

U.S. Department of Energy

Oak Ridge Operations

ORO O 250
Chapter V

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SUBJECT: DEVELOPMENT AND APPROVAL OF WORK SMART STANDARDS DOCUMENTS

1. PURPOSE. This Chapter correlates to DOE P 450.3, AUTHORIZING USE OF THE NECESSARY AND SUFFICIENT PROCESS FOR STANDARDS-BASED ENVIRONMENT, SAFETY AND HEALTH MANAGEMENT; DOE N 450.3, USE OF THE NECESSARY AND SUFFICIENT PROCESS; AND DOE M 450.3-1, THE DEPARTMENT OF ENERGY CLOSURE PROCESS FOR NECESSARY AND SUFFICIENT SETS OF STANDARDS, dated January 25, 1996. It assigns responsibility and accountability and provides administrative and contractual guidance to Oak Ridge Operations (ORO) and its principal contractors, Lockheed Martin Energy Systems (LMES) and Lockheed Martin Energy Research (LMER). Nothing in this issuance changes any requirements contained in any DOE Order.
2. CANCELLATION. This Chapter cancels and replaces ORIG 1300.X1A, OAK RIDGE OPERATIONS STANDARDS MANAGEMENT PROGRAM, Attachment B, Chapter 4, Change 1, dated April 2, 1996.
3. APPLICABILITY. The provisions of this Chapter apply to ORO Principal Staff and to LMES and LMER as provided by contract. Other contractors that decide to develop Work Smart Standards (WSS) documents (formerly called Standards/Requirements Identification Documents [S/RID]) shall determine which protocols to adopt for their particular application; they are not covered by this Chapter.
4. RESPONSIBILITIES.
 - a. Manager approves LMES' and LMER's WSS documents for initial applications or major revisions, unless a cognizant Secretarial Officer (CSO) retains approval authority for a particular WSS document.
 - b. Principal Staff participate in development, confirmation, and maintenance activities for contractor WSS documents.
 - c. Leader, Directives Management Group (DMG).
 - (1) Provides advice and assistance to ORO staff on subjects covered in this Chapter.
 - (2) Coordinates review and approval of initial WSS documents and changes thereto.
5. REQUIREMENTS AND PROCEDURES.
 - a. Introduction. Identification of standards and requirements is an essential part of the standards management program. Contractors may elect to comply with applicable DOE directives or may choose to use the Necessary and Sufficient (N&S) Process to develop appropriate WSS documents. LMES and LMER have elected to use the process to select a set of environment, safety, and health (ES&H) and related requirements. WSS documents contain the set of requirements and standards, including all applicable laws and regulations, that is necessary and sufficient to provide an adequate level of protection to workers, the public, and the environment.

The requirements in the WSS document are selected to be appropriate to the work to be performed and the hazards associated with that work. Organizations revise their WSS documents because of changes in the work, the hazards, the laws, or the management expectations.

The process described below is not strictly a linear process. It may be appropriate to move back and forth from one step to another several times or to conduct several steps in parallel. The important point is that all steps must be performed with integrity to ensure adequacy of the WSS document.

- b. Scope of the WSS Program. LMES' and LMER's S/RID were developed at the contract level and included multi-level information on the applicability of specific standards/requirements within each contractor's organization (i.e., specific types of facilities or activities). An S/RID contains the standards and requirements that the contractor is contractually obligated to implement, and it provides information on where those requirements are applied within the organization. The line management responsible for conducting the work is responsible for ensuring the accuracy and appropriateness of the S/RID. Implementation of the requirements, including how requirements are tailored for specific facilities, is through various work controls such as procedures which must be consistent with the S/RID. LMES and LMER are currently revising these documents using the N&S Process, and as this process is completed, the S/RID will be renamed WSS documents. All changes to an S/RID or WSS document must be made using the N&S Process as outlined in this Chapter.
- c. Initiating the Process. LMES and LMER have an approved S/RID that provides adequate safety, and they have initiated the process to upgrade the S/RID to WSS documents. The primary ongoing need is for determining when changes to the approved documents are necessary. Either ORO or a contractor may identify the need for a change. The person desiring a change should contact the appropriate site compliance organization (for LMES or LMER) or the DMG (for ORO) for assistance in identifying the appropriate personnel to be involved in a preliminary discussion of the change. Depending on the scope and applicability of the contemplated change, each party may identify single subject matter experts or representatives from a single line organization, or the discussion may involve representatives from multiple organizations and subject matter areas. The discussion may range from an informal phone call to multiple meetings. See Attachment 2 of this Chapter for an overview of the components of the N&S Process.
- d. Team Makeup and Identification.
 - (1) Process Leader. Once a decision is reached that a change is needed and further actions are necessary, the contractor appoints a process leader acceptable to all parties. This person shall be responsible for coordinating the change.
 - (2) Technical Convened Group. The process leader and the people from ORO and the contractor brought together to discuss the change (plus others determined by this group to be appropriate) form the technical convened group. This group shall:
 - (a) Identify any technical expectations for the proposed change.
 - (b) Ensure adequate interfaces with other functional areas.

- (c) Appoint the identification team or teams, if appropriate.
- (d) Determine if a formal confirmation process is needed and appoint a confirmation team, when deemed necessary (see subparagraphs 5d(4) and 5n below).
- (e) Ensure appropriate stakeholder representation.
- (f) Develop additional protocols as needed.
- (g) Resolve technical disputes when these cannot be resolved within the identification team(s).

The process leader documents the membership of the technical convened group as part of the adequacy report (see subparagraph 5k below).

- (3) Identification Teams. The quality of a WSS document depends on the quality of the team responsible for its development and maintenance. These teams shall include an appropriate mix of personnel knowledgeable in the subject area, site, or facility, including both subject matter experts and representatives of line management. Identification teams may include contractor, ORO, or other DOE personnel, and they may also include stakeholders, outside experts, personnel from other contractor organizations, etc. Teams need not be large; for a Category 1 or 2 change, the team could consist of a single person if that individual has both operational and subject matter expertise (see subparagraph 5o(3) below). The composition and qualifications of identification teams must be documented as part of the adequacy report.
 - (4) Confirmation Teams. A separate confirmation team is required for Category 3 changes. Category 3 changes require formal confirmation and approval in accordance with subparagraph 5n(1). Confirmation teams consist of one or more subject matter and operational experts that are independent from the organization performing the work. These teams may include contractor, ORO, or other DOE personnel, and they may also include stakeholders, outside experts, or others as appropriate. The confirmation teams are responsible for confirming the adequacy of the set of standards prepared by the identification teams. The composition and qualifications of confirmation teams must be documented as part of the adequacy report (see subparagraph 5k below).
- e. Stakeholder Participation.
- (1) Stakeholder participation is an essential part of the N&S Process. For purposes of the ORO Standards Management Program, stakeholders are defined as Headquarters program officials; contractor employees and their representatives; regulators from DOE, state, local, and other Federal agencies; and the public, including individuals and elected and appointed public representatives.

- (2) Technical convened groups determine the appropriate stakeholders for each application and the appropriate degree of stakeholder involvement, using the guidelines given below. The degree of participation may range from notification and opportunity to comment to membership on one or more of the various teams.
 - (a) Stakeholder involvement is usually not required for Category 1 or 2 changes.
 - (b) Minimum stakeholder involvement in any Category 3 change includes Headquarters program officials, contractor employees and their representatives, and regulators involved in the functional area(s) under consideration.
 - (c) Minimum stakeholder involvement in any Category 3 change is notification of the proposed change and opportunity to comment. Initial notification must take place before the technical convened group completes its deliberations.
- f. Definition of the Work and Hazards. The first step in the process of identifying standards and requirements or proposing changes to those standards is to ensure adequate definition and understanding of the work and the associated hazards. The process leader ensures adequate understanding by all identification team members of the work processes and associated hazards and describes this information in the WSS document or associated adequacy report. For simple changes not being made as a result of changed work or work processes, this step may require only brief consideration and no changes to the existing description.
- g. Development of Benchmark to Address Adequacy and Define Interfaces. The second step in the process of standards identification is the development of a program structure that describes the functional areas, elements, and subelements of a program that is adequate to control the ES&H hazards identified for the work to be performed. This structure must be tailored to the work and hazards of the organization covered by the WSS document, as the adequacy determination process relies heavily on its use as a benchmark. The identification team charged with making changes to the WSS document must ensure the continued adequacy of the structure, the narrative description defining that structure, and the description of interfaces with other functional areas.

The following functional areas are included in the scope of WSS documents:

1. Management Systems
2. Quality Assurance
3. Configuration Management
4. Training and Qualifications
5. Emergency Preparedness
6. Safeguards and Security
7. Design Engineering
8. Construction
9. Operations
10. Maintenance
11. Radiation Protection
12. Fire Protection
13. Packaging and Transportation
14. Environmental Restoration
15. Decontamination and Decommissioning
16. Waste Management
17. Research and Development
18. Nuclear Safety
19. Occupational Safety and Health
20. Environmental Protection

NOTE: Functional areas may be combined, deleted, or new areas added, with agreement of the appropriate technical convened group(s) involved in the change.

h. Identifying Requirements from Laws and Regulations.

- (1) After the element and subelement structure has been defined for a particular functional area, the identification team identifies applicable Federal, state, and local laws and regulations, including DOE Rules, and sorts them against the defined structure. All applicable laws and regulations must be included in the set, including those for which exemptions are being sought. Once an exemption is approved, the law or regulation can be removed from the set.
- (2) After requirements from laws and regulations are organized into functional areas, elements, and subelements, the identification team screens them to identify overlaps and conflicts.
 - (a) Overlaps. When two or more requirements overlap, the subject matter expert selects a primary standard and lists the others as secondary sources. The one selected should be the one that combines the broadest scope with the greatest degree of specificity. Where two or more requirements are equivalent in this regard, the one selected shall be the highest level standard (i.e., laws would control over regulations, Federal regulations over state regulations, etc.).
 - (b) Conflicts. When conflicts are identified between laws, regulations, or Rules, the contractor shall initiate actions with ORO to resolve the conflict with the appropriate regulatory authorities.
- i. Ensuring Adequacy. By comparing the requirements from laws and regulations against the defined structure, the team identifies where there are no standards or requirements that address a particular element or subelement or where the standards and requirements are not sufficient to provide adequate protection. The identification team then selects standards to fill any such gaps by drawing requirements from any of the following:
 - (1) DOE directives.
 - (2) Technical standards, including DOE, international, and national consensus standards.
 - (3) Other documents as appropriate, such as compliance agreements and regulatory enforcement actions, DOE responses to Defense Nuclear Facilities Safety Board (DNFSB) recommendations, and documents issued by various Headquarters program offices.

Requirements from internal documents (such as procedures, Safety Analysis Reports, technical safety requirements, and permits) are not normally included in the WSS document. These are considered to be implementing documents for higher-level requirements. They are included only when needed for sufficiency and when no other standard is available that meets the need.

- j. Implementation Assumptions. Identification teams develop implementation assumptions when necessary to provide a "bridge" between the requirement text and the manner in which it is implemented. These assumptions may further define applicability within the contractor's organization; identify requirement tailoring decisions and key decision criteria; clarify the intent of the requirement; provide cross-references; or provide other explanatory material that may help in understanding how the requirement will be implemented. Approved implementation assumptions are subject to the same change control process as requirements.
- k. Justification of Adequacy. The last step in the identification process is the preparation of a justification of adequacy for the WSS document. This report accompanies the WSS document and may be incorporated into it. The report should be as brief and concise as possible, and no format is prescribed. As a minimum, it must include the following information:
 - (1) Scope and coverage of the WSS document, including a description of the organization, site, and facilities covered. For changes to an already approved WSS document, this paragraph describes the scope of the proposed changes.
 - (2) A summary description of the work and the hazards, including appropriate references to existing documents, and the process used for determining work and hazards. If proposed changes to a WSS document are not the result of new or changed work, this section need only confirm that the description is adequate to support the proposed changes.
 - (3) Structure of the WSS document, including a description of the functional area, element, or subelement structure and how interfaces between functional areas are handled in the WSS document. For changes to an approved WSS document, any modifications to this structure must be described, and if none are proposed, the report need only confirm that the existing structure is adequate to support the proposed changes.
 - (4) The degree and extent of stakeholder involvement.
 - (5) The reasoning for the need or lack of need for confirmation.
 - (6) Reasons why the set is believed to be adequate.
 - (7) The identity and qualifications of the people involved in preparation and confirmation of the WSS document or any proposed changes.
- l. Content of the WSS Document. The WSS document shall include or be accompanied by the justification of adequacy report. The WSS document shall include the following information in addition to the material required in the adequacy report:
 - (1) Requirements and standards sorted by functional area, element, and subelement. Complete references to sources of the requirement shall be provided. Requirements that are included shall be pertinent to the scope of the WSS document and shall be necessary and sufficient to provide adequate ES&H protection.

- (2) Applicability information. For each requirement unit, applicability within the contractor's organization should be defined to the extent practicable.
- (3) Implementation assumptions, if necessary (see subparagraph 5j above).

NOTE: S/RID prepared under the earliest versions of the ORO standards management program were required to include all requirements from the 51 Orders of interest to the DNFSB. To focus proper attention on the requirements and standards most important to safety in a time of shrinking resources, S/RID development and maintenance teams categorized requirements as Key, Law, Best Management Practice, or Other. The categorization was intended to support prioritization of implementation actions and to determine the appropriate amount of resources to apply to administration, self-assessment, and other related activities. As S/RID and WSS documents are revised, only requirements that are necessary and sufficient to provide adequate protection to employees, the public, and the environment will be included; therefore, the above-named categories are no longer necessary.

- m. Expressing Requirements in the WSS Document. Use the following criteria to determine how to express standards and requirements identified for inclusion in WSS documents.
 - (1) Source documents are broken down into discrete requirements within the WSS document where necessary to ensure adequate understanding of applicability. To enhance clarity, requirements may be listed separately or grouped with other related requirements into a unit. For example, if an entire standard is applicable and lists requirements related to one major topic, the requirement listed in the WSS document may be the entire standard.
 - (2) Requirements included within WSS documents must be specific enough that technical experts within the particular program area can agree on the criteria necessary to demonstrate compliance. Statements of policy, definitions, or broad statements of intent are not requirements.
 - (3) Requirements may be quoted, characterized, or edited for inclusion in the WSS document. When a requirement from a law or a regulation is edited, care must be taken to ensure that only inappropriate or unnecessary portions of the requirement are removed and that the intent of the requirement is preserved. Where characterizations are used, the source reference controls interpretation of the requirement statement. For example, if a particular section of a standard is lengthy or is copyrighted and the entire section is applicable to the site or facility, it may be referenced and descriptively summarized.
 - (4) It is acceptable to generate a new requirement statement by combining two or more similar requirements. When combining requirements from law or regulation, care must be taken to ensure the constructed statement accurately and completely reflects the intent of the sources. The WSS document must reference all original requirements as secondary sources and clearly identify in the primary source that the requirement statement is a construct.

- (5) All requirement statements must be expressed in the WSS document as "shall" statements. If a nonmandatory statement is selected for inclusion and revised as a "shall" statement, it should be noted as such in the Assumptions field.

n. Confirmation and Approval Process - General.

- (1) Confirmation. For all Category 3 changes as defined in subparagraph 5o(3)(c) below, confirmation of the adequacy of the set is necessary before approval. The technical convened group appoints the confirmation team. The team reviews the WSS document or the proposed changes and forwards a report to the process leader within 60 days from the date confirmation was initiated. This report shall be signed by the confirmation team and must contain one of the following:
 - (a) A statement that the WSS document is adequate; or
 - (b) A statement that the WSS document is adequate with a set of identified changes.
- (2) Contractor Approval. Contractor approval is a sign of acceptance of the content of the WSS document and willingness to implement the requirements and standards contained therein. If a confirmation review was performed, the contractor approves the WSS document after the confirmation review. The contractor shall approve all WSS documents and associated changes prior to submission to DOE. If the contractor disagrees with the conclusions of the confirmation team regarding any needed changes to the set, the contractor justifies its position in writing as part of the approval memorandum.
- (3) DOE Approval. DOE shall approve WSS documents in accordance with the approval categories specified in subparagraph 5o(3) below. Initial WSS documents and Category 3 changes are approved by the ORO Manager unless delegated formally in writing or unless approval authority for a particular WSS document is retained by a CSO. Based on the confirmation team's recommendation and the contractor's approval, the DOE approving authority takes one of the following actions:
 - (a) Approves the WSS document or changes thereto as proposed;
 - (b) Conditionally approves the WSS document, contingent on the contractor making agreed-upon changes to the WSS document;
 - (c) Conditionally approves the WSS document, directing the contractor to make changes identified in the confirmation team's report and overruling the contractor's objections; or
 - (d) Accepts the contractor's rationale and justification for not agreeing to all or some of the changes identified by the confirmation team and approves the WSS document without changes.

o. S/RID and WSS Document Maintenance: Review and Approval of Revisions.

- (1) General. S/RID and WSS documents are living documents and must be kept up to date to reflect current hazards, missions, and expectations. Once an initial document is approved, it may need revision in response to (a) evaluation of new or revised source documents; (b) operating experience, related experience from other DOE and commercial nuclear facilities, relevant research, and lessons learned; (c) changes in mission, activities, or configuration; or (d) changing expectations. Some of the necessary changes will be significant and extensive, and others will be minor and narrowly focused. The approval process defined below is designed to provide flexibility in making changes within the context of the N&S Process while ensuring an adequate degree of control is maintained over the document.

Approval of changes to S/RID or WSS documents does not mean an associated implementation plan, request for funding, or exemption request is approved. Approval processes for those documents are well defined. DOE-approved changes that are incorporated into the WSS document may be subject to change at the time of final approval of an implementation plan or exemption request.

- (2) Schedule for Submission of Updates. Revisions to S/RID or WSS documents may be submitted at any time. In addition, contractors formally resubmit the documents to the DMG on an annual basis by the end of the fiscal year to provide an up-to-date version and a list of all changes made during the year. If no changes have been made, a memorandum to this effect satisfies this requirement.
- (3) Process for Confirmation and Approval of WSS Document Changes. The approval process is organized around three categories that address types of changes. This process assumes that the technical convened group has discussed and generally agreed upon the categorization of proposed changes before they are submitted.
 - (a) Category 1: No Formal DOE Approval Required for Change. This category applies to two types of changes:
 - 1 Specific, written direction by DOE to make a change to the WSS document. This may occur through a WSS document review (as a result of a formal confirmation team process), from an assessment finding, or because of the identification of an omission of an applicable law or regulation in the approved WSS document. All such changes are transmitted formally to the contractor through the DMG.
 - 2 Editorial changes that are necessary to ensure the documents are current and accurate. Editorial changes also include changes to the format of the WSS document, updating requirement sources when the requirement itself has not changed, changing assignment of functional areas to better match the contractor's internal structure, etc., but they do not include addition or deletion of requirements or implementation assumptions. Care must be taken to ensure that Category 1 changes do not impact the level of commitment or the interpretation of requirements.

- (b) Category 2: Advance Notification and Tacit Approval of Changes. This category includes all proposed changes to the WSS document that do not require specific, formal confirmation and DOE approval as described below under Category 3. Many of the changes falling in this category will be updates to reflect issuance of new or revised laws or Rules. The intent of this category is to permit rapid changes to be made on routine or less significant issues.

At least 30 days in advance of making a proposed Category 2 change to the WSS document, the contractor provides the DMG with a notification of intent to make the change. This notification must include the following:

- 1 Summary of the changes;
- 2 The reasons for the changes;
- 3 Why the contractor feels that the changes fall into Category 2;
- 4 Revisions to the adequacy report, if needed;
- 5 A matrix showing the specific additions, deletions, or modifications proposed to the WSS document; and
- 6 Brief discussion of any expected impact of the changes on ES&H protection and the mission.

NOTE: This information may be addressed in the revised adequacy report or in an accompanying memorandum.

The DPI and appropriate COR perform a review to the depth and degree necessary to determine if the change can take place without a formal confirmation review or whether the change should be held until formal confirmation and approval can be conducted. If DOE decides that a formal confirmation review is needed, it must notify the contractor within the 30-day period of the intent to perform further review. If no notification is received within the 30-day period or if DOE responds by approving the Category 2 changes, the contractor is authorized to proceed with the proposed changes.

- (c) Category 3: Formal Confirmation and Approval. This category includes the following types of changes:

- 1 A request for an exemption from a Rule or law requirement.
- 2 A change that is prohibited in a Rule or law without prior DOE approval;
- 3 A change that appears to involve a significant change in the level of safety provided or in the scope of the ES&H program;

- 4 A change that involves a significant request for additional funding beyond the current budget, or one that impacts negatively on currently approved funding or schedules in other areas; and
- 5 Any other change where DOE or the contractor wishes to conduct a formal confirmation.

The contractor's submission must include an adequacy report addressing the points in subparagraph 5o(3)(b) above. It is expected that DOE will have been fully involved in preparing Category 3 changes through participation in the technical convened group or identification teams, as appropriate, so a specific matrix addressing the changes is not required. However, if changes are few in number, a matrix as described above will be useful in the confirmation process and assist in implementing the changes.

The depth and rigor of the confirmation process depends on the nature and extent of the proposed revision, and it may range from a single reviewer to a multi-disciplined team similar to that used for initial WSS documents. Minimum requirements include a statement confirming adequacy with or without specifically required changes signed by the confirmation team members and a formal approval memorandum signed by the appropriate approval authority. The decision on the scope of the review is made by the technical convened group involved in the change.

- p. Implementation of the WSS Document. After a contractor's WSS document is approved, it is the list of ES&H requirements that are enforceable by contract. Contractors initiate implementation planning for unimplemented WSS requirements as soon as the confirmation process has been completed, without waiting for completion of the approval process. Noncompliance with existing WSS requirements and planning for new requirements are handled in accordance with Chapter VI of this Order.

6. REFERENCES. None.
7. DEFINITIONS. None.
8. CONTRACTOR REQUIREMENTS DOCUMENT. See Contractor Requirements Document, Attachment 1 of this Chapter.
9. ATTACHMENTS.

Attachment 1 - Contractor Requirements Document.

CONTRACTOR REQUIREMENTS DOCUMENT

LMES and LMER are responsible for developing and maintaining WSS documents that meet the requirements of paragraph 5 of this Chapter.

COMPONENTS OF THE NECESSARY AND SUFFICIENT PROCESS

