Schedules and time limitations.* The schedule for completing the N&S Process may need to be linked to internal or external commitments, or to schedules for related activities such as ISMS implementation or contract renegotiation.

- *Resolution of differing opinions within the Convened Group and the team(s).* Careful and thoughtful application of the N&S Process will often result in differing opinions among team members. Since this is an expected part of the N&S Process dynamic, this protocol should provide a means for reaching closure on important issues while ensuring due consideration (and, if necessary, documentation) of differing opinions. Existing site practices or protocols for conflict resolution or differing professional opinions may prove helpful. Such a protocol should also address how collective differences of opinion among various groups (for example, Identification and Confirmation Teams) would be resolved.

- *Interactions between the Convened Group and the team(s).* These protocols should address the formality and frequency of interactions between the Convened Group and the Identification and Confirmation Teams, including how the Convened Group will provide direction to and address questions from the team(s). In many cases it has been found helpful to conduct all communications between the Convened Group and the team(s) via the Process Leader. Consideration should be given to the size of the team(s) and whether all members are at the same geographic location.

- *Interactions among the Convened Group and the Stakeholders and Interested Parties.* Appropriate interaction with Stakeholders and Interested Parties is critical to the success of the Process. The Convened Group provides the primary point of contact for Stakeholders and Interested Parties relative to the N&S Process. The value of a carefully thought-out approach for communicating with Stakeholders and Interested Parties about the Process has been proven even when interactions with these groups are expected to be relatively minor. Existing mechanisms for Stakeholder and Interested Party involvement and input should be used where feasible.

The above areas represent the minimum protocols established by the N&S Manual that must be considered by the Convened Group. The Convened Group may well discover other areas for which protocols and agreements should be established. Protocols and agreements should be clearly communicated to all other Process participants. A sample of a charter which includes a protocol developed during a N&S Process application is included in Appendix 5.

10.2.2 Establishing Documentation Requirements

The Convened Group establishes requirements for which items need to be documented during the Process and the level of detail for each. For some items, determination of an appropriate format and level of detail may need to be accomplished iteratively as the Identification Team develops the set of standards and provides recommendations concerning its documentation. The N&S Manual specifies five areas for which the Convened Group must establish documentation requirements. These and additional areas that may need to be documented to ensure an adequate record of how the N&S Process is to be implemented are discussed below.

- *Definition of the work, hazards, and performance expectations and objectives.* Existing safety documentation concerning work and hazards may be useful, but should be evaluated to ensure that all hazards are addressed. Definition of performance expectations and objectives may include schedules for completion of the WSS set, determination of costs, or establishment of performance measures. Documentation for this area should be planned to:

    - identify the linkage between the work and associated hazards;
    - match the level of detail to the specific application;
    - support documentation of the safety program;
    - establish buy-in for performance metrics; and
    - establish the basis for composition of the teams.

- *Documenting the Set of Work Smart Standards.* This documentation compiles the set of standards appropriate for safe conduct of work, including all applicable laws and regulations. There are a number of considerations for deciding how to document a WSS set:

  - How standards are to be expressed in the WSS set: Successful N&S Process applications have used a variety of means to document the set of standards selected including citing the overall regulation or standard, the specific applicable subsection of a regulation or standard, and even the text of the requirement. A high degree of specificity may facilitate development of local procedures from the standards. However, attempting to precisely identify specific sub-sections may risk excluding some applicable portions of a regulation or standard. Listing the full text of all standards may make the set unwieldy, but may be useful when internal standards are used or when only minor portions of a source document are relevant.

  - How the WSS set is to be organized: Documentation of the WSS set should be planned to provide ease of use for all potential users. Computerized databases offer enhanced ability to sort and search the standards list.

  - Tools to be used for documenting the set: The expected size of the WSS set and how it will be used should be considered. Word processing and spreadsheet programs have limited searching and sorting capabilities as compared to data base systems.

- *Justification for the WSS set's adequacy.* Documentation should clearly show that the N&S Process has been faithfully followed by qualified people. Documentation should clearly establish the linkage between the work, the hazards/safety issues, and the WSS set. Key factors to document are : (1) a qualified group of individuals considered the work and hazards, logically selected an appropriate set of standards, justified the selections, and resolved any differences of opinion; and (2) a second group of qualified individuals confirmed the chosen set as adequate and feasible. Documentation of these activities, to whatever level of detail the Convened Group deems appropriate, should include the following components:

- team member names, responsibilities, and qualifications;
- results of the confirmation process;
- discussion of differing opinions and their resolution; and
- documentation of linkage between the WSS set, the work, and the hazards.

- *Implementation assumptions and interfaces.* Assumptions are statements that provide additional information helpful to understanding and implementing the WSS set. They may provide limits on applicability, interpretation of scope, clarifications, feasibility, or acceptable degrees of implementation. Interfaces clarify where information is located, the boundaries of the work scope, and how the WSS set relates to other sitewide safety standards. The level of detail is an important consideration in planning how to document interfaces and assumptions. Guidance on where to document the information (for example, in connection with a particular standard in the WSS set, or in the Process description documentation) should be carefully considered to support later demonstrations of feasibility.

- *Justifications to support exemptions from legal requirements.* Exemption requests should be considered for regulatory requirements that are deemed unnecessary for adequate protection. Documentation to support requests for regulatory exemptions will need to be rigorous and meet any requirements established in applicable regulations. Exemption requests will normally need to be supported by additional documentation beyond that which satisfies the requirements of the N&S Process.

- *Involvement of Stakeholders and Interested Parties.* Documentation of Stakeholders' involvement in the Process provides a vehicle for meaningful input while recognizing that Stakeholders are not decision makers in the N&S Process. Documentation may include a summary of organizations or individuals contacted, public or other meetings held, feedback from those meetings, desire for further participation by attendees, and disposition of comments received. Stakeholders may provide opinions and comments but the scope of their involvement must adhere to the requirements of the FACA.

Stakeholders do not participate directly in the deliberative process. Documentation should demonstrate that Stakeholders have been appropriately involved consistent with protocols and FACA constraints. Interested Parties may participate more directly in the Process, and the Process documentation similarly should make clear what Interested Parties were invited to participate, the extent of their involvement, and the disposition of their input.

In establishing requirements for each area of documentation, the Convened Group should consider both the appropriate level of detail of documentation and the target audience. Specific considerations concerning the target audience are discussed in Section 10.4. A discussion of documentation characteristics and considerations can be found in DOE Guide 450.3-1, *Documentation for Work Smart Applications*.

10.3 Role of the Process Leader

The Process Leader works closely with team members to establish protocols for the internal operation of the Identification and Confirmation Teams. These protocols should mesh with the overall Process protocols developed by the Convened Group, and include the following:

- *Establishing team members' roles and responsibilities.* The Process Leader and team members should agree on the responsibilities and time commitments expected of team members.

- *Orienting team members*. Initially, most team members may not be familiar with the N&S Process, so some amount of training and orientation will be necessary. The means and schedule for accomplishing this should be planned early on in the Process so that team members can be prepared to assume their duties.

- *Developing plans and procedures, including schedules and cost estimates.* These should be consistent with the overall Process schedule developed by the Convened Group, though they will necessarily reflect a greater degree of detail.

- *Resolving team comments within the team.* Before beginning their deliberations, the teams should have a common understanding of how they will work to reach consensus on important issues while ensuring that differing opinions are fairly considered. In the event that a team cannot reach consensus on an issue, then the "differing opinions" protocol developed by the Convened Group should be applied.

- *Interacting with non-members.* The teams should be expected to consult Operational and Technical Experts or other parties to clarify information included in the definition of work and hazards. Plans for these exchanges, including assignment of responsibilities and points of contact within the teams, should be made before the teams begin their work. Interactions with Stakeholders and Interested Parties will generally be conducted via the Convened Group and according to protocols they have established. The Process Leader may be tasked to interact on behalf of the Convened Group with these various parties.

As with the Process protocols developed by the Convened Group, the team protocols should be documented. The Process Leader and team members should also establish any additional requirements for documentation of team activities that they deem appropriate and that are not included in the Convened Group's documentation requirements.

10.4 Audiences for Documentation

Documentation requirements should be planned with an awareness of the target audience and their concerns. Primary audiences for N&S Process documentation are:

- workers and staff (such as ES&H and technical staff) associated with the safe performance of the work for which the N&S Process was performed;

- management, contracting, and legal personnel (both DOE and contractor) who may need to establish and monitor compliance with contract requirements;

- individuals performing the N&S Process, particularly the Convened Group;

- inspection, enforcement, and legal personnel from the site, the cognizant DOE Operations Office, or DOE Headquarters who may need to review compliance with the WSS set and adherence to the Process;

- Stakeholders and Interested Parties, including federal, state and local regulatory authorities with legally assigned interests in the work for which the N&S Process was performed; and

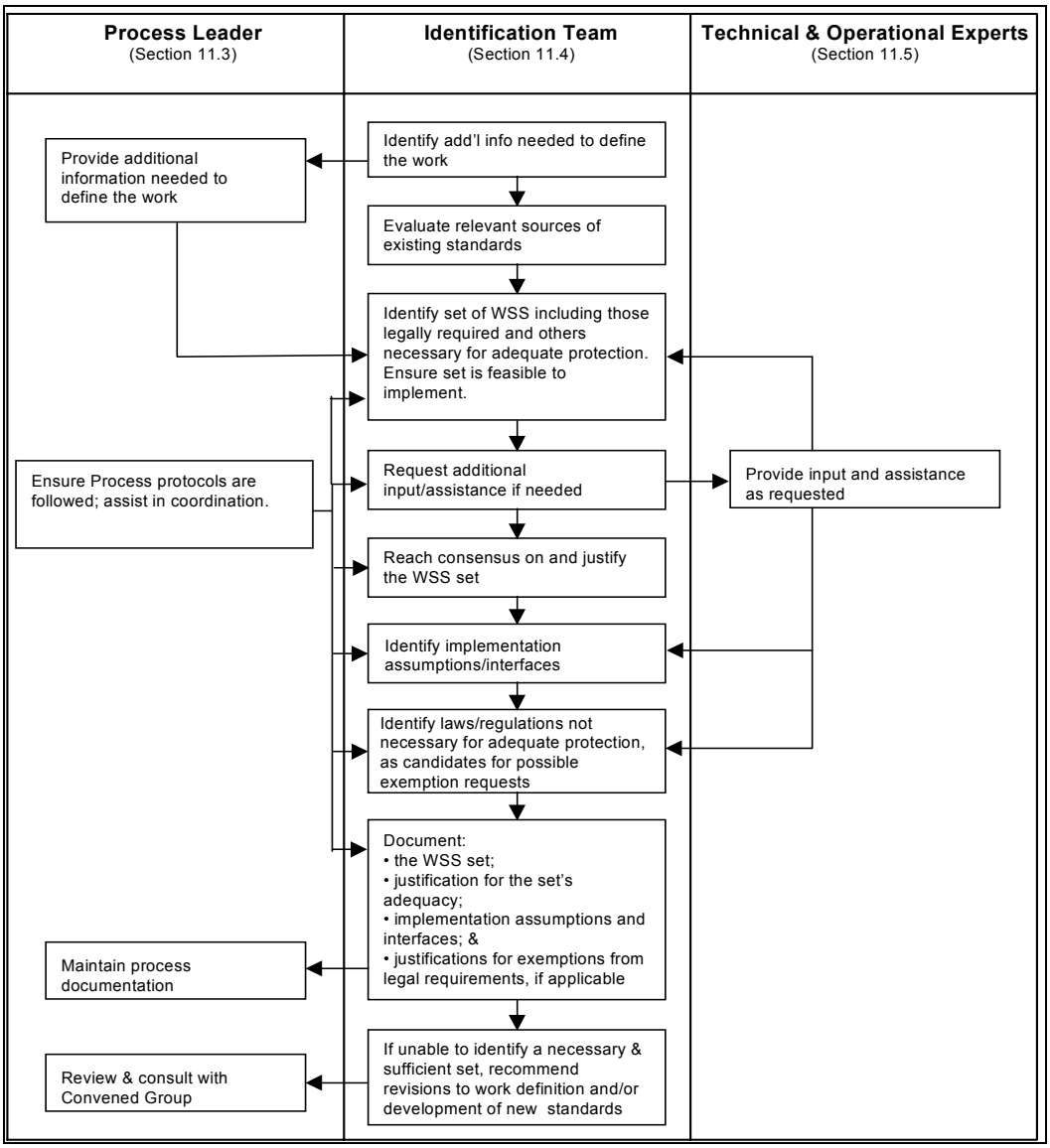
- Confirmation Team members and Approval Authorities who will judge the adequacy and feasibility of the WSS set.

It is intended that the performance of the N&S Process will be progressively documented as it is performed and that a report will be developed that documents the basis for the identification of the work, the identification of the hazards, and the development of the selected set of standards. The final report should be made available to the public. The report may need to be reviewed for security and business proprietary concerns before being released.

Process documentation should be prepared to be understood by objective and reasonably informed individuals knowledgeable of technical and management safety practices. The substance of Process documentation is to establish that the N&S Process has been applied with fidelity to produce an appropriate WSS set that is feasible to implement. Most items of documentation will need to serve multiple audiences, perhaps with markedly different interests and backgrounds. Some may desire information in greater detail. Detailed backup information progressively maintained as the N&S Process is performed can be used to augment the report for audiences who need additional detail.

Process documentation justifies the sufficiency of the outputs in a positive sense, by demonstrating that the Process was applied with fidelity. No rationale or justification is needed for standards that are not selected as part of the WSS set. Examples of N&S Process documentation can be found on the WSS home page (http:tis.eh.doe.gov/dsc/worksmart.html).

11.0 Identifying the Set of Work Smart Standards



11.1 Identifying the Set

A Work Smart set of standards is the principal product of a successful N&S Process application. A WSS set includes all applicable federal, state, and local laws and regulations as well as other standards that are necessary and sufficient to provide adequate protection for workers, the public, and the environment. The set must also be feasible for implementation,

meaning that it can be implemented within expected resource and time constraints. The work of identifying standards is carried out by the Identification Team, operating within the protocols and documentation requirements previously established.

Experience has shown that properly performing the identification process will often require more time than initially expected. Identification Team discovery time can be reduced if participants are provided adequate training, a well thought out charter or statement of work from the Convened Group, and strong liaison between the Team and the Convened Group (via the Process Leader).

11.2 Standards Reference Base

The term "standards" is intended to have broad meaning. Standards are the expressed expectations for performance of work. Standards may be reference points against which to measure excellence or may become enforceable requirements (either under law or under Department contract.) Standards includes: Federal, state, and local laws and regulations; Department Orders; nationally and internationally recognized standards; and other documents (such as industrial standards) that protect the environment and the safety and health of our workers and the public. Standards are an accepted way of communicating to our workers and the public the performance we expect in our daily operations. They are supportive of work, not barriers or extra burdens.

The “starting point” for determination of which standards will be considered during application of the N&S Process is a thorough understanding of the work and its associated hazards. The WSS set is expected to include standards that, when properly implemented, will provide reasonable assurance of adequate protection for workers, the public, and the environment. The WSS set is expected to include all applicable requirements in federal, state, and local laws and regulations, as well as other standards identified through the N&S Process which are necessary and sufficient to provide adequate protection to workers, the public, and the environment. Potential sources of such other standards include, but are not limited to, DOE directives, DOE Technical Standards, and nationally and internationally recognized commercial consensus standards.

Some safety control topics that are of particular or unique interest to DOE are typically identified for standards definition only in DOE directives. These directives represent a broad-based collective knowledge developed over a wide expanse of often unique hazards and should be considered for applicability to the particular work and hazards under consideration by the WSS set. Safety control topics that are uniquely addressed and invoked by DOE Orders must be addressed in the WSS set if they are relevant to the work and the hazards. Direct incorporation of DOE Orders into the WSS set is one, but not the only, means of addressing these topics. Considerations for the Identification Team in identifying a standard for inclusion in the WSS set from among competing standards reference bases include:

- the expectations of the Convened Group,
- acceptability of the identified standard to the collective judgment of the Identification Team,
- confidence in the identified standard by the audiences for Process documentation,
- feasibility of implementing the identified standard in the context of the work and hazards,
- experience in practices for implementing the identified standard,
- specificity with which the identified standard addresses the work and the hazards,
- familiarity of the work force with implementation of the identified standard, and
- the synergistic effect of implementing the identified standard to control more than a single hazard.

In some cases, it has proven valuable when documenting the adequacy of the WSS set to include a mapping matrix which illustrates where the topical area of a DOE directive is linked to the same topical area in the identified standards. Such mapping is not mandatory but will facilitate familiarization with the WSS set by other parties. A sample of a mapping matrix which was developed during a N&S Process is provided as Appendix 6.

11.3 Role of the Process Leader

The Process Leader plays a vital role in the performance of the Identification Team. The Process Leader facilitates and coordinates the activities of the Identification Team, providing the team with direction and focus that are consistent with direction from the Convened Group. Acting as the formal liaison between the Identification Team and the Convened Group, the Process Leader will need to ensure frequent communication and feedback between the two groups, in accordance with the protocols established previously. In particular, the Process Leader must ensure that the definition of the work and hazards being used by the Identification Team becomes clear and complete. The Process Leader should be alert for the need to seek clarification on this or other issues from the Convened Group, and ensure that the Convened Group stays actively engaged in the Identification Team's activities. Finally, the Process Leader should guide the Identification Team in documenting their work so that the documentation requirements are met.

11.4 Role of the Identification Team

The work of the Identification Team depends on a good definition of the defined work and hazards, and proceeds according to the pre-established protocols under the guidance of the Process Leader. While the team is provided with the definition of the work and the hazards, they should know the work sufficiently to verify that the input they are provided is correct and complete. Because the definition of the work and hazards is intimately related to the process of identifying a set of standards, further refinement of these definitions is an appropriate function for the Identification Team. Throughout their work, they should continue to validate this and challenge the adequacy of the work and hazards definitions. This philosophy should be part of the training for the team.

The feasibility of the WSS set depends upon the standards implementors' recognition of the work as defined. In the event that a significant re-organization of a current work scope is being implemented (for example, with the transition from a Management and Operating to Integrating type contract), this often leads to alternative mechanisms for work planning, increased interfacing among groups and thus different roles and responsibilities. The Identification Team must thoroughly examine the context in which the work will be performed and include standards that address these features. ISM Plans often reflect such standards.

Identification Team members should work together to satisfy objectives and expectations established by the Convened Group as a whole, and not to represent individual or organizational agendas. Even with the proper mix of committed, knowledgeable personnel, some time will be needed for the group to "jell" as a team, and to begin working productively under a common set of expectations. The Process Leader's earlier work with team members in developing protocols and documentation requirements will provide an important foundation for developing a common team approach. Central to this team approach is the need for all team members to be fully qualified, empowered to make decisions, and dedicated to participate. The N&S Process is designed to be carried out by a team, not by an active few reporting back to a larger group of individuals who are only marginally or sporadically involved. Reliance on "alternate" Team members, while permitted, will often impede the timely and effective resolution of issues.

The N&S Process is designed to be iterative. As work proceeds in one process element, information from a previous element may need to be revised or expanded. During identification a number of factors (such as the need for different/additional team members, or the need to better define the work and hazards) may arise that require revisiting one or more of the earlier process elements.

In addition to identifying other information or expertise needed, the Identification Team performs the following:

- *Evaluate relevant sources of standards.* Drawing on their expertise, the Identification Team evaluates relevant existing standards that address the identified hazards as discussed in Section 11.2, Standards Reference Base. Though it may be tempting at this point to "cut and paste" from the standards set used by another (perhaps similar) DOE site, experience has proven the value of conducting a zero-based analysis to focus on the specific work, hazards and work environment. Such local tailoring ensures that potential feasibility issues are fleshed out and addressed, if necessary, by the Convened Group.

- *Identify the standards that constitute a necessary and sufficient set and are feasible to implement.* The WSS set must include all applicable federal, state, and local laws and regulations plus any other standards that are judged necessary to provide adequate

protection for workers, the public, and the environment. The determinations of adequacy and feasibility are based on team members' judgment and experience, buttressed by team interaction and discussion, and the involvement of additional experts if needed. Feasibility relates to the local context and the Responsible Organization's readiness to implement the WSS set. Contentious issues of feasibility should be referred to the Convened Group as they are responsible for line management buy-in with the WSS set.

- *Reach consensus on and justify the WSS set.* It is essential that team members begin by "agreeing to agree" and engage in constructive dialogue to reach consensus. Protocols for group decision-making and consensus should be applied. Since experience has shown the value of synergistic interactions among team members with different technical backgrounds, most of the team's work should be conducted in face-to-face meetings. Justification means that a rationale is developed for the adequacy and feasibility of the standards proposed for inclusion in the WSS set. Consideration of feasibility should be in consonance with the conclusion that the standards set provides reasonable assurance of adequate protection. Feasibility focus is not on the ability of the standards to guide performance (i.e. "adequacy"), but rather on a potential future failure to achieve standards-based and safe work. Such failures could occur if management systems and processes are not capable of delivering work based on the WSS set or if resources are not sufficient to design and perform the work consistent with the WSS set. The N&S Closure Process requires the Identification and Confirmation Teams to assess both the adequacy and feasibility of the standards set. The agreed upon definition of the work and the institutional implementing assumptions about how that work will be carried out are first developed as a description of initial conditions by the Convened Group during Process Element 1: Defining the Work and Hazards. The requirements for describing both work objectives and a relationship for those work objectives to some organized system for the delivery of that work are equally important to the ultimate utility of the WSS set. By starting with the Convened Group's core of guidance, the identification team is reasonably expected to further refine the definition of work, hazards and controls in a way that integrates implementability and technical sufficiency to provide for adequate protection. Explaining the disposition of standards which were not selected is neither required nor desired. It is often helpful to provide a mapping matrix which illustrates how the topical area of identified standards

link to the same topical area of DOE directives. Although not required, such cross-referencing will facilitate later review of the WSS set. Mapping the proposed WSS set back to the identified work and hazards has proven to be an effective way to evaluate the comprehensiveness of a proposed WSS set. Also, experience has shown that a WSS set derived from the work and hazards may result in a need to modify existing management systems. Mapping is an extremely valuable tool to aid in transitioning from the as-is management systems to revised management systems that can effectively deliver the WSS set.

- *Identify any implementation assumptions and interfaces.* Implementation assumptions include any unique resource requirements or time constraints for the use of certain selected standards. Interfaces relate to the relationship between the requirements associated with the work to be performed and others beyond the scope of that work. These requirements may be organizational, physical, or programmatic. Clear identification of any implementation assumptions and interfaces is critical to prevent the WSS set from being applied counter to the Identification Team's intentions. These factors should be addressed in detail to support the Confirmation Team's review for the feasibility of the set.

- *Identify legal requirements that may be candidates for exemption requests.* The Identification Team may judge the value of applicable regulatory requirements included in the WSS set. Exemption requests may be appropriate for regulatory requirements that are deemed unnecessary for adequate protection. If such requirements are found, the Identification Team should provide a thorough justification to support an exemption request from the appropriate regulatory body. Actual preparation and follow up of any exemption requests will be performed separately from the N&S Process itself, but will rely heavily on the work of the Identification Team. Each applicable legally binding requirement is mandatory and continues in force until and unless the mandating authority provides an exemption to the requirement.

- *Document results.* Documentation should be prepared according to the Process and team protocols discussed earlier. The importance of careful and thorough documentation cannot be overemphasized. Documentation prepared by the Identification Team will form the basis for demonstrating fidelity to the N&S Process, for

understanding the WSS set, and for communicating Process results to the Confirmation Team, the Approval Authorities, and to Stakeholders and other Interested Parties.

11.5 Role of Technical and Operational Experts

Assistance from Technical Experts or Operational Experts may be requested when the Identification Team requires additional expertise in a specific area. Technical and Operational Experts are not necessarily members of the Identification Team, but are requested as required to provide input and assistance for a specifically defined area. The use of such contributing experts will be dictated by the complexity of the Process application and the composition of the Identification Team. The Identification Team is solely responsible for its work product; use of subject matter experts is not a compensatory measure for inadequate range of knowledge and experience on the Identification Team. The Team should recommend its membership be expanded if it becomes dissatisfied with its collective knowledge and experience.

11.6 Process Documentation

General considerations for developing N&S Process documentation have been discussed earlier in Section 10.2.2. Documentation from the Identification process will be needed to support confirmation, approval and maintenance of the WSS set. The bases documentation should be sufficient to clearly identify the bases for the WSS set. This is of significant importance for maintaining the standards set. Specifically, documentation from the identification process should demonstrate the following:

- *Identification Team members are adequately qualified, both collectively and individually, in relation to the work and hazards addressed by the WSS set.* Since the qualification of team members is crucial, documentation should relate the team's qualifications to the standards set. An adequately formed Identification Team must demonstrate that it is more than the sum of narrow discipline expertise.

- *The N&S Process was implemented with fidelity to the requirements of the N&S Manual.* This may include documentation describing the initiation of the Process, assignment of responsibilities within the Identification Team, meeting notes, results of deliberations, plans, schedules, training records, issue identification and resolution, and others. In

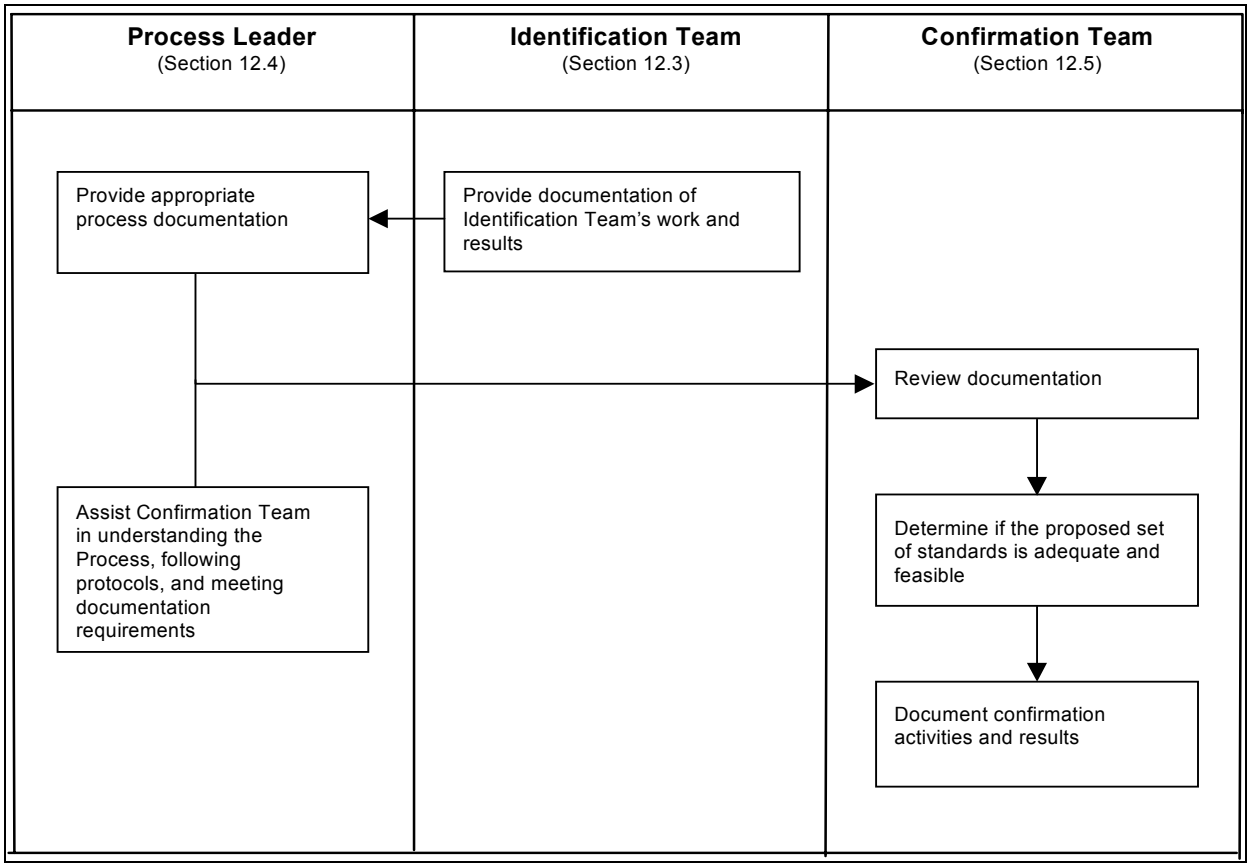
addition, documenting input from contributing experts, resolution of differing opinions, and development of consensus among the Identification Team will provide valuable insights for confirmation.

- *The proposed set of WSS addresses all hazards related to the work and, when properly implemented, will provide adequate protection from those hazards for workers, the public, and the environment.* When the use of locally developed standards is judged necessary, the documentation for these standards needs particular care. Documentation of feedback from Identification Team members and contributing experts is important.

- *The proposed set of WSS is feasible to implement within the context of the work to be accomplished and known resource constraints.* The Identification Team's consideration and determination of feasibility should be clearly documented to facilitate review by the Confirmation Team and the Approval Authorities.

The quantity and detail of documentation should support and not overwhelm subsequent reviewers or the eventual users. Simply "documenting everything" will not necessarily ensure that the needs of all (or even most) users will be met. Documentation that reflects some synthesis or summary is generally more useful than a mass of raw data (for example, a summary of issues raised by the team and their resolution versus detailed minutes of every meeting and phone conversation). However, documentation and retention of certain items of "raw data" obtained during the Process may be important to preserve corporate memory of the Process and to corroborate summary reports. A discussion of documentation characteristics and considerations can be found in DOE Guide 450.3-1, *Documentation for Work Smart Applications*.

12.0 Confirming the Set of Work Smart Standards



12.1 Confirming the Set

Confirmation occurs after satisfactory completion of the identification process, when the Identification Team's results are turned over by the Convened Group to the Confirmation Team. The confirmation process is akin to peer review of a scientific paper or research results. It may identify serious flaws or minor adjustments needed in the WSS set, or may completely confirm the Identification Team's selections with no changes. In each case, confirmation strengthens the N&S Process by providing assurance that conclusions reached by the Identification Team were sound. The results of confirmation allow the Approval Authorities and other parties -- particularly those external to the Process application -- to have greater confidence in the adequacy and feasibility of the WSS set.

12.2 Readiness for Confirmation

The WSS set is ready for confirmation when the Process participants (including the Process Leader, the Identification Team, and the Convened Group) are satisfied that they can demonstrate fidelity to the Process; can justify that the WSS set will afford reasonable assurance of adequate protection for workers, the public, and the environment; and that the WSS set is feasible for implementation. This means that confirmation may begin when, in their view, the Process participants have completed, documented, and are prepared to report the results of their use of the N&S Process.

Confirmation itself is neither a self-assessment nor a forum for adjudicating issues unresolved by the Identification Team. Self-assessments of the Process and its results can be of great value and should be conducted prior to confirmation. Such self-assessments (sometimes referred to as “murder boards”) should be rigorous to ensure the WSS set and Process documentation are ready to withstand scrutiny by the Confirmation Team. Issues or questions raised during confirmation should be resolved between the Confirmation and Identification Teams, or if necessary, with the Convened Group. Confirmation itself should not be undertaken until all participants, including the Convened Group, are satisfied that all previous process elements have been fully completed and appropriately documented. A sample of evaluation criteria to be used in the development of self-assessment programs for evaluating the performance of the N&S Process and confirming readiness is provided in Appendix 7.

Experience with the Process has demonstrated that on occasion readiness for confirmation is judged primarily against the adequacy of the WSS set and at the expense of demonstration that implementation of the set will be feasible. The Confirmation Team may lack the Identification Team’s familiarity with local infrastructures for planning and doing work. Confirmers may benefit from briefings or documentation regarding the “as is” condition that is the foundation upon which the new WSS set will be laid.

12.3 Role of the Identification Team

The work of the Identification Team, including their documentation, provides the starting point for confirmation as well as approval of the WSS set. It is essential for the Identification Team to understand the confirmation and approval processes and to prepare documentation that will

clearly demonstrate, under rigorous review, fidelity to the N&S Process and the adequacy and implementability of the WSS set. Complete documentation justifying the adequacy of the proposed WSS set should be prepared for transmittal to the Confirmation Team, along with a list of the complete set of proposed standards linked to the work and hazards.

12.4 Role of the Process Leader

The Process Leader plays a key role in confirming the WSS set. The Process Leader facilitates and coordinates the activities of the Confirmation Team and provides the team with direction and focus that are consistent with direction from the Convened Group. Although the Confirmation Team is expected to operate more independently than the Identification Team, the Process Leader should be sufficiently involved in the confirmation process to ensure that a proper understanding of the N&S Process application and the protocols established by the Convened Group are followed. Any significant issues raised by the Confirmation Team should be brought to the attention of the Convened Group as they are raised, in the event that the Convened Group may need to act on issues raised by the Confirmation Team. Since the Confirmation Team will likely involve individuals who are new to the N&S Process, the Process Leader should orient the team members to the goals, objectives, and methods of the N&S Process in general as well as to the particulars of the individual Process application. Finally, the Process Leader should guide the Confirmation Team in documenting their work to meet the previously established documentation requirements.

12.5 Role of the Confirmation Team

The role of the Confirmation Team is to independently assess whether the proposed WSS set developed by the Identification Team is adequate and feasible. Membership qualifications, criteria, and assignments are developed by the Convened Group earlier in the Process. Typically membership of the Confirmation Team is independent from the Identification Team. Should members of the Identification Team be included in the Confirmation Team, those members should not review their own work. Once constituted, the Confirmation Team performs the following tasks:

- *Review the material provided by the Identification Team and any other documentation required for confirmation.* Documentation and presentations provided by the

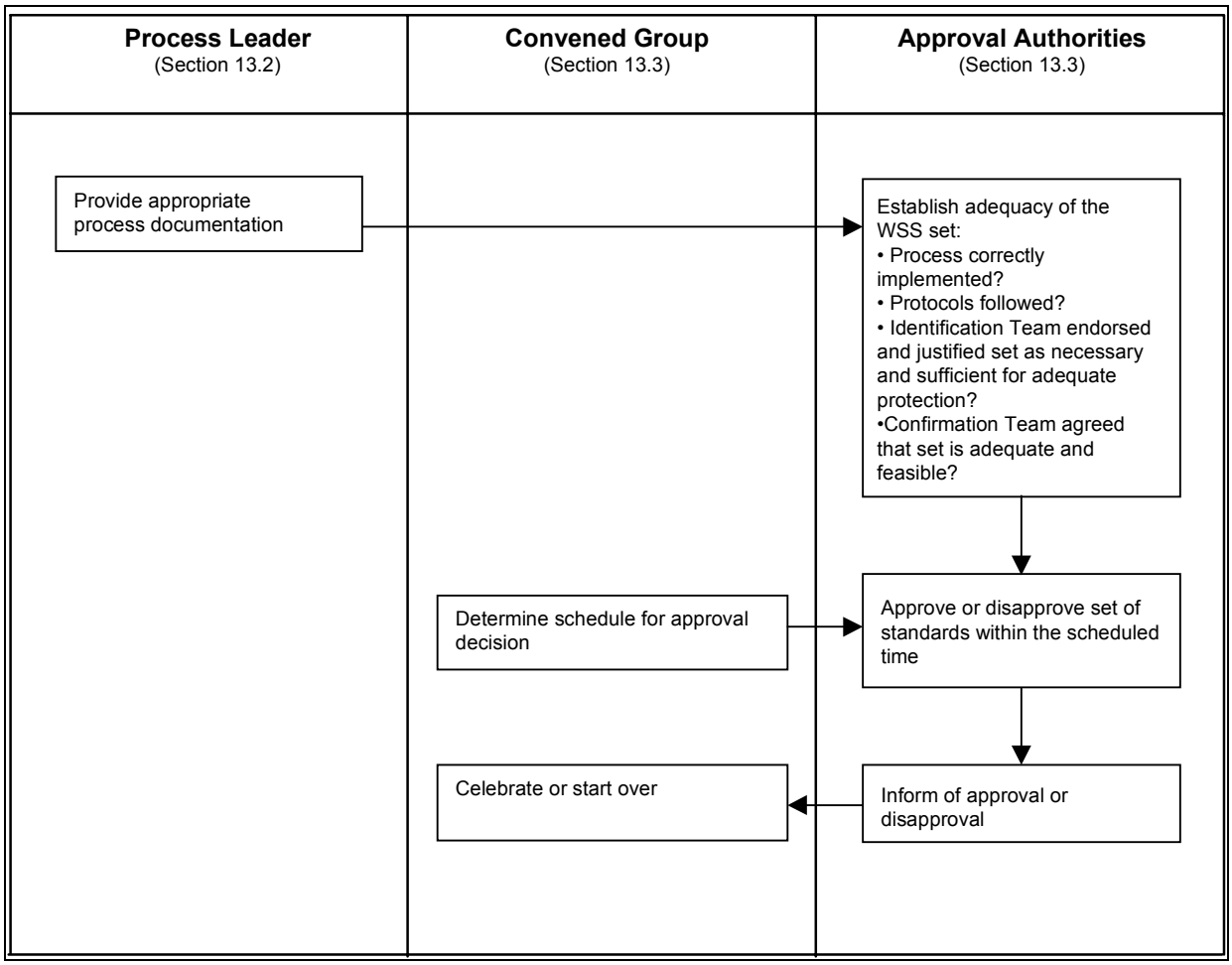
Identification Team should facilitate an understanding of the work and the set of standards selected and the rationale for a judgment of adequacy. The Confirmation Team should be free to draw upon whatever additional resources they feel are necessary to arrive at an independent conclusion. If additional documentation from the identification process is needed, this should be requested through the Process Leader. The Confirmation Team's principal focus is to assess the adequacy and feasibility of the proposed WSS set, not to repair shortcomings identified or to lobby for alternative standards.

- *Determine whether the proposed set of standards is adequate and feasible.* These conclusions should represent independent judgments by the Confirmation Team, based on their collective knowledge and experience. Confirmation does not seek to reproduce the WSS set from scratch, nor is it a "rubber stamp" for judgments made by the Identification Team. Rather, the Confirmation Team provides an independent assessment of the adequacy and feasibility of the proposed WSS set. The confirmation process is guided by the expectations defined by the Convened Group and draws upon the results and documentation from the identification process.

- *Document the confirmation activities and their results.* As in the identification process, documentation from the confirmation process should be prepared according to the Process and team protocols developed earlier. This documentation together with that prepared by the Identification Team will form the basis for a decision by the Approval Authorities. It will also be a key tool for communicating the Process and its results to Stakeholders and other Interested Parties, and should be prepared accordingly.

If the Confirmation Team judges the proposed WSS set to be inadequate or infeasible, the Convened Group should be informed and the Confirmation Team's findings should be referred back to be addressed by either the original or a new Identification Team. The Confirmation Team should provide a thorough explanation and rationale for their decision, so that problematic areas can be appropriately addressed. Even if the proposed WSS set is judged to be adequate or feasible, information from confirmation may suggest the need for rework or improvement in some areas. Such actions should be dispositioned and followed up by the Process Leader according to the previously established Process protocols.

13.0 Approving the Set of Work Smart Standards and Authorizing Work to the Set



13.1 Approving the Set

Approval of the WSS set is based on the results of the identification and confirmation processes, and requires continuous engagement by the Approval Authorities from the beginning of the N&S Process. Approval of a WSS set means that the management of the involved organizations (generally DOE and a contractor) formally agree to the following:

- that proper implementation of the proposed WSS set will provide reasonable assurance of adequate protection, and that any residual risks are acceptable;

- that Resource Authorities will provide, or seek through the normal budget process, the resources necessary to implement the WSS set; and

- that the WSS set is authorized and accepted for use for the defined scope of work, subject to any implementation assumptions.

In many cases, the agreed-upon WSS set resulting from an N&S Process application will need to be incorporated into a contract in order to become effective and binding upon the contractor. Approval itself does not incorporate the WSS set into a contract. However, approval of a WSS set represents a significant agreement between DOE and a contractor and should be planned so that it facilitates contractual modifications. In previous N&S Closure applications, the appropriate DOE Contracting Officer has served as the WSS DOE Approval Authority. The Contracting Officer was involved as an Approval Authority at the beginning of the N&S Closure Process application and was engaged throughout the Process. Contractual negotiations for changes to the contract followed directly from approval of the WSS set. As stated in DEAR 970.5204-78*. Laws, Regulations and DOE Directives*, paragraph (C):

> "Environmental, safety, and health (ES&H) requirements appropriate for work may be determined by a DOE approved process to evaluate the work and the associated hazards and identify an appropriately tailored sets of standards, practices, and controls, such as a tailoring process included in a DOE approved Safety Management System implemented under 48 CFR (DEAR)970.5204-2. When such a process is used, the set of tailored ES&H requirements, as approved by DOE pursuant to the process, shall be incorporated into List B as contract requirements with full force and effect." Should the scope of work be revised in such a manner that the work or hazards bases are significantly altered, a reinitiation of the N&S Closure Process may be appropriate. If the standards set is used to identify contractual requirements, a revision to the WSS set will typically be incorporated into List B as a revision to the contract.

13.2 Role of the Process Leader

The Process Leader ensures that all appropriate documentation is made available to the Approval Authorities. The documentation should be sufficiently clear and concise to stand alone and to facilitate decision making by the Approval Authorities.

13.3 Role of the Approval Authorities

Following confirmation, the WSS set is presented to the Approval Authorities who have been previously designated by the Convened Group. Approval of the WSS set should be at the level of management where allocation of resources and direction of work clearly reside. It is at this level that the authority to approve will be matched with the responsibility to carry out the work safely.

The role of the Approval Authorities is not to “second-guess” the set of standards selected by the Identification and Confirmation Teams, nor to single-handedly replicate the identification and confirmation processes. Rather, the Approval Authorities are tasked to evaluate three specific areas:

1) Whether the Process has been implemented with fidelity, including the provision of proper documentation as defined by the Convened Group.

2) Whether the Identification Team has endorsed and justified the WSS set as providing reasonable assurance of adequate protection when properly implemented.

3) Whether the Confirmation Team has confirmed the adequacy and feasibility of the WSS set.

In other words, the Approval Authorities should evaluate whether the N&S Process has been followed with fidelity. The Approval Authorities should not insert changes; however, they may question the results as appropriate. Each step in the N&S Process is designed to build confidence that the WSS set, when properly implemented, will provide reasonable assurance of adequate protection for workers, the public and the environment. Early and continuous close involvement by those who will ultimately approve the set ensures a smooth approval process.

Examples of Approval Authorities for some successful applications are presented in Tables 1 and 2. Examples of a request for approval of the WSS set and the final approval document are included in Appendix 8. The approval of the WSS set should be the final step by the Approval Authorities to assure themselves that the Process has been conducted with fidelity and that all parties involved in developing the set have confidence in the product of the Process.

13.4 Criteria for Sufficiency of the Process Elements

Among other things, the Approval Authorities are required to determine whether the N&S Process has been implemented in accordance with the requirements of the N&S Manual. The process elements defined in the Manual are written in performance-based terms, and do not form a prescriptive or generally applicable checklist for determining Process sufficiency. The Convened Group, in implementing the N&S Manual, sets performance expectations and objectives for each step of the N&S Process. If these expectations and objectives have been effectively established, full performance to those expectations and objectives should demonstrate that the Process is sufficient. Appendix 7 provides a comprehensive assessment tool that can be used to obtain insight about the extent of Process fidelity demonstrated during the application.

14.0 Implementing the Set of Work Smart Standards

For any particular scope of defined work, an approved Work Smart Standards set forms an essential component of the basis for the related DOE-approved Safety Management System. The WSS set can be viewed as the specifications to the integrated implementing mechanisms, (i.e. procedures and manuals of practice) for the delivery of standards based work. Application of these specifications provides confidence work will be done safely. Throughout the Identification, Confirmation and Approval steps, participants should consider the feasibility of implementing the WSS set through the ISM system. They should identify and document changes that may be required to existing equipment, infrastructure or work processes and cost. The existing procedures and practices may enable implementation of the WSS set or it may be necessary to develop new administrative controls. Where discrepancies are identified with existing implementing mechanisms, these discrepancies are targeted for corrective action and should be tracked to closure. In the case of a new organization that is initiating activities not previously authorized, the implementation of operational readiness review provisions in the

WSS set may dictate that a significant level of activity and structure be applied to the conduct of implementation.

Criteria for implementation accrue during the Process. As the work of the Process progresses, effective implementation must be an ongoing concern of the Approval Parties, Process Leader, the Convened Group, the Identification Teams and the Confirmation Team. Line management and staff are responsible for implementing the set. The N&S Process participants are responsible for the implementability of the set. The Necessary and Sufficient Closure Process Manual requires that a WSS set be both adequate and feasible. To have a set accepted as feasible it must be implementable. (See also Appendix 1, Q&A 20 on Feasibility.) Under the guidance of the Convened Group the Process participants complete responsibilities that will provide most of the criteria for adequate implementation. The following serve to guide managers in the Responsible Organization.

In Process Element 1: Defining the Work and Hazards, the requirements for describing both work objectives and a relationship of the work objectives to some organized system for the delivery of that work are equally important to the ultimate utility of the WSS set. By starting with the Convened Group's core of guidance, the Identification Team refines the definition of work, hazards, and control infrastructure in a way that integrates implementability and technical sufficiency to provide for adequate protection. Records of these considerations are made to aid those charged with implementation.

In Process Element 4: Identifying the Necessary and Sufficient Set of Standards, relevant knowledge of the work and the available mechanisms of performance are brought to bear to achieve an adequate and feasible WSS set. The requirement that the Identification Team confirm and document implementing assumptions serves to address issues of feasibility in going from the pre-WSS situation of the organization to a post-Process state of WSS conformance. Properly developed WSS sets will document assumptions about the specific "system for managing the work" into which the care and implementation of the new standards set will be entrusted.

During Process Element 5: Confirming the Necessary and Sufficient Set of Standards, the Confirmation Team examines how well the Convened Group and the Identification Team in working to closure on the proposed WSS set have anticipated and addressed the conditions in

the implementing organization. This is done to provide the Approval Parties assurance that the existing "system for managing the work" can "get there" (to WSS conformance) "from here" (the prevailing condition of the organization).

The Process Leader, in presenting the documentation of the WSS set to the Approval Parties, should indicate what prior steps have been taken toward adequate implementation. Additional implementability actions recommended in the Process documentation should be brought to the attention of the Approval Parties. While the bulk of any needed actions will normally fall to the Responsible Organization, in many situations some supporting actions may be necessary by the other Agreement Parties. These actions should be coordinated by means of the normal processes for contract change control at the level of ISMS approval for the defined scope of work (e.g. DOE to prime contractor, or prime contractor to major subcontractor).

In addition to the verification that the WSS set has been faithfully applied in the sense of a specification, there is often a cultural component involved with implementation. The successful application of the Process as a decision-making discipline has often worked a notable transformation of attitudes between the Responsible Organization participants and their DOE counterparts. This product of the Process may stand in considerable contrast to expectations of cooperative engagement that exist elsewhere in the organizations. In such instances, the Convened Group is expected to have considered the necessity of widespread cultural adjustment as a factor in WSS set implementation. As with any significant safety initiative, senior management has the authority to employ many proven techniques to facilitate organizational acceptance of the transition to a more standards-based and work-centered approach to the conduct of work. DOE Guide 450.3-2, *Attributes of Effective Implementation*, provides a description of outcome criteria for evaluation of WSS set implementation effectiveness. This Guide identifies 21 measurable attributes which have been correlated with effective standards implementation.

15.0 Maintaining the Set of Work Smart Standards

Work and its hazards are dynamic. Static sets of requirements – even when carefully developed and fully complied with – cannot be relied upon indefinitely to provide assurance of safety. A number of conditions may indicate a need to revise the WSS set or some portion thereof. Such conditions could include:

- changes in mission and work, or work conditions, resulting in a different set of hazards;
- discovery of new hazards or better understanding of existing hazards;
- input from Stakeholders, Interested Parties, or Departmental lessons learned that suggests the existing standards set may not be necessary and sufficient to adequately address all hazards;
- changes to laws, regulations, standards, or DOE directives that are included in the WSS set; or
- changes in contract or contractor.

Effective maintenance of the WSS set requires continuing vigilance for change. Changes to mission, equipment, facilities, processes, materials, etc. may introduce new hazards. Changes to procedures, personnel or budgets may likewise introduce new circumstances that should be evaluated. New regulations, revision of standards or DOE directives are also sources of changes that must be evaluated. Robust change control mechanisms are a requirement of Integrated Safety Management and WSS sets should be controlled through these mechanisms. When changes are noted that may raise safety concerns, the WSS standards basis should be evaluated to determine if the WSS set should be revised. In practice it is considered advisable that the WSS set contain a standard for controlling the set. The guiding principle should be that a single standards change control mechanism for controlling all standards, including the WSS set, should be established as part of the ISMS.

Many of the above noted potential change conditions mirror the N&S Process initiation criteria that are stated in the N&S Manual and discussed in Section 7.1 of this Handbook. These criteria apply not only to an initial application of the N&S Process, but also to subsequent conditions under which the N&S Process may be reinitiated. Change control, therefore, may often amount to reinitiating the N&S Process, although typically on a more limited scale.

Change control for a set of WSS should preserve or renew the integrity of the original N&S Process determination of adequacy and feasibility. By design, the N&S Process uses the collective expertise of carefully selected teams to reach a thorough understanding of the work

and its associated hazards and to identify and confirm a set of standards that can be implemented to provide reasonable assurance of adequate protection from those hazards. If changes to the resulting WSS set are not made with fidelity to the N&S Process, then the integrity of the entire standards set, and the assurance of protection that it represents, may be compromised. “Replacement parts” for the WSS set must be identified and considered with the same rigor that went into the original set. Documentation for the approved WSS set should be sufficient to clearly identify the standards bases. When changes to the WSS set are made, the WSS documentation should be revised to reflect the changes and the bases for those changes. This is of significant importance for maintaining the WSS set.

At the same time, a WSS change control process should be simple enough to be readily usable within the existing organizational structure. An overly complex process or one which takes great effort to initiate will only invite disuse, with correspondingly negative impacts to the integrity of the WSS set. While the change control process should include the basic elements of the N&S Process, it need not (and in most cases, should not) duplicate the scale and scope of the original N&S Process effort. Change control amounts to a focused application of the N&S Process, appropriate to the scope of the proposed change.

Change control for the WSS set is an integral part of the ISMS. Establishment of an ISMS will include a hierarchy of documents to flow down contractual requirements for the work. A change control process is an expected component of such a document system. Since the same document hierarchy will also contain the WSS set and lower-level requirements flowing from it, the change control process established as part of the ISMS should be designed to handle changes to the WSS set as well as other site documents. Change control for the WSS set is therefore not divorced from other site processes, but rather is an integral part of the ISMS.

Establishing fixed organizational responsibilities for change control allows change control to be accomplished in a routine manner while preserving fidelity to the N&S Process. And finally, the change control process should screen proposed changes on the basis of their safety significance, so that the system does not become clogged with items of low importance. It may be helpful to collect “minor” changes for periodic (for example, quarterly, semiannual) review by the appropriate team(s) rather than reviewing them individually, or to provide for streamlined processing of certain types of changes.

In summary, an effective change control process should be characterized by the following:

- The change control process should be a part of the organization's Integrated Safety Management System, as is the N&S Process.

- The change control process should be implemented at an appropriate point in the N&S Process, typically after approval of the initial WSS set.

- The change control process should provide for screening of new inputs (for example, information about new work or changed hazards) to determine the need and appropriate mechanism for further action. Not all changes will require the same degree of attention. Minor administrative changes to existing standards could be issued with little review, while information about a new hazard may require more extensive review to identify appropriate standards.

- The standards bases described in the documentation of the approved WSS set should be used as the principal configuration control reference.

- When changes to the WSS set are made, the WSS documentation should be revised to reflect the changes and the bases for those changes.

- The change control process should replicate the N&S Process, with roles and responsibilities that correlate to those in the N&S Process, to ensure that changes to the WSS set are made deliberately and are adequately justified.

- The change control process should be well-defined, so that potential changes can be handled "routinely," within a framework of defined tasks and responsibilities.

- The change control process should be managed by a single organization to ensure consistency and comprehensiveness in addressing potential changes.

- The change control process should be integrated with existing site mechanisms for documenting and promulgating standards so that changes can be communicated to those who use the standards in a timely fashion.

- The change control process should be integrated with existing processes and personnel responsibilities for contract modification, since some changes to the WSS set may be required.

An example of a change control process used at the Los Alamos National Laboratory that exhibits these characteristics is presented in Appendix 9.

16.0 Providing Feedback and Lessons Learned

Providing feedback and continuous improvement is the fifth core function of ISM. This function, however, is more than simply a single step in a five-step process. Continuous evaluation and improvement should characterize all the functions and activities of an effective ISMS. The development and application of lessons learned is an effective means of doing this. Since the N&S Process provides one means for carrying out some of the ISM core functions (definition of work scope, analysis of hazards, and development of hazards controls), the N&S Process should similarly involve a deliberate and purposeful search for and application of lessons learned.

Because the N&S Process and ISM are consonant and share a common conceptual foundation, lessons learned during an N&S Process application can be particularly valuable in implementing ISM. A consistent focus on the work; the development of tailored sets of standards to perform work and control hazards; and, the involvement of Stakeholders, Interested Parties, and workers are central tenets of both ISM and the N&S Process. An application of the N&S Process will provide a wealth of practical insight into these and other principles and their application in the context of a specific site, facility, or project. In order to effectively translate and utilize these insights in establishing an ISMS, individuals experienced in the N&S Process should be selected to help spearhead ISM implementation. Similarly, application of the N&S Process should be undertaken as part of an overall ISMS rather than as a separate activity.

This Handbook is a compilation of lessons learned from N&S Process applications and pilots. The initiation and implementation of the N&S Process has occurred widely across the complex since 1995. Through early pilots and follow on N&S Process applications, a considerable

number of lessons were learned. The N&S Process is most effective when the lessons learned in developing, implementing, and maintaining the set of standards are shared. Sharing lessons learned in the N&S Process is an effective means to ensure that the lessons learned in one application will be effectively communicated. A discussion of these lessons learned can be found on the Work Smart Standards home page (http://tis.eh.doe.gov/dsc/worksmart.html). General information about Integrated Safety Management implementation is available at the ISM home page (http://tis-nt.eh.doe.gov/ism/). In addition, the Department's Lesson Learned home page (http://tis-eh.doe.gov.ll) has specific information useful to managers and participants who intend to use the N&S Process in the future.

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APPENDIX A

THE NECESSARY AND SUFFICIENT CLOSURE PROCESS FREQUENTLY ASKED QUESTIONS

THE NECESSARY AND SUFFICIENT CLOSURE PROCESS

Frequently Asked Questions

The following questions have been raised during training sessions and applications of the "Closure Process for Necessary and Sufficient Sets of Standards. They address issues about the functioning of the Process and about the product of the Process, the Work Smart Standards set. The answers are based on the experience of Process practitioners as collected by the Department Standards Committee.

Q1 Does the N&S Closure Process put aside Department responsibilities for safety standards to the contractor?

A1 No, the N&S Closure Process does not put aside the Department's responsibilities for safety standards. Rather, it emphasizes thorough understanding of the work and the hazards as conditions for identifying and approving the controlling safety standards. The N&S Process requires that both DOE and the contractors be fully engaged at the management, worker and technical levels throughout the Process. Both DOE and the contractors must approve the set of standards and agree that the set when properly implemented will provide reasonable assurance of protection to the public, the workers and the environment. DOE and contractor personnel who have successfully completed the N&S Process report that they have gained an improved shared understanding of the work, the hazards and why the standards selected are appropriate to provide adequate safety. Several sites have expanded their standards base as a result of the N&S Process. Sites now "own" the WSS set, whereas before sites often viewed standards as forced upon them by DOE.

The N&S Closure Process supports the implementation of Department of Energy Acquisition Regulation (DEAR) clause concerning integration of environment, safety, and health into work planning and execution (48 CFR 970.5204-78), and is a Department-approved tailoring process for inclusion in the DEAR-required contractor Safety Management System. The Department's N&S Closure Process is described with requirements for its application in DOE M 450.3-1. The N&S Closure Process relies on a thorough understanding of the work to be performed and of the hazards associated

with that work and on knowledge of appropriate controls to identify a set of standards (The Work Smart Standards set) that when implemented will provide reasonable assurance of adequate protection of the workers, public and environment. The requirements and process for approval of the Work Smart Standards set are within DOE M 450.3.1.

Q2 How do we know that the Work Smart Standards set will provide adequate protection?

A2 Each element of the N&S Closure Process is designed to establish confidence in the governing set of standards resulting from proper Process application. Key features of the Process are teams of knowledgeable people well grounded in the work and hazards, technical justification, peer review and stakeholder involvement. All of these are hallmarks of successful standards and regulatory processes.

The N&S Closure Process emphasizes:

- Team-enhanced collective competence, knowledge, and experience of qualified practitioners

- Thorough understanding of the work and associated hazards and of experience-supported controls for those hazards.

- A documented justification, available for review of the correctness of the WSS set for the work and the hazards.

- The identification, review, and approval practices of the N&S Closure Process.

These key features of the Process, joint DOE and Contractor approval of the standards set, continuing feedback and improvement with rigorous change control provide confidence in the protection provided by a properly implemented standards set.

Q3 How can we be assured of adequate safety if some alternative standards to the DOE ES&H Orders are identified for the WSS set?

A3 Proper application of the N&S Closure Process establishes a WSS set that provides reasonable assurance of adequate protection whether or not particular standards, including DOE Orders, are identified within the WSS set. It is the collective control of the WSS set, developed according to the N&S Closure Process, that provides adequate protection when appropriately implemented through Integrated Safety Management.

The DOE ES&H Orders represent an effective way of achieving safety for certain work done by the Department, particularly for work which is essentially unique to the Department. The DOE Order system has provided a consistent approach across the Department for control of the hazards considered in the Order development. The Orders are by necessity somewhat broad in scope. The focus of the N&S Closure Process is on understanding the particular work to be performed, hazards associated with that work and identification of a proper experienced-based set of standards for control of those hazards.

Fidelity to the N&S Closure Process leads to identification of the proper WSS set. The Process does not specify sources of standards. The principal issue is adequate protection not the source(s) of the standards selected.

Consideration of the DOE Orders developed for particular hazards within the scope of a specific N&S Closure Process application is appropriate where selection of a particular DOE Order may be advantageous because of:

- Familiarity and experience of the work force with the DOE Orders
- Existing implementation processes for the Orders
- Ease of explaining to DOE and order-experienced personnel the coverage of the WSS set
- Linking controls of the WSS set to the controls exercised through the Orders.

In some cases, DOE Orders may not be appropriate for specific work and hazards; or, other standards, such as commercial standards, may more closely correspond to the

work and hazards environment. Similarly, the work force may be more familiar with working to consensus standards.

In ensuring that the appropriate safety topics are addressed in a WSS set, it may be beneficial to provide a mapping of the coverage of the safety topics by a WSS set and by the DOE Safety Orders.

Q4 Are there any ES&H Orders that must be included in the WSS set identified by the Closure Process?

A4 As the responsible federal agency, the Department of Energy has the authority, unless prohibited by law, to require of its contractors the inclusion of specific conditions (requirements) within DOE contracts. In accordance with normal contracting practices, such inclusion is subject to negotiation between the DOE and the contractor. The contents of the set are governed by the actual work and hazards in the contract statement of work and the hazards associated with that actual work. The elements of a WSS set are mandatory if:

- They include applicable Federal, state, and local laws and regulations, or
- The WSS set, or portions of it, become contract requirements by inclusion within a DOE contract.

By agreeing to the application of the N&S Closure Process, the DOE has strongly indicated that it intends to accept the WSS set resulting from the faithful application of the N&S Closure Process.

Q5 Is the N&S approach the same as the “graded approach?”

A5 The “tailored approach” of the N&S Closure Process is not the same as the “graded approach” even though the two approaches may arrive at a similar objective of applying requirements in a manner that recognizes the significance of the hazard being controlled. Tailoring is work and hazards based; grading is primarily requirements based.

The Tailored Approach is based on an understanding of the specific work, the work environment, and the hazards associated with the specific work and on knowledge of experience-supported standards that control the specific hazards. The N&S Closure Process identifies a tailored set of standards from applicable standards sources. When implemented, the standards provide for those hazards reasonable assurance of adequate protection of workers, the public and the environment. The N&S Closure Process "tailoring" is fundamentally work and hazards based.

The "graded approach" means grading selection of standards or grading application of standards. In the graded approach the standards are DOE Orders or specific requirements within DOE Orders. The application of "grading" varies the degree, intensity or rigor of application of the standards across a range of defined work depending on the relative significance of work hazards to be controlled. "Grading" is fundamentally requirements based. A definition appears in the SAR Order (DOE O 5480.23.)

Q6 What happens if oversight personnel do not agree that the set provides adequate protection or was developed without the required fidelity to Process requirements?

A6 If oversight personnel challenge the adequacy of the WSS set or challenge the bases for its approval, the challenge must be resolved.

Resolution is provided by:

- Under Chapter 1 of the N&S Closure Process any challenge to the WSS set is to be submitted to the Agreement Parties where the challenge is decided on its merits.

- If the Agreement Parties decide the challenge has merit, action will be taken to correct the deficiency. This may include re-performing the N&S Process for the area(s) of concern.

- If the Agreement Parties decide the challenge does not have merit, the basis for this decision is provided to the challenging party. If the challenging party does not agree with the basis for the decision, as necessary, the challenge is argued before the appropriate level of line management.

Once a standards set has been established and implemented any challenges to the adequacy of the set are typically addressed through change control mechanisms.

Q7 Does agreement on the set of standards require a change of the contract?

A7 Whether the standards set is included and specified as contract requirements depends on the purpose of the standards set.

- If the standards set is intended to be used to identify contractual requirements, the set must be incorporated into the contract. Information on the use of standards sets for this purpose is described in the ISM DEAR clause.

- If, under existing contract provisions on safety standards and requirements, the N&S Closure Process is used to identify standards to implement existing contractual requirements, no contract recognition of these implementing standards is necessary.

Q8 How do we know that the contractors won't choose a minimal set of standards?

A8 Application of the N&S Closure Process does not allow a contractor "to chose" the WSS set. No single party to the N&S Closure Process can control it to the degree that a set unacceptable to the other parties.

The N&S Closure Process is a participative process which focuses on understanding the particular work to be accomplished and the hazards associated with that work, and subsequent identification of standards through the collective qualification of teams. The participative, iterative process among qualified teams leads to agreement on the appropriate – not minimal – set of standards that when implemented, provides reasonable assurance of adequate protection. Also, the N&S Closure Process calls for

appropriate confirmation and specific approval of the application of the Process as well as the set of standards. Documentation, subject to review, that justifies the standards set is a strong additional incentive to identify the controlling standards with care.

A principal guard against minimal standards is the focus on understanding the work and its hazards preliminary to identifying controlling standards and justifying, on the record, that the standards are adequate. The N&S Closure Process closely joins the understanding of the work and its hazards with knowledge of appropriate controls.

Q9 Will the documentation for WSS sets be standardized in the future?

A9 The documentation of a WSS set is inherently tailored to the Work it addresses and the local contract in which those standards are to be implemented. From the present experience of more than four years there is little evidence that documentation expectations can be standardized beyond the basic requirements stated in Process Element 3, “Defining and Agreeing to Protocols and Documentation Requirements.” The Convened Group defines the specific requirements for this documentation and may include additional documentation requirements to suit the specific application of the Process.

Q10 How will the Department know what’s going on?

A10 As with all aspects of its commitment to ISM, the Department is a party to the Process in all applications requiring Department agreement on the set of standards. Specific Department elements will be Agreement Parties and Resource Authorities, and other DOE headquarters and field elements may participate as appropriate.

Q11 How does EH get involved in the Process?

A11 EH elements have participated in the Process as Convened Group Members, Technical Operational Experts, or as Confirmation Team members depending on the situation. However, as a matter of EH policy, EH independent oversight elements do not participate. EH oversight may assess whether specific applications of the Process have

been conducted in accordance with the Manual (M 450.3), and whether the agreed upon requirements are adequately implemented.

Q12 How do we assure consistency in the Work Smart Standards sets of standards across the complex?

A12 The Department's Integrated Safety Management goal is to achieve consistent and excellent protection of workers, the public, and the environment. Because the work, work definitions, expected hazards, and conditions of work vary widely across the complex, the standards necessary to achieve this goal must also vary from place to place. Consistent adequacy of tailored protection controls demands consistent, excellent management of the Department's work, dedication of its employees, and a willingness to accept the responsibility that this entails.

It is recognized that when applying the N&S Closure Process that fidelity to the requirements and the underlying logic given in DOE M 450.3-1 are important to the integrity and thus the acceptance of the Process as a legitimate means of standards identification. The Department Standards Committee, on behalf of Department line management, oversees Process applications and promotes a high standard of Process fidelity as the most important Process contribution to consistency in adequate protection.

Q13 Will the sets of standards be similar for similar facilities?

A13 Similar facilities are likely to identify similar, but not identical, sets of standards. Differences in physical plant or process, organizational structure, management policies, work force capabilities, and political factors are all potential sources of differences in sets of standards. Similarity is often a more meaningful basis in the comparison of safety performance outcomes.

Q14 If the Work Smart Standards set incorporates external standards, who interprets those requirements?

A14 Existing contracts (and Orders) contain or reference external standards, such as laws, regulations and consensus standards, that may require interpretation. The incorporation

of external standards into WSS sets does not require a change from the existing policies or practices regarding interpretation. In general, the chain of authority for the interpretation of standards used by contractors is: contractor line management, Department line management, the sources of the standard (regulatory or consensus organization), and the courts. Under the practices established by the ISM DEAR clause, the contract, that includes explicit DOE approved provisions for safety management, becomes both the operational and regulatory basis for interpretation of the integrated set of requirements for safe work. Thus, the contract agreement processes established by the DEAR clause address all the various interpretive situations that might be encountered during the life of the contract. Of course, where requirements are grounded in law or regulation the contract defers its interpretive authority to the source agency.

Q15 Is there a preference for applying the N&S Closure Process at the site level or the activity level?

A15 Application of the Process at the site level and the activity level are not mutually exclusive. The Process can be applied at any level where the Department and the contractor must agree on the standards to be applied. This clearly includes the contract requirements, and may include any site level and activity level work controls that require Department approval prior to the authorization of work

Q16 Who is going to make sure that the standards are used appropriately?

A16 The contractor must plan work in keeping with the DOE-approved ISM system to meet all applicable contractual requirements and subordinate commitments. Department line management will review the contractor's ISM plan and selected work plans and the contractor's implementation of those plans. Under ISM principles the Department depends on aggressive self-assessment by the contractor in combination with its own management reviews and independent oversight assessments. Performance incentives encourage effective self-assessment and self-improvement but if these are unsuccessful, the Department will expand its own line management and independent oversight.

Q17 What has to be in the authorization agreement called for in the ISM DEAR clause?

A17 An authorization agreement establishes the conditions for the authorization of work. The details of a specific agreement are locally tailored to factors such as agency risk exposure, threat to mission completion or safety performance trends that might impede that standards-based work plan. It should define limiting conditions of normal operations, approval conditions that may not be changed without prior Department approval, and conditions that may be acceptably changed by the contractor with only subsequent notice to the Department.

Q18 How do DOE and the contractor come to agreement called for by the ISM DEAR clause?

A18 There are many ways for the Department and the contractor to come to agreement. Each time a contract or a work authorization is signed, an agreement has been reached. The N&S Closure Process is used by the Department and contractor line management as a mechanism to focus on the work and hazards and on planning as the basis for achieving adequate protection. The agreements called for in the ISM DEAR clause are considered to be anchored in the Annual Program and Budget guidance process and therefore include both relatively fixed (e.g., infrastructure standards) and dynamic components.

Q19 How long will it take to develop a set of standards?

A19 Clearly, there is not a definitive answer to this question, because applications of the Process will vary widely in scope and complexity. The level of effort required for contract requirements will, equally clearly, be greater than that required to insert boilerplate, one-site-fits-all requirements. However, this added effort in defining necessary and sufficient sets of contract requirements and a focus on work planning involving necessary and sufficient work controls will save the enormous effort that used to be devoted to stove-piped implementation plans and assessments of compliance with inappropriate requirements which added little to the level of protection.

Q20 How can the Confirmation team approach its responsibility to determine whether the proposed Work Smart Standards set is “feasible”?

A20 The confirmation test that the Work Smart Standards set is “feasible” is a process safeguard against adopting standards that those responsible for implementation *might* not reasonably be expected to achieve. Feasibility focus is not on the ability of the standards to guide performance (i.e. “adequacy”), but rather on a potential future failure to achieve standards-based and safe work. Such failures could occur if management systems and processes are not capable of delivering work based on the WSS set or if resources are not sufficient to design and perform the work consistent with the WSS set. The N&S Closure Process requires the Identification and Confirmation Teams to assess both the adequacy and feasibility of the standards set. The agreed upon definition of the work and the institutional implementing assumptions about how that work will be carried out are first developed as a description of initial conditions by the Convened Group during Process Element 1: Defining the Work and Hazards. The requirements for describing both work objectives and a relationship of those work objectives to some organized system for the delivery of that work are equally important to the ultimate utility of the WSS set. By starting with the Convened Group’s core of guidance, the Identification Team is reasonably expected to further refine the definition of work, hazards and controls in a way that integrates implementability and technical sufficiency to provide for adequate protection.

In the N&S Closure Process Element 4: Identifying the Necessary and Sufficient Set of Standards, relevant knowledge of the work and the available mechanisms of performance are brought to bear to achieve an adequate and feasible WSS set. The requirement that the Identification Team confirm and document implementing assumptions serves to address issues of feasibility in going from the pre-WSS situation of the organization to a post-Process state of WSS conformance. As stated in Chapter III of the Manual, “Planning and performing work in accordance with the approved set of standards requires an adequate system for managing the work.” Properly developed WSS sets will document assumptions about the specific “system for managing the work” into which the care and implementation of the new standards set will be entrusted. Such documentation serves primarily to inform those within that “system” what considerations the Process applications had in mind when settling to closure on a particular WSS set.

During Process Element 5: Confirming the Necessary and Sufficient Set of Standards, the Confirmation Team examines how well the Convened Group and the Identification Team in working to closure on the proposed WSS set have anticipated and addressed the conditions in the receiving (i.e. implementing) organization. This is done to provide the Approval Parties assurance that the existing "system for managing the work" can "get there" (to WSS conformance) "from here" (the prevailing condition of the organization). It is critical to recognize that, as with the "adequacy" of protection test, the Confirmation Team is not expected to develop a fully independent assessment of "feasibility." Rather the evidence of feasibility should come primarily from the documented work of the Convened Group and the Identification Team to assure that the WSS set is understandable both in terms of protection and its context for implementation. This point simply restates the recognition that a WSS set must address both technical and management considerations and takes it one step further by requiring that the managerial aspects of the proposed set be grounded in the specific local conditions of an existing management system.

As with adequacy confirmation, there can be no explicit limits upon the ability of the Confirmation Team to assess the credibility of the implementing assumptions and other elements of the set that address feasibility for implementation. The Convened Group and Identification Team will necessarily apply some presumed effectiveness of the receiving management system's ability to take the WSS set and then develop the needed system or upgrade the existing management system to the new set of standards. To the extent that documentation of the Process application makes clear what was assumed about the management system; what level of capability was assigned to that system; and what evidence upon which the expectation of competence was established, the Confirmation Team might have a relatively simple task of *confirming* feasibility. Conversely, to the extent that the work is radically different, the organization for implementation non-existent or immature in its capabilities, or that some proposed standards are more challenging to meet than prior performance levels achieved by the management system, the Confirmation Team may need to dig deeply into the credibility of the implementation assumptions made by the Convened Group and the Identification Team.

In order to prevent the Confirmation Team from exceeding the process-intended scope of the WSS set feasibility determination, confirmation protocols might stress that the burden of proof for feasibility is ultimately and necessarily on the earlier steps in the Process. There is a recognition in the Process that the Confirmation Team is dependent to some significant degree upon the knowledge, relevant experience and collective work of both the Convened Group and the Identification Team. By selecting a Confirmation Team membership with equal or stronger credentials, there is an expectation that such a group can draw upon both the tangible and intangible parts of its own collective experience to more or less rapidly determine if the proposed WSS set is feasible. If the Confirmation Team is inclined to conclude that it needs to do a separate assessment of implementing organization capability, this inclination is best viewed as a failure on the part of the Convened Group and the Identification Team to make clear how they concluded the set was feasible and the set should be returned to those groups for further work. In this sense the Confirmation Team's role is analogous to that of judge and jury in a trial, it is the prosecutor's job to develop both the facts (i.e. standards for adequate protection), and the case for the conclusions it suggest be drawn from the facts (i.e. that the standards can reasonably be implemented.)

Q21 What is the significance of the finding that the N&S Closure Process has been correctly implemented; that is applied with "fidelity"? How can fidelity confirmation to be approached?

A21 Process fidelity verification relates to the confidence that others who were not directly involved in standards identification, ought to have in the results of the Process. The basis for depending upon fidelity as a measure of Process effectiveness is the demonstration that the Process requirements draw plentifully upon the recognized DOE Integrated Safety Management concepts, plus the fact that application of such concepts has demonstrated its value in numerous other high technology, high hazard industries.

The N&S Process Elements follow the logic of the Core Functions of ISM. Through frequent iteration among the various intermediate closure points, the Process elements progressively develop an agreed upon and integrated expression of work, hazards, and controls that always starts from and returns to the need to Do Work Safely. The structure for reaching agreement is robust, with multiple, explicit, and semi-independent

levels of definition (Process Leadership and Convened Group), analysis (Teams) and verification (Confirmation Team and Approval Parties). The ISM Guiding Principles of clear roles and responsibilities, demonstrated team competence, tailoring, and balancing of priorities are all explicitly incorporated in Process Manual requirements. Process documentation is required for both WSS set components and for records of decision-making that support the justification of WSS set as adequate and feasible; thus the N&S Closure Process ensures that readiness for operations proposed to be authorized, on the basis of the identified standards and implementing assumptions, can in fact be reached.

Throughout the Process application, Line Management bears the lead responsibility for the WSS set, its development, and its justification of adequacy. With elaborate process logic detail, and frequent reference to performance attributes that must be addressed in order to make the WSS set both adequate and feasible, the N&S Closure Process manual requirements self-define the elements of demonstrating fidelity to the Process. However, precisely because the N&S Closure Process is built on ISM principles, “fidelity” can rarely be deduced from a simple verification checklist. It is a matter of practical experience that Convened Group understanding (or “profound knowledge” in the words of W. Edwards Deming) about the kind of safety management system needed to embody the ISM principles is a predictor for achieving evident demonstration of Process fidelity. Manual requirements provide many effective lines of inquiry for Confirmation Teams and Approval Parties to test this understanding.

Q22 What lessons were learned at LLNL from following the N&S Process?

A22 Lessons learned from the LLNL N&S Process application are summarized below, and are also reflected in the body of the N&S Handbook.

The N&S Process should include all ES&H aspects of the performance and management of work. Work activities are performed within the total programmatic and safety environment of the institution. Selection of safety standards is best done based on the hazards associated with the work and an understanding of the management philosophy and processes. Also, standards for the management of safe work are often critical first line elements for creating a safe work environment and should be considered in selecting a complete WSS set.

Since the N&S Process is an integral part of ISM, the activities should be initiated at the same time. ISM and the N&S Process have a synergistic relationship. Standards identification is a key step in the ISM work functions. Similarly, having a strong foundation in the principles and functions of ISM will allow the N&S Closure Process to proceed more efficiently and provide a context for the selection of both technical and management standards.

Complete documentation supporting justification of adequacy of proposed standards should be provided to the Confirmation Team. The N&S Process identifies various types of documentation and the responsible party as a normal part of the Process. A complete and integrated set of documents describing and documenting the Process is necessary before confirmation to permit the Confirmation Team to understand and evaluate the Process. This information should be provided to the Confirmation Team 3-5 weeks before their site visit to allow adequate time for review.

Confirmation Team members should make a separate visit to tour facilities and become familiar with the site. The Confirmation Team needs to have adequate information, understanding and first hand experience of typical work environments and their safety systems. A separate visit allows sufficient dedicated time for site familiarization and a helpful background for review of documentation prior to the confirmation visit.

The entire safety management system should be described to the Confirmation Team so they can assess the feasibility of the WSS Set. The Confirmation Team needs to clearly understand the nature of the entire safety management system. This is needed to build confidence in the current safety system and proposed ISM system before they can take on the task of assessing the feasibility of the WSS Set.

A list of the complete set of proposed standards should be given to the Confirmation Team. The Confirmation Team should be given the full set of ES&H standards so they can evaluate both the completeness and adequacy of the final product.

Interested Parties need to be identified early in the Process (e.g., DOE/HQ, DNFSB) and kept up to date. The N&S Process can result in significant changes to the way LLNL performs work safely. Interested Parties must be identified early in the Process

and kept informed throughout the Process to ensure that they understand the potential changes, their ramifications and to be better prepared to continue their relationship with LLNL.

Top management engagement throughout the entire Process is a key success factor. Laboratory and DOE Oakland Operations Office top management must be continually engaged to ensure the success of the Process. Their continued involvement by attending Convened Group and Standards Identification Team meetings clearly demonstrated to all the importance of the Process to safety at LLNL. Management is also then in a better position to provide the necessary resources and eliminate barriers to progress.

The N&S Process requires a transition from an expert based system to a standards based system. LLNL works to manuals that have been maintained by safety subject matter experts based on their extensive experience at LLNL and knowledge of related safety areas. With the implementation of the WSS set of standards, the subject matter experts will need to improve their knowledge of the current standards and be prepared to propose modifications of the WSS set based on improvements of existing standards.

The N&S Process requires a commitment to formality and rigor for an organization such as LLNL. The management of a N&S Process where a wide variety of work and hazards, including nuclear, are involved requires a commitment to extensive review and complete documentation following the requirements outlined in DOE Manual 450.3.1.

The N&S Process is a manpower intensive activity which can create operational resource conflicts unless managed properly. Assigned program staff, Assurance Managers, ES&H Subject matter experts and line managers are major contributors to the N&S Process. A careful assessment of day-to-day ES&H Program needs has to be balanced with N&S Process support. ISMS also adds another demand on their time.

There are different kinds of workers who all need to be included in the N&S Process. The N&S Process should include all types of workers in the identification of work and characterization of the hazards. Upper, mid and first level supervisors as well as hands

on technicians and crafts workers should be included in the N&S Process in order to benefit from their various perspectives and experience.

The selection of standards to manage work safely is based on the work and the broad experience of its managers. Safety standards can be selected based on the work and its associated hazards. The selection of standards to manage work safely is not only based on a knowledge of the work, but also the broad experience of managers who understand the institutional philosophies and complexities of managing work safely at LLNL. In fact, it was our experience that in some management areas broad managerial experience was more important than detailed knowledge of the work.

Local Standards were developed to build on, add to and quantify information in existing DOE Orders and consensus standards. Over the years, research and development activities at LLNL on the many and complex national needs has resulted in LLNL performing unique work and developing special expertise in dealing with certain hazards. In moving from an experience based to a standards based ES&H system, LLNL needed to develop and codify local standards controlling the unique work and hazards to supplement the existing body of consensus and DOE standards. Also, in several more common areas, e.g., ergonomics and the use of HEPA filters, we found that adequate national standards were not available.

As a part of the N&S Process OAK and LLNL Staff with similar technical qualifications developed and demonstrated a common understanding of the work and associated hazards. The process of selecting the standards brought together DOE OAK and LLNL staff to understand the work, its hazards and the available standards. This common understanding was clearly demonstrated in several internal reviews held prior to confirmation where the reviewers could not readily determine whether the presenters were from LLNL or DOE/OAK.

The N&S Process leads to a better understanding of requirements and expectations by the various participants. The N&S Closure Process required participation by the workers, as well as DOE and LLNL program managers and ES&H professionals and required them to focus on the work and the hazards. This common focus, with its exchange of information and experience regarding the work and the standards to

provide adequate safety resulted in a shared understanding of requirements and expectations by all involved.

Readiness for Confirmation is multifaceted:

(a) Required N&S Process elements and the appropriate documentation should be reviewed. The Confirmation Team expects to understand the context, including the implementation of the N&S Closure Process, in which the standards were selected. Careful documentation of how the Process was implemented is critical to meeting this expectation.

(b) The Convened Group and the Standards Identification Team need to have evaluated the feasibility of the set and be prepared to articulate this to the Confirmation Team. The Confirmation Team is asked to confirm the adequacy and feasibility of the set of standards. Understanding the assumptions and agreements made in determining the adequacy of a standard together with an understanding of the LLNL management system constitute the minimum elements necessary for the Confirmation Team to assess feasibility of the WSS set. Although not required by the N&S Closure Process, internal reviews in preparation for the confirmation process were very useful.

Confirmation Team Co-Chairs should visit the site several weeks before confirmation, review the schedule and documentation and develop a strategy to follow during the Confirmation Team visit. For a large N&S Process the Confirmation Team Co-Chairs should visit the site and become familiar with the documentation, review the schedule for presentations and tours and meet with key staff. These interactions will permit the Co-Chairs to develop an effective and efficient strategy for the full team s visit.

The Change Control Process for the WSS set and ISM implementation should be integrated and an organization identified to administratively manage the set. The WSS set is an integral part of the ISM process and any changes to the set need to be implemented in a timely manner. By having a combined Change Control Board, the selection and revision of standards will be fully integrated with their implementation to assure the maintenance of an adequate safety system at LLNL.

APPENDIX B

ACTIONS AND ASSIGNED RESPONSIBILITIES FOR STAKEHOLDER INVOLVEMENT IN THE N&S PROCESS AT THE SAVANNAH RIVER SITE

NOTE: This Savannah River (SRS) example which demonstrates considerable outreach to stakeholders and interested parties was developed to support the SRS Pilot project to validate the Necessary and Sufficient Closure Process. Since that time, the use of the term "Stakeholder" has been modified. The SRS example includes DOE, contractor and public groups under the general category of stakeholder. The Pilots and subsequent WSS Applications have clarified that the term "Stakeholder" should be limited to involvement of non-DOE or contractor groups. Public interest groups or unions are examples of stakeholders. The definition of "Stakeholders" provided in the Glossary is consistent with the provisions of the Federal Advisory Committee Act which establishes controls for participating in Federal policy-making bodies. DOE and contractor personnel groups that are involved in the identification, approval or implementation of standards should be included as participants in the N&S Closure Process. The Defense Nuclear Facilities Safety Board, due to their legislative mandate, are included as Interested Parties.

STAKEHOLDER INVOLVEMENT

Approval Authorities

The WSRC-ER and DOE-SR approval authorities for the set of N&S standards for this pilot were stakeholders because they are responsible for the set of standards and its implementation. Communications with the approval authorities were through WSRC-ER and DOE-SR process team members and the steering committee.

Project Manager and Operations Manager

The WSRC-ER Project Manager and Operations Manager were stakeholders because they are responsible for safe installation and operation of the treatment unit and supporting structures. The Operations Manager represents the workers who will eventually operate the F/H Groundwater Water Treatment Units; these operators are not yet identified. Communications with the Project Manager and Operations Manager were through the WSRC-ER process team leader and by the members of the standards identification/confirmation teams. These continual communications lead to better definition of the project scope, schedule, and operational requirements. Both the Project Manager and Operations Manager were involved in design decisions throughout the F/H Groundwater Remediation project (Ref. 22, 5/5/95). A presentation of the set of site design and safety documentation N&S standards was made to the Project Manager and Operations on July 13 (Ref. A1).

Engineering

The various engineering organizations within WSRC were stakeholders because they can affect and may be affected by the results of this process. Other engineering organizations that can affect the outcome include the design engineers that are responsible for using the identified standards in the project design and other engineering organizations that may want to implement this process in the future on their facilities/activities. Communications with the engineering organizations were through the WSRC-ER process team leader and by the members of the standards identification/confirmation teams. For example, several of the standards for the electrical scope of F/H Groundwater Remediation were discussed with the Power Engineering Department, as they are the custodians of most of the power lines at SRS. Their input provided

the ER N&S standards identifiers with a better understanding of site requirements and commercial practices (Ref. A2).

Environment, Safety, Health, and Quality Assurance

Various Environment, Safety, Health, and Quality Assurance (ESH-QA) organizations within WSRC and DOE are stakeholders because they may affect or be affected by the results of this process. ESH&QA is responsible for the SRS approach to a standards-based program, in response to DNFSB recommendation 90-2. The Standards/Requirements Identification Document is the SRS response to 90-2. The WSRC-ER process team leader is also the ER S/RID point of contact and ensured that SRS S/RID requirements determined to not be N&S as a result of this F/H Groundwater Remediation N&S pilot are identified as such (REF. 41, A3).

Department of Energy - Headquarters

Various organizations and committees within DOE-HQ are stakeholders because they can affect the results of this process. DOE-Environmental Management (EM) authorized the use of the DOE Standards Committee's N&S process on an SRS-ER project (Ref. 5). In July, 1995, DOE-EM-23 initiated bi-weekly conference calls with all of the EM N&S pilots across the complex. These calls were effective forums for learning the status, issues and lessons learned from other pilots. DOE-Environment, Safety and Health (DOE-EH), which endorses a standards-based program, met with the SRS N&S pilot team in June 1995 to monitor the progress of this pilot (Ref. 22 - 6/22/95). WSRC provided DOE with feedback on the process and DOE provided WSRC with feedback on our implementation of the process. In addition, DOE-EH's Office of Oversight conducted a scheduled surveillance on the N&S Pilot Public Meeting held on September 7, 1995. The results of this surveillance was that the meeting was informative, conducted professionally, and afforded the public the opportunity to become knowledgeable of SRS activities which may affect their health, safety, environment or quality of life (Ref. A4). DOE-Defense Programs visited SRS in January 1995 to investigate the use of commercial codes/standards within the DOE complex; WSRC-ER presented information on this ER N&S pilot to the DOE-DP Industry Codes/Standards committee. Communications with DOE-HQ were through the DOE-SR (ER and EH) process team members and the DOE-SR (EH) steering committee member.

Environmental Advisory Committee

The Environmental Advisory Committee (EAC) consists of nationally recognized experts in the environmental field. The purpose of the committee is to provide independent review and consultation on strategic and long-range environmental issues affecting SRS. The EAC was a stakeholder because it can affect the outcome of the work through their recommendations process. The EAC's comments were related to the level of safety ensured by commercial standards and the commitment by DOE to implement a standards based program. Their endorsement of this process was a significant recognition that a standards-based program is a safe, technically sound, and cost-effective method to manage ER activities. The WSRC-ER process team leader presented this N&S pilot to the EAC in May, 1995 (Ref. 22 - 5/5/95; Ref. A5).

Regulators, Federal and State

The regulators were stakeholders because they define the scope, requirements, and schedule of ER activities at SRS. EPA and SCDHEC regulations, as they apply to this pilot, are part of the N&S set of standards. Communications with the regulators on this pilot were through DOE-SR (ER). In February 1995, DOE-SR briefed the regulators on the pilot and requested their participation, but they declined the invitation (Ref. 22 - 2/23/95; A6). Also, the regulators were invited to the September 7 public meeting, but did not send a representative. The EPA did, however, call WSRC to verify that environmental laws and regulations would still be met. EPA supports a process that streamlines the current remedial process while ensuring compliance with all environmental laws and regulations.

Defense Nuclear Facilities Safety Board

The DNFSB is a stakeholder because it can affect the outcome of the work through their recommendations process. The DNFSB supports a standards-based program, as stated in recommendation 90-2. Communications with the DNFSB on this pilot were through the DOE-SR (EH) representative on the Pilot Steering Committee.

Public

Although the specific scope of this pilot does not impact the public from a hazards standpoint, the public is a stakeholder in all ER activities at SRS. Communications with the public are usually in the form of public meetings, as organized by the appropriate WSRC and DOE departments. The scope, permit conditions, and schedule of the F/H Area Seepage Basins Groundwater Remediation project has been the subject of numerous public meetings in 1995. These have focused on the RCRA Part B Permit renewal, the CERCLA proposed plans, and the intent of the Citizens Advisory Board to do an independent technical review of the project. A separate public meeting was held on September 7, 1995 to obtain stakeholder feedback on the use of the N&S Process on the F/H Groundwater Remediation Project. The primary goal of this meeting was to reach the site workers ("valve turners") and members of the public. This meeting was extensively advertised through individual invitations to approximately 800 SRS stakeholders (companies and individuals), news releases and newspaper advertisements, and an announcement to employees over the SRS electronic mail system. The 800 stakeholder invitations included 280 invitations to an internal RCRA-related WSRC distribution, 485 to the other (non-SRS) individuals on the RCRA mailing list (i.e. Citizens Advisory Board, local elected officials, contiguous landowners, and interested members of the public), and 60 to area construction and environmental contractors. Additionally, local union presidents and members of professional societies were invited. The news releases issued by WSRC were not published by the local newspapers.

Fifteen stakeholders representing unions, local newspapers, members of the public, and WSRC employees who will be responsible for future implementation of the N&S Process attended the meeting. Two members of the SRS N&S Pilot Process Team presented information on the current use of DOE Orders, the need for change, the N&S process, how it was used on F/H Groundwater Remediation, and technical changes (and cost savings) resulting from the use of the process.

Questions and answers discussed at the Public Meeting, as well as questions and comments received in phone calls both before and after the public meeting are listed below:

1. Meeting Question

Q: Who resolves disputes if agreement on standards can't be reached?

A: A third party, who is technically qualified, is used to resolve disputes.

2. Meeting Question

Q: Is there a connection to the Committee for External Regulations? Are activities of DOE and FAC parallel?

A: The Committee for External Regulations is aware of the DOE Standards Program and the N&S Pilots. There is no direct connection.

3. Meeting Question

Q: What qualifications should a stakeholder have to get involved with the system? Sounds like stakeholder purpose would be to have input into the process but not the standards. Is the stakeholder to review the process or the standards?

A: Any stakeholder can comment on the process. We don't set qualification criteria for stakeholders who want to comment. If the public has a concern, we will try to address it.

4. Meeting Question

Q: What is the benefit stakeholders will bring to the process? What value is there in stakeholder comment?

A: We will listen to anyone's concerns. If the stakeholder has a technical background, of course we'll discuss the standards selection. If the stakeholder is not technically oriented, we'll explain the situation and listen to their concerns.

5. Meeting Question

Q: Is the Defense Board going to be consulted? What is their role?

A: The DNFSB has been briefed on the process and the scope of the pilots. DOE is considering their input.

6. Meeting Question

Q: What is SRS doing relative to bringing different standards to the Site (i.e., how will non-SRS subject matter experts be brought into the picture - outside groups, agencies, companies' N&S standards)?

A: The process allows and encourages us to get experts from the outside if necessary. In addition, we've done commercial benchmarking to find out what standards are used in the commercial sector.

7. Meeting Question

Q: What are you doing to broaden use of SMEs? I recognize this is a significant difference, but there is still lots that is being done differently outside of SRS. It will require extensive work (go out and beat the bushes) to bring in outside SMEs.

A: The process allows and encourages us to get experts from the outside if necessary.

8. Meeting Comment

The process defined is useful and worthwhile. But the decision to initiate should be made much earlier, e.g., at F&H should this process have begun when the basins were closed? You need to look at higher risk sites. Timing is off for F&H; should pick another project that isn't as far along. We're spending short dollars on this and not doing something else. Look at another project; concentrate effort on highest risk project (TRU waste, DWPF). Process is good.

9. Meeting Comment

The problem of DOE is credibility. If this process will improve DOE credibility and will generate credibility with public, then you should do it.

10. Meeting Question

Q: Why wasn't a Chemical Engineer on your standards teams? A Chemical Engineer needs to be involved in the water treatment unit process.

A: The Environmental Engineer on the standards team is knowledgeable of processes used for groundwater remediation.

11. Written Question (on Meeting Comment Card)

Q: Will process ultimately result in a needed overhaul of DOE Orders?

A: In parallel to the efforts in development of the Necessary and Sufficient standards Closure Process, DOE is also re-evaluating and upgrading the current Orders. Newly revised Orders will more clearly delineate the policies, requirements and guidelines to facilitate more efficient implementation by the field. While the Necessary and Sufficient Closure Process allows application of the most appropriate standards (based on the hazards and activities) to provide adequate protection of the public, workers, and the environment, the new Orders will be available and may be used where deemed appropriate by the team of qualified personnel.

12. Pre-Meeting Comments and Questions

On September 5, Brian Costner, leader of the Energy Research Foundation environmental activist group, called the WSRC-SW&ER Public Involvement Manager to request a chart describing the technical changes as a result of the N&S Process (Ref. A7). Mr. Costner also questioned whether a public meeting was really needed for this issue. After reviewing the chart, Brian Costner offered that this proposed design and construction standards appeared to be a reasonable way to plan and complete remediation work. His support was limited on the health and safety requirements under

OSHA though. He expressed some doubt as to the thoroughness and the level of protection offered/provided to SRS waste site workers, as SRS is currently implementing/satisfying OSHA requirements. He is not convinced that our current methods of giving waste site workers a site-specific document, such as a HASP, to read and a 15 minute site-specific briefing is adequate to ensure the health and safety of workers is protected. He acknowledged these workers receive general OSHA training, but questioned whether the site-specific training, outlining the risks at each site was adequate to ensure worker protection. WSRC acknowledged his concern. Satisfied that his input was being considered, Mr. Costner stated that he would not need to attend the public meeting.

13. Post-Meeting Question and Comment

Jeff Crane, EPA, called the WSRC-SW&ER Public Involvement Manager to ask general questions about whether compliance with environmental regulations/laws would be an objective of this proposed process. The Public Involvement Manager assured him that legal requirements would be met. He said EPA supports a process that streamlines the current remedial process while ensuring compliance with all environmental laws and regulations.

14. Pre- and Post- Meeting Requests for Information

About ten (10) requests from SRS employees for additional information and copies of meeting handouts were received. The information was mailed to the requesters.

15. Post-Meeting Written Comments

One of the more vocal meeting attenders also sent a letter to WSRC with additional comments on the process (Ref. A8). He suggests that independent oversight be conducted to validate the standards that are selected.

WSRC Response to Comment: The level of independent review used for the F/H Groundwater Remediation N&S Pilot was adequate for the scope and hazards addressed. Should this process be implemented further, the level of independent review

will be considered on a case-by-case basis. The N&S Process Description recognizes the need for varying levels of independent review - "The use of a team for confirmation of the necessary and sufficient set of standards is intended to provide an adequate basis for approval of the set. The criteria for the team members, and the degree of individual and team independence needed for this purpose will have to be determined by the convened group (steering committee) in each case. For simple cases, the identification process itself may provide sufficient evidence of the adequacy and feasibility of the set. For more complex or controversial cases, it will be necessary to use more rigorous and independent methods for confirmation, for example, a formal independent peer review."

16. Post-Meeting Comments

The day after the public meeting, both local newspapers published positive articles about the meeting, the N&S Process, and the benefits resulting from the use of the Process (Ref. A9, A10).

APPENDIX C

A PROTOCOL DEFINING THE QUALIFICATION REQUIREMENTS FOR IDENTIFICATION TEAM MEMBERS WHO PARTICIPATED IN THE N&S PROCESS PILOT AT THE LOS ALAMOS NATIONAL LABORATORY

LANL Radiation Protection Program Pilot

Charter

Effective August 24, 1995

QUALIFICATIONS OF THE IDENTIFICATION TEAM MEMBERS

Members of the Standards Selection Team shall be selected in such a manner that the team as a whole has as a minimum the following experience and technical qualifications. A team member may represent more than one of the qualifications.

Operating Expertise:

Professional experience in performing or managing operations in each of the following areas:

- radiation producing machines,
- accelerator operations,
- explosives operations,
- tritium,
- actinides,
- metallurgical operations,
- laboratory scale chemistry, and
- environmental restoration operations.

Current assignment is in facility management at LANL.

Standards Expertise:

There is training or professional experience in writing or interpreting radiation protection standards for application in work situations.

Radiation Protection Expertise:

There is professional work experience in the following areas:

- field experience in applied health physics,
- external and internal dosimetry,
- practicing Health Physics technician,

- Certified Health Physicist,
- Radiation Protection training experience, and
- environmental restoration radiation protection.

Quality Assurance:

There will be professional experience in developing or applying QA programs.

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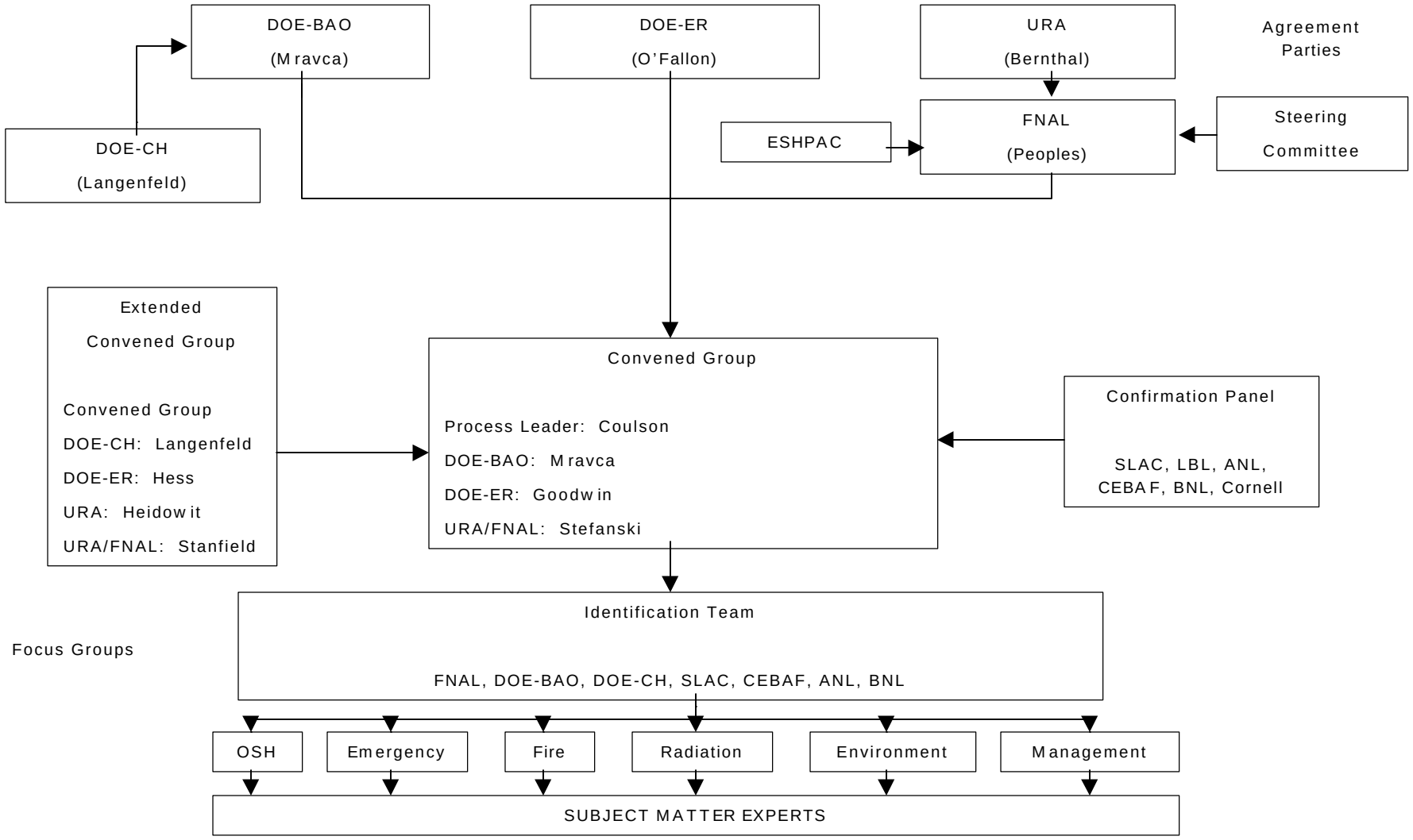
APPENDIX D

N&S PROCESS ORGANIZATIONAL STRUCTURE AT THE FERMI LABORATORY

Fermilab N&S Pilot Organizational Structure



APPENDIX E

THE CHARTER AND THE CONFIRMATION PROTOCOL USED DURING THE N&S PROCESS CONDUCTED AT THE FERMI LABORATORY

Charter

Department of Energy

Fermilab Standards Closure Process

6/14/95 - Revision 1

Objective:

This document outlines the plans and protocols for conducting a pilot of the Department of Energy's Necessary & Sufficient Closure Process (Attachment A) at Fermilab National Accelerator Laboratory (FNAL) in Batavia, Illinois. The result of this pilot will be a set of standards which will serve as the agreed-upon basis for providing FNAL with adequate Environment, Safety and Health Protection at the lowest possible cost. This pilot will seek out and emulate compatible industry practices which have been proven successful both in terms of safety performance and cost-effectiveness. This charter has been developed as a partnership effort by the parties to this agreement (see "Responsibilities" below), and is considered to be a living document.

Responsibilities:

Project Leader:

The Process Leader's responsibilities are as defined in Process Elements 1 and 3 of Attachment A. Larry Coulson of FNAL has this responsibility.

Convened Group:

This Group's responsibilities are defined in Process Elements 2 and 3 of Attachment A. This group also has ownership of this charter document. It consists of the following individuals:

Larry Coulson - Process Leader
Ray Stefanski - FNAL Representative
Andy Mravca - DOE-BAO Representative
Dave Goodwin - DOE-ER Representative

Rod McCullum - DOE-CH, Technical Resource

Extended Convened Group:

Provide management support to the Convened Group (including interactions with the Department Standards Committee and other stakeholders). This group has been formed in addition to what is called for by the Process Description because this is a pilot exercise which will receive a greater degree of Department-wide scrutiny than would normally be expected. It consists of the following individuals:

All Members of the Convened Group
Ken Stanfield - Deputy Director, FNAL
Cherri Langenfeld - Manager, DOE-CH
Bill Hess - Associate Director, High Energy Physics, DOE-ER
Ezra Heitowit - Vice President, URA

FNAL Steering Committee:

This group provides a mechanism for the Process Leader to obtain internal review and guidance on the mechanics of FNAL participation. It will consist of the following individuals:

Larry Coulson - Process Leader
Bruce Chrisman - Associate Director for Administration
Ray Stefanski - Associate Director for Operations Support
Don Cossairt - Senior Laboratory Safety Officer & Head of ES&H Section
Tim Miller - Deputy Head of the ES&H Section
Hans Jostlein - FNAL Standards Manager
Kathy Williams - Manager, Quality Assurance Office

Identification Team (IT):

This group's responsibilities for identifying and confirming the set of standards are defined in Process Elements 3, 4 and 5 of Attachment A. Its membership will be determined by the

Convened Group. The IT will consist of the Process Leader, URA representatives, DOE representatives, sister labs, other parties and subject matter experts as needed.

Agreement Parties:

The agreement parties are the authorities that must approve the Set of Standards. The Extended Convened Group has agreed that the following individuals have approval authority for the FNAL Set of Standards:

Responsible Organization - Fred Bernthal, President, Universities Research Association
Resource Authority - John O'Fallon, Director, High Energy Physics Division, Office of Energy Research
Customer Organization - Andy Mravca, Manager, DOE Batavia Area Office

Action Plan:

Actions Leading to the development of this charter:

1. 2/23/95 The Resource Authority (Bill Hess - ER) transmits a memorandum to the Customer Organization (Andy Mravca - BAO) providing instructions to proceed with a pilot of the Necessary and Sufficient Closure Process.

2. 2/24/95 The Department Standards Committee approves the Necessary & Sufficient Closure Process Description (Attachment A) and the list of proposed pilots (including FNAL).

3. 2/27/95 Kick-off meeting for this pilot held at Fermilab. Representatives of the Department Standards Committee were present to introduce the Necessary & Sufficient Closure Process (Attachment A).

4. 3/1/95 Expanded Convened Group meets to discuss expectations for the pilot project.

5. 3/16/95 FNAL Steering Committee agrees on proposed action plan.

6. 3/20/95 FNAL begins its internal baseline process of acquiring relevant information on FNAL work processes as defined in Process Element 1, [3], A-F of Attachment A. A Preliminary Hazards List will be used to begin the hazards analysis. The DOE Orders at Fermilab book, the CDF Hazards Analysis, The D0 and Accelerator Safety Assessment Documents, and the Fermilab Hazard Assessment Document will also be available for the hazard analysis.

7. 3/20/95 DOE begins the process of assembling information on its input as called for in Process Element 1, [3], A-F of Attachment A.

8. 3/22/95 The Convened Group holds its first weekly meeting to identify Customer Organization, Responsible Organization, Stakeholders, and Resource Authority. FNAL, DOE-BAO and ER input to the Process Leader in response to Process Element 1, [3], A-F of Attachment A is also discussed. It is agreed to incorporate the FNAL Steering Committee Action Plan along with agreed upon protocols into this charter document.

These meetings will be scheduled at least weekly until the Convened Group responsibilities, as defined in Process Element 2, Process Element 3[1] and Process Element 3[2] are completed.

Actions Planned to complete the task of identifying a Set of Standards:

1. 3/27/95 The Process Leader will set up the Identification Team (IT):

- The IT will consist of the Process Leader, URA representatives, DOE representatives, sister labs, other parties and subject matter experts as needed. Composition of the IT will be determined by the Convened Group. If necessary, the Process Leader will interview prospective team members.

- The criteria for membership on the IT will be defined, with the agreement of the Convened Group, and documented.

- The qualifications of the IT members will be documented.

2. 4/26/95 Under the direction of the Process Leader, Fermilab prepares materials that will be used for the closure process by this date. These materials, which will include an initial hazard

analysis, will be presented to a full meeting of the Fermilab ES&H Policy Committee (ESHPAC). A progress report will be submitted to URA.

3. 5/1/95 Materials assembled by the Process Leader and distributed to the IT.

4. 5/8/95 IT meets to begin the process of developing the "final" Necessary and Sufficient Set. A presentation to the Fermilab Director will take place before the Necessary and Sufficient Set is finalized.

Somewhat concurrently, the Agreement Parties will evaluate the Necessary and Sufficient Set for resource requirements. ESHMAP (The Fermilab ES&H Management Plan) would be drawn upon for budget data.

5. 6/8/95 External Stakeholder involvement (if any) will be scheduled. Appropriate meetings and reviews will be set up with identified stakeholders by the stakeholder liaisons on the IT.

6. 7/12/95 IT presents the NS set to the Convened Group.

7. 7/14/95 NS sent to Agreement Parties for approval. This should complete the closure process if the Approval Authority approves the NS. If not, the IT will meet again to modify NS and resubmit for final approval.

Upon approval of the Necessary and Sufficient Set of Standards, the FNAL contract will be modified to incorporate them.

8. When needed. If there is a need in the future to modify the NS, the Convened Group will be consulted.

Protocols:

Approval of Standards Set:

The Standards Set will be considered approved when it has been agreed to and signed by the following parties in the order listed:

Responsible Organization - Fred Bernthal, President, Universities Research Association, Inc.
Resource Authority - John O'Fallon, Director, High Energy Physics Division, Office of Energy Research
Customer Organization - Andy Mravca, Manager, DOE Batavia Area Office

Instructions to the Identification Team (IT):

The Convened Group will issue a charter letter to the IT outlining its expectations for their conduct of this pilot process.

Scope of Standards Set:

The Necessary and Sufficient Set of Standards will focus on standards in the area of Environment, Safety and Health (ESH). This is defined as any functional area that is addressed in DOE's Guidance Manual for the ESH Management Plan (dated October, 1994). Any decision to include areas beyond ESH will be made by agreement of the Convened Group and included in the final instructions to the Identification Team (IT).

Documentation of Standards Set:

The specific format and level of detail with which the standards set will be documented will be decided by the Identification Team (IT). The Convened Group expects that this document will include, at a minimum, a listing of the standards and a summary discussion sufficient to communicate an understanding of the relationship between the FNAL's work, its associated hazards and the standards selected.

Confirmation of Standards Set:

Once the Identificaiton Team (IT) has completed assembling the set of standards, it will be expected to hold a final Team meeting(s), with all members present, to confirm that the IT believes that the set as a whole is adequate. Once that is done, they shall present the set first to FNAL for concurrence (see Attachment B for details) and then to the Convened Group. The Convened Group will assemble a panel of subject matter experts who will be expected to orally challenge the set and the IT will be called upon to defend it (see Attachment C for details).

Once the IT has successfully defended the set, it will be considered confirmed and the Convened Group will recommend it for approval.

Interactions between Convened Group and Identification Team (IT):

Throughout this process, the Process Leader will act as the liaison between the IT and the Convened Group.

Effort Tracking:

The Process Leader will be responsible for preparing an estimate of the costs incurred by the Identification Team (IT) in preparing this set sufficient to facilitate an evaluation of the impact of this pilot exercise.

Stakeholder Liaisons:

In order to keep the Identification Team (IT) to a workable size, it will not be possible to include all stakeholders on the team. Therefore, liaison relationships will be established between specific members of the IT and appropriate stakeholders. Formal communications between the IT liaisons and their assigned stakeholders will be required and documented.

Consensus:

The Identification Team (IT) will need to establish its own protocols for reaching consensus on the set of standards. If at any point, they are unable to reach consensus on any issue, they may bring this issue for resolution to the Convened Group.

Signature

Convened Group

Larry Coulson, Process Leader

Ray Stefanski, FNAL

Dave Goodwin, DOE-ER, High Energy Physics

Andy Mravca, DOE-BAO

Attachment A: Department of Energy's Necessary & Sufficient Closure Process

Attachment B: Fermilab Protocol Confirmation of the Draft Set

Attachment C: Convened Group Protocol Confirmation of the Draft Set

Charter

Fermilab Standards Closure Process

Attachment B

Fermilab Protocol

Confirmation of the Draft Set

6/7/95

* When the Identification Team releases a draft of the N&S Set of Standards, a copy will be sent to URA, ESHPAC members, and division/section heads. Instruction will go to division/section heads to orchestrate a review with appropriate personnel within their organizations and prepare written comments to go with their ESHPAC representative to an ESHPAC meeting in about 3 days. Backup information, such as the issue forms, will be provided on a server.

* At an ESHPAC meeting the draft set and division/section comments will be discussed. N&S Identification Team Focus Group leaders will be present to provide explanations and help resolve issues.

* A few days later there will be a meeting of the ESHPAC with division/section heads and the Director. The set and unresolved comments will be discussed. N&S Identification Team Focus Group leaders will be present to provide explanations and help resolve issues.

* The Lab's comments will be prepared from the minutes of the above meeting. The comments will be sent back to the Identificaiton Team.

Charter

Fermilab Standards Closure Process

Attachment C

Convened Group Protocol

Confirmation of the Draft Set

6/7/95

* A confirmation Panel of about 5 persons will be assembled to assist the Convened Group in confirmation of the draft set of standards. The Process Leader will select the Panel from a list of names approved by the Convened Group. The candidates will be peers from other Laboratories. In most cases these will be the ES&H Directors, their deputies, or higher ranking personnel.

* The Draft Set will be sent to the Convened Group and Confirmation Panel for their review prior to the confirmation meeting. Members of Extended Convened Group, observers and technical resource people will also be invited. Technical resource people for this meeting will be persons expert in the N&S Process. Protocol for this meeting and the list of technical resource people will be developed by the Process Leader in consultation with the Convened Group.

* The Convened Group will meet, if necessary, to resolve issues presented but not resolved at the Convened Group confirmation meeting. This is the final step in the confirmation process.

* At the end of the confirmation process the set will be considered confirmed and ready for signature by the Agreement Parties.

Protocols for the

Fermilab N&S Confirmation Meeting 7/12/95

The confirmation process for the Fermilab N&S Set, as defined in the protocols, requires the Identification Team to present the proposed Set and defend it to the Convened Group. The Convened Group has decided to supplement the process by inviting a group of peers from other laboratories to participate. Members of the Extended Convened Group have also been invited to participate as they wish. Each member of the Convened Group or Extended Group who participates in the confirmation process, may bring an observer as a subject matter expert (SME).

- The Standards Set and any supporting information which needs to be part of the review package will be provided to each member of the Extended Convened Group, Convened Group and the Peer Review Panel (CG/PRP) prior to the confirmation meeting.

- The first phase of the confirmation meeting will consist of a presentation, by the Identification Team, of the N&S Set and the process used to determine the N&S Set to the CG/PRP.

- There will be a break following the presentation phase of the meeting for the CG/PRP to caucus prior to questions.

- The second phase of the confirmation meeting will consist of the CG/PRP asking questions of the IT. The CG/PRP should ask sufficient questions to challenge the necessary and sufficient aspects of the set.

- The process leader will function as the moderator for the question phase of the meeting.

- A note taker will record the proceedings of the meeting.

- Only members of the Extended Convened Group, Convened Group, and Peer Review Panel will be permitted to ask questions. Subject matter experts may pass written questions to a member of one of the above groups.

- At each CG/PRP member's turn, that individual will ask one question and follow-on questions on the same topic until either the question has been answered to his/her satisfaction or the moderator determines that the question represents an "Open Issue" which will require further study by the IT.

- All follow-on questioning shall stay focused on the same issue; questions on other "related" issues must be asked as a separate turn. The Moderator shall intervene if questioning strays from the issue originally questioned.

- Open Issue forms will be made available and the CG/PRP member will be responsible for documenting his/her concern on this form when it is determined that the question cannot be answered. The forms will document the question asked and the information needed to resolve the question as its first section. The form will be assigned by the process leader to the IT which will be responsible for filling out the second section of the form (resolution section) at a later time and obtaining the questioner's signature that the resolution is acceptable. The questioner's signature will constitute closure of the issue. Once all open issues are closed, the Set will be considered closed. If multiple CG/PRP members share a common concern, multiple resolution signatures can be requested.

- Questioning will proceed until each member of the CG/PRP indicates that he/she has no further questions.

- Once all questions have been exhausted the process leader will either declare the Set confirmed, if no open issues exist, or negotiate a schedule for resolving open issues. Based on either this confirmation or schedule for confirmation, the process leader will make arrangements for the signing of the Set and its associated contract modification by the approval authorities.

- DISASTER CLAUSE: If at any point in this meeting the process leader judges that the number of issues has become so significant that the Set cannot be confirmed, he may suspend the confirmation meeting and request that the full IT reconvene at a later date to reconsider the Set. In this case, and only this case, the confirmation process would need to be repeated in its entirety.

APPENDIX F

THE LOS ALAMOS NATIONAL LABORATORY MATRIX, "ORDERS AND RULES OF INTEREST TO THE DNFSB AND APPENDIX G OF THE LANL CONTRACT," DEVELOPED FOR THE WORK SMART STANDARDS SET AT LOS ALAMOS NATIONAL LABORATORY

Crosswalk of Orders and Rules of Interest to the DNFSB and Appendix G of the LANL Contract (May 98)

Orders and Rules of Interest to the DNFSB (May 98)	Title	In Appendix G of LANL Contract? (May 4, 98)	Not Needed in Contract	Comments
DOE O 151.1	Comprehensive Emergency Management System	Yes		Cancels 5500.1B, 5500.2B, 5500.3A, 5500.4A, 5500.5A, 5500.7B, 5500.8A, 5500.9A, 5500.10A. Adopted into WSS.
DOE O 210.1	Performance Indicators and Analysis of Operations Information	No		Cancels 5480.26. Outside WSS. LAAO sent 210.1 Change 2 memo to UC 3/16/98.
DOE O 225.1A	Accident Investigations	No		Cancels 225.1; para 1-5, 6a(1) thru (10), 6b, 6d, 6f(1) thru (8), and the second misnumbered 6f, and Chapters I and II of 5484.1. Outside WSS. Sent to UC 2/18/98
DOE O 231.1	ES&H Reporting	No		Cancels specific paragraphs in : 5400.1, 5400.2A,5400.5, 5440.1E, 5480.3, 5480.26, 5483.1A, 5630.12A, 5634.1B. Outside WSS. LAAO sent 231.1 Change 2 memo to UC 3/16/98.

Orders and Rules of Interest to the DNFSB (May 98)	Title	In Appendix G of LANL Contract? (May 4, 98)	Not Needed in Contract	Comments
DOE O 232.1A	Occurrence Reporting and Processing of Operations Information	Yes		Canceled 232.1 Ch 2, which is in App G. Outside WSS. LAAO sent to UC 3/16/98.
DOE O 251.1	Directives System	Yes		Outside WSS. LAAO sent 251.1 and DOE M 251.1-1, Change 1 memo to UC 3/16/98.
DOE O 252.1 (Draft)	Technical Standards Program	No	TBD	In draft. Applies to DOE only.
DOE O 420.1	Facility Safety	No		Cancels 5480.7A, 5480.24, 5480.28, and Division 13 of 6430.1A. Addressed by other WSS. Re-assessment will include 420.1 in App G. LAAO to work change. Also, see comments for 5480.28
DOE O 425.1	Startup and Restart of Nuclear Facilities	Yes		Cancels 5480.31. Adopted into WSS. Still working to AL Supplemental 5480.31. AL Supplemental Directive 425.1 in final comment resolution. A Laboratory Notice for non-nuclear facilities will be developed and a Focus Group will follow.

Orders and Rules of Interest to the DNFSB (May 98)	Title	In Appendix G of LANL Contract? (May 4, 98)	Not Needed in Contract	Comments
DOE O 430.1	Life Cycle Asset Management	No* *Applies to DOE only	X	Upon meeting implementation conditions of this order, the following orders will be canceled: 1332.1A, 4010.1A, 4300.1C, 4320.1B, 4320.2A, 4330.4B, 4330.5, 4540.1C, 4700.1, 4700.3, 4700.4, 5700.2D, 6430.1A. Implementation of Life Cycle Asset Management is accomplished through actions: C Establishment of DOE expectations with attendant contractor performance measures - App F is used for this purpose at LANL. C Incorporation of primary expectations in the contract - these expectations are found in the ?Functional Requirements Documents.? The FDRs were written by the functional program managers for the five Facilities Management functions: site planning, project management, maintenance, utilities, and real property.
DOE O 440.1	Worker Protection Management for DOE Federal and Contractor Employees	Yes		Cancels 3790.1B except Chap VIII, 5480.7A, 5480.8A, 5480.9A, 5480.10, 5480.16A, & 5483.1A. Addressed by parts of this Order plus other WSS. Only Attach 1, para 3, Firearms Safety; para 6, Pressure Safety Requirements; and Attach 2, para 13, Construction Safety.

Orders and Rules of Interest to the DNFSB (May 98)	Title	In Appendix G of LANL Contract? (May 4, 98)	Not Needed in Contract	Comments
DOE P 441.1	DOE Radiological Health and Safety Policy	No	X	DOE N 441.1 implements DOE P 441.1 per OSHD. The subject notice was reviewed and deemed unnecessary to include in the work smart standards effort. The functionality of the requirements were incorporated directly into existing LANL and Work smart standards. The only noticeable difference is the exemption levels for radioactive source accountability. Proposed revisions to 10 CFR 835 will close the gap. AL and LAAO have reviewed, understand and have accepted these differences.
DOE O 451.1A	National Environmental Policy Act Compliance Program	No	X	Cancels 451.1. This order has no contractor requirements and is applicable internally to DOE personnel as noted in the Order. As part of WSS, the lab is responsible for supporting the requirements of the National Environmental Policy Act (NEPA), the Endangered Species Act (ESA), and the Federal Water Pollution Control Act (FWPCA).
DOE O 452.1A	Nuclear Explosive and Weapons Surety Program	Yes		Cancels 452. Outside WSS.
DOE O 452.2A	Safety of Nuclear Explosive Operations	Yes		Cancels 452.2 Outside WSS.

Orders and Rules of Interest to the DNFSB (May 98)	Title	In Appendix G of LANL Contract? (May 4, 98)	Not Needed in Contract	Comments
DOE O 460.1	Packaging and Transportation Safety	Yes		460.1A cancels 460.1. Addressed by parts of 460.1A, Attachment 1 - Contractor Requirements Document, paragraphs 2 and 6, plus other WSS which are in the contract. LANL, in coordination with DOE, is developing a P&T LIR to address standards and implementation issues for off-site, intra-site, and on-site P&T.
DOE O 460.2	Departmental Materials Transportation and Packaging Management	Yes		Cancels 1540.1A, 1540.2, 1540.3A Outside WSS. LANL, in coordination with DOE, is developing a P&T LIR to address standards and implementation issues for off-site, intra-site, and on-site P&T.
DOE 1300.2A	DOE Technical Standards Program	Yes		Outside WSS
DOE 1360.2B	Unclassified Computer Security Program	Yes		Outside WSS
DOE 1540.2	Hazardous Material Packaging for Transport - Admin Procedures	No	X	Canceled by 460.2, which is in App G.
DOE 1540.3A	Base Technology for Radioactive Material Transportation Packaging System	No	X	Canceled by 460.2, which is in App G.
DOE 3790.1A	Federal Employee Occupational Safety and Health Program	No	X	Order 3790B has been canceled by 440.1, except for Ch VIII. Applies to DOE only.

Orders and Rules of Interest to the DNFSB (May 98)	Title	In Appendix G of LANL Contract? (May 4, 98)	Not Needed in Contract	Comments
DOE 4330.4B	Maintenance Management Program	No* * Functional Requirements Documents being developed.	X	Canceled by 430.1, which applies to DOE only. Implementation of Life Cycle Asset Management is accomplished through actions: C Establishment of DOE expectations with attendant contractor performance measures - App F is used for this purpose at LANL. C Incorporation of primary expectations in the contract - these expectations are found in the ?Functional Requirements Documents.? The FDRs were written by the functional program managers for the five Facilities Management functions: site planning, project management, maintenance, utilities, and real property. ? Requirements for maintenance management are contained in Appendix E and F and included in LIR 230-04-01, Maintenance Management..
DOE 4700.1	Project Management Program	No* * Functional Requirements Documents being developed.	X	Canceled by 430.1, which applies to DOE only. Outside WSS. Implementation of Life Cycle Asset Management is accomplished through actions: C Establishment of DOE expectations with attendant contractor performance measures - App F is used for this purpose at LANL. C Incorporation of primary expectations in the contract - these expectations are found in the ?Functional Requirements Documents.? The FDRs were written by the functional program managers for the five Facilities Management functions: site planning, project management, maintenance, utilities, and real property. ? Requirements contained in DOE Construction Project Management Guide are included in LIR 220-02-02, Construction Project Management..

Orders and Rules of Interest to the DNFSB (May 98)	Title	In Appendix G of LANL Contract? (May 4, 98)	Not Needed in Contract	Comments
DOE 5000.3B	Occurrence Reporting and Processing of Operations Information	No	X	Canceled by DOE O 232.1, which is in App G. Outside WSS.
DOE 5400.1	General Environmental Protection Program	Yes		Ch II; para 2d, and the second sentence of para 3(b) of Ch III; and para 10(c) of Ch IV are canceled by 231.1 Addressed by parts of 5400.1 except Chap 2, paragraphs 2, 4.d and 5, plus other WSS.
DOE 5400.2A	Environmental Compliance Issue Coordination	No	X	Specific paragraphs canceled by 231.1. Canceled by DOE N 251.6. Addressed by other WSS.
DOE 5400.3	Hazardous and Radioactive Mixed Waste Program	No		Canceled by DOE N 1321.139. Not reviewed as part of WSS.
DOE 5400.4	Comprehensive Environmental Response, Compensation, and Liability Act Requirements	No	X	Canceled by DOE N 251.6. Addressed by other WSS.
DOE 5400.5	Radiation Protection of the Public and the Environment	Yes		Paragraph 1A(3)(A) of Chapter II are canceled by 231.1. Addressed by 5400.5 Ch 2 plus other WSS.
DOE 5440.1E	National Environmental Policy Act Compliance Program	No	X	Specific paragraphs canceled by 231.1. Canceled by DOE N 251.4 Canceled by 451.1. DOE O 451.1 has no contractor requirements and is applicable internally to DOE personnel as noted in the Order. LANL addresses NEPA requirements with other WSS.

Orders and Rules of Interest to the DNFSB (May 98)	Title	In Appendix G of LANL Contract? (May 4, 98)	Not Needed in Contract	Comments
DOE 5480.1B	ES&H Program for DOE Operations	No	X	Canceled by DOE N 251.4. Addressed by other WSS.
DOE 5480.3	Safety Requirements for the Packaging and Transportation of Hazardous Materials, Hazardous Substances, and Hazardous Waste	No	X	Specific paragraphs canceled by 231.1. LANL, in coordination with DOE, is developing a P&T LIR to address standards and implementation issues for off-site, intra-site, and on-site P&T.
DOE 5480.4	Environmental Protection, Safety, and Health Protection Standards	No	X	Addressed by other WSS.
DOE 5480.5	Safety of Nuclear Facilities	No	X	Canceled by 5480.21, 5480.22, and DOE N 1321.140. 5480.21 and 5480.22 are in App G.
DOE 5480.6	Safety of DOE-Owned Nuclear Reactors	Yes		Outside WSS.
DOE 5480.7A	Fire Protection	No	X	Canceled by 420.1, 440.1. DOE O 420.1 being reviewed for inclusion in App G. Update when 420.1 is included in App G. Addressed by additional WSS.
DOE 5480.8A	Contractor Occupational Medical Program	No	X	Canceled by 440.1, only Attach 1, para 3, Firearms Safety; para 6, Pressure Safety Requirements; and Attach 2, para 13, Construction Safety. Addressed by other WSS.

Orders and Rules of Interest to the DNFSB (May 98)	Title	In Appendix G of LANL Contract? (May 4, 98)	Not Needed in Contract	Comments
DOE 5480.9A	Construction Safety and Health Program	No	X	Canceled by 440.1. Addressed by other WSS.
DOE 5480.10	Contractor Industrial Hygiene Program	No	X	Canceled by 440.1. Addressed by other WSS.
DOE 5480.11	Radiation Protection for Occupational Workers	No	X	Canceled by DOE N 441.1. Addressed by other WSS.
DOE 5480.15	DOE Laboratory Accreditation Program for Personnel Dosimetry	No	X	Canceled by DOE N 441.1. Addressed by 10 CFR 835..
DOE 5480.17	Site Safety Representatives	No	X	Canceled by DOE N 251.4
DOE 5480.18	ES&H Program for DOE Operations	No	X	Canceled by 5480.18A.
DOE 5480.18B	Nuclear Facility Training Accreditation Program	No	X	Canceled by DOE N 251.22. The objectives of 5480.18B can be met through implementation of existing requirements contained in DOE Order 5480.20A.
DOE 5480.19	Conduct of Operations Requirements for DOE Facilities	No	X	The LANL-specific LPR 240-01-00. Facility and Operating Limits and Configuration have been revised to replace the current WSS citation, ?LANL LPR Management of Operations (to be developed).? LPR 240-01-00 is consistent with UC Contract Clause 5.14 and requires that Facility Safety Plans incorporate the philosophy and guidance of 4580.19. This contract mod was recently recommended to the joint DOE-UC-LANL ISM Change Control Board.

Orders and Rules of Interest to the DNFSB (May 98)	Title	In Appendix G of LANL Contract? (May 4, 98)	Not Needed in Contract	Comments
DOE 5480.20A	Personnel Selection, Qualification, Training, and Staffing Requirements at DOE Reactor and Nonreactor Nuclear Facilities	Yes		
DOE 5480.21	Unreviewed Safety Questions	Yes		
DOE 5480.22	Technical Safety Requirements	Yes		
DOE 5480.23	Nuclear Safety Analysis Reports	Yes		
DOE 5480.24	Nuclear Criticality Safety	No	X	Canceled by 420.1, which is under review for inclusion in App G. Addressed during WSS by ANSI Standards Update when 420.1 is included in App G.
DOE 5480.25	Safety of Accelerator Facilities	Yes		Addressed by parts of 5480.25, Sections 9f-j, 10, plus other WSS.
DOE 5480.26	Trending and Analysis of Operations Information Using Performance Indicators	Yes		Canceled by 210.1, which is being reviewed by LANL. 5480.26 will be canceled after 210.1 is accepted Specific paragraphs canceled by 232.1 Outside WSS. See comments for 210.1.

Orders and Rules of Interest to the DNFSB (May 98)	Title	In Appendix G of LANL Contract? (May 4, 98)	Not Needed in Contract	Comments
DOE 5480.28	Natural Phenomena Hazards Mitigation	No	X	Canceled by 420.1 Seismic concerns are under review for inclusion in App G. Recommended actions include replacing the WSS citation DOE-STD-1020-94 (Natural Phenomena Hazard Design and Evaluation Criteria for DOE Facilities) with DOE Order 420.1 (Facility Safety), paragraphs 4.4 thru 4.4.6 and its implementing guide ?Interim Guidelines for the Mitigation of Non-Nuclear Facilities?. This contract mod was recently recommended to the joint DOE-UC-LANL ISM Change Control Board.
DOE 5480.29	Employee Concerns Management System	Yes		Outside WSS.
DOE 5480.30	Nuclear Reactor Safety Design Criteria	No	X	Canceled by 460.1 and DOE N 251.4 Outside WSS. LANL work doesn't include reactor design.
DOE 5480.31	Startup and Restart of Nuclear Facilities	No	X	Canceled by 425.1, which is in App G. The Authorization Basis LIR will also address non-nuclear facilities.
DOE 5481.1B	Safety Analysis and Review System	No	X	Canceled by DOE N 251.4. Addressed by other WSS. The Authorization Basis LIR will also address non-nuclear facilities.
DOE 5482.1B	ES&H Appraisal Program	Yes		Outside WSS.

Orders and Rules of Interest to the DNFSB (May 98)	Title	In Appendix G of LANL Contract? (May 4, 98)	Not Needed in Contract	Comments
DOE 5483.1A	Occupational Safety and Health Program for DOE Contractor Employees at Government-Owned Contractor-Operated Facilities	No	X	Specific paragraphs canceled by 231.1. Canceled by 440.1. The following parts of DOE O 440.1 plus other WSS address this order: Only Attach 1, para 3, Firearms Safety; para 6, Pressure Safety Requirements; and Attach 2, para 13, Construction Safety.
DOE 5484.1	ES&H Information Reporting Requirements	Yes		Para 1-5, 6a(1) thru (10), 6b, 6d, 6f(1) thru (8), and the second misnumbered 6f, and Chapters I and II canceled by 225.1A. Specific paragraphs are canceled by 231.1. Outside WSS.
DOE 5500.1B	Emergency Management System	No	X	Canceled by 151.1, which is in App G.
DOE 5500.2B	Emergency Categories, Classes, and Notification and Reporting Requirements	No	X	Canceled by 151.1, which is in App G.
DOE 5500.3A	Planning and Preparedness for Operational Emergencies	No	X	Canceled by 151.1, which is in App G.
DOE 5500.4A	Public Affairs Policy and Planning Requirements for Emergencies	No	X	Canceled by 151.1, which is in App G.
DOE 5500.7B	Emergency Operating Records Protection	No	X	Canceled by 151.1, which is in App G.
DOE 5500.10	Emergency Readiness Assurance Program	No	X	Canceled by 151.1, which is in App G.
DOE 5530.1A	Accident Response Group	Yes		Addressed by this Order plus other WSS.

Orders and Rules of Interest to the DNFSB (May 98)	Title	In Appendix G of LANL Contract? (May 4, 98)	Not Needed in Contract	Comments
DOE 5530.2	Nuclear Emergency Search Team	Yes		Addressed by this Order plus other WSS.

Orders and Rules of Interest to the DNFSB (May 98)	Title	In Appendix G of LANL Contract? (May 4, 98)	Not Needed in Contract	Comments
DOE 5530.3	Radiological Assistance Program	Yes		Addressed by this Order plus other WSS.
DOE 5530.4	Aerial Measuring System	No	X	LANL does not have responsibility for implementation per Peggy Mayville?s memo dated 11/5/91.
DOE 5600.1	Management of the DOE Weapon Program and Weapon Complex	Yes		Outside WSS.
DOE 5610.10	Nuclear Explosive and Weapon Safety Program	No	X	Canceled by 452.1, which is in App G. Outside WSS.
DOE 5610.11	Nuclear Explosive Safety	No	X	Canceled by 452.2, which is in App G. Outside WSS.
DOE 5610.12	Packaging and Offsite Transportation of Nuclear Components, and Special Assemblies Associated with the Nuclear Explosive and Weapon Safety Program	No		Cancels 5610.1. The Change Control Board has approved addition of 5610.12 to App G.
DOE 5632.1C	Protection and Control of Safeguards and Security Interests	Yes		Outside WSS.
DOE 5632.11	Physical Protection of Unclassified Irradiated Reactor Fuel in Transit	No	X	LANL work doesn?t include reactor fuel. Outside WSS.
DOE 5700.6C	Quality Assurance	Yes		

Orders and Rules of Interest to the DNFSB (May 98)	Title	In Appendix G of LANL Contract? (May 4, 98)	Not Needed in Contract	Comments
DOE 5820.2A	Radioactive Waste Management	Yes		

Orders and Rules of Interest to the DNFSB (May 98)	Title	In Appendix G of LANL Contract? (May 4, 98)	Not Needed in Contract	Comments
DOE 6430.1A	General Design Criteria	Yes* * Division 13 only		Division 13 canceled by 420.1. 420.1 under WSS review for inclusion in App G. This Order canceled by 430.1 LCAM, except for specific facilities under the purview of the DNFSB. Implementation of Life Cycle Asset Management is accomplished through two actions: C Establishment of DOE expectations with attendant contractor performance measures - App F is used for this purpose at LANL. C Incorporation of primary expectations in the contract - these expectations are found in the ?Functional Requirements Documents.? The FDRs were written by the functional program managers for the five Facilities Management functions: site planning, project management, maintenance, utilities, and real property.
10 CFR 820	PROCEDURAL RULES FOR DOE NUCLEAR ACTIVITIES	No	X	Applies to DOE only.
10 CFR 830.120	QUALITY ASSURANCE REQUIREMENTS	Yes		DNFSB Tech 16, List A Adopted into WSS.
10 CFR 835	OCCUPATIONAL RADIATION PROTECTION	Yes		DNFSB Tech 16, List A Adopted into WSS.

APPENDIX G

CRITERIA FOR EVALUATING THE PERFORMANCE OF THE N&S PROCESS AND CONFIRMATION OF READINESS

EVALUATION CRITERIA FOR N&S CLOSURE PROCESS PERFORMANCE EFFECTIVENESS AND CONFIRMATION READINESS (Rev 4)

Objective:

Provide a basis for assessment, to be applied late in the course of standards identification, that the record of N&S Closure Process application supports a judgement by the Convened Group that the proposed Work Smart Standards set is ready to enter the Confirmation process element. Such a judgment is based upon two related but distinct components of readiness, information about adequacy for protection and information about feasibility for implementation of the proposed set.

Applicability:

Consistent with the *Safety Management System Policy*, (DOE P450.4), the N&S Closure Process (DOE M450.3-1) is being applied to develop an adequate and feasible set of new or amended contract standards, as required under DEAR provisions 970.5204-2, *Integration of environment safety, and health into work planning and execution*, and 5204-78 *Laws, regulations and DOE directives*.

Conventions:

1. Identification of agreed upon standards is intended to satisfy the DOE procurement regulatory requirement in DEAR 970.5204-78.
2. Standards are the expressed expectations for the performance of work; as described in the Criteria for the Department Standards Program (DOE/EH-0416), work is standards-based when planned, performed, and appropriately documented as meeting agreed upon standards for protection.
3. Standards identified in conformance with the N&S Closure Process Manual, DOE M450.3-1, are termed Work Smart Standards.
4. When effectively implemented, the expectations expressed in an adequate and feasible set of Work Smart Standards will provide for standards-based work that will satisfy the Integrated Safety Management (ISM) performance outcomes called for in DEAR 970.5204-2.
5. Increased effectiveness in *Doing Work Safely* is the institutional performance objective that DOE and the contractor expect from development of the set of Work Smart Standards: this represents commitment to safety performance that exceeds minimum compliance with applicable laws and regulations.
6. The N&S Closure Process manual is a performance standards that incorporates the five Core Functions of ISM into the work of standards identification; implementation proceeds by means of an inherently iterative process for definition and description of the

contract work, associated hazards and an appropriate set of Work Smart Standards until robust agreement is reached on adequacy and feasibility of the resulting standards-based approach.

7. Consistent with ISM Guiding Principles, hazards associated with the contract Statement of Work comprise a broad category that includes direct sources of potential harm as well as the institutional factors that cause latent conditions in the workplace (e.g. poor general housekeeping) or within the organizational infrastructures (e.g. excessive reliance on overtime in hazardous work assignments) that are known precursors to acute, unwanted safety consequences.
8. The *Safety Management System* hierarchy of implementing components, DOE P450.4, Figure 1, is reflected in the N&S Closure Manual: Chapters and Process Elements define ISM mechanisms, the protocols called for define the ISM roles, responsibilities and implementing practices needed to ensure adequacy and feasibility of the Work Smart Standards.
9. At Confirmation, demonstrating feasibility of the Work Smart Standards means that solid evidence is provided that transformation of the pre-existing infrastructure for doing work has been considered by process management and found to be achievable.

Performance Basis for Process Evaluation:

The following outcomes apply to the work of N&S Closure Process participants needed to ensure requirements for adequacy, feasibility and process fidelity are satisfied. In the instructions to a Confirmation Team, attention should be directed toward the evidence that these outcomes have been achieved. Specifically, evidence in the process record should support the conclusions of the Process Leadership and the Convened Group:

1. Intended that the Work Smart Standards being developed provide a tailored description of the work, hazards and standards to be used under the contract in the development of acceptable work activity controls (*adequate protection*).

2. Aligned the Work Smart Standards for implementation in available institutional mechanisms for the planning and performance of work (*feasible*).

3. Ensured the Work Smart Standards can be accepted as authoritative for purposes of contract performance (*fidelity: adequacy and feasibility have been appropriately established*).

Relation of the Evaluation Basis to the N&S Closure Process Manual:

The manual for the N&S Closure Process guides those responsible for the development of the Work Smart Standards set. The organization of the manual follows the process logic of the five Core Functions for Integrated Safety Management (ISM) as they are applied to the work of "Identifying Safety Standards and Requirements", which is one of the seven Guiding Principles of ISM. In particular the manual calls for iterative application of the five Core Functions until convergence of the participants' judgement is reached that the material describing the proposed Work Smart Standards is acceptable for approval and implementation.

The three conclusive outcomes, identified above as the Performance Basis for Process Evaluation, are the sufficient independent conditions needed to demonstrate closure on an adequate and feasible set. Each of the specific attributes of process effectiveness and readiness described in the manual can be allocated to one or more of these conditions and thus when evidence of actual process application is assessed, the degree of readiness for Confirmation can be determined. These assessment results, having been pegged to the intermediate process outcomes called for in the manual, can form the basis for a conclusion that the N&S Closure Process has been applied with fidelity and that there is reasonable assurance the proposed Work Smart Standards are ready for the Confirmation process element.

The detailed evaluation criteria are organized so as to illuminate the cumulative performance of N&S Closure Process participants toward the outcomes expected in each of four key Process control mechanisms. The key Process control mechanisms are: Process Management, Protocols, Work in Teams, and Documentation of Process Implementation. Each mechanism is addressed by one or more evaluation criteria. Each criteria is cross-referenced to specific expectations found in the N&S Closure Process Manual or in DEAR 5204-2 on ISM. A third column provides additional reference points to the verification objectives for ISM programmatic implementation. The specific statement of these objectives is provided in the final attachment to this document.

Use of the Evaluation Criteria:

The simplest use of the Evaluation Criteria is as a self-assessment tool applied by the responsible Process Leadership and convened Group. However, in situations with large organizations and where the impact of the Work Smart Standards set is expected to be significant, experience has demonstrated that a more independent internal assessment of Confirmation readiness can provide a valuable benchmark. Use of the Evaluation Criteria by a selected group of interested parties (a.k.a. "murderboard") from the affected organizations can strengthen confidence about the feasibility of the Proposed Work Smart Standards. Such reviews begin the necessary process of transferring the Process participants' shared core knowledge to the full organization. In order for the Evaluation Criteria to be effective in such internal reviews, users must be trained that these attributes of effectiveness relate to conformance with

Process manual requirements. The criteria only indirectly support conclusions about the technical appropriateness of the proposed Work Smart Standards set. Use of the Evaluation Criteria does not satisfy the requirements to conduct the Confirmation process element.

Outcome: The Work Smart Standards being developed are intended to provide a tailored description of the work, hazards and standards to be used under the contract in the development of acceptable work activity controls (*adequate protection*).

Mechanism and Criteria	Attributes of Effectiveness	ISM Verification Objectives
A. Process Management		
1) The Agreement Parties are identified and the criteria triggering use of the Process are known to process management.	A. The applicable contract provides for use of the Process. [M-I.2] B. Properly conducted the Process is intended to produce a set of N&S standards appropriately tailored to the specific work (i.e. the contract Statement of Work including ISM). [M-2.b] C. Agreement parties include, but are not limited to, the contracting officer and counterpart in the contractor organization. [M-Def. 1] D. The contractor shall ensure that ES&H functions are a visible part of work planning and execution. [D-(b)] E. An agreed-upon set of adequate ES&H standards and requirements are established. [D-(b),(5)] F. Documentation (of the SMS) shall be submitted to the contracting officer for review and approval in accordance with that official's guidance (i.e. Apply the Process). [D-(e)]	DOE.1, BBC.1, MG.2
2) Process management provides Process training for participants.	A. The process in intended to provide a disciplined and collaborative analysis of the work and hazards. [M-Purpose] B. Personnel possess competence necessary to discharge their responsibilities. [D-(b),(3)] C. The DSC management training course on the Process is required for management team members. [N-3] D. Participants understand the role of the Process within the larger context of the Department's Standards Program. [M-Summary, 2.a]	BBC.3, HAZ.3

3) Process leader(s) are identified and charged with faithful Process application to identify an integrated set of safety standards.	A. Agreement Parties formally designate a Process Leader(s), preferably from the Responsible Organization. [M-I.2.(b),(1)] B. The Process Leader(s) will be responsible for conducting the Process [M-I.2.(b),(1)] C. The WSS set is approved upon the determination that the Process has been correctly implemented. [M-2.e]	BBC.2, MG.1
4) A Convened Group is assembled that clearly represents those DOE and contractor affected parties with significant resources committed during implementation of the WSS.	A. Parties who must agree on the set of standards shall participate in Process planning. [M-Summary, 2.c.(1)] B. Clear and unambiguous lines of authority and responsibility for ensuring ES&H are established and maintained. [D-(b),(2)] C. Members are designated from Agreement Parties, Resource Authorities, and other appropriate Federal Officials. [M-I.2.b] D. Documentation shall describe how commitments respond to DOE program and budget execution guidance. [D-(d)]	DOE.1, BBC.2
5) Process leadership and the Convened Group are comprised mainly of managers who are responsible for safe and effective translation of the contract Statement of Work into budgeted work activities and are empowered to act for their constituents within the Process.	A. In general, members of the Convened Group shall be selected from the lowest level of management responsible for allocating resources and managing the work affected by the WSS. [M-I.2.c] B. Members of the Convened Group must be empowered to make commitments on behalf of their organizations. [M-I.2.c] C. Contractor line management shall be responsible for protection. [D-(b),(1)]	DOE.1, BBC.1, BBC.2, BBC.3
6) Working knowledge of standards & expectations *tailoring*, by means of the N&S Closure Process, is included among Process leadership and the Convened Group, or Process mentoring is provided.	A. Line management has the lead in ensuring that the Process is employed with integrity. [P-Policy] B. The DSC will provide assistance to line management in ensuring the Process is employed with integrity. [P-Policy] C. Personnel possess the competence necessary to discharge their responsibilities. [D-(b),(3)] D. As understanding is gained with the Process, it will often be necessary to repeat the various elements (iterate) to incorporate changes to the scope, expectation, team(s), or set of standards. [M-II.1.a]	DOE.1, BBC.3, HAZ.3

B. Protocols

1) Process leadership develops and communicates an initial definition of the work and hazards to which the standards will apply.	A. A clear definition of the work performance expectations, work environment, and associated hazards and uncertainties is critical to successful standards identification. [M-II.2.b] B. The Process leader(s) organize information received from the Convened Group as the initial basis for identifying the WSS. [M-II.2.c] C. Initial conditions for standards identification address: 1. Performance expectations and objectives such as goals for safety quality and operations. 2. What actions will be performed. 3. Physical conditions for doing work. 4. Materials and conditions that could cause adverse consequences. 5. Uncertainties about the work. 6. Organization and Management considerations. 7. Resource availability and constraints. [M-II.2.c] D. The SMS shall be integrated with the contractor's business processes for work planning, budgeting, authorization, execution and change control. [D-(e)]	DOE.1, BBC.1
2) The Convened Group establishes configuration controls for refinement of the definition of the work and hazards during the work of various teams.	A. The Convened Group endorses the initial definition of the work, hazards, and performance expectations compiled by the Process Leader which is then subject to refinement during the Process. [M-II.2.(c)] B. The Convened Group establishes the documentation requirements for the definition of the work, hazards, and performance expectations and objectives. [M-II.4.c.(1)]	HAZ.1

3) Process leadership and the Convened Group identify the population of Stakeholders and the DNFSB as interested parties to the WSS and define mechanisms for interaction.	A. The Convened Group record of decision shows it established appropriate channels of communication with stakeholders, provided process information and obtained views. [M-II.2.c.(2)] B. The Convened Group establishes protocols and agreements for resolution of differing opinions and for interactions between itself and the teams. [M-II.4.c.(1),(a)]	BBC.2
4) Process leadership and the Convened Group communicate expectations for “iteration”, “closure”, and the criteria for “agreement” to the participants.	A. As understanding is gained with the Process, it will often be necessary to repeat the various elements (iterate) to incorporate changes to the scope, expectation, team(s), or set of standards. [M-II.1.a] B. Documentation (i.e. participant guidance)describes how the contractor implemented the five Core Functions of ISM. [D-(c)]	DOE.2, HAZ.2
5) Process leadership and the Convened Group identify criteria for recognition of “issues” in the Process application and Process-consistent methods for their resolution.	A. The Convened Group establishes protocols and agreements for resolution of differing opinions and for interactions between itself and the teams. [M-II.4.c.(1),(a)] B. Protocols should reflect the intention that teams perform most deliberations in face-to-face group meetings. [M-II.4.b]	BBC.2, MG.1, HAZ.2,
6) Process leadership and the Convened Group provide sufficient instructions to guide the work of the Standards Identification Team(s) toward consensus agreement on an acceptable tailored description of the work, hazards and standards.	A. The Convened Group protocols require high quality and rigor of documentation to provide confidence that the WSS meet the performance expectations and objectives of the work. [M-II.4.b] B. ES&H is a priority whenever activities are planned. [D-(b),(4)] C. Administrative and engineering controls to prevent or mitigate hazards are tailored to the work. [D-(b),(6)] D. Planning emphasis should be on reducing or eliminating hazards. [D-(b),(6)] E. Planning emphasis should be on preventing accidents and unplanned releases. [D-(b),(6)] F. Contractor shall comply with and assist DOE in complying with all applicable laws and regulations. [D-(f)]	MG.2, HAZ.3

7) Process leadership and the Convened Group provide sufficient instructions to guide the work of the Confirmation Team toward a basis to recommend acceptance of the proposed WSS as providing for adequate protection.	A. The Convened Group protocols require high quality and rigor of documentation to provide confidence that the WSS meet the performance expectations and objectives of the work. [M-II.4.b] B. The Convened Group establishes protocols and agreements for resolution of differing opinions and for interactions between itself and the teams. [M-II.4.c.(1),(a)] C. Protocols should reflect the intention that teams perform most deliberations in face-to-face group meetings. [M-II.4.b]	MG.2, HAZ.3
8) The Convened Group designates WSS Approval Authority	A. One or more Department and contractor employees are formally designated to determine the adequacy of the WSS set and approve or disapprove. [M-Def.-2]	MG.2, HAZ.3
C. Work in Teams		
1) Process leadership possesses institutional familiarity with the Responsible Organization and experiential knowledge of the contract Statement of Work.	A. The Process leader is preferably a member of the contractor's organization. [M-I.2.(b)] B. Personnel possess the competence to discharge their responsibilities. [D-(b),(3)]	DOE.1, MG.2, BBC.3, HAZ.3
2) The Convened Group collectively applies sufficient managerial and technical experience that is relevant to the contract Statement of Work and the institutional expectations of the affected parties to the WSS.	A. The Convened Group must consist of organizational representatives, including the Agreement Parties, empowered to make the necessary commitments. [M-Def. 4]	DOE.1, MG.2, BBC.3, HAZ.3
3) The Standards Identification Team(s) collectively applies an adequate composite of technical and operational knowledge of work, hazards, and available standards for the activities needed to accomplish the contract Statement of Work.	A. Team members are selected to provide a breadth of knowledge on the nature of the work, its complexity, hazards and uncertainties. [M-II.3.b] B. Personnel possess the competence to discharge their responsibilities. [D-(b),(3)]	BBC.3, HAZ.3

4) A Confirmation Team collectively applies an adequate composite of technical, operational and managerial knowledge in work of the types included in the contract Statement of Work, to a degree that meets or exceeds the qualifications of the Standards Identification Team(s).	A. Team members are selected to reflect the full breadth of issues as well as knowledge of the work, its complexity, hazards and uncertainties. [M-II.3.b] B. Personnel possess the competence to discharge their responsibilities. [D-(b),(3)]	BBC.3, HAZ.3
D. Documentation of Process Implementation		
1) The agreed-upon description of the work and hazards provides clear, concise expansion of the contract Statement of Work at a level of detail suitable for correlation with the proposed WSS.	A. Protocols shall establish documentation requirements for definition of work, hazards, and performance expectations and objectives. [M-II.4.c.(1)] B. Documentation shall describe how the contractor will establish, document and implement safety commitments. [D-(d)] C. Documentation shall describe how performance objectives, performance measures, and commitments respond to DOE program and budget execution guidance. [D-(d)]	BBC.1
2) The Agreement Parties approve a charter for the application that addresses performance expectations and qualifications of Process leadership and Convened Group membership.	A. Agreement Parties jointly designate individuals and organizations to be part of Process Management and confirm their ownership and sponsorship of the Process application. [M-I.2.b] B. The degree of formality and the extent of documentation is proportional to that appropriate for establishing contract-level requirements. [M-II.4.b] C. Clear and unambiguous lines of authority and responsibility for ensuring ES&H are established and maintained. [D-(b),(2)]	BBC.1, MG.2

3) Evolution of definition of work and hazards as adequate to support standards identification is generally traceable in the work records of the Convened Group and subordinate teams.	A. The Convened Group establishes criteria for approval of the identified standards. [M-Def.4] B. The Convened Group endorses the initial definition of the work and hazards and refinements to that definition as the Process proceeds. [M-II.2.c.(2).(c)] C. Administrative and engineering controls to prevent or mitigate hazards are tailored to the work being performed and associated hazards. [D-(b),(6)]	HAZ.1, HAZ.2
4) Evidence of standards/expectations tailoring is found in the work records of the Convened Group and subordinate teams.	A. Process leadership and the Convened Group assemble information on work performance expectations and environment, associated hazards and uncertainties to provide a contract-specific start point and end point for standards identification. [M-II.2] B. The Convened Group establishes the functions, relationships and composition of teams based on work complexity, range of technical disciplines involved and potential for differences of opinion about standards sufficient to provide adequate protection. [M-II.3.c.(1)] C. Documentation shall describe how the contractor will establish, document and implement safety performance commitments. [D-(d)]	DOE.2, BBC.1, HAZ.2
5) Evidence of interactions with Stakeholders and the DNSFB is found in the work records of Process leadership and the Convened Group.	A. The Convened Group establishes channels of communications with affected groups, provides Process information and obtains views as input to the Process. [M-II.2.c.(2).(a)] B. Stakeholder input to the Process will be managed by the Convened Group. [M-II.3.b.(5)] C. The contractor shall ensure that ES&H functions and activities are a “visible” part of work planning and execution. [D-(b)]	HAZ.2

6) Information provided by the Standards Identification Team(s) establishes the justification of collective adequacy for the WSS selected to guide the agreed-upon definition of the work and hazards.	A. The Identification Team reaches team consensus of the N&S set of standards by drawing on the team's collective experience. [M-II.5.a] B. The Identification Team demonstrates with implementing assumptions and interfaces that the N&S set is feasible. [M-II.5.b.(3)] C. The Identification Team documents the N&S set, the justification for the set including implementation assumptions and interfaces. [M-II.5.b.(9)] D. The conditions and requirements for operations (authorization basis) to be initiated and conducted are agreed upon between DOE and the contractor. [D-(b),(7)] E. The extent of authorization documentation is established in the contractor's Safety Management System. [D-(b),(7)]	HAZ.1, HAZ.2

Outcome: The Work Smart Standards are aligned for use in available institutional mechanisms for the planning and performance of work (*feasible*).

Mechanism and Criteria	Attributes of Effectiveness	ISM Verification Objectives
A. Process Management		
1) Process leadership and the Convened Group enact line management responsibility for safety in DOE and the Responsible Organization.	A. Agreement Parties, who are responsible for the contents of the contract, establish the Process Leader(s) and Convened Group to represent their respective organizations. [M.I-2] B. Members of the Convened Group must be empowered to make the necessary commitments on behalf of their organizations. [M-I.2.c] C. Contractor line management is responsible for protection. [D-(b),(1)]	DOE.1, BBC.1
2) Working knowledge of Integrated Safety Management is included among Process Leadership and the Convened Group.	A. Tailoring a necessary and sufficient set of standards to the work and hazards ensured that the desired level of protection is achieved efficiently. [M-II.2.b] B. The Convened Group should be guided by Criterion 6 of the "Criteria for the Department's Standards Program" which calls for integrated safety management, beginning with work, hazards and standards identification, at the level appropriate to effective management. [M-I.2.c] C. Personnel possess the experience, knowledge, skills, and abilities (i.e. of ISM for standards identification) needed to discharge their responsibilities. [D-(b),(3)]	DOE.1, BBC.3

3) Process leadership and the Convened Group are charged with identification of safety standards applicable to the contract between the Responsible Organization and DOE.	A. The applicable contract requires (via DEAR 970.5204-78) identification of standards and the Agreement Parties adopt the Process for that purpose. [M-I.2.a] B. The Agreement Parties to the contract designate Process leadership and Convened Group membership and expected performance outcomes. [M-I.2.b] C. When an approved DOE process (i.e. N&S Closure Process) is used, the set of tailored ES&H requirements, as approved by DOE pursuant to the Process, shall be incorporated into List B as contract requirements with full force and effect. [DEAR 5204-78,(c)]	DOE.1, BBC.1
4) Process leadership and the Convened Group implement Process interfaces consistent with the key roles defined in the manual.	A. Process leadership and the Convened Group represent affected parties to implementation of the agreed-upon standards. [M.I.2.b] B. The Process Leader(s) organizes and if necessary, re-evaluates the work definition. [M.II.2.c.(1)] C. The Convened Group establishes and manages communications with Stakeholders (and the DNFSB). [M.II.2.c.(2)] D. The Convened Group interfaces with Technical and Operational Experts, and Resource Authorities to establish critical information for the work definition and resolves issues developed by the Identification Team(s). [M.II.2.c.(2)] E. The first business of the Convened Group is to identify individuals who have agreed to act as the Approval Authority for the WSS. [M.I.2.d] F. Clear and unambiguous lines of authority and responsibility for ensuring ES&H are established and maintained. [D-(b), (2)]	BBC.1, MG.2

5) Process leadership and the Convened Group define initial conditions as the basis for standards identification that are consistent with the integrating conventions for DOE Safety Management Systems.	A. Definition of the work and hazards reflects expected outcomes and treatment of work environment uncertainties, organization and management conditions, resource availability and constraints. [M-II.2.c] B. Protocols direct the Identification Team to recommend changes to the work definition or development of new standards if unable to identify an N&S set. [M-II.5.b.(8)] C. Documentation shall describe how integrity of the Safety Management System is maintained during the establishment of performance objectives, performance measures and commitments. [D-(d)]	BBC.1, HAZ.1, MG.1
B. Protocols		
1) Guidance to the Standards Identification Team for description of the work and hazards, called for by the Convened Group, requires clear, concise expansion of the contract Statement of Work at a level of detail suitable for correlation with the proposed WSS.	A. The Convened Group establishes protocols and agreements for interactions with the teams. [M.II.4.c.(1).(a)] B. The Convened Group arranges for individuals to be assigned to the team(s) consistent with the membership criteria which include knowledge of the existing set of standards and methods for their implementation. [M-II.3.c] C. The set must be feasible for implementation considering the implementation assumptions and interfaces (i.e. with existing practices) used by the Identification Team. [M-II.5.b]	BBC.1, HAZ.1 HAZ.2
2) Guidance for development of the proposed WSS includes instructions to ensure consideration of existing institutional infrastructures (manuals of practice and other systems for implementation) to assess compatibility.	A. The Standards Identification team is responsible for evaluating existing relevant sources including work-specific standards and local procedures. [M-II.5.b.(2)] B. The Standards Identification team calls upon Technical and Operational Experts with knowledge of existing work, hazards and practices. [M-II.5.b.(4)] C. Documentation of the WSS set includes expression of implementation assumptions and interfaces. [M-II.5.b.(9)]	BBC.2

3) Guidance for development of the proposed WSS includes instructions for incorporation of the performance-based contracting perspective in the planning and conduct of work.	A. The WSS set identifies DOE procurement regulation safety clauses, such as DEAR 970.5204-2, as applicable. [M-II.5.b.(7)] B. Documentation shall describe how the contractor will establish, document and implement safety performance objectives, performance measures, and commitments. [D-(d)]	DOE.1, BBC.1
4) Protocols for the Process application describe how the results are to be incorporated in contracts or other authorization agreements.	A. The Convened Group identifies the Approval Parties, communicates expectations for approval consistent with Process Element 6. [M-I.2.d] B. Approval constitutes agreement with the adequacy of the set and commitment by the Resource Authorities to provide, or seek necessary resources through the normal budget process. [M-II.7.b.(1)] C. The Responsible Organization ensures that the WSS set and associated implementation assumptions become part of the operating basis for all activities covered by the (contract level) set. [M-III.1] D. The conditions and requirements for operations to be authorized are agreed-upon between DOE and the contractor. [D-(b),(7)] E. Authorization requirements are binding under the contract. [D-(b),(7)]	DOE.1, BBC.1
C. Work in Teams		
1) The Convened Group and the Standards Identification Team(s) demonstrate knowledge of the seven Guiding Principles and five Core Functions of ISM.	A. People properly qualified by experience and training (including DOE P450.4 for ISM contract sets) identify and confirm the WSS set. M-2.c.(3)] B. Properly conducted the Process is intended to produce a WSS set appropriately tailored (as tailoring is described in DOE P450.4) to the (contract-)specific work and hazards. [M-2.b] C. The contractor shall demonstrate implementation of the five Core Functions of ISM in application of its SMS. [D-(c)]	BBC.2

2) The Standards Identification Team(s) tailors Implementation Assumptions and Interfaces for the WSS to characteristics of the actual infrastructures or identifies feasible alterations to these infrastructures.	A. Implementation assumptions are a mechanism by which uncertainties in the work process are addressed. [M-2.d] B. Resources are effectively allocated among ES&H, programmatic and operational considerations. [D-(b),(4)]	HAZ.2
3) Provisions for change management of the WSS are designed to be consistent with the attributes of the ISM plan.	A. Agreement Parties may initiate the Process if the existing WSS set is no longer appropriate due to changes (including and change criteria identified in the WSS set). [M-I.2.a.(2)] B. The iterative nature of the Process is such that changes to the work scope, expectation may warrant re-application of the Process elements (in some circumstances even after WSS set approval). [M-II.a] C. Planning and performing work in accordance with the WSS set includes an organization with defined management information and reporting systems that include change controls. [M-III] D. The SMS shall be integrated with the contractor's business processes for change control. [D-(e)] E. An annual review and update of SMS documentation shall be submitted for DOE approval. [D-(e)]	MG.1, HAZ.2
D. Documentation of Process Implementation		
1) The documentation of the WSS provides sufficient detail about implementation assumptions and interfaces to permit efficient and effective implementation by owners of the actual infrastructures for work planning and conduct.	A. Implementation assumptions are a *mechanism* by which uncertainties in the *defined work* are addressed. [M-2.d] B. Documentation shall describe how the contractor will implement the five Core Functions of ISM. [D-(c)] C. The SMS (including the WSS set) shall be integrated with the contractor's business processes for work planning, budgeting, authorization, execution. [D-(e)]	MG.1, HAZ.2

2) The documentation of the WSS provides sufficient detail about the justification of adequacy to permit effective use as the basis for future change control of the set.	A. A clear definition of the work performance expectations, work environment, and associated hazards and uncertainties is critical to successful identification of WSS. [M-II.2.b] P. The Standards Identification Team documents the justification for the set as well as implementation assumptions and interfaces. [M-II.4.b.(9)] C. The Responsible Organization ensures that the WSS set and associated implementation assumptions become part of the operating basis for all activities covered by the set. [M-III.1] D. Documentation shall describe how the contractor will establish, document and implement safety requirements. [D.(d)]	MG.1, HAZ.2
3) The documentation of the WSS addresses the extent to which the set establishes explicit performance measures and objectives for evaluating the effectiveness of the Safety Management System.	A. Planning and performing work in accordance with the WSS set includes and organization with defined performance evaluation systems. [M-III] B. Documentation shall describe how the contractor establishes, documents, and implements safety performance objectives, performance measures, and commitments. [D-(d)] C. Documentation shall describe how the contractor will measure SMS effectiveness. [D-(d)] D. Documentation shall describe how the integrity of the SMS is maintained during the establishment of performance objectives, performance measures and commitments. [D-(d)]	BBC.1, MG.1

Outcome: The Work Smart Standards are accepted as authoritative for purposes of contract performance(*adequacy and feasibility have been confirmed*).

Mechanism and Criteria	Attributes of Effectiveness	ISM Verification Objectives
A. Process Management		
1) Agreement Parties are recognized and fully represented in the selection of Approval Parties.	A. The responsibility for oversight to confirm effective performance is defined by current management systems. [M-2.a] B. It is a guiding principle of Process design that the WSS set represent a basis of agreement among all parties who must agree (that the standards provide adequate protection and are feasible). [M-2.c] C. To provide flexibility the Process permits the Convened Group (who represent the authority of the Agreement Parties) to designate the level and identity of the Approval Authority. [M-2.e] D. The contractor shall ensure that ES&H functions (including WSS approval) are a visible part of work planning and execution. [D-(b)] E. Clear and unambiguous lines of authority and responsibility for ensuring ES&H are established and maintained. [D-(b), (2)]	DOE.1, BBC.1, MG.1
2) Process leadership and the Convened Group demonstrate that inputs of Stakeholders and the DNFSB were solicited and dispositions provided.	A. The value of affording all appropriate Stakeholders (and other affected parties) an opportunity to contribute to the Process cannot be overemphasized. [M-2.f] B. The Process leader(s) and Convened Group identify Stakeholder (and other affected party) concerns. [M-II.2.c] C. Stakeholder input to the Process is managed by the Convened Group. [M-II.3.b.(5)] D. The contractor shall ensure that ES&H functions are a visible part of work planning (including standards identification) and execution. [D-(b)]	BBC.2, HAZ.2, MG.3

3) Independent, peer-level or higher, confirmation of the WSS set is required.	A. Complexity or controversy surrounding the work warrant independent confirmation. [M-2.e] B. Authorization requirements are tailored to the complexity of the work. [D-(b),(7)] C. Authorization requirements are tailored to the hazards of the work. [D-(b), (7)]	BBC.3, HAZ.2
B. Protocols		
1) Guidance to teams establishes target audiences for the results of Process application.	A. One benefit of the Process is the enhanced communication among DOE, contractors, and stakeholders that fosters better understanding of the work and hazards, and acceptance of the WSS. [M-2] B. The members of the Convened Group shall be selected from the lowest level of management responsible for allocating resources and managing the work affected by the WSS set. [M-I.2.c] C. An implicit assumption for all WSS sets is that a management system (with clear roles and responsibilities) exists to apply the standards. [M-III] D. The SMS (including applicable contract ES&H standards and requirements) shall be integrated with the contractor's business processes for work planning, budgeting, authorization, execution and change control. [D-(e)]	MG.2, BBC.1
2) Process management establishes guidelines for interactions with Stakeholders and the DNFSB.	A. Stakeholders, as defined in the Manual, provide individual views, consistent with the Federal Advisory Committee Act. [M-2.f] B. The contractor shall ensure that ES&H functions are a visible part of work planning. [D-(b)]	BBC.2, HAZ.2

3) Guidance provides for formal disposition of Confirmation Team, Stakeholder and DNFSB comments on the WSS.	A. For complex situations (such as setting contract-level standards) it will be necessary to use relatively rigorous methods for confirmation (of acceptance as well as adequacy and feasibility) of the WSS set. [M-II.3.b.(2)] B. The Convened Group shall establish the functions and relationships (e.g. issue management rigor and formality) of the teams based upon the extent to which relevant communities are known to hold differing opinions on the issues under review. [M-II.3.c.(a)] C. Documentation shall describe how integrity of the SMS is maintained during the establishment of performance objectives, performance measures, and commitments. [D-(d)]	BBC.2
C. Work in Teams		
1) The Convened Group resolves all issues raised during the Process as a group or by reference to the Agreement Parties.	A. An implicit assumption for all WSS sets is that a management system (with clear roles and responsibilities) exists to apply the standards. [M-III] B. The Convened Group members are empowered to represent the Agreement Parties and designated-affected DOE organizations. [M-I.2.c] C. The Convened Group controls refinement of the work definition (including hazards description and identified standards) during application of the Process. [M-II.2.(c)] D. The contractor shall comply with and assist Doe in complying with all applicable laws and regulations. [D-(f)] E. The conditions and requirements for operations (including the WSS set) to be initiated and conducted are agreed-upon between DOE and the contractor (i.e. Agreement Parties and their representatives). [D-(b),(7)]	BBC.1, MG.2

2) The Standards Identification Team formally achieves group closure and endorses its work product.	A. The Standards Identification Team must establish that implementation of the set is feasible and that the set provides a basis for adequate protection. [M-II.3.b.(1)] B. The Standards Identification Team reach consensus on and justify (including documentation of each) the WSS set. [M-II.5.(b).(5) C. The contractor shall ensure that ES&H functions and activities (including Process application) are a visible part of work planning and execution. [D-(b)] D. Clear and unambiguous lines of authority and responsibility for ensuring ES&H are established and maintained. [D-(b)]	HAZ.2
3) The Confirmation Team formally achieves group closure and reports is acceptance of the proposed WSS set.	A. Confirmation of the adequacy and feasibility of the WSS set strengthens the credibility of the Process and confidence in the set of standards. [M-II.3.b.(2)] B. The Confirmation Team determines adequacy and feasibility and documents the confirmation activities and results (including reaching agreement as directed in Convened Group instructions.) [M-II.6.b]	DOE.2, HAZ.2
D. Documentation of Process Implementation		
1) Records of Process implementation are made available to interested or affected parties, including workers, Stakeholders and the DNFSB.	A. Because acceptance of the WSS set is one of the underlying goals of the Process, the appropriate Stakeholders (and other affected parties) should always be informed and invited to contribute. [M-I.2.b] B. Planning and performance in accordance with the WSS set is carried out by an organization with defined performance evaluations management information systems (that support Stakeholders and other affected non-DOE parties). [M-III] C. Documentation shall describe how the contractor will measure (and demonstrate to others) SMS effectiveness. [D-(d)]	MG.1, HAZ.2

Integrated Safety Management System Phase I Verification Objectives

Business, Budget, and Contracts (Program Management) (BBC)

BBC.1 DOE and contractor procedures ensure that missions are translated into work, expectations are set, tasks are identified and prioritized, and resources allocated.

BBC.2 DOE and contractor budgeting and resource assignment procedures include a process to ensure the application of balanced priorities. Resources are allocated to address safety, programmatic, and operational considerations. Protecting the public, workers, and the environment is a priority whenever activities are planned and performed.

BBC.3 The contractor procedures and practices ensure that personnel who define the scope of work and allocate resources have competence that is commensurate with the assigned responsibilities.

Department of Energy (DOE)

DOE.1 DOE has established processes that interface efficiently and effectively with the contractor's organization to ensure that work is performed safely.

DOE.2 DOE has established processes that interface efficiently and effectively with the contractor's organization to provide feedback and continuous improvement. Feedback information on the adequacy of controls is gathered, opportunities for improving the definition and planning of work are identified and implemented, line and independent oversight is conducted, and, if necessary, regulatory enforcement actions occur.

Hazards Identification and Standard Selection (HAZ)

HAZ.1 Hazards associated with the work are identified, analyzed, and categorized.

HAZ.2 Applicable standards and requirements are identified and agreed-upon.

HAZ.3 Contractor procedures ensure that contractor personnel responsible for analyzing the hazards and developing, reviewing, or implementing the controls, have competence that is commensurate with their responsibilities. DOE roles and responsibilities are clearly defined to ensure appropriate oversight and review of the analysis of hazards and the identification of controls. Personnel shall possess the experience, knowledge, skills and abilities that are necessary to discharge their responsibilities.

Management (MG)

MG.1 The ISMS Description is consistent and responsive to DOE Policies 450.4, 450.5, and 450.6; the DEAR; and the direction to the contractor from the Approval Authority. The contractor policies and procedures ensure that the ISMS Description is maintained, implemented, and that implementation mechanisms result in integrated safety management.

MG.2 Contractor roles and responsibilities are clearly defined to ensure satisfactory safety, accountability and authority. Line management is responsible for safety. Competence is commensurate with responsibilities.

MG.3 Feedback information on the effectiveness of the ISMS is gathered, opportunities for improvement are identified and implemented, line and independent oversight is conducted, and if necessary, regulatory enforcement actions occur.

MG.4 Contractor procedures provide a method to ensure that controls are implemented during preparation for the initiation of work at each leve3l. The procedures ensure that adequate controls are identified to mitigate the identified hazards and the controls are effectively implemented. Contractor procedures provide assurance that controls will remain in effect so long as the hazards are present.

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APPENDIX H

REQUEST FOR APPROVAL OF THE WSS SET AND THE FINAL APPROVAL DOCUMENT USED DURING THE N&S PROCESS CONDUCTED AT THE FERMI LABORATORY

Fermilab

Director's Office

July 13, 1995

To: Convened Group Members

From: Larry Coulson, Process Leader

Subject: Confirmation and Approval of the N&S Set

This memo documents the confirmation of the ES&H N&S SET contained in the Fermilab Pilot Necessary and Sufficient Identification Team Document, signed and submitted to the Convened Group on July 12, 1995 (Attachment 1), which was challenged at our meeting on July 12, 1995. In accordance with The Department of Energy Closure Process for Necessary and Sufficient Sets of Standards (February 24, 1995), the Convened Group verified:

- The information available to and used by the Identification Team was found satisfactory.
- The Convened Group and the Peer Review Panel confirmed that the set of standards is necessary and sufficient to satisfy the performance expectations and objectives of the work.
- Implementation of the set of standards should be feasible.

Three issue sheets were collected during the confirmation process. All three have been resolved to the satisfaction of those who raised the issue. I am maintaining documentation of the issues and their satisfactory resolution. They have resulted in some minor modification to the SET. A revised, and final SET is attached (Attachment 2).

The two issues discussed in the Team report have also been resolved as follows:

1. Property protection: The contract will continue to use DOE Order 5480.7 for property protection purposes only. The Convened Group will apply the N&S process at a later date to the property protection issue.

2. Management Systems: The Convened Group decided that it would apply the criteria from the Department Standards Program to specify management requirements to implement the N&S set. The DOE/URA contract modification will require that FNAL continue to maintain management systems that ensure that the agreed-upon standards are implemented.

The Identification Team followed all applicable protocols and documentation requirements, therefore, I request that you indicate approval to proceed with this process by recommending to the Agreement Parties that they approve the N&S SET as attached to this memo.

Ray Stefanski — Date 7/13/95

Dave Goodwin — Date 7/13/95

Andy Mravca — Date 7/14/95

Attachment 1: Fermilab Pilot Necessary and Sufficient Identification Team Document

Attachment 2: Fermilab N/S Set of ES&H Standards

Fermilab

Fermi National Accelerator Laboratory
P.O. Box 500 • Batavia, IL • 60510-0500
708-840-3211 Fax: 708-840-2939

Director's Office

July 14, 1995

Dr. Fred Bernthal, President, URA
1111 19th Street, NW, Suite, 430
Washington, D.C. 20036

Dr. John R. O'Fallon, Director
High Energy Physics Division, U.S. DOE
19901 Germantown Road
Germantown, MD 20874

Mr. Andrew E. Mravca, Manager
Batavia Area Office, U.S. DOE
P.O. Box 2000
Batavia, IL 60510

Dear Dr. Bernthal, Dr. O'Fallon, and Mr. Mravca:

Subject: Fermilab Pilot on the Closure Process--Necessary and Sufficient ES&H Standards Set Approval

Attached is documentation of the successful conclusion of the Fermilab Pilot for the Department of Energy Closure Process for Necessary and Sufficient Sets of Standards. The pilot has successfully produced a confirmed set of ES&H standards which fully meets the requirements of the process. Therefore, we recommend that you indicate approval of the attached set by signing below.

Responsible Organization - Fred Bernthal 7/14/95
Fred Bernthal, President — Date
Universities Research Association

Resource Authority - John R. O'Fallon 7/14/95
John R. O'Fallon, Director — Date
High Energy Physics Division
Office of Energy Research

Customer Organization - Andrew E. Mravca 7/14/95
Andrew Mravca, Manager — Date
DOE Batavia Area Office

Yours truly,

Larry Coulson

Larry Coulson, Process Leader for the
Convened Group: Larry Coulson
Ray Stefanski
Dave Goodwin
Andy Mravca

APPENDIX I

THE PROCEDURE FOR MANAGING CHANGE CONTROL OF LABORATORY OPERATING STANDARDS AND REQUIREMENTS (INCLUDING THE WSS SET) AT THE LOS ALAMOS NATIONAL LABORATORY

1.0 Introduction

1.1 Overview

This document formally establishes the requirement for the Laboratory process that shall be implemented for managing change control of institutional operations standards and requirements. The current processes that have been independently implemented to develop the Laboratory's work smart standards (WSS), Laboratory performance requirements (LPRs), Laboratory implementation requirements (LIRs), Laboratory implementation requirements guidance (LIGs), alerts, notices, and urgent memorandums must be integrated to ensure effective change control for these interrelated processes. Specifically, the process must be interactive for developing, revising, documenting, communicating, and managing the Laboratory's WSS, LPRs, LIRs, LIGs, alerts, notices, urgent memorandums, and proposed changes to the contract.

This document shall complement the expectations contained in LA-UR-98-3287, "Los Alamos National Laboratory Integrated Safety Management," and LPR 300-00-00, "Integrated Safety Management."

Note: The requirements for issuing and managing Laboratory implementation requirements, guidance, alerts, notices, and urgent memorandums are specified in LIR 301-00-01, "Issuing and Managing Laboratory Operations Implementation Requirements and Guidance."

The requirements of this LIR shall be effective upon the issue date.

See Attachment G (Guidance) for Recommended Major Implementation Criteria for Self-Assessment.

1.2 In this Document

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3.0	Scope/Applicability	2
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2.0 Purpose

This LIR defines the requirements that shall be implemented for managing change control of the institutional WSS process and the supporting LPRs, LIRs/LIGs, alerts, notices, urgent memorandums, and proposed WSS changes to the contract to ensure that each is current, formally approved, effectively managed, consistent, and that each complements the Laboratory's Integrated Safety Management System (see Attachment A).

3.0 Scope/Applicability

The requirements contained in this LIR shall apply to all Laboratory organizations and employees that issue or recommend changes to institutional operations standards, requirements, or guidance (see definition in Sec. 4.0). It shall not apply to the developing or issuing of facility-, organization-, or activity-specific documents, or to other types of institutional documentation.

4.0 Definitions

alert—a rapid Labwide notification on an urgent or life-threatening subject.

CFM (contract functional manager)— the individual that manages Appendices G and F of the UC/DOE contract for a given functional area. The CFM also represents the Laboratory as the principal point of contact with the UC and other Laboratories for DOE directives and for other contract compliance or performance-based management issues. A CFM has been appointed for each of the following areas:

(1) the institution

(2) Laboratory management

(3) environmental restoration/waste management

(4) environment, safety, and health

(5) facilities management

(6) financial management

(7) human resources

(8) information management

(9) procurement

(10) property management

(11) safeguards and security

change—to add, revise, or delete institutional operations standards and requirements.

Convened Group—a steering committee for conducting the Necessary and Sufficient Closure Process (Laboratory work smart standards process); it represents the agreement parties (i.e., DOE/AL, DOE/LAAO, UC, and LANL), and establishes the criteria for approving WSS recommended by the ID and focus teams.

DOE—Department of Energy

ESH—Environment, Safety, and Health Division

ES&H—used in this LIR to refer to all activities that are included in the term "safety," i.e., environment, safety, health, waste minimization, and pollution prevention.

ID team/leaders—individuals with knowledge relevant to the work, the site and the hazards addressed by the necessary and sufficient WSS and who establish, when relevant, focus teams.

institutional operations standards and requirements — Laboratory expectations and requirements for environment, safety, and health; pollution prevention; packaging and transportation; and facility operations and maintenance. Also included are expectations and requirements that affect or complement the implementation of these requirements.

ISM—integrated safety management

ISM CCB— Integrated Safety Management Change Control Board

ISM PM—Integrated Safety Management Program Manager

LAAO—Los Alamos Area Office

LANL—Los Alamos National Laboratory

LIG (Laboratory implementation guidance)—provides discretionary guidance and/or good business approaches relating to ES&H practices.

LIR (Laboratory implementation requirements)— provides detailed mandatory implementing requirements for the safe performance of work.

LPR (Laboratory performance requirement)— establish institutional performance expectations that directly reference the Appendix G standards as mandatory Laboratory standards; provide the general requirements and expectations that are augmented by performance criteria which, when implemented, ensure that contractual performance requirements are met.

LSRP/ESH-OIO (Laboratory Standards and Requirements Project)—a project team chartered to lead and manage the Laboratory's processes for issuing operations requirements and guidance (LPRs, LIRs, and LIGs) and for developing work-smart standards and proposed WSS contract changes, when relevant.

notice—a notification of an important situation or change in requirements or practices.

OIC (office of institutional coordination)— normally the group or office leader responsible for establishing, coordinating, and supporting the implementation of a requirement and any guidance related to the requirement.

POC (point of contact)— an individual appointed by a division, program, or office director to act on the director's behalf in (1) coordinating communication on institutional requirements between the organization, OICs, and LSRP/ESH-OIO Office, and (2) managing the status of implementation of institutional requirements and guidance that are applicable to the work and hazards associated with the work performed in the organization.

quick change—the process used to issue a change to a document *only* when the change is the result of a typographical, grammatical clarification or a simple, no-impact correction.

SFM (safety function manager)—the individual appointed by the Director to be responsible for coordinating and monitoring the implementation of safety expectations relating to one of the following safety functions (see LIR 307-01-01, "Safety Self-assessment).

(1) emergency management

(2) environmental protection

(3) facility management (including nuclear safety)

(4) fire protection

(5) management system (e.g. training, quality assurance, occurrence reporting, performance assurance)

(6) occupational safety and health

(7) packaging and transportation

(8) radiation protection (including criticality safety)

TLC (team liaison coordinator)—members of the LSRP/ESH-OIO responsible for ensuring adherence to the fidelity and the authorized use of the necessary and sufficient process for standards-based management and the requirements of this LIR (see Sec.5.3).

UC—University of California

WSS (work smart standards)—work performance standards (expectations) that are based upon worker and subject matter expert knowledge of the work performed and the hazards associated with that work.

5.0 Implementation Requirements

5.1 Division, Program, and Office Directors

As in the ISM safety-responsible line-management chain, managers for the Laboratory, division directors, program directors, and office directors shall, when requested, provide co-ID team leaders and experienced workers or subject matter experts to serve on focus teams.

5.2 ESH Division Director

The ESH Division Director shall

- manage the institutional operational requirements processes, including contractual WSS and operations implementation requirements and guidance.
- ensure the necessary and sufficient process for performance- and standards-based ES&H management and the closure process for necessary and sufficient sets of standards are applied when relevant.
- review all proposed revisions to LPRs other than quick changes.

5.3 Requirements for Change Control

Requirements for change control derive from two sources: those external to the Laboratory and those internal to the Laboratory.

External Changes.

- Proposed changes in requirements from external sources to the Laboratory shall be reviewed initially by the DOE/LAAO for the applicability and necessity to determine the need for the change(s) to the Laboratory's Appendix G of the UC/DOE contract.
- If a proposed change in the requirement *is not* applicable to or necessary for the work being performed by the Laboratory, DOE/LAAO shall be responsible for the final disposition of the change request.
- If a proposed change in the requirement is applicable and necessary for the Laboratory to take action and is not an operations WSS requirement, DOE/LAAO shall notify LANL/QP, in writing, of the intent to revise the Applicable Directives List (list) referred to in Appendix G of the UC/DOE contract. LANL/QP shall ensure the provisions of clause 5.5 (c)-(e) of the UC/DOE contract are satisfied.
- If a proposed change in the requirement is applicable and necessary for the Laboratory to take action and is an operations WWS requirement, the DOE/LAAO shall forward the change request (which shall be documented on the "Institutional Operations Standards and Requirements Change Request Form-External," Attachment B) through the responsible contract functional manager (CFM) to the Laboratory's LSRP/ESH-OIO. LSRP/ESH-OIO shall ensure adherence to the WSS necessary and sufficient process contained in

clause 5.5(f) of the UC/DOE contract.

Internal Changes.

Proposed changes in requirements from sources internal to the Laboratory

(1) shall be submitted to the LSRP/ESH-OIO using the "Institutional Operations Standards and Requirements Change Request Form-Internal," see Attachment C; then

(2) shall be screened for action in accordance with the process contained in Sec. 5.4.

5.4 LSRP/ESH-OIO

The LSRP/ESH-OIO shall

- manage the operations standards and requirements change control process for the Laboratory.
- review all external and internal change requests and determine the required process(es) (i.e., WSS, LPR, or LIR/LIG) to be followed.
- assign a team liaison coordinator (TLC) to facilitate the required actions.
- maintain work packages and records of actions taken or completed.
- forward proposed changes or requests that warrant a potential change to the contractual WSS or LPRs to the affected SFM(s) for disposition.
- forward proposed change requests for requirements that are addressed in the WSS and LPRs, but warrant a change to a LIR or require an alert or notice to be issued to the affected OIC.
- ensure this LIR is reviewed every 3 years.
- assess the process required by this LIR for continuous quality improvement in managing change control of Laboratory operational standards and requirements. The LSRP/ESH-OIO managers shall be involved in this assessment. The results of this assessment shall be documented, and follow-up actions shall be taken.

  Note: OICs making changes to a LIR, LIG, alert, or notice shall follow the requirements in LIR 301-00-01, "Issuing and Managing Laboratory Operations Implementation Requirements and Guidance."
- approve quick changes to LPRs.
- when acting as the agent for the ISM PM, process and control all change requests that are to be considered by the ISM CCB (see Attachment F).

5.5 TLCs

TLCs shall

- be the LSRP/ESH-OIO process managers assigned to facilitate change request work packages;
- ensure the necessary and sufficient process for performance- and standards-based management and the closure process for necessary and sufficient sets of standards are applied when relevant;
- maintain documentation for the change request work packages;
- assist the SFM or appointed ID team leaders in ensuring the ID and focus teams contain workers from affected Laboratory organizations and the DOE;
- provide logistical, administrative, and scheduling support to the ID team leaders and focus teams; and
- maintain documentation and process traceability for the ID and focus teams.

5.6 SFMs

SFMs shall

- manage the development of the proposed course of action for contract changes (WSS process) or changes to LPRs, LIRs, LIGs, alerts, and notices.
- take no action if the requirement is either not necessary or is already sufficiently addressed.
- be the ID team leader or co-leader with a POC (or designee) or appoint another individual and a POC (or designee) to be the ID team leader(s) for the WSS process.
- when serving as an ID team leader or co-leader,
  - secure DOE participation in the WSS process;
  - form at least one focus team that comprises at least two workers from the Laboratory who have first-hand knowledge of the work and hazards, a Laboratory subject matter expert, and a DOE AL/LAAO technical representative if the change request requires a modification to the contractual WSS);
  - provide direction, facilitate issues resolution, and ensure integration of actions if more than one focus team is required;
  - ensure all ID team and focus team activities are documented; and
  - present proposed changes to the contractual WSS to the ISM CCB or appoint a designee to make the presentation (the change request form, Attachment E, shall be used to document all proposed changes to the ISM CCB).

5.7 Focus Teams

The SFM ID team leader shall task the focus team(s) to

- make recommendations to the SFM or designated ID team leaders on the course of action to take for a change request and develop the documentation and the traceability of any change(s);
- develop LPRs using the format in Attachment D (the Laboratory Performance Requirement Signature Sheet. Attachment F shall be used to submit any revisions to LPRs);
- develop an impact analysis for instituting the proposed change; and
- present the proposed change to the contractual WSS to the ISM CCB when requested by the ID team leaders.

5.8 POCs

POCs shall serve as ID team co-leaders when appointed by a SFM and shall perform the ID team and co-leaders' duties contained in Sec. 5.6.

5.9 CFMs

CFMs shall be

- the primary interface with DOE/LAAO on proposed changes that have potential impact on the WSS contained in Appendix G of the UC/DOE contract.
- responsible for coordinating issues or changes with the Tri-Laboratory Committee.

5.10 ISM PM

ISM PM shall

- concur/nonconcur on changes to contractual WSS;
- sponsor all contractual WSS change requests that are submitted to the ISM CCB; and
- approve all proposed revisions to LPRs *except* (1) quick changes and (2) changes to LPRs that require a change to the contractual WSS through the ISM CCB process.

5.11 ISM Change Control Board

Serving as the WSS convened group, the ISM CCB shall act upon proposed changes to contractual WSS in accordance with the process outlined in Appendix E of LA-UR-98-2387, "Integrated Safety Management."

5.12 Deputy Laboratory Director for Operations

The Deputy Laboratory Director for Operations shall approve changes to LPRs that also require a change to the contractual WSS under the following two conditions.

If...	Then...
the change to the LPR will be included or is currently in the WSS set in Appendix G of the UC/DOE contract.	approval of the LPR must be obtained from the DLD-OPs *before* consideration by the ISM CCB and approval authorities.
the change to the LPR is contingent upon a proposed change to the WSS set in Appendix G of the UC/DOE contract.	approval of the LPR must be obtained from the DLD-OPs *after* the ISM CCB and approval authorities have approved the change to the Appendix G, WSS set.

5.13 DOE/LAAO

DOE/LAAO shall

- initiate actions to modify Appendix G of the UC/DOE contract when the approval authorities have approved the changes to the contractual WSS; and
- forward all approved changes to the contractual WSS to the UC contracting officers for incorporation into Appendix G of the UC/DOE contract and notify LANL/QP, the Laboratory ESH or Facility Management CFM, and policy@lanl.gov of the impending changes to the WSS in Appendix G of the UC/DOE contract.

6.0 Documentation/Records

To formalize the managing of the change control process for the Institution's Operations Standards and Requirements, the following documents shall be retained.

- By the LSRP/ESH-OIO:
  - A copy of the "Institutional Operations Standards and Requirements Change Requests Forms" (external, Form 1778, and internal, Form 1779).
  - A copy of the disposition actions, including
    - a copy of the work package that documents the actions taken/completed on each change request.

6.0 Documentation/Records (cont)

- a copy of record of the completed documentation prepared by the ID team(s)/focus teams,
- a copy of the "ISM Change Control Form" (Form 1789) submitted to the ISM Change Control Board requesting changes to the WSS in Appendix G of the UC/DOE contract,
- a copy of record of changes made to the contractual WSS, LPRs, LIRs, LIGs, alerts, notices, or urgent memorandums, and
- a copy of the ISM change request forms.

- By the ID/team leader(s): a copy of the documentation generated by the ID team and any focus team(s) that supports a change to institutional operations and requirements

7.0 References

7.1 Document Ownership

The OIC for this document is the LSRP/ESH-OIO (**policy@lanl.gov**).

7.2 Documents

UC/DOE Contract No. W-7405-ENG-36, "Appendix G, Work Smart Standards Set for LANL."

DOE P 450.3, "Authorizing use of the Necessary and Sufficient Process for Standards-Based Environment, Safety, and Health Management."

DOE M 450.3-1, "The DOE Closure Process for Necessary and Sufficient Sets of Standards."

LAUR-98-3287, "Los Alamos National Laboratory Integrated Safety Management."

LIG 302-100-03, "Guide for Developing Laboratory Operations Implementation Requirements and Guidance Documents."

LIR 301-00-01, "Issuing and Management Laboratory Operations Implementation Requirements and Guidance."

LIR 301-00-02, "Exceptions or Variances to Laboratory Operations Requirements."

LIR 307-01-01.0, "Safety Self-Assessment."

LPR 300-00-00 ,"Integrated Safety Management."

8.0 Attachments

Attachment A: "Managing Change Control of the Institutional Operations Standards and Requirements Process"

Attachment B: "Institutional Operations Standards and Requirements Change Request Form—External"

Attachment C: "Institutional Operations Standards and Requirements Change Request Form—Internal"

Attachment D: Laboratory Performance Requirement (LPR) (Format)

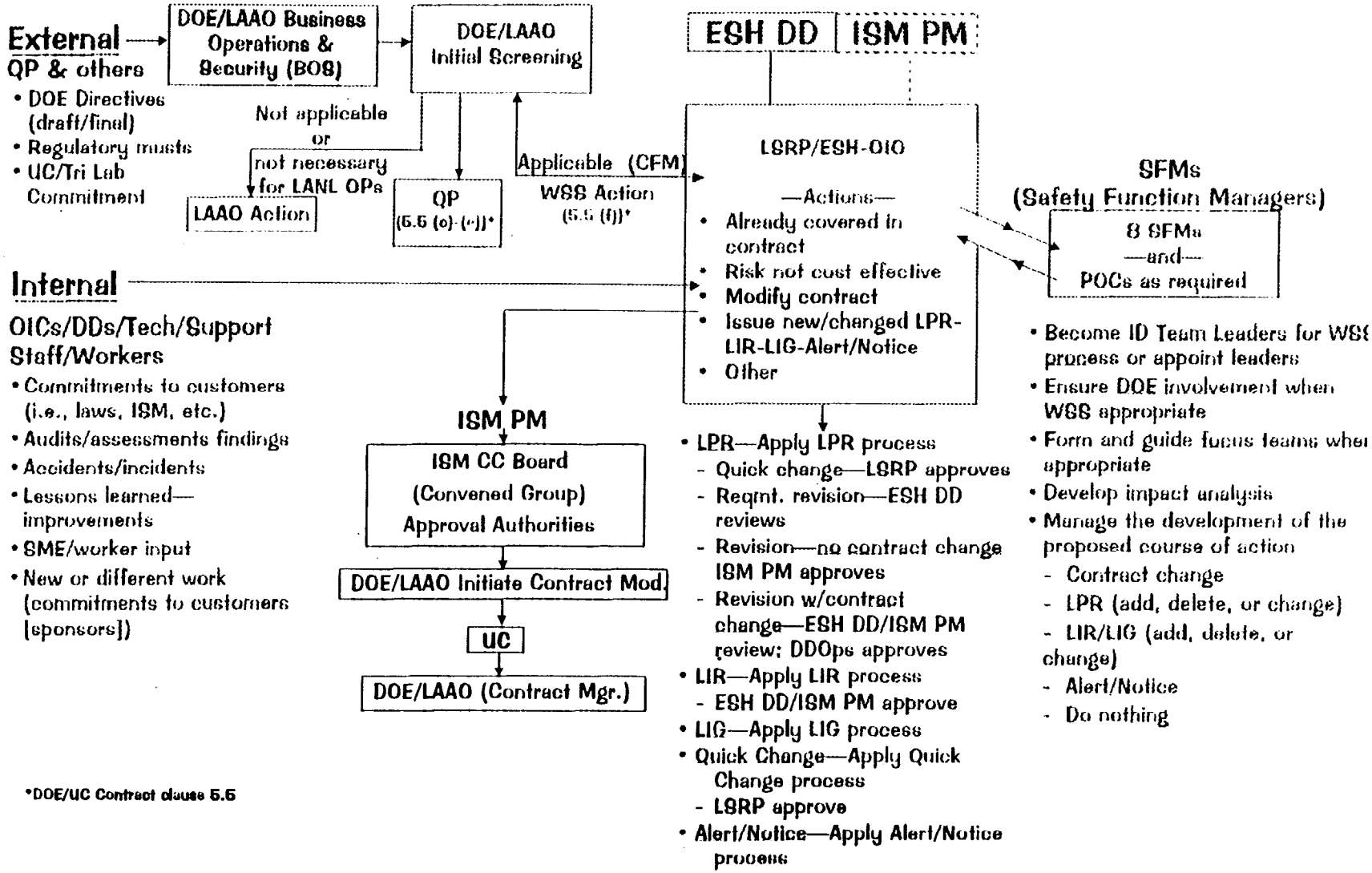
Attachment E: Laboratory Performance Requirement Signature Sheet

Attachment F: Integrated Safety Management Change Request Form

Attachment G: Recommended Major Implementation Criteria for Self-Assessment.

Attachment A

Managing Change Control of Laboratory Operations Standards and Requirements Process



*DOE/UC Contract clause 5.5

Attachment B
Institutional Operations Standards and Requirements
Change Request Form—External

1. Date: _____

2. DOE/LAAO Rep: _____ CFM(s): _____

3. Description of change(s) being requested (include driver(s) and document(s) number(s). (Use continuation sheets, if necessary.):

4. Are the requirements applicable to the Laboratory? ❒ Yes ❒ No

5. DOE/LAAO and WSS Screening recommendations (include possible impacts, i.e., Appendix G, Appendix F, etc.) (Use continuation sheets, if necessary.):

6. Forward to LSRP/ESH-OIO.

For LSRP/ESH-OIO Use Only

Date Received: _____ Work package No.: _____

TLC assigned, if required: _____

SFM: _____ OIC: _____

Summary of actions taken (use continuation sheet(s), if necessary):

Action closeout: _____

Form 1778 (1/99) (LIR 301-00-00.0) (OIC, LSPT)

Attachment C
Institutional Operations Standards and Requirements
Change Request Form—Internal

1. Originator of Change Request: _____ Group: _____ Ph: _____

2. Description of change(s) being requested (include driver/ document(s) number(s), etc.)

   (Use continuation sheet(s), if necessary.):

3. Forward to LSRP/ESH-OIO MS C303

For LSRP/ESH-OIO Use Only

Date Received: _____ Work package No.: _____

TLC assigned, if required: _____

SFM: _____ OIC: _____

Summary of actions taken (use continuation sheet(s), if necessary):

Action closeout: _____

Form 1779 (1/99) (LIR 301-00-00.0) (OIC, LSPT)

Attachment D

Laboratory Performance Requirement (LPR)

(Format)

Standard Statement: (The standard statement is an expressed expectation for the performance of work that, when satisfied, will meet the requirements identified in the contractual work smart standards.)

Characteristics of the "Standard Statement:"

- A concise statement—1 or 2 sentences
- Simple, precise, and in LANL lay persons' terms
- Performance-based, expressed as desired results or outcomes
- Expresses the absolute (no "try to" statements)
- Targeted to LANL workers at all levels

Performance Criteria: [Statement(s) of fact, requirement, or practice that, when satisfied, will contribute toward accomplishing this standard.]

Characteristics of "Performance Criteria":

- Mandatory
- Help to understand the standard
- Expressed to avoid undesirable outcomes from "gaming the system"
- Achievable (realistic/practical)
- Simple
- Measurable

Contractual Work Smart Standards: (Documents the work smart standards in Appendix G of the UC/DOE contract that were the basis for developing this LPR.)

Attachment E

Los Alamos
NATIONAL LABORATORY

Laboratory Performance Requirement Signature Sheet

Provide properly edited revised document in paper copy and electronic form.

Document No.	Document Title	Issue Date

○ new ○ revised document contents

Section 1: Synopsis (use continuation sheets, if necessary).

Section 2: Recap of value added by issuing document (use continuation sheets, if necessary).

Focus Team Leader Name (optional)	Signature	Date	Organization

Review and Approvals

ID Team Leader Name (Print)	Signature	Date

Reviewed by ESH Division Director

Name (Print)	Signature	Date

Reviewed/approved by ISM or DLD-OPS

Name (Print)	Signature	Date

Reviewed and forwarded by:

Laboratory Standards and Requirements Project Leader (Print)	Signature	Date

Form 1788 (LIR 301-00-00) (1/99) (LSRP/ESH-OIO, OIC)

Attachment F

Los Alamos
NATIONAL LABORATORY
Integrated Safety Management

Change Request Form

IP Activity ID#	Activity Description

Description of Change Requested:

Justification for Change Request:

Submitted: _____ _____
LANL Change Control Coordinator Date

Recommendation: _____ _____
Approve/Disapprove CCB Chairman Date
(circle one)

Approved: _____ _____
Manager, LAAO Date

Form 1789 (LIR 301-00-00) (1/99) (LSRP/ESH-OIO, OIC)

Guidance

Attachment G

Recommended Major Implementation Criteria for Self-Assessment

(Non-Mandatory)

LIR Title	LIR Number
Operations Standards and Requirements	LIR 301-00-00.0

The major implementation criteria listed below are provided to assist Laboratory organizations assess their implementation of this LIR. These criteria provide an objective basis for self-assessing implementation of the major requirements contained in the LIR. The LIR also states requirements in other areas, such as, scope, and implementation requirements that, when applied, complement the successful implementation of these major requirements.

1. **The most important criterion for assessing the implementation status of this LIR should be, if applicable: Have the requirements contained in the LIR been communicated to the individual(s) responsible for performing the work?**
2. **In addition, the recommended major implementation criteria for self-assessment of this LIR are the following:**
   - Laboratory division directors, program directors, and office directors shall, when requested, provide co-ID team leaders and experienced workers or subject matter experts to serve on focus teams.
   - External changes: If a proposed change in requirement(s) is applicable and necessary for the Laboratory to take action and is an operations WWS requirement, the DOE/LAAO shall forward the change request (which will be documented on the "Institutional Operations Standards and Requirements Change Request Form-External," Attachment B) through the responsible CFM to the LSRP/ESH-OIO.
   - Internal changes shall be submitted to the LSRP/ESH-OIO using the "Institutional Operations Standards and Requirements Change Request Form-Internal," Attachment C.
   - The LSRP/ESH-OIO shall manage the operations standards and requirements change control process for the Laboratory.
   - SFMs shall manage the development of the proposed course of action(s) for contract changes (WSS process) or changes to LPRs, LIRs, LIGs, alerts, and notices.
   - POCs shall serve as an ID team co-leader when appointed by a SFM and shall perform the duties in Sec. 5.6, for ID team and co-leaders.
   - ISM PM shall concur/nonconcur on major changes to contractual WSS and shall approve all proposed revisions to LPRs *except* (1) quick changes and (2) changes to LPRs that require a change to the contractual WSS.
   - Serving as the WSS convened group, the ISM CCB shall act upon proposed changes to contractual WSS in accordance with the process outlined in Appendix E of LA-UR-98-2387, "Integrated Safety Management."
   - The Deputy Laboratory Director for Operations shall approve changes to LPRs that also require a change to the contractual WSS.
   - DOE/LAAO shall initiate actions to modify Appendix G of the UC/DOE contract when the approval authorities have approved the changes to the contractual WSS.