



Department of Energy

Washington, DC 20585

January 29, 1996

The Honorable John T. Conway
Chairman
Defense Nuclear Facilities Safety Board
625 Indiana Avenue, NW
Suite 700
Washington, DC 20004

Dear Mr. Chairman:

This letter transmits the following documents which describe and govern the necessary and sufficient process:

- Policy: Authorizes use - subject to the requirements and guidance of the attached DOE Notice and adherence to the attached DOE Manual. (Approved by the Secretary on January 25, 1996)
- Manual: Describes the Necessary and Sufficient Closure Process and details the steps which must be followed to produce a necessary and sufficient set of standards.
- Notice: Provides requirements and guidance for near-term use of the process including management requirements and criteria which should be applied to decide where and how to use the process.

We will work with Dr. Kouts and Mr. DiNunno in the very near future to make arrangements for a meeting.

Sincerely,

A handwritten signature in cursive script, appearing to read "Tara O'Toole".

Tara O'Toole, M.D., M.P.H.
Assistant Secretary
Environment, Safety and Health

cc: The Honorable Herbert Kouts
The Honorable Joseph DiNunno



DRAFT 4 - As Amended by the DSC
December 1, 1995

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

DOE P 450.3

Subject: Authorizing Use of the Necessary and Sufficient Process
for Standards-Based Environment, Safety and Health
Management

PURPOSE

This policy statement establishes the Closure Process for Necessary and Sufficient Sets of Standards (Necessary and Sufficient Process) described in DOE M 450.3 as one means of addressing the selection of Environment, Safety and Health (ES&H) standards.

SCOPE

The Necessary and Sufficient Process has been developed by the Department Standards Committee (DSC) as part of the ES&H standards program defined in the "Criteria for the Department's Standards Program" (DOE/EH/-0416). Carrying out the Necessary and Sufficient Process with fidelity and effectively implementing the results will lead to adequate protection of the workers, the public and the environment and will increase stakeholder trust and confidence.

POLICY

Effective immediately, all Department Elements are authorized to use the "Closure Process for Necessary and Sufficient Sets of Standards" except for defense nuclear facilities. The Department will consult with the Defense Nuclear Facility Safety Board on the Closure Process for Necessary and Sufficient Sets of Standards. In the interim, all Department Elements are authorized to use this process to begin planning next steps at defense nuclear facilities. Finalization of this planning may occur after the Department has had the opportunity to take into account the views and comments of the board.

DOE N 450.3 provides requirements and guidance for near term use of the Necessary and Sufficient Process. The Necessary and Sufficient Process should be applied where substantial benefit - in terms of worker and public safety, environmental protection, mission accomplishment and cost - can be realized. Use of this process is encouraged, but is not mandatory. If the Necessary and Sufficient Process is used, use of DOE M 450.3 is required. Line Management has the lead in ensuring that the Necessary and Sufficient Process is employed with integrity. The DSC will provide assistance to line management in this regard and will maintain the manual and related guidance.

U.S. Department of Energy

Washington, D.C.

NOTICE

DOE N 450.3

ADVANCE COPY

1-24-96

EXPIRES 1-24-97

SUBJECT USE OF THE NECESSARY AND SUFFICIENT PROCESS

1. **OBJECTIVE.** This Notice transmits DOE M 450.3-1, THE DEPARTMENT OF ENERGY CLOSURE PROCESS FOR NECESSARY AND SUFFICIENT SETS OF STANDARDS (Necessary and Sufficient Process), and provides requirements and guidance for transition to widespread use of the Necessary and Sufficient Process. Use of the Necessary and Sufficient Process is not mandatory; however, if the Necessary and Sufficient Process is used, adherence to the Process described in the Manual is mandatory. The Department of Energy (DOE) developed the Necessary and Sufficient Process with an awareness that the relationship among the Department's work, associated hazards, and requirements and standards has not always been clear. By working across program lines and using the Necessary and Sufficient Process to build agreements on standards into the front end of work planning, DOE believes that Departmental Elements can overcome this difficulty.

Standards-based work involves four activities:

- a. definition of work and hazards,
- b. identification of standards,
- c. performance of work in accordance with standards, and
- d. performance assessment.

The Necessary and Sufficient Process involves the first two of these activities.

2. **APPLICABILITY.** The Necessary and Sufficient Process is one example of the Department's commitment to using integrated management systems to ensure adequate protection for workers, the public, and the environment. Not every activity, facility, or site must use the Necessary and Sufficient Process. Where appropriate or required, Standards/Requirements Identification Documents (SRID), Safety Analysis Reports (SAR), and equivalent approaches may be used to meet this commitment. To avoid duplication of effort and rework, many sites may "stay the course" with these other approaches.
 - a. The Necessary and Sufficient Process can be used to determine whether any new nonregulatory Environment, Safety and Health (ES&H) standard should be applied to a given work scope. This may be particularly useful when deciding whether to include new DOE Orders in management and operating (M&O) contracts.

DISTRIBUTION:
All Departmental Elements

INITIATED BY
Department Standards Committee

- b. Contract reform initiatives are intended to provide a flexible approach to how work is performed in the DOE complex. One approach being considered is substituting the approved set of standards developed using the Necessary and Sufficient Process for the ES&H requirements contained in standard contract clauses.
- c. The Department remains committed to rulemaking for nuclear safety requirements of general applicability. The Department intends to propose revisions to its rule on exemption procedures to provide for appropriate consideration of judgements, reached through the Necessary and Sufficient Process, that particular DOE rule requirements do not contribute to the achievement of adequate protection in particular circumstances.
- d. In implementing the Necessary and Sufficient Process, a transition period will be required to develop the expertise and program infrastructure to ensure that the Necessary and Sufficient Process will be properly applied. During this period, it will be necessary for management to carefully choose high-value candidate projects and provide priority management attention and support. Such choices must be consistent with the priorities set by the Department in implementing its integrated safety management program. The following considerations should guide these choices.
- (1) Optimize benefits to the entire Department. Focus on work where significant safety benefits or high dollar cost savings/avoidance can be achieved by developing new or revised sets of standards. One way to accomplish this is to apply the Necessary and Sufficient Process to work conducted at several facilities or sites so that resulting knowledge and benefits can be shared. The Necessary and Sufficient process has not been approved for privatization.
 - (2) Take advantage of current experience. As a result of the Department Standards Committee (DSC) authorized pilot demonstrations, pockets of experience have been developed. Management teams should integrate the experience and lessons learned into future applications of the Necessary and Sufficient Process.
 - (3) Achieve near-term successes. Focus on those types of projects that build on established infrastructure, expertise, experience, and enthusiasm to achieve near-term successes. Such successes would serve to further validate the robustness and effectiveness of the Necessary and Sufficient Process and provide more case studies for the benefit of the Department as a whole. This would also serve to quickly increase the number of people qualified to apply the Necessary and Sufficient Process and to speed the learning process for the rest of the Department.

- (4) Capitalize on additional learning opportunities. Early application of the Necessary and Sufficient Process to activities where higher levels of uncertainty or complexity exist will give the Department the opportunity to gain additional valuable experience. This will address Stakeholder concerns, and provide significant return on the Department's investment in the Necessary and Sufficient Process.

The criteria described below should be used to determine the overall benefit that would accrue from applying the Necessary and Sufficient Process when several potential candidate projects compete for resources. The criteria are intended to be considered as a set, not as individual decision points.

Environment, Safety and Health

- The environment, safety and health basis for the work is inadequate or non-existent.
- The Necessary and Sufficient Process can reduce confusion stemming from multiple or conflicting standards.

Work Start-up or Restart

- New work.
- Shutdown or restart.
 - Operations terminated for safety reasons.
 - Prolonged shutdown with lost or inadequate safety basis.
- Standards do not exist.
- Major mission change.

Cost Effectiveness

- Major business re-engineering.
- New design, construction, and/or activity.
- Excessive requirements.
- Business competitiveness.
- Tailored standards provide for equivalent performance.

3. REQUIREMENTS. Management teamwork is essential in introducing the Necessary and Sufficient Process across the Department. Therefore, during transition to use of the Process, Secretarial Officers, Field Managers, and Contractor Heads shall form line management teams to develop priorities for use of the Necessary and Sufficient Process, to select initial Process applications in accordance with these priorities, and to ensure that sufficient support is available to conduct the process properly. The DSC management training course on the Necessary and Sufficient Process, "Necessary and Sufficient: An Overview," is required for management team members.

Because the purpose of the management teams is to guide the transition, the teams will not necessarily perform the same functions or consist of the same

individuals as the "Agreement Parties" or "Convened Groups" referenced in DOE M 450.3-1. The Department Standards Committee (DSC) should be advised of Necessary and Sufficient Process activities.

4. RESPONSIBILITIES.

- a. Secretarial Officers, Field Managers, and Contractor Heads are responsible for forming the line management teams.
- b. Management Teams.
 - (1) In guiding the transition to use of the Process, the management teams are responsible for maintaining the correctness of the Necessary and Sufficient Process and for (a) developing priorities for use of the Necessary and Sufficient Process, (b) selecting initial process applications in accordance with the priorities, (c) ensuring that sufficient support is available to conduct the process properly, and (d) providing DSC approved training on the Necessary and Sufficient Process.
 - (2) Management teams should deploy the Necessary and Sufficient Process as follows:
 - (a) Communicate expectations to and provide training for those involved in the Necessary and Sufficient Process to create a common and accurate understanding of the Necessary and Sufficient Process.
 - (b) Redeploy existing resources to support application of the Necessary and Sufficient Process.
 - (c) Consider resources devoted to the Necessary and Sufficient Process an investment in the future. Improvements will be realized in terms of both enhanced safety and operating efficiencies.
 - (d) Improve planning by applying available expertise and developing the program infrastructure to ensure the Necessary and Sufficient Process is properly executed.
 - (e) Initiate Necessary and Sufficient Process applications in stages in accordance with deployment criteria and resource availability.
 - (f) Optimize use of technical and management capabilities and seek outside expertise as appropriate. Use of expertise from outside the Department is encouraged to promote stakeholder confidence and build the available knowledge base.

- (g) Establish mentoring programs across internal DOE organizations to share Necessary and Sufficient Process knowledge.
- (h) Capitalize on similarities among activities across the DOE complex while accounting for their differences. Maximize information transfer regarding issues common to multiple sites and Necessary and Sufficient Process lessons learned. It may be helpful to use personnel from other sites who have experience with the Necessary and Sufficient Process.

- (3) Management teams should develop success indicators and performance measures that provide DOE personnel, contractor management, and other interested parties with objective indices to determine the effectiveness of specific applications of the Necessary and Sufficient Process. These success indicators and performance measures should reflect the best knowledge of the various elements of the Department and its contractors.

c. The Department Standards Committee (DSC).

- (1) The DSC will not have direct authority over application of the Necessary and Sufficient Process. However, the DSC will maintain and interpret the Necessary and Sufficient Process description, which is contained in DOE M 450.3-1. The DSC will also answer questions and help resolve problems regarding application of the Necessary and Sufficient Process and will remain involved in other aspects of standards management.
- (2) The DSC owns and will maintain the training curriculum. In addition, the DSC will provide training on the use of the curriculum to those DOE and contractor personnel who are responsible for training Necessary and Sufficient Process team members. Mentoring and assistance are also available through the DSC to assist with deploying any aspect of the Necessary and Sufficient Process. Members of the management teams are encouraged to participate in the mentoring program.

5. CONTACT. Questions concerning this Notice should be addressed to the Department Standards Committee at (301) 903-0077.

BY ORDER OF THE SECRETARY OF ENERGY:



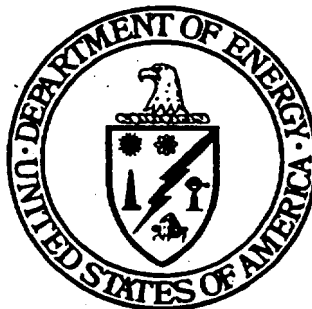
ARCHER L. DURHAM
Assistant Secretary for
Human Resources and Administration

ADVANCE COPY

DOE M 450.3-1

1-24-96

**THE DEPARTMENT OF ENERGY
CLOSURE PROCESS FOR NECESSARY AND
SUFFICIENT SETS OF STANDARDS**



**U.S. DEPARTMENT OF ENERGY
Department Standards Committee**

**Distribution:
All Departmental Elements**

**Initiated By:
Department Standards
Committee**

1-24-96

SUBJECT: THE DEPARTMENT OF ENERGY CLOSURE PROCESS FOR NECESSARY AND SUFFICIENT SETS OF STANDARDS

1. PURPOSE. In 1994, the Department Standards Committee (DSC) established an integrated standards-based management system, which is reflected in the "Criteria for the Department's Standards Program" (DOE/EH/0416). The Criteria's primary objective is to promote a culture based on ES&H standards tailored to work and to move away from a "one size fits all" approach. The Criteria establishes the expectations of how DOE personnel, contractors, and other interested parties should interact in defining standards necessary for performing work, integrating those standards into the process for planning and accomplishing work, evaluating the efficacy of the standards in light of current missions, and continuously assessing the effectiveness of the standards in providing adequate protection to the worker, the public, and the environment.

One of the DSC's first tasks was to encourage a common understanding that the Department's work should be planned, performed, and appropriately documented in accordance with a set of agreed-upon standards to ensure adequate protection of the safety and health of workers, the public, and the environment. The DSC recognized that a key to the success of the Department Standards Program is the availability of a process that provides a disciplined and collaborative analysis of the work to be performed and the potential hazards associated with that work.

The DSC charged a Standards Process Action Team (SPAT 3/4) to develop a Department-wide process for identifying the standards necessary and sufficient to ensure adequate protection against the hazards associated with the work of the Department. The draft Closure Process produced by the Standards Process Action Team was successfully demonstrated by several pilots at a variety of activities, facilities, and sites throughout the DOE complex.

2. SUMMARY. This Manual describes the six elements established for the "Closure Process for Necessary and Sufficient Sets of Standards," herein referred to as the Process, and summarizes "lessons learned" from the pilots. The Process can be applied at any organizational level and by any organization within the DOE complex, and can be used to establish contractual commitments between the Department and its contractors.

The pilots demonstrated that several intangible benefits accrue when the Process is conducted properly to tailor sets of standards to specific work and hazards. One benefit is the enhanced communication among DOE, contractors, and Stakeholders, fostering a better understanding of the work and the hazards and acceptance of a set of standards. Feelings of synergy, team spirit and empowerment were created among the various team members and teams. In the longer term, more tangible benefits will include measurable improvements in the performance of Department work.

The pilots also demonstrated that the following aspects of the Process required clarification:

- a. The role of the Process needs to be understood within the larger context of the Department's Standards Program. In the "big picture," the Process provides for the establishment of an agreed upon, necessary and sufficient set of standards, which then must be implemented in the performance of work. Responsibility for implementation will be addressed by the management infrastructure already in place. Likewise, the responsibility for oversight to confirm effective performance is defined by current management systems.
- b. If conducted properly, the Process is intended to produce a set of necessary and sufficient standards appropriately tailored to specific work to be performed and the hazards associated with that work. The set will include all applicable requirements in Federal, State, and local laws and regulations. Other sources of potential standards are DOE directives, DOE Technical Standards, and nationally and internationally recognized industry consensus standards.
- c. The six Process Elements, when followed, ensure the integrity of the Process and provide a readily defensible response if the set of standards is challenged. Because these elements were intentionally written in performance-based terms, they do not form a prescriptive checklist. Therefore, the conduct of the Process and the approaches followed to implement the elements will vary. This is to be expected. However, inherent in these Process Elements are five principles that should guide all users of the Process.
 - (1) To establish a basis for agreement, all parties who must agree on the set of standards shall participate in the Process planning.
 - (2) Additional Stakeholders (i.e., parties who are materially affected by or who can materially affect the outcome) are always invited to contribute to the Process.
 - (3) People properly qualified by experience and training identify and confirm the set of standards.
 - (4) The Process shall be documented and the necessary and sufficient set of standards confirmed to demonstrate that the Process has been applied properly.
 - (5) The approved set of standards shall be accepted by all Departmental Elements as the basis for the performance of work and of oversight.

Experience shows that approval of the necessary and sufficient set of standards is readily obtained if the Process Elements are followed and the principles are fulfilled.

- d. The justification of the Necessary and Sufficient set includes identification of any implementation assumptions and interfaces. Implementation assumptions are a mechanism by which uncertainties in the work process are addressed. These assumptions may deal with management issues such as the availability of resources, hardware issues such as the availability of control systems, or process issues such as the compatibility of materials used in accomplishing the work. 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 as in the case of work specific training requirements as a subset of a larger set of requirements, hardware requirements as in the case of an Heating Ventilation and Air Conditioning (HVAC) system serving the work area as a segment of a larger HVAC system, or programmatic requirements as in the case of quality assurance requirements for the work in the context of a larger quality assurance program. These interface requirements must be identified and satisfied before work can proceed.
- e. Depending on the complexity or controversy surrounding a particular situation, the Convened Group responsible for planning and conducting a particular necessary and sufficient process may decide that confirmation to an independent team is needed for support approval of the set. This is a matter of judgment to be exercised by the Convened Group.

To provide as much flexibility as possible, the Process permits the Convened Group to designate the level and identity of the Approval Authority during the initiation of the Process. The Approval Authority will approve the set as adequate on the basis of a determination that the Process has been correctly implemented.

- f. The value of affording all appropriate Stakeholders an opportunity to contribute to the Process cannot be overemphasized. The value of inviting Stakeholder to provide their views, even when they decline, has been proven by experience. Because acceptance of the set is one of the underlying goals of the Process, the appropriate Stakeholders should always be informed of the intent to conduct the Process and be invited to contribute input. Consistent with guidance related to the Federal Advisory Committee Act, stakeholders (i.e., individuals who are not Federal employees or Department contractor employees) provide their individual views on issues raised by the Process, but may not be members of the consensus seeking groups. The Convened Group must ensure that stakeholders are provided with appropriate opportunities for input, and that their views are shared in a manner consistent with the Federal Advisory Committee Act.

Care should be taken to ensure that the degree of rigor and the resources applied for specific application of the Process are appropriate for the degree of complexity of the work and hazards. The scope, detail, and rigor of hazard analysis and work definition, the amount and detail of process documentation, the size and composition of the teams, and the degree of expertise and independence needed for team members may vary widely between different applications. For example, the Process should be relatively simple and inexpensive in situations where the work and associated hazards are well-understood and commonly accepted in the private sector and widely accepted standards exist for controlling those hazards.

To ensure a common understanding of the Department's new approach to performing work, programs to orient managers not directly participating in the Process and to train Process participants are being made available through the Department Standards Committee. Future participants in the Process must have completed the appropriate training course prior to participation.

3. CONTACT. Questions concerning this Manual should be addressed to the Department Standards Committee at (301) 903-0077.

BY ORDER OF THE SECRETARY OF ENERGY:



ARCHER L. DURHAM
Assistant Secretary for
Human Resources and Administration

DEFINITIONS

1. 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; for example, parties to a contract, as in the case of DOE and an M&O contractor.
2. Approval Authority. One or more Department employees designated by the Convened Group to determine the adequacy of the necessary and sufficient set of standards and to approve or disapprove a set of standards.
3. 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.
4. 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.
5. Customer Organization. The organization with direct responsibility, accountability, and authority for having the work performed subject to the agreed-upon set of standards.
6. 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.
7. 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.
8. 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 typical resource authorities in matrix organizations. Some organizations may have resource managers who are independent of programs and projects.
9. Responsible Organization. The organization with direct responsibility, accountability, and authority for performing the work subject to the agreed-upon set of standards.

10. Stakeholder. Any party other than Federal employees or DOE contractor 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).
11. 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).

TABLE OF CONTENTS

CHAPTER I - INITIATING THE NECESSARY AND SUFFICIENT PROCESS

1. OBJECTIVE.....I-1
2. DISCUSSION.....I-1

CHAPTER II - PRODUCING A NECESSARY AND SUFFICIENT SET OF STANDARDS

1. OBJECTIVE.....II-1
2. PROCESS ELEMENT 1: DEFINING THE WORK AND HAZARDS.....II-1
 a. Objective.....II-1
 b. Discussion.....II-1
 c. Responsibilities.....II-2
3. PROCESS ELEMENT 2: CREATING THE TEAM(S).....II-3
 a. Objective.....II-3
 b. Discussion.....II-3
 c. Responsibilities.....II-4
4. PROCESS ELEMENT 3: DEFINING AND AGREEING TO PROTOCOLS AND DOCUMENTATION
 REQUIREMENTS FOR THE TEAMS.....II-5
 a. Objective.....II-5
 b. Discussion.....II-5
 c. Responsibilities.....II-5
5. PROCESS ELEMENT 4: IDENTIFYING THE NECESSARY AND SUFFICIENT SET OF
 STANDARDS.....II-6
 a. Objective.....II-6
 b. Responsibilities.....II-6
6. PROCESS ELEMENT 5: CONFIRMING THE NECESSARY AND SUFFICIENT
 SET OF STANDARDS.....II-7
 a. Objective.....II-7
 b. Responsibilities.....II-7
7. PROCESS ELEMENT 6: APPROVING THE NECESSARY AND SUFFICIENT SET OF STANDARDS
 AND AUTHORIZING WORK TO THE SET.....II-8
 a. Objective.....II-8
 b. Discussion.....II-8
 c. Responsibilities.....II-8

CHAPTER III - USE OF THE APPROVED SET OF STANDARDS.....III-1

CHAPTER I

INITIATING THE NECESSARY AND SUFFICIENT PROCESS

1. OBJECTIVE. To determine whether to initiate the Process and to assign responsibility for conducting the Process.
2. DISCUSSION.
 - a. Agreement Parties may initiate the Process if one or more of the following criteria is satisfied.
 - (1) A set of standards does not exist, as in the case of a new activity.
 - (2) An existing set of standards (e.g., 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.
 - (3) The applicable contract requires that the Process be used.
 - (4) A Stakeholder demonstrates to the satisfaction of the Agreement Parties that the existing set of standards is either not necessary or not sufficient to provide adequate protection. Evidence provided should be based on the set of standards, not on the way the standards are implemented.
 - b. When the Agreement Parties determine that at least one of the criteria is satisfied, they:
 - (1) jointly designate, preferably within the Responsible Organization, a Process Leader who will be responsible for conducting the Process,
 - (2) designate individuals within their respective organizations to serve as members of the Convened Group,
 - (3) identify Resource Authorities and any other Federal officials to be approached for participation as members of the Convened Group, and
 - (4) identify interested Stakeholders to be approached to provide input to the Convened Group.

The value of inviting Stakeholder contribution, even when it merely provides them with an opportunity to decline, has been proven by experience. Because acceptance of the set is one of the underlying goals of the Process, the appropriate stakeholders should always be informed of the intent to conduct the Process and be invited to contribute.

- c. The designation of individuals as members of the Convened Group should be guided by Criterion 6 of the Criteria for the Department's Standards Program" (DOE/EH/0416), which states that identification, approval, and maintenance of necessary and sufficient sets of standards will be at the organizational level appropriate for effective management. 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 necessary and sufficient set of standards. Members of the Convened Group must be empowered to make the necessary commitments on behalf of their organizations.

- d. The Process Leader will convene the first meeting of the Convened Group. The first business of the Convened Group will be to decide on the protocols for its ongoing meetings and to identify individuals who have agreed to act as the Approval Authority for Process Element 6 (Chapter II, paragraph 7), Approving the Necessary and Sufficient Set of Standards for use in performing the defined work.

CHAPTER II

PRODUCING A NECESSARY AND SUFFICIENT SET OF STANDARDS

1. **OBJECTIVE.** To produce and reach closure on a necessary and sufficient set of standards to meet performance expectations and objectives for providing adequate protection to workers, the public, and the environment.
 - a. This phase consists of the following six major Process Elements.
 - (1) Defining the work and hazards.
 - (2) Creating the team(s).
 - (3) Defining and agreeing to protocols and documentation requirements for the teams.
 - (4) Identifying the necessary and sufficient set of standards.
 - (5) Confirming the necessary and sufficient set of standards.
 - (6) Approving the necessary and sufficient set of standards and authorizing work to the set.
 - b. The level of detail and effort required for each of the elements will vary depending on the particular application and experience in applying the Process. For example, the element on "defining work and hazards" will require less effort for established and ongoing activities than for a new startup.

As understanding is gained through use of the Process, it will often be necessary to repeat the various elements to incorporate changes to the scope, expectation, teams, or set of standards.

2. **PROCESS ELEMENT 1: DEFINING THE WORK AND HAZARDS.**
 - a. **Objective.** To define the work and performance expectations to which the standards apply.
 - b. **Discussion.** A clear definition of the work performance expectations, work environment, and associated hazards and uncertainties is critical to the successful identification of a necessary and sufficient set of standards. Tailoring a necessary and sufficient set of standards to the work and hazards ensures that the desired level of protection is achieved efficiently.

The definition of the work and hazards provides an opportunity to determine if any of the identified hazards can be reduced or eliminated (e.g., by the use of alternative materials or methods).

Such redefinition of the work should occur prior to starting Process Element 4, "Identifying the Necessary and Sufficient Set of Standards."

c. Responsibilities.

(1) Process Leader has the following responsibilities.

- (a) Acquires relevant information on the work to be performed from the members of the Convened Group.
- (b) Organizes information received from the Convened Group as an initial basis for identifying the necessary and sufficient set of standards, in terms of the following initial conditions.
 - 1 Performance expectation and objectives (for example, goals for safety, quality, and operations).
 - 2 What actions will be performed.
 - 3 Physical conditions within which the work will be performed.
 - 4 Materials and conditions that could cause adverse consequences.
 - 5 Uncertainties about the work.
 - 6 Organization and management.
 - 7 Resource availability and constraints.
 - 8 Stakeholder concerns.
- (c) If necessary, re-evaluates the work definition on the basis of feedback obtained during the Process.

(2) The Convened Group has the following responsibilities.

- (a) Establishes appropriate channels of communication with stakeholders; provides stakeholders with information concerning process activities; and obtains stakeholder views as input to the Process.
- (b) Provides information on initial conditions as follows:
 - 1 Agreement Parties, with the assistance of Technical and Operational Experts, provide information on:

- a Performance expectations and objectives (for example, goals for safety, quality, and operations).
- b What actions will be performed.
- c Physical conditions within which the work will be performed.
- d Materials and conditions that could cause adverse consequences
- e Uncertainties about the work.
- f Organization and management

2 Resource Authorities provide information on Resource availability and constraints.

(c) Endorses the initial definition of the work, hazards, and performance expectations compiled by the Process Leader. The initial definition is subject to refinement during the application of the Process.

3. PROCESS ELEMENT 2: CREATING THE TEAM(S).

- a. Objective. To create one or more teams to identify a necessary and sufficient set of standards and confirm that the set is adequate and feasible.
- b. Discussion.
 - (1) The identification of a necessary and sufficient set of standards for a defined scope of work relies on the collective judgment of a team of knowledgeable people. The team must establish that implementation of the set is feasible and that the set provides a basis for adequate protection.
 - (2) Confirmation of the adequacy and feasibility of the necessary and sufficient set of standards strengthens the credibility of the Process and confidence in the set of standards. The level of formality and independence of the confirmation process will depend on the specific circumstances. For complex or controversial issues, it will be necessary to use relatively rigorous methods for confirmation, perhaps even a formal, independent peer review.
 - (3) The nature of the work, its complexity, hazards, and uncertainties will determine the breadth of knowledge needed within the identification and confirmation teams. It is important that the criteria for selecting team members reflect

the full breadth of issues to be addressed, and that qualified individuals are made available for assignment of the teams. The confirmation team may include members of the identification team or be an entirely independent group.

- (4) When the relevant expertise is not available in the organizations directly involved, it will be necessary to recruit experts from other organizations inside or outside of the DOE complex. Use of experts from other organizations has the benefit of enhancing the credibility and defensibility of the Process and of the resulting set of necessary and sufficient standards. When recruiting expertise from outside the DOE complex, individual viewpoints must be sought.
- (5) Based on consideration of the Federal Advisory Committee Act, membership on the Identification Team and Confirmation Team is limited to DOE and other Federal employees and DOE contractor employees. Stakeholder input to the Process will be managed by the Convened Group.

c. Responsibilities. The Convened Group has the following responsibilities.

- (1) Define the specifications for the identification and confirmation teams that will be formed.
 - (a) Establish the functions, relationships, and composition of the teams based on:
 - 1 the complexity of the work or the existing set of standards to be reviewed;
 - 2 the number of disciplines (technical and otherwise) involved; and
 - 3 the extent to which the relevant communities (i.e., technical, scientific, programmatic, and Stakeholder) are known to hold differing opinions on the issues under review.
 - (b) Establish team member qualifications.
- (2) Arrange for individuals to be assigned to the teams, consistent with the membership criteria. Individuals assigned to the teams must be able to participate fully in all team meetings and team decision making.

4. PROCESS ELEMENT 3: DEFINING AND AGREEING TO PROTOCOLS AND DOCUMENTATION REQUIREMENTS FOR THE TEAMS.

- a. Objective. To establish protocols, agreements, and documentation requirements for a credible and efficient Process.
- b. Discussion. The degree of formality and the extent of documentation required will depend on the work and the following considerations: (1) the potential impact of the identified hazards and associated uncertainties of the work, (2) the complexity of the work, and (3) the quality and rigor required to provide confidence that the standards selected meet the performance expectations and objectives of the work.

The protocols should reflect the intention that teams will perform most of their deliberations in face-to-face group meetings. If subgroups must be used, coordination responsibilities of the subgroups must be adequately defined.

c. Responsibilities.

(1) The Convened Group has the following responsibilities.

(a) Establish protocols and agreements for:

- 1 schedules and time limitations;
- 2 resolution of differing opinions within the Convened Group and the teams;
- 3 interactions between the Convened Group and the teams; and
- 4 interactions between the Convened Group and the stakeholders

(b) Establish documentation requirements for:

- 1 definition of the work, hazards, and performance expectations and objectives;
- 2 the necessary and sufficient set of standards;
- 3 justification for the set's adequacy:
 - a team member names, responsibilities, and qualifications;
 - b results of the confirmation process;
 - c differing opinions and their resolution;

- 4 implementation assumptions and interfaces necessary for reaching closure on the set (e.g., any unique resource requirements, or any time constraints for the use of certain selected standards); and
 - 5 justifications to support exemptions from legal requirements;
 - (2) The Process Leader, with the participation of team members, has the following responsibilities.
 - (a) Establish team protocols, as necessary for:
 - 1 establishing team members' roles and responsibilities;
 - 2 orienting team members on the Necessary and Sufficient Process;
 - 3 developing plans and procedures, including schedules and cost estimates;
 - 4 resolving team comments within the team (differing opinions that cannot be resolved within the team will be handled in accordance with the protocol established by the Convened Group); and
 - 5 interacting with non-members when it is necessary to clarify information included in the definition of work and hazards.
 - (b) Establish any additional team documentation requirements necessary.
 - (3) Team members will provide qualifications information to the Convened Group. Team members must conduct the Process in accordance with the protocols and documentation requirements.

5. PROCESS ELEMENT 4: IDENTIFYING THE NECESSARY AND SUFFICIENT SET OF STANDARDS.

- a. Objective. To identify and reach team consensus on the necessary and sufficient set of standards by drawing on the team's collective experience.
- b. Responsibilities. The Identification Team has the following responsibilities.
 - (1) Identify any additional information needed to define the work.

- (2) Evaluate relevant sources of existing international, national, State, local, and work-specific standards including laws, regulations, orders, and procedures.
- (3) Identify which standards constitute a necessary and sufficient set, including those standards that are legally required and other standards that are necessary to provide adequate protection of workers, the public, and the environment, the set must be feasible for implementation.
- (4) If needed, request additional resources, such as additional Technical or Operational Experts.
- (5) Reach consensus on and justify the necessary and sufficient set of standards.
- (6) Identify any implementation assumptions and interfaces used by the team.
- (7) Identify those applicable Federal, State, and local laws and regulations that must be included in the necessary and sufficient set of standards but are judged not to add value to the achievement of adequate protection, and provide a justification for the team's view that can be used as the basis for pursuing exemption from these requirements.
- (8) If it is not possible to identify a necessary and sufficient set to meet the current performance expectations and objectives, recommend revisions to the work definition, development of new standards, or both, that would allow a necessary and sufficient set of standards to be identified.
- (9) Document:
 - (a) the necessary and sufficient set of standards,
 - (b) the justification for the set,
 - (c) implementation assumptions and interfaces, and
 - (d) a justification to support an exemption from regulatory requirements that are judged by the team not to add value to the achievement of adequate protection.

6. PROCESS ELEMENT 5: CONFIRMING THE NECESSARY AND SUFFICIENT SET OF STANDARDS.

- a. Objective. To confirm the adequacy and feasibility of the necessary and sufficient set of standards identified by the Identification Team.

- b. Responsibilities. The Confirmation Team has the following responsibilities.
- (1) Review the documentation produced by the Identification Team and any other documentation required for confirmation.
 - (2) Determine whether the proposed set of standards is adequate and feasible.
 - (3) Document the confirmation activities and their results.

7. PROCESS ELEMENT 6: APPROVING THE NECESSARY AND SUFFICIENT SET OF STANDARDS AND AUTHORIZING WORK TO THE SET.

- a. Objective.
- (1) To accept the level of protection provided by implementation of the necessary and sufficient set of standards.
 - (2) To accept and authorize the use of the necessary and sufficient set of standards, subject to any implementation assumptions.
- b. Discussion.
- (1) Approval constitutes agreement with the adequacy of the set and a commitment by the Resource Authorities to provide, or seek through the normal budget process, the resources necessary to implement the standards.
 - (2) Approval does not constitute approval of exemptions from standards in applicable laws and regulations that have been judged not to add value to the achievement of adequate protection. Exemption from those standards must be sought and granted in accordance with the applicable provisions for such exemptions. For DOE nuclear safety regulations, an exemption request, and the justification contained therein, will be processed in accordance with 10 CFR 820.
- c. Responsibilities. The Approval Authority designated by the Convened Group has the following responsibilities.
- (1) Establish the adequacy of the necessary and sufficient set of standards by determining whether:
 - (a) the Process has been correctly implemented and has been documented in conformance with the protocols established by the Convened Group;
 - (b) the Identification Team has endorsed and justified the set of standards as necessary and sufficient to provide adequate protection when implemented; and

- (c) the Confirmation Team has confirmed the adequacy and feasibility of the set of standards.
- (2) Approve or disapprove the set of standards for use in performing the defined work, within any time limitations established by the Convened Group.
- (3) Inform the Convened Group of the approval or disapproval.

CHAPTER III

USE OF THE APPROVED SET OF STANDARDS

To ensure that the expectations and agreements established between the Responsible Organization and the Customer Organization are successfully implemented, the Responsible Organization:

1. ensures that the necessary and sufficient set of standards and associated implementation assumptions become part of the operating basis for all activities covered by the set; and
2. performs any agreed upon actions approved with the set.

Planning and performing work in accordance with the approved set of standards requires an adequate system for managing the work. This includes an organization with defined roles and responsibilities, performance evaluation systems, and management information and reporting systems that include configuration and change controls. An implicit assumption for all necessary and sufficient sets of ES&H standards is that such a management system exists. Characteristics of a desirable integrated management system are addressed in the "Criteria for the Department's Standards Program" (DOE/EH/0416).