

March 1, 1996

MEMORANDUM FOR ALL DEPARTMENTAL ELEMENTS

FROM: Archer L. Durham /s/
Assistant Secretary for
Human Resources and Administration

SUBJECT: DOE M 450.3-1, THE DEPARTMENT OF ENERGY CLOSURE PROCESS FOR NECESSARY
AND SUFFICIENT SETS OF STANDARDS

Pursuant to the Office of Environment, Safety and Health's concurrence of February 26, 1996, the attached subject Manual, previously approved on January 25, 1996, is being issued for simultaneous implementation and coordination for a six-month period. This document is being published in conjunction with the issuance of the Secretarial Policy Statement, DOE P 450.3, AUTHORIZING THE USE OF THE NECESSARY AND SUFFICIENT PROCESS FOR STANDARDS-BASED ENVIRONMENT, SAFETY AND HEALTH MANAGEMENT and DOE N 450.3, USE OF THE NECESSARY AND SUFFICIENT PROCESS, approved on January 25, 1996. These documents were prepared by the Department's Standards Committee under the leadership of the Assistant Secretary for Environment, Safety and Health (ES&H). The documents authorize use of the Necessary and Sufficient Process which addresses how the Department will select its standards to protect workers, the public, and the environment; and, form the basis for the Department's move to integrating standards activities into a consistent, coordinated system of standards-based safety management.

DOE M 450.3-1, THE DEPARTMENT OF ENERGY CLOSURE PROCESS FOR NECESSARY AND SUFFICIENT SETS OF STANDARDS is hereby approved for simultaneous implementation and coordination.

Attachment

DATE: MARCH 4, 1995

REPLY TO
ATTN OF: CORPORATE MANAGEMENT PRACTICES GROUP, HR-62 /s/

SUBJECT: DOE N 450.3, USE OF THE NECESSARY AND SUFFICIENT PROCESS, DOE M 450.3-1, THE DEPARTMENT OF ENERGY CLOSURE PROCESS, AND DOE P 450.3, AUTHORIZING USE OF THE NECESSARY AND SUFFICIENT PROCESS

TO: DIRECTIVES POINTS OF CONTACT

The attached Notice and Manual are forwarded for your review and comment. Both the Notice and Manual are being simultaneously implemented and coordinated. These documents are being published in conjunction with the approval and issuance of the Secretarial Policy Statement on Authorizing the Use of the Necessary and Sufficient Process (N&S) for standards-based environment, safety and health (ES&H) management.

The N&S Process is one means of addressing the selection of ES&H standards, and has been developed by the Department Standards Committee (DSC) as part of the ES&H standards program as defined in the "criteria for the Department's Standards Program" (DOE/EH-0416). The use of the N&S Process is encouraged, but is not mandatory. The DSC and sub-teams developed the N&S Process over the past year, with an awareness that the relationship between the Department's work, associated hazards, and requirements/standards has not always been clear. Overcoming this difficulty will require Departmental Elements to work in partnership across program lines and to use the N&S Process to build agreements on standards in the front end of work planning.

In implementing the N&S Process, the Department recognizes that a transition period will be required. The Policy Statement authorizes application of the Process where substantial benefit can be realized. The Notice provides requirements and guidance for the transition to widespread use of the N&S Process. If the N&S Process is to be used, the Manual is mandatory and must be followed.

Comments on the Notice and Manual are due by September 2, 1996. MAJOR ISSUES OR SUGGESTED COMMENTS should be designated as such when submitted. MAJOR ISSUES shall be limited to instances where a directive in its entirety, or its requirements, would have a serious, adverse affect on mission accomplishment, economy, efficiency, policy, objectives, or other management concerns that would preclude its publication. The following procedures shall be followed for the submission of comments:

Directives Points of Contact at Headquarters Elements: Submit comments to Ms. Maggie Sturdivant, Department Standards Committee Support Group, EH-31, CENTXXI/GTN; send facsimiles to (301) 903-0557, INTERNET address: MAGGIE.STURDIVANT@HQ.DOE.GOV; or forward via electronic mail. Submit a second set of comments to Ms. Susan C. Smith, Corporate Management Practices Group, HR-62, Room 4B-222, FORRESTAL; send facsimile to (202) 586-9585, INTERNET address: TEST6.HR05@HQ.DOE.GOV; or cc-mail to HR05, TEST6.

Directives Points of Contact at Field Elements: Submit consolidated field and contractor comments to Ms. Sturdivant at one of the addresses given in the preceding paragraph. Send an additional copy to Ms. Smith.

Operations Offices will send an additional copy to the Associate Deputy Secretary for Field Management.

CONTRACTOR ORGANIZATIONS: Submit comments directly to their appropriate Field Elements.

CONTACTS: Questions concerning the content of the Notice and Manual should be directed to Ms Sturdivant, EH-31, (301) 903-0077. Questions concerning the processing of the Notice and manual should be directed to Ms. Smith, HR-62, (202) 586-3296.

Attachments

DOE M 450.3-1

1-25-96

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 Environment, Safety, and Health (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 a 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 by an independent team is needed to 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 Stakeholders 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 or subcontractor 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 team(s), 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

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 TEAM(S).....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 and Authorizing Work to the Set."

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 team(s).
 - (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.

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, team(s), or set of standards.

- 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.
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 team(s). 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 team(s). 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 seek input from experts from other organizations inside or outside of the DOE complex. Input from 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 consulting with experts 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 and subcontractor 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 team(s) that will be formed.
 - (a) Establish the functions, relationships, and composition of the team(s) 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 team(s), consistent with the membership criteria. Individuals assigned to the team(s) 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 TEAM(S).

- 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 the team(s) 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 team(s);
- 3 interactions between the Convened Group and the team(s); 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).

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 and contractor 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 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).
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).